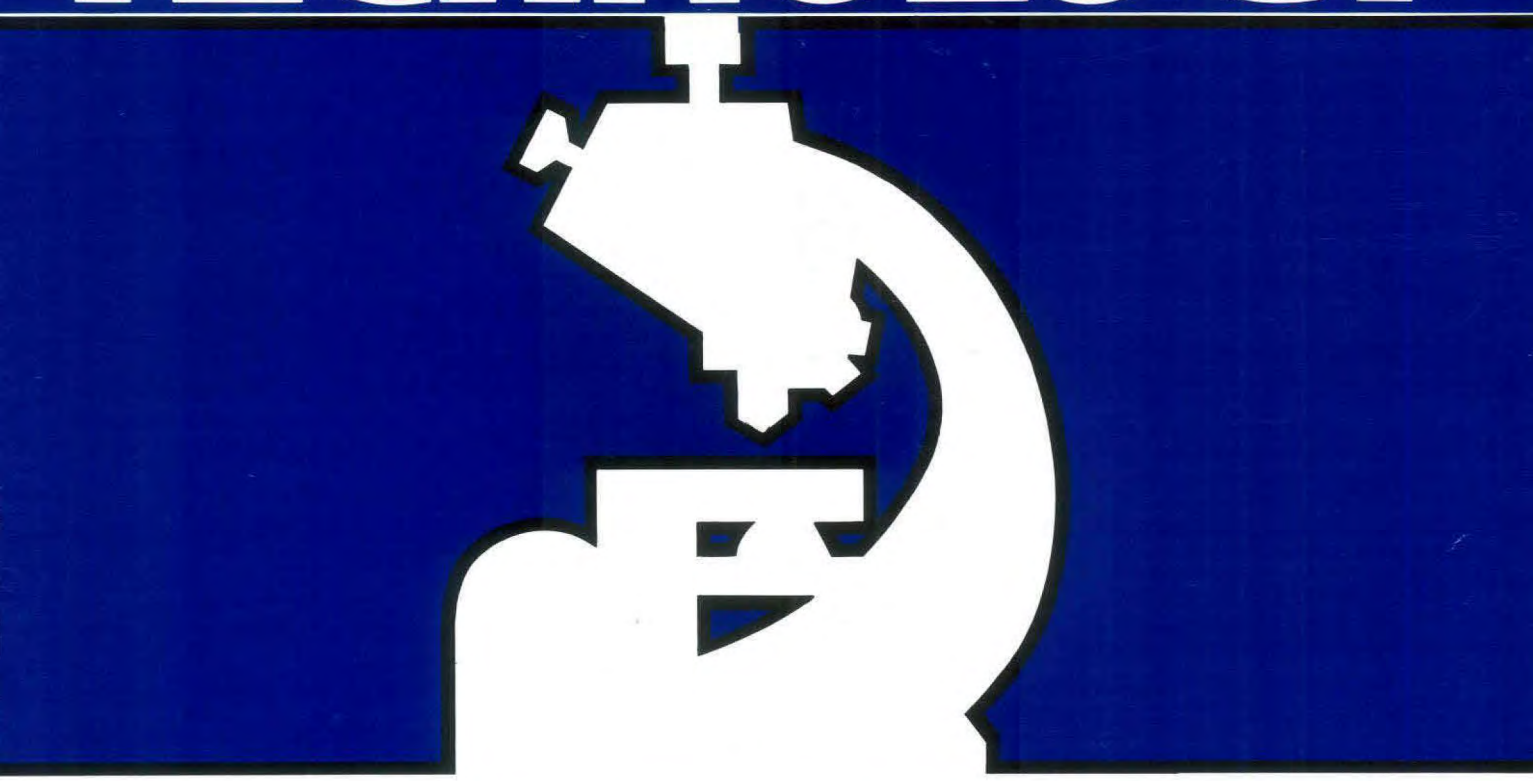
Vol. 42 No. 2 May 1988

ISSN.0028-8349

NEW ZEALAND JOURNAL OF

MEDICAL LABORATORY TECHNOLOGY



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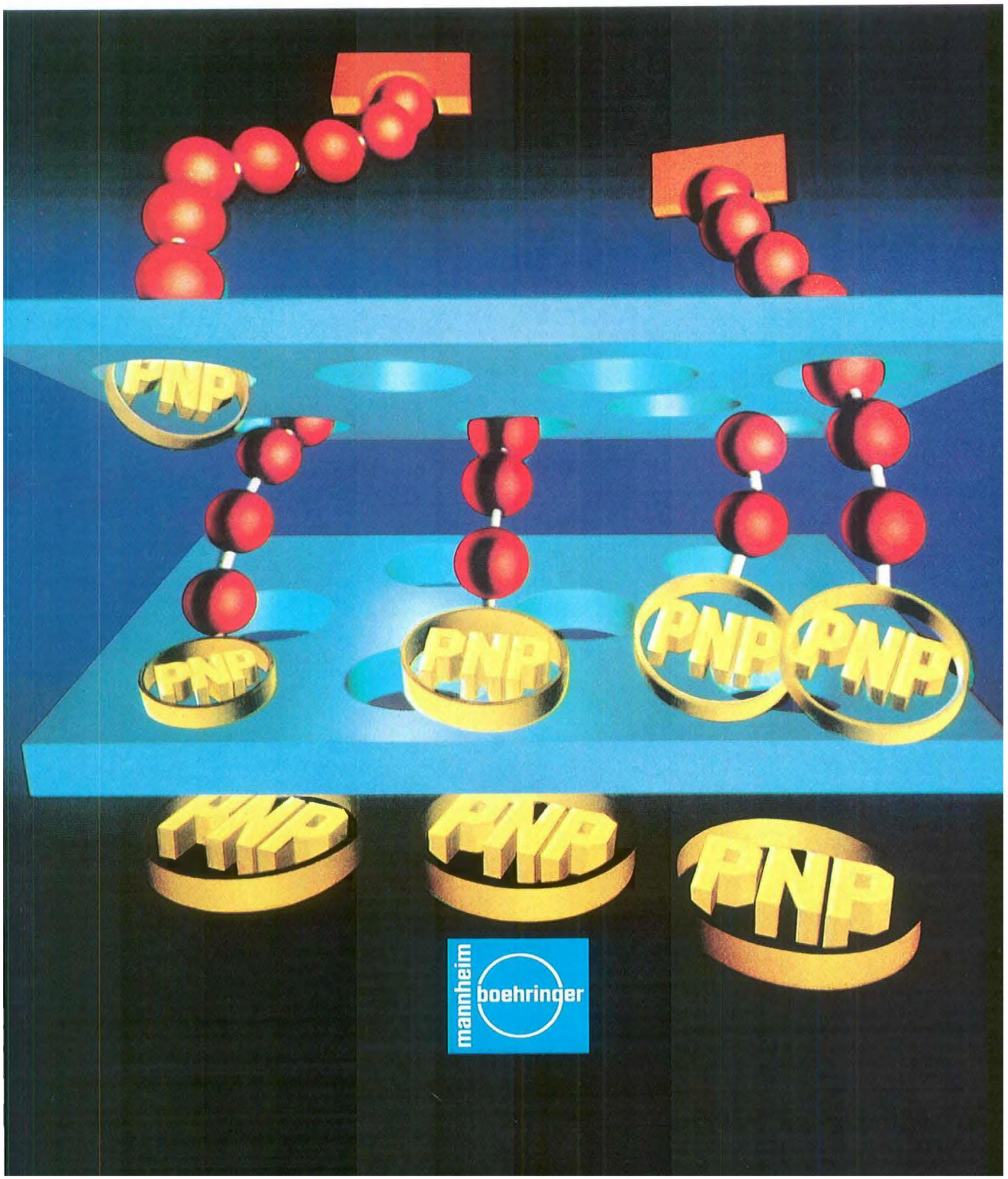

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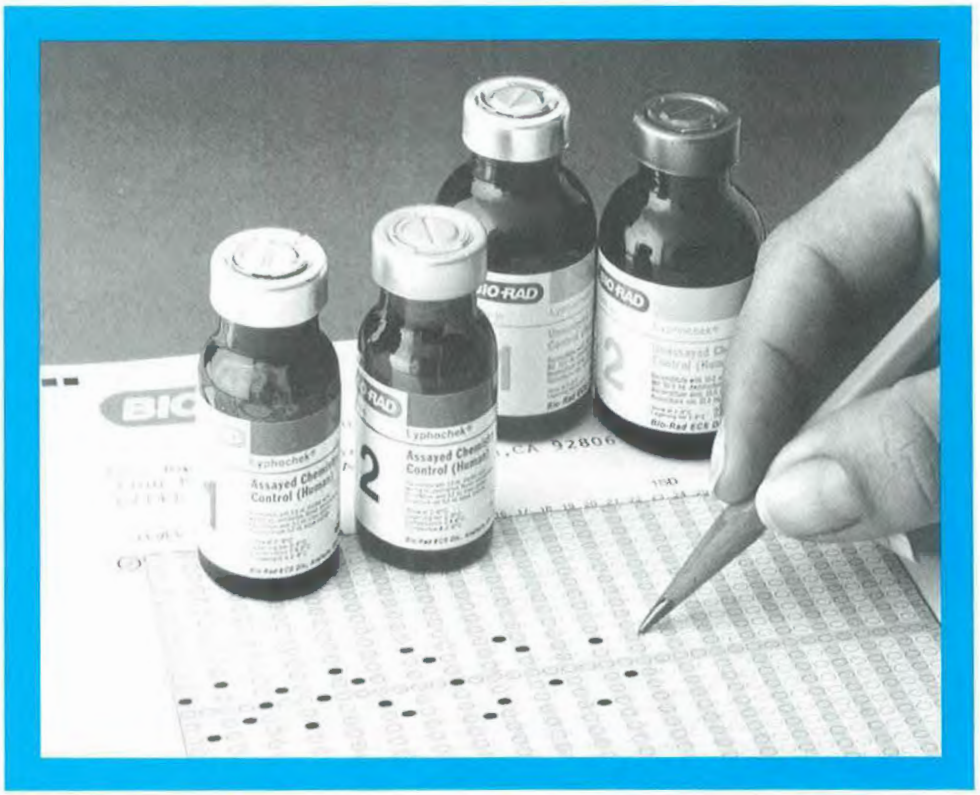

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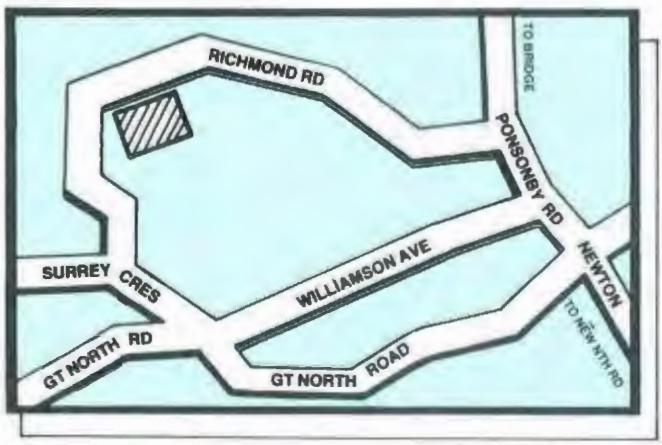

THE NEW ZEALAND JOURNAL OF
MEDICAL LABORATORY TECHNOLOGY

Vol. 42 No. 2 May 1988 ISSN 0028-8349

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DATES OF PUBLICATION

The months of publication for 1988 are March, May, August and November.

This Journal is abstracted by: Biological Abstracts, Chemical Abstracts, Cumulative Index Nursing and Allied Health Literature, Current Clinical Chemistry, Hospital Abstracts, Institut nautchnoi informatsii.

An Evaluation of Three Commercial Anti-HBc Detection Assays

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Abstract

Performance characteristics together with technical requirements are discussed for three commercially available anti-HBc detection assays. As all methods possessed similar levels of sensitivity and specificity technical considerations and assay cost played important roles in determining the method for screening clinical and blood donor sera at the Auckland Regional Blood Centre (ARBC).

Key Words

anti-HBc, competitive, EIA, RIA, bead, microplate

Introduction

One indication of active viral multiplication in Hepatitis type B (HBV) infection in humans is the presence of complete virions in sera. The Dane particle (42nm diameter) can be subdivided into (a) an internal nucleocapsid region containing ds DNA, DNA polymerase, a protein kinase activity and a DNA-linked protein (b) the envelope which houses the Hepatitis B surface antigen (HBsAg). Between these layers is the capsid which has the Hepatitis B core antigen (HBcAg) (1). Also related to the capsid but only when entire virions are present is the soluble Hepatitis B "e" antigen (HBeAg). Detection of this marker is indicative of high infectivity (2). Often, instead of Dane particles more spherical/filamentous 22nm diameter particles are observed. These are empty envelopes containing HBsAg(1).

Laboratory diagnosis of human HBV infection has been simplified by the introduction of EIA and RIA technology which enables sensitive and specific detection of viral markers associated with the disease. The appearance and persistence of markers during a typical acute HBV infection (Figure 1) allows monitoring of the progression of illness.

Awareness of the usefulness of the anti-HBc(IgM) marker in being able to differentiate between the acute and chronic carrier viral states of HBV infection (3, 4) has not detracted from the importance of testing for total anti-HBc, of which uses are: - (a) to act as a confirmatory test of a positive HBsAg result, (b) to illustrate the "window phase" of infection where HBsAg and anti-HBs markers are below detectable levels and (c) in conjunction with the enzyme alanine aminotransferase (ALT) it has been used in some countries as a surrogate test for non-A, non-B hepatitis (5). In view of these varied and important roles it is essential that a sensitive and specific assay be used for detection purposes.

This article details the findings of an evaluation of three commercial methods (one RIA and two EIA) for the detection of anti-HBc when tested against 86 clinical sera and comments on the technical requirements for the performance of each method.

Materials and Methods

Sera

Eighty-six sera from randomly selected clinical sources were collected and stored at -20°C in 1.8mL Nunc cryotubes (Inter-Med) prior to testing. Sera were thawed at 37°C for 20 minutes, then inverted three times before being assayed by the commercial methods.

Assays

Three commercial assays for detection of anti-HBc were supplied by the following companies:

1. ABBOTT LABORATORIES — Diagnostic Division (CORAB) [North Chicago, IL, U.S.A.].
2. ROCHE DIAGNOSTICA (Anti-HBc EIA) [Basle, Switzerland].
3. BEHRING INSTITUTE (Enzygnost Anti-HBc) [Marburg, W. Germany].

All methods were of the competitive type whereby any anti-HBc present in sera would compete with conjugated anti-HBc for binding sites on a solid phase. The solid phase in the Behring supplied assay (ECOR) is a microplate well, whereas in the Abbott (CORAB) and Roche (RCOR) assays, it is a polystyrene bead.

It was determined (see results) that differences in incubation time and temperature as offered by the RCOR and ECOR assays had significant effects on control optical density (O.D.) and, after consideration of these effects the following incubation protocols were used to screen the 86 clinical sera for anti-HBc:

	ASSAY		
Incubation phase	ECOR	RCOR	CORAB
Serum	37°C/2h	—	—
Conjugate	37°C/1.5h	—	—
Serum plus Conjugate	—	37°C/ overnight	37°C/ overnight

These regimes were chosen in order to maximise the sensitivities and reliability of the ECOR and RCOR assays. All methods were performed as per the manufacturers instructions. In all methods except for ECOR, reagents supplied with the assays were used. For the ECOR assay, the wash and stopping solutions were substituted with our laboratory prepared reagents (0.5% saline-tween and 1.0N H_2SO_4 respectively). These substitutions were found to have no deleterious effect on assay performance.

Statistical analysis

Individual sera were determined as being either positive or negative if there existed complete agreement between the three methods. All such sera had cut-off/sample signal ratios (CO/S) calculated. The positive and negative population ratios were log transformed, and then the following statistics were calculated: geometric means (x), standard deviations (SD), standard errors (SEM) and mean/standard deviation ratios (x/SD). Significant differences between control O.D.'s were determined using t-tests.

Results

Incubation temperature and duration effects upon the control O.D. values of the ECOR and RCOR assays.

A 37°C incubation temperature (as opposed to 45°C-RCOR or room temperature ECOR) significantly ($P < 0.001$) enhanced the optical densities of the negative controls (Table 1). The enhancement did not appear to be associated with incubation duration as at 37°C the ECOR assay had an initial

ASSAY	INCUBATION REGIME	CONTROL	LOG MEAN O.D.
RCOR	45°C:2h/37°C:ON	NEGATIVE	0.16/0.55***
RCOR	45°C:2h/37°C:ON	POSITIVE	-0.75/-0.77^{ns}
ECOR	37°C:2h/RT:ON	NEGATIVE	0.20/0.08***
ECOR	37°C:2h/RT:ON	POSITIVE	-1.42/-1.66***

Table 1 *Effect of incubation temperature and duration on mean log transformed optical densities for the negative and positive controls of the ECOR and RCOR assays.*

ON : denotes overnight incubation
RT : denotes room temperature
*** : denotes significant at $P < 0.001$
ns : denotes not significant

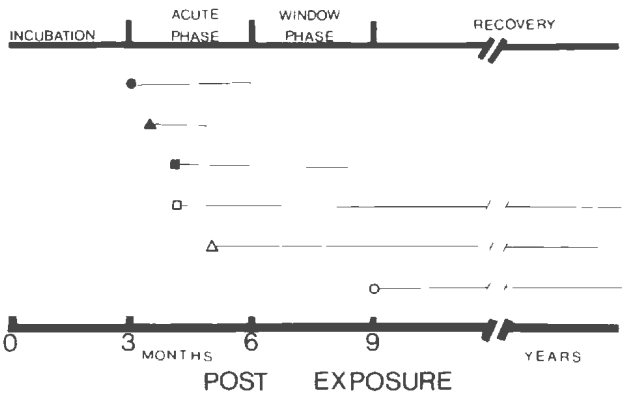

Figure 1: *Serologic profile in a typical case of acute HBV infection*

● HBsAg ○ anti-HBs ▲ HBeAg Δ anti-HBe
■ anti-HBc (IgM) □ HBcAb

serum binding of 2h, whereas the RCOR assay was run overnight. The 37°C temperature appeared optimal for binding of conjugated anti-HBc irrespective of the assay system used.

Incubation effects were confined almost entirely to the optical densities of the negative controls (Table 2). A likely reason for this was that both assay systems may have been saturated by use of a high titre anti-HBc preparation.

Clinical sera screening

Of the 86 clinical sera screened for anti-HBc, 49 (57%) were positive and 29 (34%) were negative by all methods giving an agreement between methods of 91%.

Forty-five (92%) of the anti-HBc positive sera were HBsAg positive. Two of the four HBsAg sera had clinical details indicating a previous HBV infection, whilst two sera were supplied with no clinical details. All 29 anti-HBc negative sera were negative for HBsAg and anti-HBs.

An examination of HBV serology and clinical details on the 8 sera that gave discordant results (Table 3) showed that only one serum (5) had clinical details indicative of a true positive; however, due to the negative result of the anti-HBs marker, and no Hepatitis B e antibody (HBeAb) serology having been performed, confirmation was not possible. An interesting feature of the 8 samples was that 6 had the sera pre-separated before their arrival at the laboratory, the significance of which is commented on in the discussion. Assuming that the 8 samples giving discordant results are false positives generated by the three assays, ECOR and RCOR have calculated specificities of 97.7% while the CORAB assay's specificity was slightly less at 95.4%.

A comparison of the log transformed positive and negative CO/S ratio's (Figure 2) revealed that all methods gave results that were clearly either positive or negative, although there are indications (as shown by the wide spread of CO/S ratios) that the CORAB assay could generate both false positive and negative results. The RCOR assay despite having the largest

ASSAY	CONTROL TYPE	INCUBATION REGIME	(%) DIFFERENCE BETWEEN REGIMES
RCOR	POSITIVE	45°C:2h/37°C:ON	2.7
ECOR	POSITIVE	37°C:2h/RT:ON	16.9
RCOR	NEGATIVE	45°C:2h/37°C:ON	70.3
ECOR	NEGATIVE	37°C:2h/RT:ON	60.6

Table 2. *Partition of incubation effects upon control type for the ECOR and RCOR assays.*
ON : denotes overnight incubation
RT : denotes room temperature

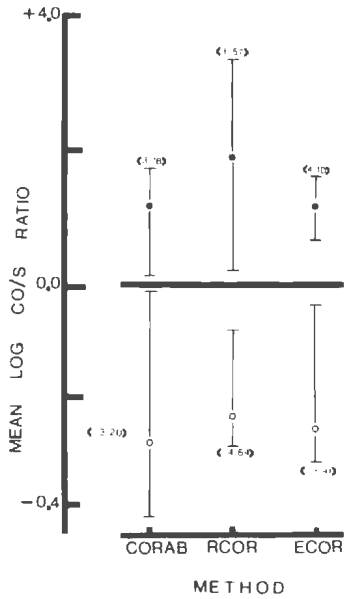

Figure 2: *Responses (mean log transformed cut-off/sample signal ratios) of three commercial assays to a group of 49 positive (●) and 29 negative (○) anti-HBc sera.*
Vertical bars represent the range of values associated with derived means. Bracketed values are x/SD ratios.

positive log mean (1.93) is still likely to produce false negatives, whereas the ECOR assay is more likely to produce false positives (figure 2).

Discussion

Anti-HBc testing is a routine aspect of any laboratory dealing with hepatitis B serology. The ARBC routinely tests the following categories of samples for anti-HBc: (a) all HBsAg positive sera (b) those clinical sera with accompanying details that indicate acute HBV infection and (c) those clinical sera that request "immune status hepatitis B" or "past history of HBV infection". These protocols result in the performance of approximately 3000 anti-HBc tests/annum.

As a reference centre for hepatitis disease serology the ARBC frequently receives specimens that are HBsAg positive by EIA at other laboratories around the country. In most cases the serum has been pre-separated, and, it is this group where anomalies between HBsAg positive and anti-HBc negative results arise most frequently. Recently, in Africa (6), a new strain of hepatitis B virus (HBV 2) has appeared which shares some of the epitopes of HBsAg but is not associated with presence of core antigen. Although this possibility might

SPECIMEN	SAMPLE TYPE	**METHOD	OTHER SEROLOGY	CLINICAL DETAILS
1	serum P/S	ECOR	HBsAg- HBsAb-	*screen pos. HBsAg
2	serum P/S	CORAB	HBsAg- HBsAb- anti-HBc(IgM)-	*screen pos. HBsAg
3	serum P/S	CORAB	HBsAg- HBsAb-	pre-vaccine screen
4	serum P/S	CORAB	HBsAg- HBsAb-	pre-vaccine screen
5	serum P/S	CORAB/ ECOR	HBsAg- HBsAb-	post HBV infection
6	clotted blood	RCOR	HBsAg- HBsAb-	none available
7	serum P/S	CORAB	HBsAg- HBsAb- HBeAb-	none available
8	clotted blood	RCOR	HBsAg- HBsAb-	routine screen

Table 3. *Production of discordant anti-HBc positive results by three commercial assays.*
P/S : denotes pre-separated sample
* : denotes result positive at a different institution and referred for confirmation
** : denotes anti-HBc methods giving a positive result

account for the discrepancies, the fact that three quarters of the samples producing discordant results were from pre-separated samples is strong circumstantial evidence for cross contamination rather than the appearance of a new HBV strain in New Zealand.

Although the mean CO/S values of both positive and negative populations for all three methods allowed good discrimination, it was considered that the wide variation of positive CO/S ratios generated by the CORAB and RCOR assays which, may in turn, lead to the production of false negatives, poor characteristics of these two methods.

All methods were accompanied by comprehensive instruction booklets detailing performance steps, reagent preparation, interpretation of results and safety precautions. While the methods have some technical requirements in common, the type of solid phase together with the form of immunoassay (EIA versus RIA) would be the main features determining the financial outlay that would be required to perform the assays. With regard to this, the necessary acquisition of a gamma counter and the segregation of an area for the safe use of radioisotopes would increase the performance costs of the CORAB assay over the two enzyme immunoassays. Apart from processing equipment costs, consideration must be made of the shorter shelf lives of RIA as opposed to EIA reagents.

An important feature of the ECOR and RCOR assay protocols is the provision of a grey zone around the cut-off to accommodate weak responses. Only sera having O.D. values within the zone are required to be re-tested, however, in the CORAB assay any sample determined as being initially reactive have to be retested to confirm their status. This represents not only a substantial cost increase, but also a delay in communication of results to clinicians.

Cost per unit test (as of January 1988) for the CORAB and RCOR assays are similar ($4.31 and $4.63 respectively), however, the ECOR assay priced at $2.12 represents a considerable cost saving.

In conclusion, this investigation demonstrates that all methods performed to similar levels of sensitivity and specificity, although the CORAB and RCOR assays may have the capacity to produce false negative results. In view of this, together with the useful microplate format, same day result acquisition, long reagent shelf life, technical simplicity, use of non-radioactive materials and low cost per unit test, the ECOR assay was found to be the best alternative of those assays evaluated for screening large numbers of samples at the ARBC for total antibody against hepatitis B core antigen.

Acknowledgements

We would like to thank Dr D.G. Woodfield for his valuable comments, and Carol Chapman for her skilled assistance in the preparative stages of this manuscript.

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Experience using High Sensitivity TSH as a Frontline Test in Thyroid Function Screening.

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From a Paper presented at N.Z.I.M.L.T. Conference, Nelson, August 1987

Abstract:

432 consecutive patient samples submitted for routine thyroid function screening, were analysed in duplicate by a new hTSH assay in parallel with the existing frontline Free T_4 assay. Retrospective clinical evaluation of thyroid status was sought on all patients with an abnormal or discordant result.

Correlation between hTSH and clinical thyroid illness was good, confirming the superiority of hTSH over FT_4 as a first line test. However, a substantial pool of 40 equivocal results were found, most of these being patients over sixty years old. There is obviously a significant pool of subclinical or compensated thyroid dysfunction within the community which required careful clinical assessment before diagnosing thyroid disease per se on the basis of laboratory findings.

Introduction

Thyroid function testing has been a significant growth industry in laboratory circles for a number of years. The impetus behind this activity has been on the one hand, a need for specific information about a common disorder with wide ranging symptomatology, and on the other hand, advances in monoclonal antibody technology. The latter has enabled increasingly accurate measurement of analytes present in minute concentrations, to a degree that often outstrips a clinician's ability to detect physical evidence of disease.

There are some fifty variations of thyroid disease and a battery of some thirty tests that can be utilised to elucidate these. Not surprisingly, thyroid disorder is frequently a consideration in initial consultations, a fact that generates a substantial demand for screening test protocols.

Recently new test systems utilising immunoradiometric assay (IRMA) and monoclonal antibody technology to achieve greater levels of sensitivity have become available commercially (2, 3, 4, 5, 8, 14, 16). This advance has increased the sensitivity of Thyrotropin (TSH) detection tenfold thereby raising the possibility of utilising the assay as a frontline screening test (1, 6, 7, 15). While there will probably never be a single test covering all thyroid eventualities, two or three tests will now trap between them most (if not actually all) of the various causes of hyper and hypo-thyroidism. (The concept of a combined FT_4/TSH assay is of interest (9, 10, 11) but is not without problems at the present level of development.)

In order to ascertain the suitability of the new test as a frontline screen in the general practice setting, we ran the test (Biorad Echo-clonal hTSH), in parallel with our existing screening system. This consisted of an initial Free T_4 assay (Clinical Assay's Gammacoat), with a Total T_3 and TSH back-up for marginal and abnormal results. After fifteen weeks, we retrospectively assessed the results and sent a medical questionaire to all doctors with patients showing abnormal or discordant results. All tests were run on a Kontron Gammamatic counter linked to our own computer system for data reduction purposes (point-to-point log-logit analysis).

Materials and Methods

All patients on whom a thyroid function screen had been requested over a fifteen week period were tested in duplicate for both Thyrotropin (TSH) and Free Thyroxine (FT_4). Samples not tested on the day of collection were stored frozen then thawed at room temperature prior to analysis. A total of 432 samples were tested.

Methods:

Free T_4: Clinical Assays Gammacoat system. A one-step competitive assay in which the free T_4 fraction in each sample competes with the free T_4 tracer for a limited number of binding sites of antibody immobilised on the lower inner wall of the coated tubes.

Thyrotropin (TSH): Bio-Rad Echoclonal hTSH system. A two-site Immunoradiometric assay (IRMA) in which sample is added to a tube coated with antibody along with a second 1^{125}-labelled tracer antibody specific for another site on the TSH molecule. The amount of TSH present in the sample is directly related to the number of counts bound to the tube.

Tests were run, without modification, by the methods described in the instruction manuals of each kit. All tests, calibrators and controls were run in duplicate.

A single kit of DPC's IRMA-Count was provided during the study. This was run in parallel with the Bio-Rad system with comparable results.

Source of Test Systems: Free T_4: Clinical Assays Gammacoat CA-555D, from Pacific Diagnostics;
TSH: Bio-Rad Echoclonal hTSH, from Salmond Smith Biolab;
DPC IRMA-Count RKTS1, from Med-Bio Enterprises.

TEST PERFORMANCE

Control	Low	Normal	High
Intra-batch C.V.			
Biorad	8.0	4.7	4.0
DPC	11.5	5.1	3.7
Inter-batch C.V.			
TSH Biorad	16.7	8.2	11.8
FT_4 C.A.	20.7	17.8	10.4

Table 1. *Coefficients of variations for TSH and FT_4 tests using Lyphocheck control sera.*

Results:

From a technical aspect, the new hTSH test performed well (Table 1). The intra-batch C.V.s were acceptable for both the Bio-Rad and the similar DPC systems. Inter-batch C.V.s for the Bio-Rad system were significantly better than those achieved with the FT_4 assay. This is a result of the improved technology of IRMA which utilises two antibodies of differing specificity, one to capture, the other to label the target molecule. The older competitive binding assay systems are less sensitive and more prone to interbatch variation, notably at lower concentrations of analyte.

THYROID FUNCTION TEST REVIEW
TOTAL TESTED : 432 ABNORMAL : 92

Confirmed Hyperthyroid	: 8
Confirmed Hypothyroid	: 9
Clinically Euthyroid	: 40
On Treatment	: 28
Information Deficit	: 7

Table 2. *Breakdown of patients with an abnormal TSH or FT_4 result, and clinical status.*

Table 2 summarises the findings of the 432 patients screened. The correlation between clinically obvious thyroid disease as seen by general practitioners, and the new TSH test shows improvement (Table 3).

Of immediate concern however, is the large group of 40

Correlation	TSH	FT_4
Hyperthyroid	8	6
Hypothyroid	9	2

Table 3. *Correlation of patients with clinical disease by G.P. assessment and laboratory findings.*

clinically euthyroid patients having an abnormal result. This latter group could be subdivided into four categories (Table 4).

Subgroup I had TSH levels ranging from 6.1 to 23.3μI.U./mL in the presence of normal FT_4 levels. These are regarded as being subclinically hypothyroid and require low level monitoring.

CLINICALLY EUTHYROID, ABNORMAL TEST : 40		
TSH, raised, FT_4 normal	:	10
TSH low, FT_4 normal	:	12
TSH normal, FT_4 raised	:	12
TSH normal, FT_4 low	:	1
TSH low, FT_4 raised	:	5

Table 4. *Further subgrouping of clinically euthyroid patients with abnormal laboratory findings.*

Subgroup II had TSH levels of less than 0.2μI.U./mL in the presence of normal FT_4 levels. These are regarded as latent or subclinically hyperthyroid, also requiring low level monitoring.

Subgroup III had normal TSH levels but FT_4 levels ranging from 29 to 46 pmol/L. Most of these were below 33 pmol/L. Plasma binding abnormalities have not been included in this group (19).

On the basis of this study we have raised the upper limit of our reference range to 30 pmol/L although it is acknowledged that there can be no definite cut-offs, as some patients will show significant symptoms with FT4 levels in the low thirties.

Subgroup IV is a small equivocal group with low TSH and raised FT_4 levels (30-38 pmol/L). Three of these patients were being treated for chronic disorders. This pattern is known to persist in some patients for years.

The lone patient with a low FT_4 defied explanation, the test was reproducable on the original sample, but normal on subsequent ones.

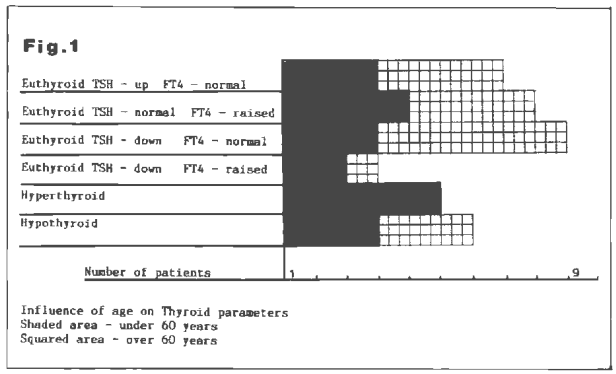
Discussion

Laboratories must provide interpretation of any tests within their repertoires in terms of accuracy, precision, likely physiological variation and other possible influences such as age, sex, or drug interferences. As far as the new TSH assay is concerned, some traps of interpretation have already been uncovered and no doubt others will emerge as the method gains acceptance.

Browning et al (12) have clearly demonstrated the problem of intra-individual and inter-individual variation that occurs in several thyroid parameters. This biological variation is greater than FT_4 assays and least (but still significant) with TSH assays. It is also known that TSH release is pulsatile. Both of these factors must be considered when interpreting differences between paired results.

The problems associated with FT_4 in non-thyroidal illness (NTI) are now well known. A recent article by John et al (18) shows that the TSH is little affected by non-thyroidal illness, giving a good indication of thyroid status when the FT_4 and T_3 are unreliable. Since it is helpful to be able to exclude thyroid disease as a contributory factor in NTI, the new test will be appreciated in that setting. Possible problems associated with heterophilic antibodies (17) seem to be averted in the Bio-Rad system by the inclusion of blocking medium (serum from the antibody-source species) in the test system.

Figure 1 illustrates the influence of age on the various groups of abnormal thyroid test results. This raises the question of a separate reference range for the elderly. Unfortunately strict



application of mathematical principles is not necessarily helpful in the clinical setting. There is obviously a considerable degree of compensation occuring in some patients, while others will present with symptoms more readily.

In this study, clinically hypothyroid patients had TSH levels ranging from 6.2 to 63μI.U./mL, while those of the compensating clinically euthyroid group ranged from 6.4 to 23 μI.U./mL. The former group had FT_4 levels of 1-16 pmol/L, while the latter had more normal FT_4 levels, ranging from 13-22 pmol/L.

We have established our reference range for TSH at 0.2-5.0μI.U./mL for all patients but advise caution in the interpretation of TSH results in patients over sixty. Subclinical hypothyroidism should be considered if the FT_4 is less than 15 pmol/L and the TSH is greater than 5.0 μI.U./mL, in the absence of a significant symptomatology. Subclinical hyperthyroidism should be considered if the FT_4 is greater than 28 pmol/L and the TSH is less than 0.2 μI.U./mL. Compensated euthyroidism is the most probable explanation in cases with raised TSH but FT_4 ranging from 15-28 pmol/L. All such cases should be referred for specialist assessment and further investigation. Final diagnosis should not be made on the basis of screening tests alone.

Conclusion

Because of the vagueness and wide range of symptomatology occurring in thyroid illness, greater reliance is placed on laboratory findings. Thyroid disease is quite common, and while rarely life-threatening, causes substantial distress that can readily be alleviated by appropriate treatment. The new TSH test is providing an increased level of diagnostic confidence in the exclusion or confirmation of thyroid illness, significantly hastening the diagnostic process. Provided that due consideration is given to the age factor, we are satisfied that the new TSH assay will serve well as a frontline screen for thyroid status. FT_4 will continue to have a supportive role in distinguishing between true thyroid illness and the compensated state. In the latter cases we advise annual follow-up.

Since completing this study it has become our practice to screen all patients by the TSH test initially then to test only those patients with a result bordering or outside our reference range of 0.2-5.0μI.U./mL by the FT_4 test, usually about 25% of patients in a batch. Exceptions are made if the clinical state warrants, and it is acknowledged that some rarer variants of thyroid illness such as T_3 toxicosis may initially be missed. Given that no frontline screening system can cover all possible variations of thyroid illness, the system currently employed is in our view the best value for the substantial financial outlay that thyroid screening now requires. It provides an acceptable compromise between clinical preference and cost.

Addendum

Since establishing the database for this article a year ago, more observations have been made by ourselves and in the literature. A brief update is in order.

The observation by John et al (19) that TSH is little affected in non-thyroidal illness, is not born out in other studies (20, 21, 22) which indicates that both high and low levels of TSH may not be due to thyroid disease. However, normal TSH levels in NTI probably indicates euthyroidism. Spencer et al (20) advocate different reference intervals for hospitalised patients. In their experience, the Free Thyroxine Index is a better indicator of thyroid disease (92.3% specificity) than TSH (90.7% specificity), and is more cost effective. This is not evident in our own setting where only 17% of requests stem from the hospital environment. It is obvious that interpretation of any thyroid test in NTI requires much care, including the TSH values found.

For the study, we applied the reference ranges provided by the manufacturers for each test, in the interpretation of the findings. These were FT_4 9-28 pmol/L, TSH 0.23-5.41 μIU/mL. We found our range for TSH little different (0.2-5.0), but our own range for FT_4 differs significantly (13-30 pmol/L). Applying the revised FT_4 range brings to 5 the number of confirmed hypothyroid cases detected in Table 3.

Further experience has re-inforced the factor of individual variation (12) complicating the interpretation of test values in relation to the reference range. It is apparent that some individual values, especially FT_4, though falling within the borders of the range are actually pathognomonic, while others just outside are not.

Our original decision to utilise the FT_4 assay only to further elucidate marginal or abnormal TSH values, is currently being re-assessed after a year of clinical application. FT_4 assays are run on about 25% of samples processed in any batch of TSH screens. The substantial saving in time and material that this represents must be balanced against the perhaps preferred optimum of screening all samples with both TSH and FT_4 (23). The current practice would fail to alert clinicians to 3% (13/432) of abnormal FT_4 results (Table 4).

Closer inspection of this euthyroid subgroup presenting with normal TSH and raised FT_4 values, reveals that five fall within the revised reference range, four had some degree of NTI and three had normal FT_4s on repeat testing. The remaining case had a level of 31, hardly a significant outlier. Despite this grey area of interpretation, FT_4 is a better indicator of functional euthyrodism than TSH, the latter providing advance warning of subclinical disease as well as more definitive information in primary hyper- and hypo-thyroidism.

We have been unable to improve upon the interbatch C.V. for the FT_4 assay over the year, and have reason to suspect that the price per kit is reflected in its performance (Table 1). The TSH assay performance has improved, and remains within acceptable performance limits for this type of assay. (Tri-level values of 15%, 7% and 10% respectively).

We conclude that, given the performance and interpretative limitations of the FT_4 assay, there is insufficient evidence to date that justifies the increased expenditure required to run both tests in parallel as a screening system for all thyroid function requests.

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A Brief Report

Emit and TDx Benzodiazepine Assay

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Introduction

For some years, the EMIT DAU procedure has been used in this laboratory for the screening of urine samples for the presence of benzodiazepines. When the Abbott TDx assay became available it was decided to make a comparison of the two methods and to determine which benzodiazepines were detected by the two assays. This is particularly relevant since an increasing number of these drugs are being marketed. An initial method comparison between the Abbott TDx benzodiazepine assay and the Syva EMIT method shows a good result correlation as a screening method for urinary benzodiazepines.

Standard Analyses:

Twelve pure benzodiazepine standards at concentrations of 500 ng/mL in TDx buffer, were assayed by both methods. Those standards which gave positive results were then reassayed at a concentration of 250 ng/mL. The results obtained are listed in Table 1.

The Emit low calibrator contains 300 ng/mL of oxazepam. When analysed by the EMIT process, this calibrator gives an absorbance change of approximately 570 units. Samples which give an absorbance change greater than that of the low calibrator are said to be positive for benzodiazepine metabolites, and similarly samples with a lower change in absorbance are negative.

Using a threshold value of 200 ng/mL of nordiazepam for the TDx, we compared the TDx and EMIT result (Table 1).

Comparisons:

At a benzodiazepine concentration of 500 ng/mL the TDx gave results clearly different from blank values for all standards except chlordiazepoxide and clonazepam. EMIT gave a change in absorbance greater than the calibrator for 8 out of these 12 standards. Negative results by EMIT were obtained for chlordiazepoxide, clonazepam, lorazepam, and bromazepam. The TDx gave results greater than 200 ng/mL for all standards positive by EMIT with the exception of flurazepam which gave a result of 155 ng/mL. This is below the recommended threshold value but still considerably greater than a buffer blank which gave results of 28 to 33 ng/mL.

	EMIT ΔA	TDx ng/mL	EMIT ΔA	TDx ng/mL
Concentration	500 ng/mL		250 ng/mL	
Bromazepam	559	135		
Chlordiazepoxide	525	46		
Clonazepam	475	47		
Diazepam	820+	402+	620+	254+
Flunitrazepam	610+	200+	531+	92
Flurazepam	620+	155+	507	59
Lorazepam	513	138		
Midazolam	683+	230	+506	78
Nitrazepam	603+	239+	529	12
Oxazepam	620+	348+	532	147
Temazepam	688+	354+	562	147
Triazolam	662+	273+	619+	197
Low calibrator	574	200		

Table 1: *Comparison of benzodiazepine standards of known concentration, analysed by EMIT and TDx.*

(+) Indicates a value which would be reported as positive because the ΔA, using the EMIT process, was greater for the prepared standard than for the EMIT low calibrator, or the TDx result for the standard was greater than the defined threshold.

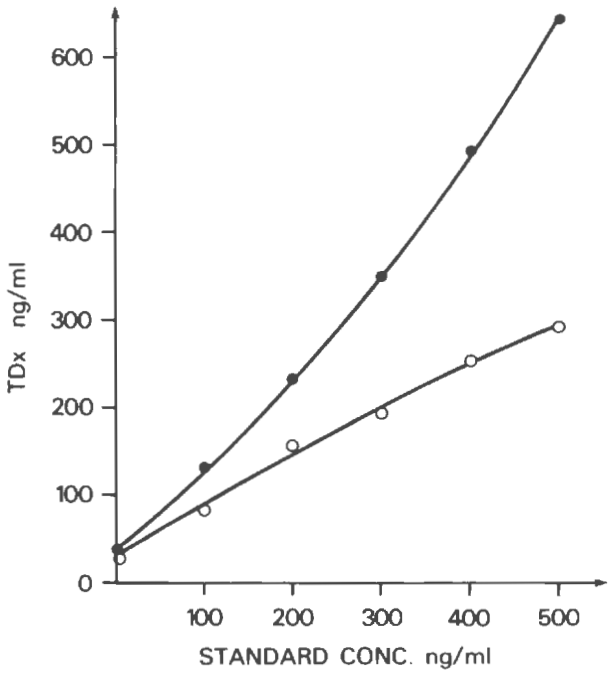

Figure 1. *Standard curves for oxazepam (o——o) and diazepam (●——●) on the TDx.*

Standard Curves:

Standard curves were prepared for diazepam and oxazepam to assess method linearity. The data is shown in Table 2 and Figure 1. A range of standards between 0 and 500

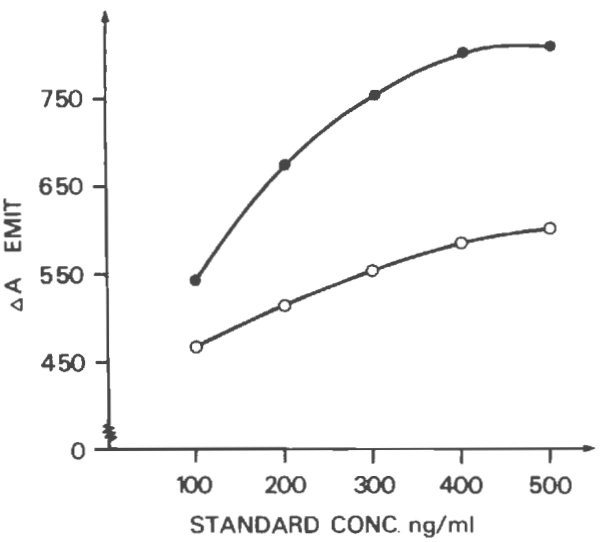

Figure 2. *Standard curves for oxazepam (o——o) and diazepam (●——●) on EMIT.*

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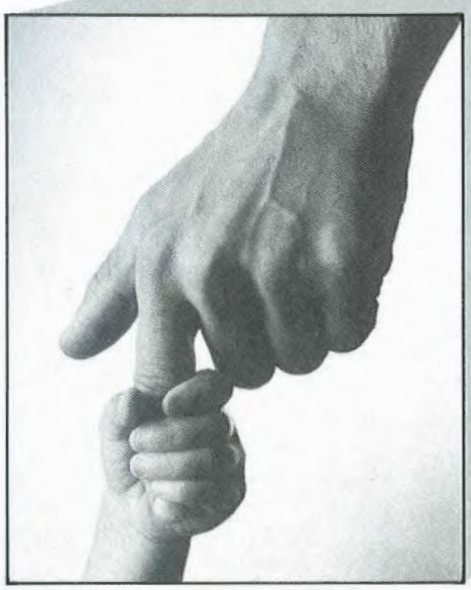

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IAMLT

Med Tec International

NUMBER 1 ISSN 0256-0107 1988

Editorial

For all organizations it is salutary to occasionally stocktake and see how well the objects of the organization are being met. Some would say that it should not be an occasional review but an ongoing continual process. What is certain is that if there are either no goals for which to aim or those goals are forgotten, there is more than a strong possibility that the organization will simply meander along and achieve little and then only in a haphazard way.

The I.A.M.L.T. clearly defines its objects within the Statutes. These are stated as:

— to afford opportunities for medical laboratory technologists to meet to discuss problems of common professional interest in an international forum.
— to provide the means of communication between medical laboratory technologists in different countries.
— to promote national organizations of medical laboratory technologists and to advise them in their continued development.
— to catalogue the training standards in different countries for medical laboratory technologists in order to:
  a) prescribe the minimum standards of training in co-operation with the World Health Organization.
  b) raise the standards of training of medical laboratory technologists.
  c) facilitate the free exchange of labour.
— to publish a journal.
— to exclude from its programme all political and religious discussions.

Whether or not we meet these goals is a matter of debate. Our biennial Congress affords an opportunity to examine the performance of the organization. The organization does not, of course, exist in isolation and has as its constituent parts its member organizations. Just as a body needs all its parts to function fully and is impoverished if an eye or a hand or a leg is missing, so too the I.A.M.L.T. needs all of its constituent parts fully working to ensure that the whole functions to its fullest capacity. Whilst it is a concern that some of our member countries participate to only a very limited extent, it is gratifying to see the high level of interest shown by other groups. The proposed Statute amendments for this year's G.A.D. to debate are indicative of this interest. The matters addressed propose some significant changes. They deserve our fullest attention and prior debate before Congress. Whatever the final decisions are regarding these, they must come after full and informed debate and be accepted as allowing the Association to more completely meet its objects. There are challenging days ahead for all health professionals and the International Association surely has a part to play in meeting those challenges. We must ensure that our Statutes (and amendments whenever these are proposed) are a means to that end and not an end in themselves.

The President's Voice

As my term of office draws toward its end the time is opportune to reflect. In my first contribution to this column I stressed the importance of communication between member societies and with Council, and although it has taken some eighteen months I am delighted to see such communication in the last edition of Med Tec. Reports of the Third International AIDS Conference, the Medical Technologists Association of Thailand and the Nordic Congress showed how some of our colleagues are dealing with changing situations. One can only hope that our colleagues in the ASEAN Association of Medical Laboratory Technologists who are not already in membership of IAMLT will become as enthusiastic as our Nordic colleagues. One disappointment to me has been the failure to increase our membership numbers in recent years and I urge member societies to encourage other societies, with whom they are in close contact, into membership. The Executive Director has been in touch with the World Federation of Scientific Workers in an endeavour to make contact with organisations in countries with whom we have no contact and we are awaiting their response.

News from the Netherlands (Holland) of the work of HAMLO was also encouraging in that it showed that what Sweden did to help third world countries and what Japan is doing in conjunction with our Congresses is being done on a continuing basis with a slightly different approach. It shows that members of our profession care and are concerned to improve health care standards throughout the world. Our aims are identical to those of WHO and I have no doubt that we could make a positive and worthwhile contribution to the work described by Dr Kirsten Staehr Johansen had we been asked as our New Zealand colleagues have cooperated with WHO. The HAMLO project is an ideal opportunity for member societies to support work for our less fortunate colleagues and, in turn, maybe make them aware of IAMLT. Member societies having individual members working in third world countries could help by sending copies of Med Tec to these members who might otherwise not be aware of IAMLT or helpful member societies in the region.

Change takes place slowly unless there is an impetus for change. Such an impetus is evident in the agenda for the forthcoming General Assembly in Kobe with proposed amendments to the Statutes on such fundamental issues as subscriptions, regional structure and a General Assembly every four years. These proposals, together with the need for elections to Council, shows there is a healthy interest in the affairs of our organisation which should neither divide us or interfere with the scientific programme of the Congress.

In conclusion may I take this opportunity of thanking Council members for their hard work and support during my term of office and the great assistance I have received

from Margareta Haag in recent months. We look forward to meeting as many of you as possible in Kobe where we will be only too pleased to discuss any matters of mutual interest.

Dennis Slade

CORRECTION
DATING ERROR
The previous issue of Med Tec International numbered No 2 1988 should read No 2 1987

From The Editor's Desk

THE ETERNAL TRIANGLE — LABORATORY VERSION

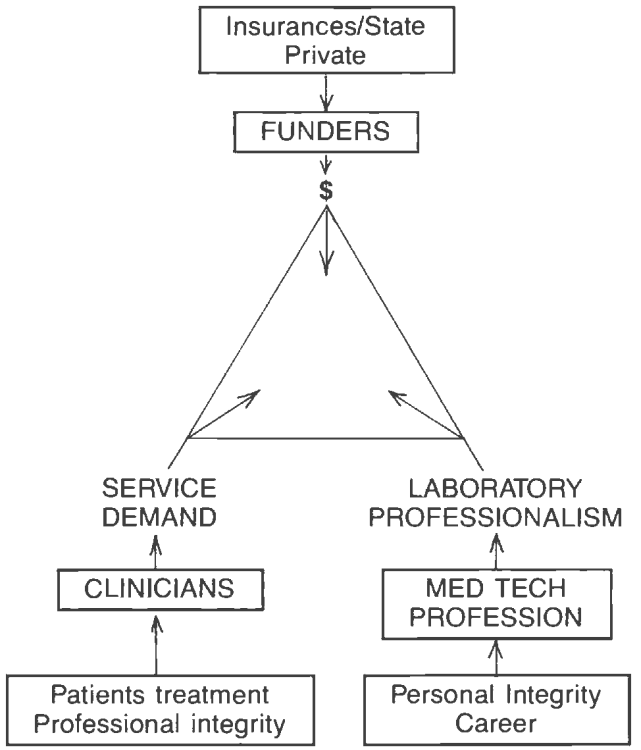
With very few exceptions the health industry around the world is struggling to find enough money to fund its activities. The heady days of the 1970's where many countries had generous (in some cases almost unlimited) finances to spend on health have gone — probably never to return again. Not only has the competition for the finance been widened as more and more areas of health open up, but the ever increasing sophistication of technologies coupled with the explosion of knowledge means that few places are able to fund all those things that modern knowledge and technology have made possible. Quite simply, our ability to perform has far outstripped our ability to pay.

Laboratory medicine is certainly not exempt from these pressures. Expensive equipment is outmoded almost before it hits the analyst's bench and the laboratorian is frustrated by knowing that a limited budget is going to preclude replacement of the outmoded model until it has come to the end of its useful life. But equipment costs are only part of the picture. Consumable costs have also risen significantly — fuelled dramatically by the earlier oil crises but never really dropping back again. Kitset analyses (once in bad odium with the professional analyst) have become the norm — but at a cost. Reliable standards and an increasing awareness of the need for quality control all helped to push costs up. Living within a budget — however that budget is imposed — has become a headache for most laboratory managers.

But outside the laboratory stands the clinician and the patient. The clinician aware that part of his armamentarium is a great and increasing range of available pathology tests. Tests that not only allow him to make more accurate diagnoses with greater confidence but allow him in the hospital situation to turn patients around more quickly. He may or may not be made aware of the cost of the testing he orders but he feels the results of not having the testing available are not only detrimental to quicker turnaround and accurate diagnosis, but are an affront to his professional standing if the decision as to whether he can have or can not have a particular test are taken by the laboratory and not himself.

There is little consolation to a clinician that at "unsociable" hours the laboratory does not offer certain tests because of one reason or another but almost always reasons related to cost.

At yet another point stands the laboratory professional — pathologist, medical laboratory technologist or scientific officer. Equally here there is a determination that professional integrity will not be sullied. No less than his clinical colleagues is he willingly prepared to compromise his training and his total professional approach to lower his standards in any way to meet a budget figure — a figure to which he may or may not have had an input. No less than anyone else in the health care team is the technologist concerned that the best is done for the end user of the service — the patient. And so the classical marital eternal triangle of husband, wife, other woman/man, can appropriately have other partners assigned and applied to the laboratory.



Although the pressures are shown here as concentrating on the laboratory one has to be aware that it is possible to put any other of the other partners in the "hot seat". The administrators can be seen as the handlers of the funds and have the funders, the clinicians and the laboratory pressurizing them etc.

For the laboratory the pressures are that it is a demand driven service, operated by laboratory staff unwilling and unhappy to compromise their professional integrity but being asked to live within a constrained buget or at least to justify why it should be at the level of spending that occurs. Increasingly there is the need to justify. For this, laboratory managers are asked to produce performance indicators or similar management units.

The basis of such indicators is an accurate measurement of costs and work performed. The collection of statistics to measure work output has been in force in laboratories for longer than this writer can remember, but always tended to be on some sort of ad hoc basis with the collection figures a useful guide on a local internal basis but of little value on a broader national or international scale. Many systems of collection existed but the need for some more unified, broader system became obvious and various associations and countries have taken steps to provide these. The introduction of the College of American Pathologists Manual for Workload Recording states "effective laboratory management and planning requires assessment of current levels of activity, review of past experiences, and projection of future trends." The ability to measure technical workloads in medical laboratories in a uniform manner was perceived to be essential for the management of these resources. To achieve this object the CAP charged its laboratory management and planning committee in 1969 with developing a workload measurement system. The

committee after surveying existing methods, concluded that its need would best be met through the approach developed by the Canadian Association of Pathologists in collaboration with other professional organisations.

In 1970 a recording method based on the Canadian data was published and has been followed by a number of additions since then and in fact over the last 10 years there has been an updated edition each year. The system is claimed to be "a dynamic system which reflects continuing changes to represent the current state of the art for laboratory medicine."

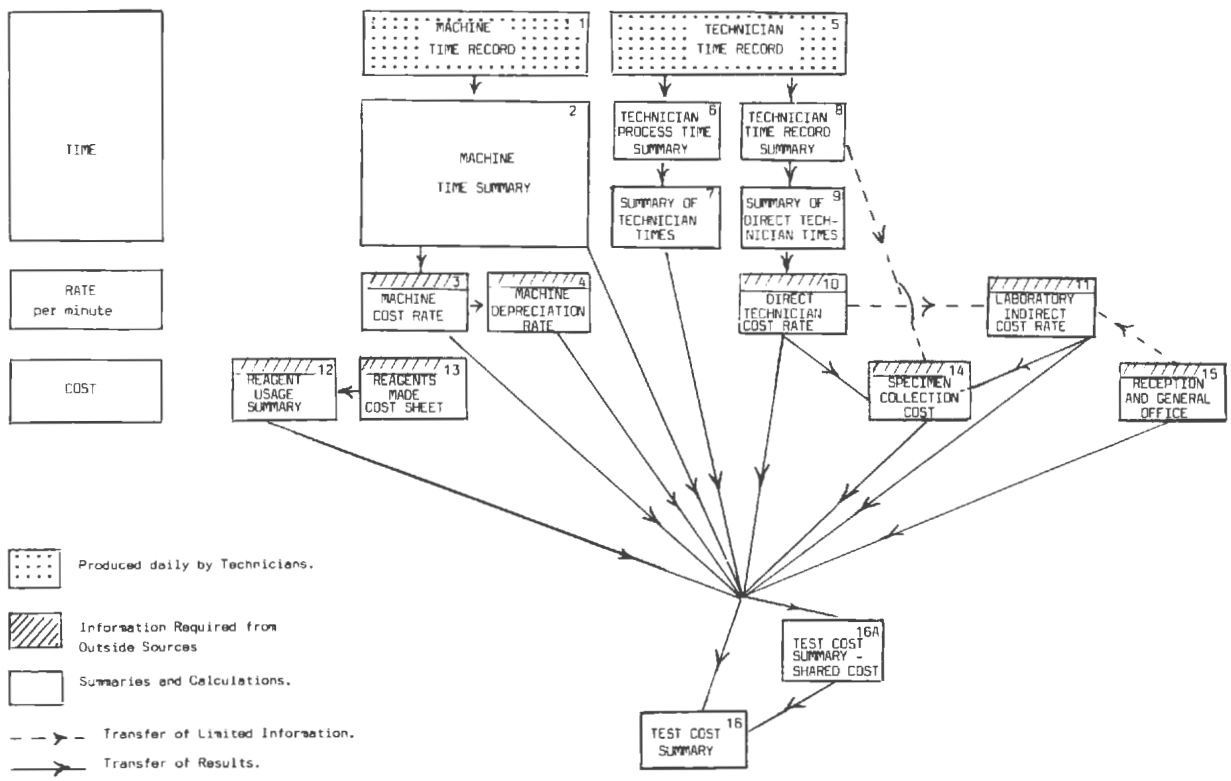
The system accords a schedule of values for every test or procedure performed in the laboratory which is related to a time value based on the average time needed to complete each test. The proposal is that each unit be equivalent to one minute of total laboratory time which is taken to perform that test. The unit values are adjusted for the methodology that is used. The unit value "is the number of minutes of technical, clerical and aide time required to perform all the activities to complete the defined procedure once." The unit value per procedure is at the very heart of the workload recording method. The unit value is derived after time studies measure the time required for the following fields:

1. **Initial handling of the specimen** — which includes the steps from the receipt of the specimen to completion of all preliminary preparation and recording before testing can start.
2. **Specimen testing** — which includes the steps after the initial handling required to perform the laboratory procedure up to the recording of the results on a work sheet.
3. **Recording and reporting** — which includes the steps required to report the results.
4. **Daily and periodic activities** which include all the steps which are performed daily and/or periodically such as instrument cleaning and warm-up, instrument calibration etc.
5. **Maintenance and repair** — of all the equipment involved in the production of a result.
6. **Direct technical supervision** — which includes the time required to directly supervise the procedure such as reviewing quality controls, statistics and validation of results.

Whilst ten years ago the Canadian Manual stated that the recording method is a laboratory management tool to assist in monitoring laboratory function, projection of staff and space requirements, identifying areas of increasing demand and implementing changes in methodology, it also stated that it was **not in itself a cost accounting or billing system.** The latest CAP Manual (1988 edition) states that "one of the most useful items of management information is the total cost per test for each type of billed test. This can be calculated on a test by test basis by calculating the total workload units produced for the test and multiplying by the personnel cost per workload unit. To this must be added the proportionate costs of standards, control, repeats, reagents, disposables, and instrument cost. This provides a figure for the total direct cost of performing the procedure. After adding the proportionate allocated laboratory costs and allocated hospital costs the total cost of the procedure can be determined."

In the mid 1960's a system was introduced in U.K. which counted the number of requests received and used weighting factors which were calculated from timing studies to derive a final workload. The system was not without its critics who contended that the weighting factors were invalid and did not reflect differences between different specialties, were isolated from other data and gave no real information about the types of tests which were done. Despite the disadvantages of the weighting system the Körner working group did not believe that the use of Canadian workload units would overcome the criticisms of their present system. That working group considered that an approximation method using sampling techniques should be adopted for national purposes. However, the views of pathology staff (medical and technical) during two trials that were conducted questioned the value of the information derived.

The processes occurring in these three abovementioned countries can no doubt be paralleled or at least compared with similar exercises being undertaken in other countries. It is not the purpose of this discussion to try and evaluate one method against another but merely to show that there



is a wide range of methods used to record laboratory activity and a similarly wide range of different opinions about the methodologies used and the value that can be derived from them.

What is of interest is the movement away from the simple collection of laboratory statistics reflecting workload alone (or with little emphasis on other parameters) to systems which would provide accurate means of costing pathology tests. For instance, in the U.K. the DHSS used the management consultants Coopers and Lybrand Associates Limited to undertake a study to provide such a costing. The results of their study can be seen in the table on page 3.

While the simple equation for costing a test is to add up all of the costs that are involved in producing the test result this is, in fact, an extraordinarily difficult exercise and almost impossible to work out in detail. While it is a relatively simple exercise to cost technologist time, consumable costs and perhaps energy overheads, it is very difficult to estimate how much should be added for such things as specimen and report transportation and even the admission costs of a patient to hospital. Various systems have been devised to try and evaluate direct and indirect costs in the areas of consumables, labour and capital, but even using such parameters it is difficult to totally identify the costs of any one single test.

Beyond the production of "simple" costing analysis is the production of various management units. One can take the latest edition of the manual for laboratory workload recording method of the College of American Pathologists and find several chapters devoted to the production of various indicators. Such things as staffing and productivity analysis take account of workloaded and non-workloaded activities and are stated as allowing laboratory directors and managers to reach appropriately set targets, identify problem areas and make intra and inter-laboratory comparisons. A number of other indices are stated as being available from the system.

The Welsh workload measurement system for pathology 1987-88 edition prefers to call the productivity indicators operational indicators as this is more descriptive and reflects the range of indicators available other than those relating only to productivity. These operational indicators are ratios obtained using a numerator and denominator with the provision that both factors represent the same function, e.g. staffing, cost, function etc. The Welsh manual lists a number of examples as follows:

I STAFFING INDICATORS

a) Percentage WORKED hours to PAID hours by staff category

$$\frac{\text{worked hours of specified staff}}{\text{total paid hours of specified staff}} \times 100$$

II PRODUCTIVITY INDICATORS

a) Total output in units related to input in paid hours for all personnel within the laboratory budget.

$$\frac{\text{total units in time period}}{\text{total paid hours for period}}$$

b) Output in units related to input in worked hours by any section, department or whole laboratory.

$$\frac{\text{total units in period}}{\text{worked hour for period}}$$

III WORKLOAD INDICATORS

a) Output in units related to time

$$\frac{\text{total units}}{\text{time period}}$$

b) Percentage distribution of units by request source, e.g. in-patient, out-patient, general practice etc.

$$\frac{\text{units from source in time period}}{\text{total units in same period}} \times 100$$

c) Average unit value per item for count

$$\frac{\text{total units}}{\text{total raw counts}}$$

IV FINANCIAL INDICATORS

a) Direct expenses per unit for particular costing head.

$$\frac{\text{total costs}}{\text{total units}}$$

$$\frac{\text{total costs}}{\text{In patient admissions}}$$

$$\frac{\text{personnel costs}}{\text{total units}}$$

$$\frac{\text{on-call costs}}{\text{on-call units}}$$

V UTILISATION INDICATORS

a) Service (in units) provided to specified category

$$\frac{\text{in-patient units}}{\text{in-patient days}}$$

$$\frac{\text{out-patient units}}{\text{out-patient attendances}}$$

b) Service as a percentage of total service for specified category

$$\frac{\text{emergency admission 'on call' units per period}}{\text{total 'on call' units same period}}$$

The purpose of this discussion has not been to present a comprehensive system of workload recording or even an adequate overview of the history of the development of various systems. These are available in detail in various manuals and discussion papers.

What I have hoped to do is to highlight the dynamic nature of pathology laboratories — not merely in the technical areas where change and advance are so demonstrably evident, but also in the area of laboratory management.

The laboratory version of the eternal triangle is not going to go away — almost certainly the pressures will increase and there will be efforts by some outside the laboratory to wrest from the laboratory the authority to be in charge of their testing on an ongoing basis. The production of evidence that the laboratories are efficient users of funds and efficient contributors to the total care system should be the aim of us all. Equally the demonstration through operational indices that we are not doing as well as we should lead us to examine the whole operational procedure and take remedial action.

That we can cope with changing technologies has been well demonstrated. That we can meet the challenges now presented in management areas should be equally proven.

It would be good to hear from various individuals and member organizations how they are meeting the challenges. I believe Med Tec would provide a good forum for airing such information.

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W.H.O. NEWS

Influenza

Influenza is a persistent viral disease of mankind, causing acute illness, great economic losses and death. It occurs periodically in epidemics which may vary from small outbreaks to pandemics.

In the last 40 years, influenza pandemics have tended to occur at intervals of approximately 10 years and epidemics of variable density have been reported every two to three years.

The influenza pandemic spreads from a single focus of disease. Over the centuries, many but not all pandemics have emerged from within the Asian extreme Orient.

In a few months, influenza epidemics may spread from one end of the world to another. This is highly favoured by the increasing speed and proportions of modern inter-country travel. Once implanted in a receptive population, such factors as wet and cold weather, indoor life, public transport facilities, which intensify the frequency of contacts, may trigger the epidemic wave.

Influenza "excess mortality" is not only a direct result of pulmonary bacterial complication (pneumonia), but also of cardiopulmonary or other chronic diseases that are exacerbated during influenza infection.

The risk of death during an influenza epidemic is high in certain population groups such as the aged, the chronically sick (e.g. patients with rheumatic heart disease, cardiovascular disorders, bronchopulmonary disease, immunodeficiency and diabetes mellitus) and persons residing in institutions under crowded conditions. All these people should be given priority for protection by vaccination. Mortality is highest in the over-65 age group.

The first target is to alleviate the severity of influenza through adequate medical care and the competent use of antibiotics and specific antiviral drugs such as amantadine/rimantadine.

Three types of human influenza viruses, A, B and C, were recognized in 1933, 1940 and 1947 respectively. Only type A is associated with pandemics. The gravity of influenza is usually related to type A epidemics and less frequently to type B virus. Type C virus has not been found to be associated with epidemics.

The main body defence mechanism against influenza virus is production of antibodies to various proteins present in the virus, particularly a surface protein, the haemagglutinin, which allows the virus to attach itself to the host cell membrane and thus triggers the infection. The presence of such an antibody repels any new invasion with the same or very similar virus but it is ineffective against antigenically modified viruses. Recently it was found that cell immunity can play an important role in protection against influenza.

The outstanding and disconcerting feature of influenza A viruses is their capacity periodically to change the antigenic characteristics of envelope proteins, haemagglutinin and neuraminidase, and thus escape the neutralizing antibodies developed through previous infections or vaccinations.

There are two different kinds of antigenic variability of influenza viruses: antigenic **drifts** which cover the partial changes, and antigenic **shifts,** in which a complete change of the surface antigen takes place. The last kind is usually associated with pandemics.

Two major hypotheses have been proposed to explain these changes:

(a) both **drifts** and **shifts** are due to the selection of pre-existing mutants through the gradually increasing pressure of immunity built up by the spreading virus until exhaustion of almost all susceptibles;

(b) whereas antigenic drifts may occur through anitbody pressure, the major shift may originate from a hypothetical animal reservoir or as a result of reassertment between human and animal or avian strains of influenza viruses.

WHO collaborative studies are trying to elucidate these mechanisms with the object of finding a more efficient system of control of influenza. The hypothetical role of the animal reservoir for human influenza is being explored through WHO collaborative ecological studies.

Two sorts of influenza vaccines are now available: killed concentrated and purfied for parenteral administration, and live-attenuated vaccines destined for instillation or pulverization into the upper-respiratory paths. Used widely they can give up to 80% protection in the interval before the emergence of new variants of virus. Older vaccines have been found to be much less effective against new antigenic variants and useless against new pandemigenic strains.

Amantadine and rimantadine have been shown to be effective against influenza A infections, both prophylactically and therapeutically (administered within 48 hours of onset of symptoms). In prophylactic use a 70-90% reduction in infection has been achieved.

The WHO influenza programme was established in 1947. Essentially, this programme consists of rapid isolation and characterization of new strains in order to make available for research and production laboratories the ones showing substantial variation from the current strains.

It is now possible to produce recombinants (reassortants) by recombining the new antigenic variant with a strain which has been trained to grow rapidly in chick embryos or with the cold-adapted attenuated master strain, and this reduces the interval of large-scale vaccine production.

Two main objectives for influenza immunization strategies were identified: the first, to protect individuals who are at particular risk of disease, and the second, to protect other defined subsets of population, e.g. schoolchildren, factory workers, etc. In the latter case, immunization may have a direct benefit for both individuals and the community as a whole.

Tuberculosis Control
The Past, the Present, the Future

INTRODUCTION

Tuberculosis has always had and still has the dubious distinction of being a leading contender for one of the top places on the list of main causes of disability and death.

The history of tuberculosis control in the past four decades may serve as a unique example to learn about practically all aspects of any public health programme development, its efficacy, effectiveness and impact. It may sound paradoxical, but tuberculosis control represents an example of both failure and success. Failure because tuberculosis is still a major public health problem for two-thirds of the world population, and success because the elimination of tuberculosis is now considered possible for the remaining one-third who live in socioeconomically advanced societies.

Tuberculosis Control
The Past, the Present, the Future

by
Dr Jerzy Leowski, Tuberculosis Unit
Division of Communicable Diseases

THE PAST

Forty years ago tuberculosis was of such global importance that there was no doubt whatsoever that it deserved high priority within the activities of the emerging World Health Organization. At this time, the disease was considered incurable, and was feared just as much as would be, a few years later, cancer and now AIDS. Although effective chemotherapeutic agents against tuberculosis started to appear, they were costly and only a small minority of patients in industrialized countries were able to benefit from them at that time. It took another decade for the drugs to become more widely available to patients in other countries and then only for those lucky enough to have had the disease diagnosed.

One of the first tasks of the World Health Organization was to lay down the essentials of a comprehensive tuberculosis control policy. Nine expert committees on tuberculosis were convened for the purpose of elaborating recommendations on technical policy concerning control of the disease. The first two held in July 1947 and February 1948 still reported to the Interim Commission prior to the formal establishment of the Expert Committee on Tuberculosis by the First World Health Assembly in June 1948.

Already in those early days it was realized that uniform procedures for sputum examination and X-ray interpretation were necessary, and emphasis was given to accurate recognition of the tubercle bacilli using modern laboratory methods. In the early 1950s, case-finding by mass radiography became highly popular as it was believed that by this method pulmonary tuberculosis could be detected at an early stage. An interesting recommendation was adopted by the sixth Expert Committee on Tuberculosis in 1954, suggesting that mass campaigns including mass case-finding should be integrated into general health services.

During those early years, the foundation was also laid for close cooperation in tuberculosis control between WHO and UNICEF, as well as between WHO and the International Union against Tuberculosis.

THE PRESENT

Current WHO policy on tuberculosis control is based on the concept of comprehensive national tuberculosis programmes implemented through the existing health service network including the primary health care level. The objectives of the programme are twofold; to relieve human suffering by reducing morbidity and mortality caused by tuberculosis; and to progressively reduce incidence of tuberculosis in the community by breaking the chain of transmission of infection.

This concept was formulated for the first time in 1964 and, after a critical review ten years later, it was reaffirmed and enlarged upon.

Reliable diagnostic tools and efficient preventive and curative methods were by now available and had the advantage of being both simple and inexpensive. The planning and implementation of effective national tuberculosis programmes was therefore feasible provided that certain basic principles were adhered to; effective tuberculosis services must be available to rural as well as urban populations; the programme should form a permanent part of the regular on-going health care service thus avoiding risk of a resurgence of the disease due to past infection by the tubercle bacilli of many of the world's adult population.

Nevertheless, progress was very slow. In 1973, WHO's experts on tuberculosis stated that the implementation of the new approach to tuberculosis control had encountered many problems. Shortages of financial, material and physical resources together with maldistribution of trained manpower were aggravated by the lack of managerial skills. The health infrastructures of many countries left much to be desired. The situation led to an increasing feeling of dissatisfaction because of the inability to apply, on an adequate scale, the potent weapons now available to control tuberculosis. In some countries, a major constraint was the reluctance to change traditional and outmoded ways of dealing with the disease. What was needed was determined leadership.

This situation did not change substantially during the 1970s despite acceptance of the basic concepts of tuberculosis control outlined by the WHO Expert Committee.

In 1983, the Thirty-sixth World Health Assembly, after reviewing the tuberculosis situation in the world, noted that it was still an important health problem, especially in developing countries, and that little improvement had been achieved in the last two decades. It urged Member States to intensify their efforts to extend tuberculosis diagnosis, treatment and prevention services to the whole population.

Although the current WHO policy on tuberculosis was formulated more than 20 years ago, it took many years to draw up national control programmes in developing countries and still longer to implement them. It is estimated that probably less than half of the world population has access to existing tuberculosis control technology. Complacency, encouraged by the steady downward trend in tuberculosis cases since the turn of the century, most probably played a role in the slow pace of the programme's implementation.

Some feel that the downward trend, which started long before the advent of specific chemotherapy, will continue unaided by human efforts. In fact, this downward trend is continuing and evidence is now emerging that even in some developing countries with rather limited implementation of control programmes, the risk of tuberculosis infection is decreasing. Many factors may have contributed to this. In developed countries, where the trend started some 100 years ago, there has been a marked improvement in housing, in nutrition and in general living conditions with emphasis on fresh air and proper ventilation, in addition to the isolation of patients in sanatoria. The steady increase in early diagnosis and treatment of patients has also helped to decrease the spread of infection. In some developing countries, tuberculosis control activities were initiated already in the 1950s. Although on a limited scale at the beginning, they were gradually expanded. In these countries, the achievements realised during the past few decades are, most probably, responsible for the downward trend in the risk of infection. However, many countries are still far from having a satisfactory level of programme implementation, with the risk of infection remaining high.

It is now clear that the mere existence of control technology is not enough for the programme's success. Experience has provided, for instance, that the microscopic examination of sputum and the use of prolonged chemotherapy is not easy to implement in rural areas or even in high risk sectors of urban populations. Whether the present control tools are not simple enough to apply or whether the network of health care institutions is still too scarce, is an open question. Probably both factors play equally important roles, and if so, both have

to be addressed appropriately.

We are burdened with a huge reservoir of infected persons who are a major source of new cases. In developing countries at least half the population is likely to be infected with tubercle bacilli. This proportion is much lower in developed countries and in some of them only 10% or less may be infected.

It has been estimated that around 5% of those infected will develop the disease in their life time and neither the combination of prompt diagnosis and effective treatment nor even a 100% efficient vaccine can prevent the emergence of cases from the infected pool. This is particularly so in developing countries, where the risk of reinfection is very high.

In developed countries, the available control measures, and particularly early diagnosis and effective treatment, prevent the inflow and further expansion of the pool of infected persons, as well as decrease the prevalence of tuberculosis. Some specialists claim that wide-scale application of preventive therapy for infected persons may substantially strengthen this impact and allow us already to envisage the elimination of tuberculosis.

As far as most developing countries are concerned there is no evidence, however, that control measures being applied at present have any impact on the prevalence of tuberculosis. The emerging downward trend in the risk of infection has to continue for some decades to affect the tuberculosis problem there. Furthermore, it is unrealistic to expect developing countries to apply preventive treatment, when most of the existing cases of tuberculosis are not detected and treated.

THE FUTURE

The elimination of tuberculosis worldwide is not likely within the next few decades and our planning must therefore aim at a steady decrease in the inflow of infected persons which, together with demographic changes, will allow us to eventually eliminate tuberculosis. It will, however, be a matter of several generations.

The process could certainly be accelerated. It would require, however, immunological and epidemiological breakthroughs that would allow us to identify those who still harbour living tubercle bacilli, plus a therapeutic breakthrough which would result in a safe, quick and inexpensive method to kill these dormant organisms. Research along these lines has recently been initiated by WHO and there are a number of promising new drugs at various stages of development and testing that may soon become available.

These research efforts, if successful, may provide us with the possibility of predicting the development of disease in infected persons by identifying specific mycobacterial products in their blood, urine or body fluids. This, coupled with powerful drugs for treatment, including preventive treatment, may provide the key for elimination of the disease worldwide. The eradication of tuberculosis presents challenges that will surpass those encountered in the eradication of smallpox. The AIDS epidemic presents another challenge, which is somewhat disturbing, since it has shown that there is a pronounced interaction between mycobacterial and HIV infections. This has become apparent from the high incidence of tuberculosis in AIDS patients. Its future implication is that in populations where the risk of HIV infection and mycobacterial infection are high, one can expect a considerable increase in the incidence of tuberculosis. The world badly needs scientists who are ready to take up these challenges.

There is also an urgent need to transfer to developing countries the expertise and research technology that still exists in some developed countries. The sad fact is that in the past few decades, many tuberculosis research institutions in developed countries have closed down since the magnitude of the tuberculosis problem in these countries no longer justifies their existence. It is therefore up to developing countries themselves to take over the task, and for WHO to mobilize the necessary resources and provide guidance for the development of tuberculosis research institutions in countries and areas where the problem of tuberculosis will remain important for several decades to come.

AIDS

WORLD SUMMIT SETS GLOBAL DAY ON AIDS

The World Health Organization (WHO), with the overwhelming support of delegates from 148 nations at a World AIDS Summit in London, is to organize the first World Day on AIDS to promote information and education in the global struggle against AIDS. WHO Director-General Dr Halfdan Mahler, who made the announcement, said the first "World Day" will be 1 December 1988.

The "World Day" reflects the unanimous endorsement by Ministers of Health from 114 nations and hundreds of top public health experts at the Summit of a "London Declaration" making 1988 a Year of Communication and Cooperation about AIDS. The Summit of 26-28 January was jointly organized by the United Kingdom Government and the WHO Global Programme on AIDS.

WHO said the World Day on AIDS will involve people all over the world — in different countries, from different cultures — in talking in an informed way about AIDS. The day will continue the dialogue of the three-day London Summit, which stressed the importance of information and education, in the absence of a vaccine or cure, in preventing and controlling the spread of the AIDS virus.

The London Declaration also stresses the need to broaden the scope of information programmes, strengthen the exchange of life-saving information and experience among all countries, and forge a spirit of social tolerance for HIV infected persons, including those with AIDS, throughout the world. The Declaration says AIDS represents a "serious threat to humanity", and requires "urgent action by all governments and people the world over" to implement the WHO Global AIDS Strategy as defined by the Fortieth World Health Assembly and supported by the United Nations General Assembly.

"We recognize that, particularly in the absence at present of a vaccine or cure for AIDS, the single most important component of national AIDS programmes is information and education because HIV transmission can be prevented through informed and responsible behaviour", the Ministers said.

In his closing address, Dr Mahler said: "We must make sure that this exchange of information becomes a continuing process everywhere and is given high public visibility in order to induce as widespread optimism as possible. We must therefore make use of this summit as a launching pad for a sustained AIDS communication programme throughout the world.

"You have designated 1988 as a year of communication on AIDS, and I intend to promote a World Day of Dialogue on AIDS", Dr Mahler said.

The UK Government and WHO, in examining the results of the Summit, said it had been the largest and most authoritative gathering of public health officials ever assembled to map strategy to fight a single disease.

"This meeting, which included addresses by over 100 Health Ministers, senior delegates, and other experts, has

once again clearly illustrated the overwhelming international support for a global effort to fight AIDS", said Dr Jonathan Mann, Director of the WHO Global Programme on AIDS. "The call has now gone out to all corners of the earth that the fight to control and ultimately prevent the further spread of AIDS can, and indeed will be won through a worldwide effort."

The summit made the following declaration:

1. Since AIDS is a global problem that poses a serious threat to humanity, urgent action by all governments and people the world over is needed to implement WHO's Global AIDS Strategy as defined by the Fortieth World Health Assembly and supported by the United Nations General Assembly.

2. We shall do all in our power to ensure that our governments do indeed undertake such urgent action.

3. We undertake to devise national programmes to prevent and contain the spread of human immunodeficiency virus (HIV) infection as part of our countries' health systems. We commend to all governments the value of a high level coordinating committee to bring together all government sectors, and we shall involve to the fullest extent possible all governmental sectors and relevant nongovernmental organizations in the planning and implementation of such programmes in conformity with the Global AIDS Strategy.

4. We recognize that, particularly in the absence at present of a vaccine or cure for AIDS, the single most important component of national AIDS programmes is information and education because HIV transmission can be prevented through informed and responsible behaviour. In this respect, individuals, governments, the media and other sectors all have major roles to play in preventing the spread of HIV infection.

5. We consider that information and education programmes should be aimed at the general public and should take full account of social and cultural patterns, different lifestyles, and human and spiritual values. The same principles should apply equally to programmes directed towards specific groups, involving these groups as appropriate. These include groups such as:

— policy makers;
— health and social service workers at all levels;
— international travellers;
— persons whose practices may place them at increased risk of infection;
— the media;
— youth and those that work with them, especially teachers;
— community and religious leaders;
— potential blood donors; and
— those with HIV infections, their relatives and others concerned with their care, all of whom need appropriate counselling.

6. We emphasize the need in AIDS prevention programmes to protect human rights and human dignity. Discrimination against, and stigmatization of, HIV-infected people and people with AIDS and population groups undermine public health and must be avoided.

7. We urge the media to fulfil their important social responsibility to provide factual and balanced information to the general public on AIDS and on ways of preventing its spread.

8. We shall seek the involvement of all relevant governmental sectors and nongovernmental organizations in creating the supportive social environment needed to ensure the effective implementation of AIDS prevention programmes and humane care of affected individuals.

9. We shall impress on our governments the importance for national health of ensuring the availability of the human and financial resources, including health and social services with well-trained personnel, needed to carry out our national AIDS programmes, and in order to support informed and responsible behaviour.

10. In the spirit of United Nations General Assembly Resolution A/42/8, we appeal:

— to all appropriate organizations of the United Nations system, including the specialized agencies;
— to bilateral and multilateral agencies; and
— to nongovernmental and voluntary organizations

to support the worldwide struggle against AIDS in conformity with WHO's global strategy.

11. We appeal in particular to these bodies to provide well-coordinated support to developing countries in setting up and carrying out national AIDS programmes in the light of their needs. We recognize that these needs vary from country to country in the light of their epidemiological situation.

12. We also appeal to those involved in dealing with drug abuse to intensify their efforts in the spirit of the International Conference on Drug Abuse and Illicit Trafficking (Vienna, June 1987) with a view to contributing to the reduction in the spread of HIV infection.

13. We call on the World Health Organization, through its Global Programme on AIDS, to continue to:

(i) exercise its mandate to direct and coordinate the worldwide effort against AIDS;
(ii) promote, encourage and support the worldwide collection and dissemination of accurate information on AIDS;
(iii) develop and issue guidelines on the planning, implementation, monitoring and evaluation of information and education programmes, including the related research and development, and ensure that these guidelines are updated and revised in the light of evolving experiences;
(iv) support countries in monitoring and evaluating preventive programmes, including information and education activities, and encourage wide dissemination of the findings in order to help countries to learn from the experiences of others;
(v) support and strengthen national programmes for the prevention and control of AIDS.

14. Following from this Summit, 1988 shall be a Year of Communication and Cooperation about AIDS in which we shall:

— open fully the channels of communication in each society so as to inform and educate more widely, broadly and intensively;
— strengthen the exchange of information and experience among all countries; and
— forge, through information and education and social leadership, a spirit of social tolerance.

15. We are convinced that, by promoting resonsible behaviour and through international cooperation, we **can** and **will** begin **now to slow the spread of HIV infection**.

WHO, UNDP FORM UNPRECENDENTED ALLIANCE ON AIDS

The World Health Organization (WHO) and the United Nations Development Programme (UNDP) have formed an unprecedented alliance to expand the global impact of the struggle against AIDS. The agreement forming the alliance was signed today at the United Nations Headquarters in New York by Dr Halfdan Mahler, Director-General of WHO and Mr William H. Draper III, the Administrator of UNDP.

The alliance, initiated by WHO, is consistent with the U.N. General Assembly resolution of October 1987, which emphasized the need to have a well-coordinated, multi-

sectoral apprach by the U.N. system to the prevention and control of the AIDS pandemic. The alliance combines the strengths of WHO as coordinator of international health policy and scientific and technical matters relating to health with that of UNDP, the leader in the field of socio-economic development.

The alliance was approved in principle by the WHO Executive Board in January and the UNDP Governing Council in February.

Through the alliance with UNDP, the global fight against AIDS will be carried through health ministries to all levels of government, such as ministries of education and information, economic planning, development and finance, justice and the interior by using the extensive UNDP network of Resident Representatives in developing countries. UNDP maintains the largest development network in the world involved in virtually all sectors of social and economic activities.

"WHO needs allies in the U.N. system in its fight against AIDS", Dr Mahler said. "Since AIDS is a problem not only for health but social and development sectors, it is only natural that WHO should forge a major alliance with the UNDP and its development expertise".

"The unanimous decision by the UNDP Governing Council approving the alliance underscores the growing awareness that the AIDS epidemic has critical implications for developing countries well beyond the health issue created by AIDS", said Mr Draper.

The WHO-UNDP alliance is significant because it would:

— Ensure that AIDS is treated as more than a health problem by involving a wide spectrum of government ministries in designing, implementing and evaluating national programmes on AIDS;

— Help include AIDS activities in governments' overall development plans, priorities and resource allocation;

— Coordinate U.N. system support to national AIDS programmes and help governments coordinate all external support to their national AIDS programmes;

— Strengthen support for teams from the WHO Global Programme on AIDS based in many countries.

MEMBER SOCIETIES NEWS

UNITED KINGDOM

IMLS SYMPOSIA

2-4 September 1988 Sheffield	*Collection 88*—Cellular pathology	Mr A.W. Currie, Histopathology, Department, Royal Hallamshire Hospital, Glossop Road, Sheffield S10 2JF.
September 1988 Cardiff	*Microbe '88*	Mr T.C. Fitzgerald, Medical Microbiology, Llandough Hospital, Penarth, South Glamorgan.
March 1989 Nottingham	Microbiology/Virology	Mr A. Pawley, Virology Department, PHL, Queens Medical Centre, University Hospital, Nottingham.
26 April 1989 Liverpool	Clinical chemistry	Mr D. Kilshaw, Pathology Department, Arrowe Park Hospital, Upton, Wirral, Merseyside L49 5PE
2-9 September 1989 Warwick	*IMLS Triennial Conference*	Mr C.G. Smith, Pathology Department, Dudley Road Hospital, Summerfield, Birmingham B18 7QH.
30-31 March 1990 York	Microbiology/histology/ cytology	Mr B. Jones, Pathology Department, Royal Halifax Infirmary, Free School Lane, Halifax HX1 2YP.
April 1990 Durham	*Blood Group Serology '90*	Miss D.L. Trattles, Blood Transfusion Laboratory, Department of Clinical Pathology, General Hospital, Ayresome Green Lane, Middlesbrough, Cleveland TS5 5AZ.
20-23 September 1990 Sheffield	*Microbe '90*	Mr C.J.P. Brazier, Public Health Laboratory, Northern General Hospital, Herries Road, Sheffield S5 7AU.
September 1990 Birmingham	Cellular pathology	Miss L. Grosvenor, Histopathology Department, General Hospital, Steelhouse Lane, Birmingham B4 6NH.
April 1991 Durham	Microbiology	Mr G.P. Hedley, Regional Transfusion Centre, Holland Drive, Barrack Road, Newcastle upon Tyne NE2 4NG.
April 1991 Sheffield	*Haematology — in a different vein*	Mr N.R. Porter, Haematology, Floor H, Royal Hallamshire Hospital, Glossop Road, Sheffield S10 2JF.
September 1992	*IMLS Triennial Conference*	—
April 1994 Durham	Microbiology	Mr G.P. Hedley, Regional Transfusion Centre, Holland Drive, Barrack Road, Newcastle upon Tyne NE2 4NG.

SWEDEN

Svenska laboratorieassistentföreningen (SLF) and SSF:s Rikssektion för laboratoriesköterskor are planning to arrange the Nordic Group (NML) Congress in February 1989. The Congress will be arranged jointly with the Swedish Federation of Salaried Employees in the Health Services' (SHSTF's) convention at the Älvsjömässan (where the IAMLT-Congress 1986 was held). The theme for the Convention will be "Health for all — Reality or vision?". The Laboratory Programme covers HIV, Immunology, Hematology, ultrasonic diagnosis, molecular biology and analysing work close to patients. Apart from the Laboratory Programme, many other seminars will be arranged, such as Nursing Quality, Ethics, Management and Organizational Development and Health Care. The associations in Sweden hope to receive many applications for abstracts and posters from our colleagues in the Nordic countries and are trying our best to achieve a well-organized NML-Congress!

MALAYSIA

The University of Malaya Medical Centre will be celebrating its Silver Jubilee this coming July/August. In collaboration with the Malaysian Society of Medical Laboratory Technologists, a medical laboratory technology conference is organized from 1-3 August 1988. There will be papers over a wide range of laboratory activities plus a plenary session which includes papers on AIDS. COMPUTERIZATION and BIOTECHNOLOGY.

Further information is available from:
Mr Ng Lik Lin,
Department of Orthopaedic Surgery,
Faculty of Medicine,
University of Malaya,
59100 KUALA LUMPUR.

Nominations 1988 for the council of IAMLT

President:	Desmond J. Philip, New Zealand
President Elect:	Ulla-Britt Lindholm, Sweden (SLF)
Past President:	Dennis B. Slade, United Kingdom
Tresurer:	Helen Due-Boje, Denmark
Council members:	Beverly Fiorella, U.S.A.
	Marja-Kaarina Koskinen, Finland (SLaby)
	Graham Smart, United Kingdom
	Genji Suganuma, Japan
	Claudia Wilfing, Austria
	Sung-Thong Woon, Malaysia (MSMLT)

Graham Smart
United Kingdom

Graham Smart started work at the Cardiff Royal Infirmary in 1956. He became a Fellow of the Institute of Medical Laboratory Sciences, with Final Examinations in Haematology and Blood Group Serology and Histopathology in 1963, by which time he was working as a Senior Medical Laboratory Scientific Officer (MLSO) in the Haematoogy department at the Royal Berkshire Hospital in Reading. In 1965 he returned to Cardiff as a Chief MLSO at the newly opened Dental School leaving in 1977 to take up his present post as Principal MLSO to the Southampton Laboratories, for which he is responsible, employ 160 MLSO's, has an annual budget of approximately 3,000,000 pounds Sterling and deals with 820,000 requests per annum.

In 1972 Graham was awarded a Diploma in Management Studies and in 1977 a Bachelor of Arts degree in Philosophy and Social Sciences.

1972 also saw his election to the Council of the Institute of Medical Laboratory Sciences. Since that time he has served on all the principal Institute Committees and on several working parties. He is currently a Council member of the Institute and Chairman of the Fellowship Committee and of the Validation Panel.

In 1980 he became President Elect of the Institute, was President from 1982 to 1984 and Past President from 1985 to 1987.

He was an IMLS delegate at the International Association Congress in Durban in 1980, was IMLS Chief Delegate at Amsterdam in 1982 and Perth in 1984.

He was elected to the Council of the International Association in 1984 and re-elected in 1986. He has served as Chairman of the Membership Committee and as a member of the Awards and Safety Committees.

Beverly Fiorella
Department of Medical Laboratory Services
College of Associated Health Professions
690 College of Medicine East
808 South Wood Street,
Chicago, IL 60612, U.S.A.

Ms Fiorella is currently a Professor of Medical Laboratory Sciences at the University of Illinois at Chicago. She has served the American Society for Medical Technology in many positions including on the Board of Directors and as President. She has on her own already attended three IAMLT meetings and expressed an interest in IAMLT and its activities and goals.

Marja-Kaarina Koskinen
Finland

Marja-Kaarina qualified as Medical Laboratory Technologist in 1967, special training in clinical chemistry and haematology 1979-1980, teacher training of MLT 1985-87.

She was working as a MLT in town hospital laboratory in Lahti, a Assistant Chief Technologist at the laboratory of Helsinki University Hospital, a teacher of Medical Laboratory Institute in Helsinki and now as an organization secretary in The Union of Health Professionals in Finland.

She was a council member of Medical Laboratory Technologists Association in Finland 1975-81, a vice president 1981-84, a president since 1984.

She was a chief delegate at Amsterdam 1982, at Perth 1984 and at Stockholm 1986.

Genji Suganuma
Japan

Born 1934.
Qualified for Government Licence of Medical and Clinical Technologist 1960 in Japan.
Employed in Center for Adult Disease Osaka Japan 1959-1965.
Chief Technologist in Clinical Laboratory of Subsidiary of Takeda Pharmaceutical Co., 1965-70. Director of Clinical Laboratory at PL Hospital Automated Multiphasic Health Testing and Services Centre Tokyo 1970-80. President of Independent Medical Research Institute and Consultant for Government Business (ODA) 1980-88. Council member of Japanese Association of Multi-phasic Health Testing System and Services 1972-88. International Health Evaluation Association (IHEA) Director 1986-88. Region officer of Treasurer of IHEA Region-3 Asia Pacific 1986-88. Secretary General of JCCLS (Japan Committee for Clinical Laboratory Standards). Executive Director of Foundation for Musashino Kenko Kaihatsu Jigyodan 1987-present.

Claudia Wilfing
Born 1950

1968-70 — School for Medical Laboratory Technologists, Vienna - Diploma.
1971-72 — 2nd Department of Dermatology/University Clinic Vienna: Venereal Diseases; besides evening classes in Tropical Diseases.
1972-74 — District Hospital Loitokitok, Kenya, East-Africa: in charge of a well equipped laboratory, 2 co-workers.
1974-78 — 2nd Department of Dermatology/University Clinic Vienna: Venereal Diseases. Leave for several months for research purposes in Kenya and North East Zaire.
1978-79 — Maternity leave
1979-80 — L. Boltzmann Institute for experimental Anaesthesiology
1980-now — L. Boltzmann Institute for experimental Traumatology — part time besides self-employed as study coordinator and administrator.
1985 — Elected vice president of the Austrian Association of Laboratory Technologists.

Since 1984 responsible for the scientific program of the Austrian Association of Medical Laboratory Technologists.

Publications:

The Incidence of Treponemal Disease in Adult Men at Loitokitok, Kajado District. East African Medical Journal, Vol. 54, 5, 1977.

Probleme in der modernen Syphilisidiagnostik. Med. Lab. Band 32, 1979.

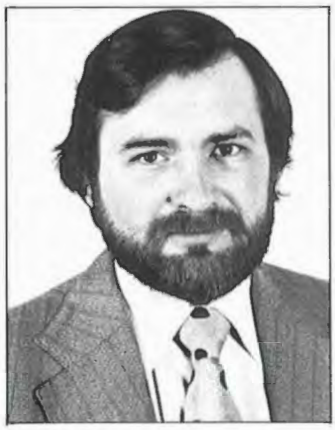
Parasitologische Ergebnisse einer medizinisch-anthropologischen Untersuchung bei den Azande Nordost-Zaires. Wiener Medizinische Wochenschrift, 129 Jahrgang 1979.

Progress in Clinical and Biological Research, Volume 236A, First Vienna Shock Forum, Part A: "Cellular Effects of Aprotinin" (165-173), Alan Ra. Liss, New York, USA.

Papers presented at the IAMLT congresses:
1978 Edinburgh: Problems in Modern Syphilis Diagnosis
1982 Amsterdam: Principles and Methods of Fibrin Sealing
1988 Kobe: Abstract Forwarded: Study Coordination and Administration; Plasma and Data Collection in a Multicenter Study Related to Mediators of Multi Organ Failure.

Mr Sung-Thong Woon

Currently President Malaysian Society of Medical Laboratory Technologists. Mr Woon is also the current Secretary of the Asean Association of Medical Laboratory Technologists (AAMLT) and Pro-tem Chairman of the Malaysian Federation of Medical Laboratory Technologists.



Graham Smart

Marja-Kaarina Koskinen

Genji Suganuma

Claudia Wilfing

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Graham Smart, Pathology Department, Southampton General Hospital, Tremona Road, Southampton, S09 4XY, United Kingdom.

Genji Suganuma, Japanese Association of Medical Technologist, 4-1-5 Kudan-kita, Chiyoda-ku, Tokyo 102, Japan.

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IAMLT Executive Office
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S-114 26 Stockholm
Sweden.
Tel: 46 8 10 30 31

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Austria: Verbande der Diplomierten Medizinish Assistentinnen Österreichs, Lazarettgasse 14, Postfach 32, A- 1097 Wien.

Belgium: Association Belge des Technologues de Laboratoire, General Secretary, Stenenmolenstraat 64, 2800, Mechelen.

Chile: The President/Secretary, Colegio de Tegnologos Medicos de Chile, Jose Miguel de la Barra 480, Clasificador 303, Santiago de Chile.

Denmark: Landssammenslutningen af Hospitalslaboranter, Norre Voldgade 90, 1358 Copenhagen K.

Fiji: Fiji Medical Laboratory Technologist Association, P.O. Box 4121, Samabula.

Finland: Laboratory Nurses in Finland, Toolontullinkatu 8, SF-00250 Helsinki 25.

Finland: Suomen Laboratoriohoitajayhdistys R.Y., Stationskarlsgatan 4, 00520 Helsinki 52.

Germany: Deutscher Verband Technischer Assistenten in der Medizen-EV, Rüttenschneider Strasse 158, D-4300, Essen 1.

Hong Kong: Hong Kong Medical Technology Association, The Secretary, The Federation of Medical Societies of Hong Kong, 4th Floor, Duke of Windsor Building, 15 Hennessy Road.

Iceland: Mainataeknafelag Islands, P.O. Box 1448, IS-121 Reykjavik.

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Ireland: Medical Laboratory Technologists Association, 29 Parnell Square, Dublin 1.

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Korea: Korean Association of Medical Technologists, 501 Choong Moo Building, 1-580 Yeouiedo Dong, Yeong Deung Po-Ku, SEOUL 150, *Republic of Korea.*

Malaysia: The Institute of Medical and Health Laboratory Technology Malaysia, c/o Institute for Medical Research, Jalang Pahang, 50588 KUALA LUMPUR.

Malaysia: The Malaysian Society of Medical Laboratory Technologists, c/o Faculty of Medicine, University of Malaya, 591 00 KUALA LUMPUR.

Netherlands: Vereniging van Medische Analisten, Wilhelminapark 52, 3581, NM Utrecht.

New Zealand: The New Zealand Institute of Medical Laboratory Technology Inc, Mr B.T. Edwards, Haematology Department, Christchurch Hospital, Private Bag, Christchurch 1.

Norway: Norsk Bioingeniørforbund, Lekkegata 19-21, 0187 Oslo 1.

Pakistan: Association of Pakistan Medical Laboratory Technologists, 1/A/1/19 Nazmabad, Karachi.

Singapore: Association of Medical Laboratory Technicians, Hon. Secr. Mr Kamarudin Ali, Medical Centre, 4-A College Road, Singapore 3.

Spain: Asociacion Espanola de Tecnicos de Laboratorio en Analisis Clinicos, Apdo 17, 169, c/o Tortosa 6-4°E, Madrid 7.

Sri Lanka: Sri Lanka Association of Government Medical Laboratory Technologists, Medical Research Institute, P.O. Box 527, Colombo 8.

Surinam: Vereniging Medische Analisten Suriname, P.O. Box 9316, Paramaribo.

Sweden: Svenska Laboratorieassistentföreningen, Östermalmsgatan 19, S-114 26 Stockholm.

Sweden: SSF:s Rikssektion för Laboratoriesköterskor, C/o Birgit Czar-Weidhagen, Arbetargatan 28 B, S-112 45 Stockholm.

Switzerland: Schweizerischer Faschverband der diplomierten medizinischen Laborantinnen und Laboranten, Case Postale 174, 1211 Geneve 12, SCHWEIZ.

Taiwan: Taipei Society of Medical Technologists, Cathay General Hospital, 280 Section 4, Jen-Ai Road, Taipei.

United Kingdom: Institute of Medical Laboratory Sciences, 12 Queen Anne Street, LONDON W1M OAU, *United Kingdom.*

United States of America: American Society for Medical Technology, 2021 L Street, NW, Suite 400, Washington DC 20036, U.S.A. (202) 785-3311.

West Indies: Caribbean Association of Medical Technologists, Pathology Department, Queen Elizabeth Hospital, Martindales Road, St Michael, BARBADOS.

Zimbabwe: Association of Medical Technologists of Zimbabwe, P.O. Box 8220, Causeway, Harare.

"Med Tec" is published twice a year. Scientific articles or papers, technical notes, Society news and letters to the editor will be considered for publication. Copy should be typewritten. Scientific material may be submitted in English, French or German. French or German articles must include a brief abstract or summary in English. Artricles indicated in the text and legends for illustrations should be typed separately.

Send two (2) copies to:

Desmond J. Philip, Editor, Med Tec International,
19 Taihiki Road, Clarks Beach, R.D.4., Pukekohe, New Zealand.

Closing Dates: Number 1 — March 1; Number 2 — September 1

MED TECH INTERNATIONAL

Editor:

Desmond J. Philip

19 Taihiki Road,
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Printed by Institute Press Ltd. Auckland

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Standard conc	Results	
Oxazepam ng/mL	EMIT ΔA	TDx ng/mL
0		28
100	471	85
200	516	153
300	556	192
400	585+	255+
500	601+	291+
Diazepam ng/mL	EMIT ΔA	TDx ng/mL
0		28
100	546	129
200	677+	235+
300	756+	352+
400	803+	494+
500	812+	644+

Table 2: *Standard curve data for both oxazepam and diazepam.*
(+) As defined in Table 1.

ng/mL were prepared using TDx buffer as a diluent. The standards were assayed by both methods (Table 2, Figures 1 and 2).

From the calibration curves it appears that specific benzodiazepines could be quantitated if it is known which benzodiazepine is present. The clear differences between the curves is an indication of the different affinity shown by the antibody for the each benzodiazepine and this is further reflected in the concentrations found by TDx or absorbance changes found by EMIT for identical concentrations of the different drugs (Table 1).

For a day to day comparison, all urines received over a period of five days for routine analysis were assayed by both methods. Of the 60 urines tested, all results greater than the EMIT calibrator also gave results greater than the chosen threshold on the TDx. With the exception of one specimen, all urines which gave a negative result by the EMIT method, gave a TDx value of less than 50 ng/mL. One urine gave a reading of 92 ng/mL by TDx but was negative by EMIT. Low concentrations of nitrazepam and flunitrazepam give negative results by EMIT, but may be detected as weak positives using the TDx assay. Metabolites of benzodiazepines which contain an aromatic nitro group in their molecule are easily confirmed by thin layer chromatography. This group of drugs includes the nitrazepam type and clonazepam. Confirmation that the specimen giving the reading on the TDx of 92 ng/mL did contain such a compound was obtained.

Laboratory Application

Over a 3 week period a slight drift was observed in the assay, with the control values falling outside the prescribed range. Since in this laboratory the benzodiazepine assay is used as a screening test only, a 200 ng/mL diazepam calibrator was prepared in urine and tested immediately after the assay had been recalibrated. This calibrator gave results between 190 and 210 ng/mL, and could be routinely used in lieu of controls. Samples which give results lower than this would be reported as negative for benzodiazepine metabolities. Samples giving results higher than the calibrator would be reported as positive. Should a quantitative result be required and the benzodiazepine is known, then a series of standards could be analysed and calibration curves prepared.

Conclusion

In all testing so far, the TDx benzodiazepine assay has proved as sensitive and reliable as the EMIT process. Both are unsuitable for measuring or identifying chlordiazepoxide and clonazepam, and show reduced sensitivity to bromazepam and lorazepam, apparently due to low affinity of the antibody for the drug.

Based on the manufacturers recommended thresholds, (300 ng/mL of oxazepam for EMIT and 200 ng of nordiazepam for the TDx) excellent correlation between the two methods was obtained. All specimens which produced a positive result by one method being confirmed by the other. Benzodiazepines containing an aromatic nitro group may be detected at a lower threshold when used in conjunction with thin layer chromatography as a confirmatory test.

The Pacific Way

Sori Tumas

The following is an extract from a paper entitled "Sori Tumas" by D. R. Hamilton, Surgeon at Nonga Base Hospital, Rabaul, Papua New Guinea. (The extracts are published with the permission of Dr Hamilton.) In these days of advanced technology and sophisticated surgical techniques the *needs of* and *long term benefits to* the patient are often overlooked in the enthusiastic approach to treatment. The patient may be informed by the Medical Team that a particular line of treatment and/or surgey is in his/her own interests — but is it always so? Should the "Sori Tumas" option be adapted more frequently and offered when the outcome is inevitable?

Sori Tumas

"Sori Tumas, sik bilong yu em i bikpela tumas"
(I am very sorry you have a large tumour)
Mi no ken katim na rausim em olgeta, mi no gat marasin long winim despela sik.
(I cannot operate and I have no medicine for it).
Ahting moabeta bai yu go long ples bilong yu.
(I think it would be better for you to go home).

A patient is admitted to Nonga under my care with an abdominal mass suggestive of a hepatoma. We order an alpha fetoprotein to confirm the diagnosis, but because of delays in the laboratory it is two weeks before we get the result back which is positive. During this time the mass has got bigger and the patient looks a bit sicker; though he has not complained about the delay in waiting for the laboratory result.

On confirming my clinical diagnosis I advise the patient that there is nothing we can do to help him, the mass is going to get bigger, he is going to die, and I advise him to go home. If the patient lives locally, about half an hour after I have spoken to him he leaves the hospital and will probably not be seen by a doctor again.

It is not that I am ignorant of alternatives. I am aware that in Malaya where hepatoma is common, patients with hepatoma may have major liver resections; hepatic artery ligation, or selective devascularisation, or canularisation with regional perfusion of cytotoxics. Although aware of the alternatives I have decided not to attempt any treatment on patients with hepatoma.

I am becoming increasingly convinced that an important part of my job here is working out when not to treat. This is most noticeable on my trips to district hospitals (Kavieng, Kimbe and Manus). On each visit I advise two or three patients to go no further i.e., "Don't go to Rabaul for surgery or Lae for radiotherapy; just go back to your village".

The criteria I use for deciding which patients not to treat is different to that which would be used in other countries. I recognise that this is a highly controversial topic; and realise that many doctors working in Papua New Guinea would consider the criteria for working out when to treat here should be the same as anywhere.

I feel that many doctors recruited from overseas find working out when to do nothing very difficult. There are several reasons for this:

(i) The question of standards. Many overseas medical graduates would feel that by declining possible treatment to a patient they have irreparably lowered their standards. The alternative argument is that they have learnt to adjust to the reality of the situation; and have learnt to distinguish between what can be done; and what should be done.

(ii) This is something we have never been taught to do. As students, residents, registrars we were encouraged to suggest further investigations that could be done for our patients; and to know and suggest all possible available means of treatment. To stand up on the ward round and suggest to the boss that the operation he is keen on doing would be a complete waste of time and not in the patient's interest, is not the way to get through the system.

(iii) It is 'Anti the God Complex' to look a patient straight in the face and admit that we have nothing to offer him is harder to do than ordering more tests, or trying further palliation, until the patient either dies or gets the message and absconds.

Most of my local patients initial approach to the hospital, and expectations from it, are quite different to those of an expatriate. The expatriate if told he has a serious problem expects to be made better quickly; or at least for SOMETHING TO BE DONE. The local patient has probably tried village medicine which has failed. He realises his views on aetiology are quite different to mine, and that I do not understand his views. He accepts the fact that he is going to die one day far better than an expatriate. His approach is more 'can something be done or would I be wasting my time staying here?' He does not necessarily appreciate it if we do something, simply for the sake of doing something.

Medical practitioners last century accepted their role as being to heal the sick; or relieve the suffering; or comfort the dying. The modern graduate knows he can do much more than was possible just a few years ago. He has been trained to treat enthusiastically that which is reasonably treatable but may be incapable of appreciating that "At some point in the degeneration process 'cure' and even rehabilitation become impossible goals; and that to continue to apply these goals is to mistreat the patient".

The Effect on the Village

A patient after noticing a swelling over his liver for 2 months presents with a hepatoma. We offer him no treatment and send him home. We have done him no good but we have done him no harm.

Wanted — Equipment That Is No Longer Used

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A hand centrifuge or a small bench centrifuge.

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Daniel Uche Chukwu,
15 Albert Street,
Island Bay,
Wellington.

A year later, his wantok after a bout of diarrhoea also develops pain and swelling over his liver. He feels he has the same sickness that killed his friend; but if he doesn't feel we did his friend any harm he may feel it worthwhile trying the hospital and if he does we are able to treat his amoebic liver abscess. If we had attempted treatment on the man with hepatoma, and had sent him home looking dreadful a week before he died, the patient with the liver abscess may well have died at home without seeking medical attention.

In conclusion I believe that knowing when to look a patient straight in the eye and say "Sori Tumas no ken winim dispela sik" is an important part of my job in Papua New Guinea — that it is important to be able to distinguish between the diagnosis of an exciting surgical challenge; and the diagnosis of a tragedy".

The title of this paper could equally well have been entitled "The Pacific Way". The judgement is not ours to make but what the article does state is common sense.

World Congress of Medical Technology Geneva, Switzerland, August 5 to 10, 1990

presented by The International Association of Medical Laboratory Technologists (IAMLT)]

Geneva, January 16, 1988

Dear Colleagues

It is our pleasure to let you have our preliminary information concerning the 19th World Congress of Medical Technology, to be held at the University Medical Center in Geneva, Switzerland, August 5 to 10, 1990. The main subject of the meeting will be Medical Technology —A Challenge To Change.

Scientific lectures given by experts in the field will cover such topics as Immunology, Hematology, Hemostasis, Blood Banking, Microbiology, Histopathology/Cytology and Genetics. Subjects like Toxicology, Drug Monitoring, Health, Safety in Laboratory, Education and Management, Data Processing, Automation etc. will be discussed in different symposia, chaired by specialists. In addition, there will be an international exhibition of medical equipment.

We hope, that many colleagues of the 35 member societies will participate at this professional event and expect, with pleasure, the submission of short lectures and/or poster presentations.

The preliminary Programme will be presented at the IAMLT Congress in Japan in July 1988.

We will be most happy to welcome a large number of guests from all over the world in Geneva, Switzerland 1990.

Geneva is an internationally well-known city, located on a beautiful lake in the French speaking part of Switzerland.

Looking forward to see you next July in Kobé, we remain with kind regards,

Yours sincerely

Anne-Marie Moppert
President
Schweiz.Fachverband der dipl.med. Laborantinnen und Laboranten

Erica Lorenz
Chairman
Scientific Committee
Geneva 1990

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Uniform Requirements for Manuscripts Submitted to Biomedical Journals

International Committee of Medical Journal Editors*

Reprinted from: Annals of Internal Medicine 1988; 108: 258-265

In January 1978 a group of editors from some major biomedical journals published in English met in Vancouver, British Columbia, and decided on uniform technical requirements for manuscripts to be submitted to their journals. These requirements, including formats for bibliographic references developed for the Vancouver group by the National Library of Medicine, were published in three of the journals early in 1979. The Vancouver group evolved into the International Committee of Medical Journal Editors (ICMJE). At the October 1981 meeting the requirements were revised slightly and published in a second edition in 1982. Since then the group has issued several separate statements, and these have been incorporated into the main part of this, the third, edition.

Over 300 journals have agreed to receive manuscripts prepared in accordance with the initial, previously published, requirements. It is important to emphasize what these requirements imply and what they do not.

Firstly, the requirements are instructions to authors on how to prepare manuscripts, not to editors on publication style. (But many journals have drawn on these requirements for elements of their publication styles.)

Secondly, if authors prepare their manuscripts in the style specified in these requirements, editors of the participating journals will not return manuscripts for changes in these details of style. Even so, manuscripts may be altered by journals to conform with details of their own publication styles.

Thirdly, authors sending manuscripts to a participating journal should not try to prepare them in accordance with the publication style of that journal but should follow the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals."

Nevertheless, authors *must also* follow the instructions to authors in the journal as to what topics are suitable for that journal and the types of papers that may be submitted (for example, original articles, reviews, case reports). In addition, the journal's instructions are likely to contain other requirements unique to that journal, such as number of copies of manuscripts, acceptance languages, length of articles, and approved abbreviations.

Participating journals are expected to state in their instructions to authors that their requirements are in accordance with "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" and to cite a published version.

This document will be revised at internals. Inquiries and comments from Central and North America about these requirements should be sent to Edward J. Huth, M.D., *Annals of Internal Medicine*, 4200 Pine Street, Philadelphia, PA 19104, USA; those from other regions should be sent to Stephen P. Lock, M.D., *British Medical Journal*, British Medical Association, Tavistock Square, London WC1H 9JR, United Kingdom. Note that these two journals provide secretariat services for the International Committee of Medical Journal Editors; they do not handle manuscripts intended for other journals. Papers intended for other journals should be sent directly to the offices of those journals.

Summary of Requirements

Type the manuscript double spaced, including title page, abstract, text, acknowledgments, references, tables, and legends.

Each manuscript component should begin on a new page, in the following sequence.

Title page
Abstract and key words
Text
Acknowledgments
References
Tables: each table, complete with title and footnotes, on a separate page
Legends for illustrations

Illustrations must be good-quality, unmounted glossy prints usually 127 by 173 mm (5 by 7 in.) but no larger than 203 by 254 mm (8 by 10 in.).

Submit the required number of copies of manuscript and figures (*see* journal's instructions) in a heavy-paper envelope. The submitted manuscript should be accompanied by a covering letter, as described under "Submission of Manuscripts", and permissions to reproduce previously published materials or to use illustrations that may identify human subjects.

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Prior and Duplicate Publication

Most journals do not wish to consider for publication a paper on work that already has been reported in a published paper or is described in a paper submitted or accepted for publication elsewhere. This policy does not usually preclude consideration of a paper that has been rejected by another journal or of a complete report that follows publication of a preliminary report, usually in the form of an abstract. When submitting a paper, an author should always make a full statement to the editor about all submissions and previous reports that might be regarded as prior to duplicate publication of the same or very similar work. Copies of such material should be included with the submitted paper to help the editor decide how to deal with the matter.

Multiple publication — that is, the publication more than once of the same study results, irrespective of whether the wording is the same — is rarely justified. Secondary publication in another language is one possible justification, provided the following conditions are met.

(a) The editors of both journals concerned are fully informed; the editor concerned with secondary publication should have a photocopy, reprint, or manuscript of the primary version.
(b) The priority of the primary publication is respected by a publication interval of at least two weeks.
(c) The paper for secondary publication is written for a different group of readers and is not simply a translated version of the primary paper; an abbreviated version will often be sufficient.
(d) The secondary version reflects faithfully the data and interpretations of the primary version.
(e) A footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper was edited, and is being published, for a national audience in parallel with a primary version based on the same data and interpretations. A suitable footnote might read as follows: "This article is based on a study first

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* Edward J. Huth, M.D.; *Annals of Internal Medicine*; Kathleen King, M.R.C. Path.; *The Medical Journal of Australia*; Stephen P. Lock, M.D., *British Medical Journal*; George D. Lundberg, M.D., *Journal of the American Medical Association*; Ian Munro, M.B., *The Lancet*; Magne Nylenna, M.D., *Tidsskrift for Den Norske Laegeforening*; Roy Rada, M.D.; *Index Medicus*; Arnold S. Relman, M.D., *New England Journal of Medicine*; Povl Riis, M.D.; *Journal of the Danish Medical Association and Danish Medical Bulletin*; Richard G. Robinson, Ch.M., *New Zealand Medical Journal*; Bruce P. Squires, M.D., *Canadian Medical Association Journal*; Dr. Ilkka Vartiovaara; *Finnish Medical Journal*; Malcolm S. M. Watts, M.D.; *The Western Journal of Medicine*.

reported in the [title of journal, with full reference]".

Multiple publication other than as defined above is not acceptable to editors. If authors violate this rule, they may expect appropriate editorial action to be taken.

Preliminary release, usually to public media, of scientific information described in a paper that has been accepted but not yet published is a violation of the policies of many journals. In a few cases, and only by arrangement with the editor, preliminary release of data may be acceptable, for example, to warn the public of health hazards.

Preparation of Manuscript

Type the manuscript on white bond paper, 216 by 279 mm (8½ by 11 in.) or ISO A4 (212 by 297 mm), with margins of at least 25 mm (1 in.). Type only on one side of the paper. Use double spacing throughout, including title page, abstract, text, acknowledgments, references, tables, and legends for illustrations. Begin each of the following sections on separate pages: title page, abstract and key words, text, acknowledgments, references, individual tables, and legends. Number pages consecutively, beginning with the title page. Type the page number in the upper or lower right-hand corner of each page.

TITLE PAGE

The title page should carry 1) the title of the article, which should be concise but informative; 2) first name, middle initial, and last name of each author, with highest academic degree(s) and institutional affiliation; 3) name of department(s) and institution(s) to which the work should be attributed; 4) disclaimers, if any; 5) name and address of author responsible for correspondence about the manuscript; 6) name and address of author to whom requests for reprints should be addressed, or statement that reprints will not be available from the author; 7) the source(s) of support in the form of grants, equipment, drugs, or all of these; and 8) a short running head or footline of no more than 40 characters (count letters and spaces) placed at the foot of the title page and identified.

AUTHORSHIP

All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content.

Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

A paper with corporate (collective) authorship must specify the key persons responsible for the article; others contributing to the work should be recognized separately (*see* Acknowledgments and Other Information).

Editors may require authors to justify the assignment of authorship.

ABSTRACT AND KEY WORDS

The second page should carry an abstract of no more than 150 words. The abstract should state the purposes of the study or investigation; basic procedures (selection of study subjects or experimental animals, observational and analytic methods); main findings (give specific data and their statistical significance, if possible); and the principal conclusions. Emphasize new and important aspects of the study or observations.

Below the abstract, provide, and identify as such, 3 to 10 key words or short phrases that will assist indexers in cross-indexing your article and that may be published with the abstract. Use terms from the Medical Subject Headings (MeSH) list of *Index Medicus*; if suitable MeSH terms are not yet available for recently introduced terms, present terms may be used.

TEXT

The text of observational and experimental articles is usually — but not necessarily — divided into sections with the headings Introduction, Methods, Results, and Discussion. Long articles may need subheadings within some sections to clarify their content, especially the Results and Discussion sections. Other types of articles such as case reports, reviews, and editorials are likely to need other formats. Authors should consult individual journals for further guidance.

Introduction: State the purpose of the article. Summarize the rationale for the study or observation. Give only strictly pertinent references, and do not review the subject extensively. Do not include data or conclusions from the work being reported.

Methods: Describe your selection of the observational or experimental subjects (patients or experimental animals, including controls) clearly. Identify the methods, apparatus (manufacturer's name and address within parenthesis marks [round brackets]), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (*see* below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Ethics: When reporting experiments on human subjects, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) or with the Helsinki Declaration of 1975, as revised in 1983. Do not use patients' names, initials or hospital numbers, especially in any illustrative material. When reporting experiments on animals indicate whether the institution's or the National Research Council's guide for, or any national law on, the care and use of laboratory animals was followed.

Statistics: Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid sole reliance on statistical hypothesis testing, such as the use of *P* values, which fails to convey important quantitative information. Discuss eligibility of experimental subjects. Give details about randomization. Describe the methods for, and success of, any blinding of observations. Report losses to observation (such as dropouts from a clinical trial). References for study design and statistical methods should be standard works (with pages stated) when possible rather than to papers where designs or methods were originally reported. Specify any general-use computer programs used.

Put general descriptions of methods in the Methods section. When data are summarized in the Results section, specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid non-technical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal", "significant", "correlation", and "sample". Define statistical terms, abbreviations, and most symbols.

Results: Present your results in logical sequence in the text, tables, and illustrations. Do not repeat in the text all the data in the tables, illustrations, or both; emphasize or summarize only important observations.

Discussion: Emphasize the new and important aspects of the study and the conclusions that follow them. Do not repeat in detail data or other material given in the Introduction or the Results section. Include in the Discussion section the implications of the findings and their limitations, including implications for future research. relate the observations to other relevant studies. Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not completely supported by your data. Avoid claiming priority and alluding to work that has not been completed. State new hypotheses when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

ACKNOWLEDGMENTS

At an appropriate place in the article (title-page footnote or appendix to the text; *see* the journal's requirement) one or more statements should specify: (a) contributions that need acknowledging but do not justify authorship, such as general support by a departmental chairman; (b) acknowledgments of technical help; (c) acknowledgments of financial and material support, specifying the nature of the support; (d) financial relationships that may pose a conflict of interest.

Persons who have contributed intellectually to the paper but whose contributions do not justify authorship may be named and their function or contribution described, for example, "scientific adviser", "critical review of study proposal", "data collection", "participation in clinical trial". Such persons must have given their permission to be named. Authors are responsible for obtaining written permission from persons acknowledged by name because readers may infer their endorsement of the data and conclusions.

Technical help should be acknowledged in a paragraph separate from those acknowledging other contributions.

REFERENCES

Number references consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by arabic numerals within parenthesis marks. References cited only in tables or in legends to figures should be numbered in accordance with a sequence established by the first identification in the text of the particular table or illustration.

Use the style of the examples below, which are based on the formats used by the U.S. National Library of Medicine in *Index Medicus*. The titles of journals should be abbreviated according to the style used in *Index Medicus*. Consult *List of Journals Indexed in Index Medicus*, published annually as a separate publication by the Library and as a list in the January issue of *Index Medicus*; also see the list of journal titles and abbreviated titles at the end of this document.

Try to avoid using abstracts as references; "unpublished observations" and "personal communications" may not be used as references, although references to written, not oral, communications may be inserted (within parenthesis marks) in the text. Include among the references papers accepted but not yet published; designate the journal and add "in press" (within parenthesis marks). Information from manuscripts submitted but not yet accepted should be cited in the text as "unpublished observations" (within parenthesis marks).

The referencesimust be verified by the author(s) against the original documents.

Examples of correct forms of references are given below

Journals

1. Standard Journal Article (List all authors when six or less; when seven or more, list only first three and add et al.)
   You CH, Lee KY, Chey RY, Menguy R. Electrogastrographic study of patients with unexplained nausea, bloating and vomiting. Gastroenterology 1980; 79: 311-4.
2. Corporate Author
   The Royal Marsden Hospital Bone-Marrow Transplantation Team. Failure of syngeneic bone-marrow graft without preconditioning in post-hepatitis marrow aplasia. Lancet 1977; 2: 242-4.
3. No Author Given
   Anonymous. Coffee drinking and cancer of the pancreas [Editorial]. Br Med J 1981; 283:628.
4. Journal Supplement
   Mastria AR. Neuropathy of diabetic neurogenic bladder. Ann Intern Med 1980; 92(2 Pt 2):316-8. Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan [Abstract]. Blood 1979; 54 (Suppl 1): 26a.
5. Journal Paginated by Issue
   Seaman WB. The case of the pancreatic pseudocyst. Host Pract 1981; 16 (Sep): 24-5.

Books and Other Monographs

6. Personal Author(s)
   Eisen HN. Immunology: an introduction to molecular and cellular principles of the immune response. 5th ed. New York: Harper and Row, 1974:406.
7. Editor, Compiler, Chairman as Author
   Dausset J, Colombani J, eds. Histocompatibility testing 1972. Copenhagen: Munksgaard, 1973:12-8.
8. Chapter in a Book
   Weinstein, L, Swartz MN. Pathogenic properties of invading microorganisms. In: Sodeman WA Jr, Sodeman WA, eds. Pathologic physiology: mechanisms of disease. Philadelphia: WB Saunders, 1974:457-72.
9. Published Proceedings Paper
   DuPont B. Bone marrow transplantation in severe combined immunodeficiency with an unrelated MLC compatible donor. In: White HJ, Smith R, eds. Proceedings of the third annual meeting of the International Society for Experimental Hematology. Houston: International Society for Experimental Hematology, 1974:44-6.
10. Monograph in a Series
    Hunninghake GW, Gadek JE, Szapiel SV, et al. The human alveolar macrophage. In: Harris CC, ed. Cultured human cells and tissues in biomedical research. New York: Academic Press, 1980:54-6. (Stoner GD, ed. Methods and perspectives in cell biology; vol 1).
11. Agency Publication
    Ranofsky AL. Surgical operations in short-stay hospitals: United States-1975. Hyattsville, Maryland: National Center for Health Statistics, 1978; DHEW publication no. (PHS) 78-1785, (Vital and health statistics; series 13; no 34).
12. Dissertation or Thesis
    Cairns RB. Infrared spectroscopic studies of solid oxygen [Dissertation]. Berkeley, California: University of California, 1965. 156 p.

Other Articles

13. Newspaper Article
    Shaffer RA. Advances in chemistry are starting to unlock mysteries of the brain: discoveries could help cure alcoholism and insomnia, explain mental illness. How the messengers work. Wall Street Journal 1977 Aug 12:1 (col 1), 10 (col 1).
14. Magazine Article
    Roueche B. Annals of medicine: the Santa Claus culture. The New Yorker 1971 Sep 4:66-81.

TABLES

Type each table double spaced on a separate sheet. Do not submit tables as photographs. Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Give each column a short or abbreviated heading. Place explanatory matter in footnotes, not in the heading. Explain in footnotes all nonstandard abbreviations that are used in each table. For footnotes, use the following symbols, in this sequence: *, †, ‡, §, ||, ¶, **, ††, ...

Identify statistical measures of variations such as standard

deviation and standard error of the mean.

Do not use internal horizontal and vertical rules.

Be sure that each table is cited in the text.

If you use data from another published or unpublished source, obtain permission and acknowledge fully.

The use of too many tables in relation to the length of the text may produce difficulties in the layout of pages. Examine issues of the journal to which you plan to submit your paper to estimate how many tables can be used per 1000 words of text.

The editor, on accepting a paper, may recommend that additional tables containing important back-up data too extensive to publish be deposited with an archival service, such as the National Auxiliary Publication Service (NAPS) in the United States, or made available by the authors. In that event, an appropriate statement will be added to the text. Submit such tables for consideration with the paper.

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Submit the required number of complete sets of figures. Figures should be professionally drawn and photographed; freehand or typewritten lettering is unacceptable. Instead of original drawings, roentgenograms, and other materials, send sharp, glossy black-and-white photographic prints, usually 127 by 173 mm (5 by 7 in.) but no larger than 203 by 254 mm (8 by 10 in.). Letters, numbers, and symbols should be clear and even throughout, and of sufficient size that when reduced for publication each item will still be legible. Titles and detailed explanations belong in the legends for illustrations, not on the illustrations themselves.

Each figure should have a label pasted on its back indicating the number of the figure, author name, and the top of the figure. Do not write on the back of the figures, or scratch or mar them using paper clips. Do not bend figures or mount them on cardboard.

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Type legends for illustrations double spaced, starting on a separate page, with arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend. Explain internal scale and identify method of staining in photomicrographs.

Units of Measurement

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Temperatures should be given in degrees Celsius. Blood pressures should be given in millimetres of mercury.

All hematologic and clinical chemistry measurements should be reported in the metric system in terms of the International System of Units (SI). Editors may request that alternative or non-SI units be added by the author before publication.

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Use only standard abbreviations. Avoid abbreviations in the title and abstract. The full term of which an abbreviation stands should precede its first use in the text unless it is a standard unit of measurement.

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Manuscripts must be accompanied by a covering letter. This must include (a) information on prior or duplicate publication or submission elsewhere of any part of the work; (b) a statement of financial or other relationships that might lead to a conflict of interest; (c) a statement that the manuscript has been read and approved by all authors; and (d) the name, address, and telephone number of the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs. The letter should give any additional information that may be helpful to the editor, such as the type of article in the particular journal the manuscript represents and whether the author(s) will be willing to meet the cost of reproducing colour illustrations.

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PARTICIPATING JOURNALS

The journals listed in Table 1 are those that notified the ICMJE of their willingness to consider for publication manuscripts prepared in accordance with the guidance given in the second (1982) edition of the Uniform Requirements for the Submission of Manuscripts to Biomedical Journals. Their listing here does not imply that they endorse this present version (3rd) of "Uniform Requirements ....". The *Index Medicus* abbreviations for journal titles are given within square brackets.

Table 1: Journals Participating in the Uniform Requirements Agreement

Acta Medica Colombiana [Acta Med Colomb]
Acta Orthopaedica Scandinavica [Acta Orthor Scand]
Acta Paediatrica Japonica [Acta Paediatr Jpn (Overseas)]
Acta Paediatrica Scandinavica [Acta Paediatr Scand]
Acta Pharmacologica Sinica [Acta Pharmcal Sin]
Activox [Activox]
AIDS: An International Bimonthly Journal [AIDS]
American Family Physician [Am Fam Physician]
The American Journal of Cardiology [AM J Cardiol]
The American Journal of Clinical Nutrition [Am J Clin Nutr]
American Journal of Diseases of Children [AM J Dis Child]
The American Journal of Emergency Medicine [Am J Emerg Med]
American Journal of Epidemiology [Am J Epidemiol]
American Journal of Hospital Pharmacy [Am J Hosp Pharm]
The American Journal of Human Genetics [AM J Hum Genet]
The American Journal of Medicine [Am J Med]
American Journal of Obstetrics and Gynecology [Am J Obstet Gynecol]
American Journal of Optometry and Physiological Optics [Am J Optom Physiol Opt]
The American Journal of Pathology [Am J Pathol]
The American Journal of Psychiatry [Am J Psychiatry]
The American Journal of Public Health [Am J Public Health]
AJR: American Journal of Roentgenology [AJR]
The American Journal of Surgery [Am J Surg]

American Review of Respiratory Disease [Am Rev Respir Dis]
The American Surgeon [Am Surg]
Anaesthesia [Anaesthesia]
Anaesthesia and Intensive Care [Anaesth Intensive Care]
Anaethesia and Analgesia [Anesth Analg]
Annals of Clinical Biochemistry [Ann Clin Biochem]
Annals of Clinical and Laboratory Science [Ann Clin Lab Sci]
Annals of Internal Medicine [Ann Intern Med]
The Annals of Otology, Rhinology and Larynogology [Ann Otol Rhinol Laryngol]
Annals of the Rheumatic Diseases [Ann Rheum Dis]
The Annals of the Royal College of Physicians and Surgeons of Canada [Ann R Coll Physicians Surg Can]
Annals of the Royal College of Surgeons of England [Ann R Coll Surg Engl]
Annals of Surgery [Ann Surg]
The Annals of Thoracic Surgery [Ann Thorac Surg]
Annals of Tropical Paediatrics [Ann Trop Paediatr]
Archives of Dermatology [Arch Dermatol]
Archives of Disease in Childhood [Arch Dis Child]
Archives of General Psychiatry [Arch Gen Psychiatry]
Archives of Internal Medicine [Arch Intern Med]
Archies of Neurology [Arch Neurol]
Archives of Ophthalmology [Arch Ophthalmol]
Archives of Otolarynogology — Head and Neck Surgery [Arch Otolaryngol]
Archives of Pathology and Laboratory Medicine [Arch Pathol Lab Med]
Archives of Surgery [Arch Surg]
Archivos de Investigacion Medica [Arch Invest Med (Mex)]
Arizona Medicine [Ariz Med]
Arteriosclerosis: A Journal of Vascular Biology and Thrombosis [Arteriosclerosis]
Australasian Journal of Dermatology [Australas J Dermatol]
Australian and New Zealand Journal of Medicine [Aust NZ J Med]
Australian and New Zealand Journal of Ophthalmology [Aust NZ J Ophthalmol]
The Australian and New Zealand Journal of Surgery [Aust NZ J Surg]
Australian Family Physician [Aust Fam Physician]
Australian Journal of Hospital Pharmacy [Aust J Hosp Pharm]
Australian Orthoptic Journal [Aust Orthopt J]
Australian Paediatric Journal [Aust Paediatr J]
Bangladesh Journal of Child Health [Bangladesh J Child Health]
Bibliothek for Laeger [Bibl Laeger]
Biomedical Bulletin [Biomed Bull]
Boletin de la Asociaction Medica de Puerto Rico [Bol Asoc Med PR]
Boletin Medico del Hospital Infantil de Mexico [Bol Med Hosp Infant Mex]
Bordeaux Medical [Bord Med]
Brain and Development [Brain Dev]
British Dental Journal [Br Dent J]
British Heart Journal [Br Heart J]
British Homoeopathic Journal [Br Homoeopath J]
British Journal of Anaesthesia [Br J Anaesth]
British Journal of Industrial Medicine [Br J Ind Med]
British Journal of Occupational Therapy [Br J Occup Ther]
British Journal of Ophthalmology [Br J Ophthalmol]
British Journal of Pain [Br J Pain]
British Journal of Rheumatology [Br J Rheumatol]
British Journal of Surgery [Br J Surg]
British Medical Bulletin [Br Med Bull]
British Medical Journal [Br Med J]
Bulletin of the Medical Library Association [Bull Med Libr Assoc]
British Osteopathic Journal [Br Osteopath J]
Bulletin of the World Health Organisation [Bull WHO]
Canadian Family Physician [Can Fam Physician]
Canadian Journal of Anaesthesia [Can J Anaesthes]
Canadian Journal of Comparative Medicine [Can J Comp Med]
Canadian Journal of Public Health [Can J Public Health]
Canadian Journal of Surgery [Can J Surg]
Canadian Medical Association Journal [Can Med Assoc J]
Canadian Veterinary Journal [Can Vet J]
Cardiovascular Research [Cardiovasc Res]
Central African Journal of Medicine [Cent Afr J Med]
Cephalagia [Cephalalgia]
Chest [Chest]
Chinese Journal of Anesthesiology [Chin J Anesthesiol]
Chinese Journal of Cardiovascular Disease [Chin J Cardiovasc Dis]
Chinese Journal of Dermatology [Chin J Dermatol]
Chinese Journal of Digestion [Chin J Dig]
Chinese Journal of Endocrinology and Metabolism [Chin J Endocrinol Metab]
Chinese Journal of Epidemiology [Chin J Epidemiol]
Chinese Journal of Experimental Surgery [Chin J Exp Surg]
Chinese Journal of Geriatology [Chin J Geriatol]
Chinese Journal of Hematology [Chin J Hematol]
Chinese Journal of Hospital Administration [Chin J Hosp Adm]
Chinese Journal of Industrial Hygiene and Occupational Disease [Chin J Ind Hyg Occup Dis]
Chinese Journal of Infectious Diseases [Chin J Infect Dis]
Chinese Journal of Internal Medicine [Chin J Intern Med]
Chinese Journal of Medical History [Chin J Med Hist]
Chinese Journal of Medical Laboratory Technology [Chin J Med Lab Technol]
Chinese Journal of Microbiology and Immunology [Chin J Microbiol Immunol]
Chinese Journal of Nephrology [Chin J Nephrol]
Chinese Journal of Neurology and Psychiatry [Chin J Neurol Psychiatr]
Chinese Journal of Neurosurgery [Chin J Neurosurgy]
Chinese Journal of Nuclear Medicine [Chin J Nucl Med]
Chinese Journal of Obstetrics and Gynecology [Chin J Obstet Gynecol]
Chinese Journal of Oncology [Chin J Oncol]
Chinese Journal of Ophthalmology [Chin J Ophthalmol]
Chinese Journal of Organ Transplantation [Chin J Organ Transplant]
Chinese Journal of Orthopedics [Chin J Orthop]
Chinese Journal of Otolaryngology [Chin J Otolaryngol]
Chinese Journal of Pathology [Chin J Pathol]
Chinese Journal of Pediatric Surgery [Chin J Pediatr Surg]
Chinese Journal of Pediatrics [Chin J Pediatr]
Chinese Journal of Physical Medicine [Chin J Phys Med]
Chinese Journal of Physical Therapy [Chin J Phys Ther]
Chinese Journal of Plastic Surgery and Burns [Chin J Plast Surg Burn]
Chinese Journal of Preventive Medicine [Chin J Prev Med]
Chinese Journal of Radiological Medicine and Protection [Chin J Radio Med]
Chinese Journal of Radiology [Chin J Radio]
Chinese Journal of Stomatology [Chin J Stomatol]
Chinese Journal of Surgery [Chin J Surg]
Chinese Journal of Tuberculosis and Respiratory Diseases [Chin J Tuberc Respir Dis]
Chinese Journal of Urology [Chin J Urol]
Chinese Medical Journal [Chin J Med]
Chronic Diseases in Canada [Chronic Dis Can]
Circulation [Circulation]
Clinica Chimica Acta [Clin Chim Acta]
Clinical Chemistry [Clin Chem]
Clinical and Experimental Optometry [Clin Exp Optom]
Clinical Diabetes [Clin Diabet]
Clinical and Investigative Medicine [Clin Invest Med]

Clinical Pediatrics [Clin Pediatr (Phila)]
Clinical Pharmacology and Therapeutics [Clin Pharmacol Ther]
Clinical Pharmacy [Clin Pharm]
Clinical Preventive Dentistry [Clin Prev Dent]
Community Dentistry and Oral Epidemiology [Community Dent Oral Epidemiol]
Community Medicine [Community Med]
Cuadernos del Hospital de Clinicas [Cua Hosp Clin]
Danish Dental Journal [Dan Dent J]
Danish Medical Bulletin [Dan Med Bull]
Diabetes [Diabetes]
Diabetes Care [Diabetes Care]
Diabetes Journal [Diabetes J]
Diabetologia [Diabetologia]
Diagnostic Cytopathology [Diagn Cytopathol]
Drug Intelligence and Clinical Pharmacy [Drug Intel Clin Pharm]
Environmental Medicine [Environ Med]
European Heart Journal [Eur Heart J]
European Journal of Cancer and Clinical Oncology [Eur J Cancer Clin Oncol]
European Journal of Clinical Investigation [Eur J Clin Invest]
European Journal of Respiratory Diseases [Eur J Respir Dis]
European Journal of Rheumatology and Inflammation [Eur J Rheumatol Inflamm]
Family Medicine [Fam Med]
Family Practice Research Journal [Fam Pract Res J]
The Finnish Medical Journal [Finn Med J]
Gastroenterology [Gastroenterology]
Gastrointestinal Endoscopy [Gastrointest Endosc]
Genitourinary Medicine [Genitourin Med]
Geriatrics [Geriatrics]
Gut [Gut]
Hawaii Medical Journal [Hawaii Med J]
Health Trends [Health Trends]
Hellenike Cheirourgike [Hell Cheir]
Helleniki Iatrike [Hell Iatr]
Hong Kong Medical Technology Association Journal [Hong Kong Med Technol Assoc J]
Hospital Pharmacy [Hosp Pharm]
Iatrike [Iatrike]
Indian Journal of Dermatology, Venereology, and Leprology [Indian J Dermatol Venereol Lepr]
Indian Journal of Gastroenterology [Indian J Gastroenterol]
Indian Journal of Urology [Indian J Urol]
International Disability Studies [Int Disabil Stud]
International Journal of Epidemiology [Int J Epidemiol]
International Journal of Pediatric Nephrology [Int J Pediatr Nephrol]
International Surgery [Int Surg]
Israel Journal of Psychiatry and Related Sciences [Isr J Psychiatry Relat Sci]
JAMA (Chicago) [JAMA]
The Journal of Allergy and Clinical Immunology [J Allergy Clin Immunol]
Journal of the American College of Cardiology [J Am Coll Cardiol]
Journal of the American Medical Association (see *JAMA*)
The Journal of Applied Nutrition [J Appl Nutr]
Journal of Biological Standardization [J Biol Stand]
Journal of the British Association for Immediate Care [J Br Assoc Immed Care]
Journal of the Canadian Association of Radiologists [J Can Assoc Radiol]
Journal of the Candian Chiropractic Association [J Can Chiropr Assoc]
Journal of Cardiovascular Surgery [J Cardiovasc Surg]
Journal of Chronic Diseases [J Chronic Dis]
Journal of Clinical Gastroenterology [J Clin Gastroenterol]
Journal of Clinical Pathology [J Clin Pathol]
Journal of the Danish Medical Association (see *Ugeskrift for Laeger*)
The Journal of Diabetic Complications [J Diabetic Compl]
Journal of Diarrhoeal Disease Research [J Diarrhoeal Dis Res]
Journal of Epidemiology and Community Health [J Epidemiol Community Health]
Journal of the Faculty of Medicine Baghdad [J Fac Med Baghdad]
Journal of the Institute of Medicine [J Inst Med]
Journal of the Irish Colleges of Physicians and Surgeons [J Lab Clin Med]
The Journal of Laboratory and Clinical Medicine [J Lab Clin Med]
The Journal of Maternal and Child Health [J Maternal Child Health]
Journal of Manipulative and Physiological Therapeutics [J Manipulative Physiol Ther]
Journal of Medical Ethics [J Med Ethics]
Journal of Medical Genetics [J Med Genet]
Journal of National Cancer Institute [JNCI]
Journal of Neurology, Neurosurgery and Psychiatry [J Neurol Neurosurg Psychiatry]
Journal of Neuropathology and Experimental Neurology [J Neuropathol Exp Neurol]
The Journal of Nuclear Medicine [J Nucl Med]
Journal of Nuclear Medicine Technology [J Nucl Med Technol]
The Journal of Palliative Care [J Palliat Care]
Journal of Pathology [J Pathol]
Journal of Pharmacy Technology [J Pharm Technol]
Journal of Psychosomatic Research [J Psychosom Res]
Journal of the Royal Army Medical Corps [J R Army Med Corps]
Journal of the Royal College of Physicians of London [J R Coll Physicians Lond]
Journal of the Royal College of Surgeons of Edinburgh [J R Coll Surg Edinb]
Journal of the Royal Naval Medical Service [J R Nav Med Serv]
Journal of the Vivekanandra Institute of Medical Sciences [J Vivekananda Inst Med Sci]
Lakartidningen [Lakartidningen]
The Lancet [Lancet]
Leprosy Review [Lepr Rev]
Malaysian Journal of Pathology [Malays J Pathol]
Manedsskrift for Praktisk Laegegerning [Manedsskr Prakt Laegegern]
Medicina Intensiva [Med Intensiv]
Medical Care [Med Care]
Medical and Pediatric Oncology [Med Pediatr Oncol]
The Medical Journal of Australia [Med J Aust]
Medical Laboratory Sciences [Med Lab Sci]
Medicina Clinica [Med Clin (Barc)]
Medicine (Oxford) [Medicine (Oxford)]
Military Medicine [Milit Med]
The Mount Sinai Journal of Medicine [Mt Sinai J Med (NY)]
National Medical Journal of China [Chung Hua I Hsueh Tsa Chih]
Nederlands Tijdschrift voor Geneeskunde [Ned Tijdschr Geneeskd]
Neurology [Neurology]
New Doctor [N Doctor]
The New England Journal of Medicine [N Engl J Med]
New York State Journal of Medicine [NY State J Med]
New Zealand Family Physician [NZ Fam Physician]
New Zealand Journal of Medical Laboratory Technology [NZ J Med Lab Technol]
New Zealand Medical Journal [NZ Med J]
Newfoundland Medical Association Journal [Newfoundland Med Assoc J]
Nigerian Medical Journal [Niger Med J]

No To Hattatsu [No To Hattatsu]
Nordisk Medicin [Nord Med]
North Carolina Medical Journal [NC Med J]
Nosokomaka Chronica [Nosokom Chron]
Nursing [Nursing]
Obstetrics and Gynecology [Obstet Gynecol]
Ophthalmology [Ophthalmology]
Otolaryngology and Head and Neck Surgery [Otolaryngol Head Neck Surg]
Papua New Guinea Medical Journal [Papua New Guinea Med J]
Pharmacy Management Combined with the American Journal of Pharmacy [Pharm Manage Comb Am J Pharm]
Pathology [Pathology]
Pediatric Emergency Care [Pediatr Emerg Care]
Peritoneal Dialysis Bulletin [Perit Dial Bull]
Pharmaceutisch Weekblad [Pharm Weekbl]
Pharmaceutisch Weekblad. Scientific Edition [Pharm Weekbl (Sci)]
Pharmacological Research Communications [Pharmacol Res Commun]
Pharmacotherapy [Pharmacotherapy]
The Physician and Sports Medicine [Physician Sports Med]
Postgraduate Doctor — Africa [Postgrad Doctor Afr]
Postgraduate Doctor — Asia [Postgrad Doctor Asia]
Postgraduate Medical Journal [Postgrad Med J]
Postgraduate Medicine [Postgrad Med]
Psychiatria Fennica [Psychiatr Fenn]
Public Health [Public Health]
Puerto Rico Health Sciences Journal [PR Health Sci J]
Quarterly Journal of Medicine [Q J Med]
Radiology [Radiology]
Revista Chilena de Pediatria [Rev Chil Pediatr]
Revista Clinicia Espanola [Rev Clin Esp]
Revista de Gastroenterologia de Mexico [Rev Gastroenterol Mex]
Revista Espanola de Reumatologia [Rev Esp Reumatol]
Revista Medica de Chile [Rev Med Chil]
Revista Medica del Instituto Mexicano del Seguro Social [Rev Med Inst Mex Seguro Soc]
Revista Mexicana de Anestesiologia [Rev Mex Anestesiol]
Revista Mexicana de Radiologia [Rev Mex Radiol]
Salud Publica de Mexico [Salud Publica Mex]
Saudi Medical Journal [Saudi Med J]
Scandinavian Journal of Dental Research [Scand J Dent Res]
Scandinavian Journal of Haematology [Scand J Haematol]
Schumpert Medical Quarterly [Schumpert Med Q]
Schweizerische Medizinische Wochenschrift [Scheweiz Med Wochenschr]
Sexually Transmitted Diseases [Sex Transm Dis]
Shinkei Byorigaku [Shinkei Byorigaku]
South African Medical Journal [S Afr Med J]
Southern Medical Journal [South Med J]
The Springfield Clinic Medical Bulletin [Springfield Clin Med Bull]
Sri Lankan Family Physician [Sri Lankan Fam Physician]
Thorax [Thorax]
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Transfusion [Transfusion]
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Ulster Medical Journal [Ulster Med J]
Undersea Biomedical Research [Undersea Biomed Res]
Veterinary Radiology [Vet Radiol]
The West Virginia Medical Journal [W Va Med J]
The Western Journal of Medicine [West J Med]
WHO Chronicle [WHO Chron]
World Health Statistics Quarterly [World Health Stat Q]
World Medical Journal [World Med J]
Yale Journal of Biology and Medicine [Yale J Biol Med]

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Membership fees for the year beginning April 1, 1988 are:

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Members wishing to receive their publications by airmail should contact the Editor to make the necessary arrangement.

Patient's Consent in Laboratory Testing

At a recent Council meeting, it was resolved that Council should seek advice on the legal position of its members with regards to the need for patient's consent for additional laboratory testing in particular with regards to AIDS testing.

Mr W J Wilson
President
NZ Institute of Medical Laboratory Technology
C/- Auckland Regional Blood Centre
Park Road
Auckland

Dear Walter

Re: Patients' Consent in Laboratory Testing

Thank you for your letter of 1 December.

Given the controversy surrounding the evidence which has been given at the Commission of Enquiry into Cervical Cancer, I can understand your concern. It seems to me, however, that the issues facing the Commission, which related to examination and treatment, are not exactly the same as those which arise for the Institute with regard to the testing of samples.

While I am not thoroughly familiar with what has been taking place at the Commission of Enquiry, I understand one of the principal complaints to be that, unbeknown to the patients, Doctor Green decided to follow a certain course of conservative treatment which was to a degree experimental. As I understand it, some patients who had consented to giving cervical smears were not told that the test results were positive and that it was intended that, on the basis of Doctor Green's belief that more radical forms of treatment were not always necessary, no treatment would be undertaken.

The point being made is that the patients should have been told of the test results so that they could make an informed decision as to the course of treatment which was to be undertaken.

It appears to be common practice for additional routine tests to be carried out on blood samples in non-controversial circumstances and I can see no particular difficulty with this course, nor with the practice of using some samples as controls. In neither case is the patient likely to be affected by the subsequent testing. However, it would be appropriate, as a matter of courtesy if nothing else, for a patient to be advised that such routine testing is commonly undertaken and may be undertaken in respect of that patient's sample. That is a matter between doctor and patient and I do not think the Institute are at risk if such advice is not given.

On the question of AIDS testing, however, the issue is one which is more closely akin to the cervical smear in that it raises serious implications concerning the treatment of patients. As I understand it there are three possible circumstances in which AIDS antibody screening might be carried out on a blood sample:

1. Where the blood sample is obtained specifically for this purpose e.g. where the patient is a blood or organ donor. One would expect the patient to have been told that the sample would be tested specifically for AIDS antibodies.
2. Where a decision is made to routinely test all samples, whatever the purpose for which they were taken, for the presence of AIDS antibodies. It seems to me to be clear that in such circumstances the patient should be informed before the sample is taken that such routine testing is carried out.
3. Where in the course of analysis the presence of other abnormalities indicates the possible presence of AIDS antibodies. As I understand your query, you are concerned to know whether it would be a breach of any patient's rights to proceed with the analysis, in order to determine conclusively whether AIDS antibodies exists without the patient's consent. It seems to me that the issue is really one between doctor and patient rather than between technologist and patient. In the event of the presence of AIDS antibodies being indicated incidentally during the course of analysis, there seems to me to be no real point in not pursuing a full analysis for the presence of antibodies. To suspend analysis while the doctor obtains the patient's consent may serve only to alarm the patient unduly. The technologist's obligation, it seems to me, is to inform the doctor that the presence of AIDS antibodies had been indicated and on subsequent analysis proven to exist. It then becomes a matter for the doctor to determine the appropriate method of informing the patient.

A distinction needs to be made, therefore, between analyses which are routinely undertaken and analyses which have arisen incidentally as a result of abnormalities being detected. In the former case, patients should be informed prior to the taking of the blood sample that such routine testing will be conducted. In the latter case the prior consent of the patient should not be necessary, but if time and other circumstances permit there is no reason why the technologist should not consult the patient's doctor prior to continuing wih analysis. The question of consultation with the patient then becomes a matter for the medical practitioner to determine.

Yours faithfully,
Kensington Swan
C.H. Toogood

South Island Seminar

1988 will long be remembered as the year that saw the resurrection of the South Island Seminar after a long recess. Our thanks to Warren Dellow and John Aitken who undertook to organise the event of the year at Maruia Springs (first on the right at the top of the Lewis Pass!) Nelson, Christchurch, Dunedin and the West Coast were all well represented and even the prospect of tenting in the rain did not prove a deterrent. The papers presented were varied and interesting and the cuisine less varied but definitely interesting. The venue came complete with a natural hot pool which featured largely in the social events of the weekend. Plans are already underway for an equally auspicious event next year to be located somewhere nearer the *nether* regions of the South Island.

Retired

It is goodbye at Dunedin Hospital to Mr John Morgan who is retiring after 20 years on the bench and 20 years as the Administrative Technologist in Laboratory Services. Dunedin born and bred John began training at the Oamaru Laboratory in 1948 and shortly afterwards joined the staff of the Bacteriology Laboratory at Otago Medical School which later became part of the Otago Hospital Board.

John has been a well known and popular figure at the hospital both within the laboratory and on the wider front. He has also been a keen member of the laboratory section of the Territorial Army, rising to the rank of Major. John served on the NZIMLT Council as Secretary from 1962-1969 and Vice President from 1969-1975. As friends and colleagues we wish him well for his retirement.

NEW PRODUCTS AND SERVICES

FIRST MICROCOAGULATION SYSTEM FROM BIODATA

BIO/DATA CORPORATION introduces the first microcoagulation system of instrumentation and reagents designed for efficient use of the patient sample, reagents and technologist time. The system, consisting of the Microsample Coagulation Analyzer TM MCA 110 and Microconcentrate coagulation reagents, performs routine coagulation testing with greater efficiency by incorporating micro-technology to decrease the required plasma, reagents and processing time.

The MCA 110 reduces the test sample to 25 microliters, one quarter the standard volume. Reagent consumption is proportionately reduced substantially cutting reagent costs. The 24-hour ready mode provides on demand access to PTs and APTTS, eliminating the repeated set-ups and breakdowns so time-consuming for the Evening and Night shifts. One button simplicity of operation gives further flexibility in staffing.

Microconcentrate coagulation reagents are packaged in thin foil-lined packets. By eliminating the costs associated with traditional vial packaging, microconcentrates can be priced below competitive products. The small compact packets can also save storage space; only one half the current refrigerator space is needed.

For more information on the microcoagulation system; the MCA 110 and microconcentrate reagents and controls, contact the Wilton Instrument Division of Salmond Smith Biolab Ltd or **circle 128 on readers reply card.**

ENHANCED PATHOLOGY COMPUTER SYSTEM

New enhancements to the Magix operating system combined with improvements to the Magix 4GL have resulted in the Magix Pathology System requiring less disk space and faster programme execution. Magix's ability to support local area networks as well as interserver communication result in a flexible yet sophisticated networking structure. The Magix Pathology package is able to meet the needs of both the private and public pathology laboratories and has also been adapted to meet the needs of the animal health laboratory.

Magix's ability to run DOS programs under the Magix Pseudo DOS utility concurrently with Magix applications means no additional hardware is required to use the myriad of 'off the shelf' DOS packages available. This could include word processing and spreadsheets applications but may also include communication packages which reference databases world wide through the use of modems.

The pathology package has been running for two years in the private laboratory environment and has proved to be a cost effective replacement for mainframe based pathology systems.

The inevitable introduction of the electronic transfer of information from laboratories to central agencies will increase the pressure on laboratories to implement data processing procedures. Magix offers up to date technology as a means solving laboratories computing problems.

For further information contact Magix Computer Systems, P.O. Box 11-780, Wellington. Phone (04) 843-725 or P.O. Box 12-561, Auckland (09) 594-722. Alternatively **circle 131 on the readers reply card.**

NEW RANGE OF LINBRO TISSUE CULTURE PLASTICS

Flow Laboratories are proud to announce the new range of Linbro Tissue Culture plastics.

This range includes 3 sizes of Tissue Culture Flasks. The 25, 75 and 150cm^2 flasks all have wide canted necks for ease of access and are available in convenient shelf packs for easy storage. The 75 and 150cm^2 flasks are available with either soft polyethylene caps or hard phenolic caps.

All flasks have graduated volume markings, frosted panels for identification and are individually pressure tested for leakage.

A full selection of multi-well plates utilise an alpha-numeric system to allow rapid well identification during microscopy and have non-reversible lids to eliminate the chance of cross contamination.

Condensation rings on the plate lids reduce to a minimum the risks of liquid evaporation from the wells.

The Linbro range also offers 6 different types of culture dish, from 30mm to 140mm diameter and 50mL centrifuge tubes in polypropylene.

Flow have a full selection of plastic disposable pipettes. These pipettes are available in 1, 2, 5, 10 and a new 25mL sizes, either single wrapped or in bags of 5 and 10. All have negative graduations for versatility and are presented in easy peel wrapping.

These colour coded pipettes fit all types of automatic pipetting devices. This new range completes the total systems package offered by Flow Laboratories to Cell Biologists. Contact KMS, P.O. Box 1234, Auckland or **circle 129 on readers reply card.**

BECKMAN INTRODUCES CLINICAL TABLETOP CENTRIFUGE

Beckman Instruments introduces Microfuge® E a miniature tabletop centrifuge for clinical and bioclinical applications. The compact instrument provides versatility, economy and efficiency for repetitive runs of small biological or clinical samples. Applications include pelleting or sedimentation of samples using either fixed angle or horizontal rotors, and density separations. The Microfuge E is particularly practical for spinning microsamples for paediatrics, and for electrophoresis or microchemical determinations.

The Beckman Microfuge E uses interchangeable rotors, with the horizontal rotor providing speeds of up to 14,500 rpm at forces of up to 13,940 g, and the fixed angle rotor running up to 15,000 rpm at centrifugal forces of up to 15,850 g. For short spins, the instrument features a 'momentary' button, allowing spins of one-second intervals. For longer runs there is a new 30-minute timer. Microfugre E accepts from 12 to 38 micro tubes, including 30 B.D. Microtainers*, and 1.5 mL, 250 mL size.

The Beckman-designed motor requires little maintenance. The motor has an expected life of over 5,000 runs, twice the duration of most microcentrifuge motors. Users simply replace worn brushes when required. A 7-year rotor warranty is offered.

Quick acceleration (6 seconds) and deceleration (18 seconds) of the Microfuge E provide efficient use of the instrument without harming the sample or generating inaccurate results.

Contact Sonatec (09) 764-533 or **circle 132 on readers reply card.**

NEW BLOOD CULTURE SYSTEM FOR RAPID DIAGNOSIS OF BACTERAEMIA

One culture system for aerobes and anaerobes . . . minimal sub-culturing . . . no automated equipment needed.

A new single bottle blood culture system for rapid detection and isolation of micro-organisms from patients with suspected bacteraemia has been introduced by *Oxoid Ltd** of Basingstoke, England RG24 OPW. The Oxoid "SIGNAL" Blood Culture System consists of a blood-culture bottle containing a medium formulated to support the growth of aerobic, anaerobic and micro-aerophilic organisms in the one bottle and a growth indicator device which allows simple visual recognition of a positive result.

Increased incidence of bacteraemia has led to a consequent rise in demand made on laboratory resources in hospital microbiology departments. Recognising that speed of treatment of bacteraemic patients is largely dependent on early recognition of pathogenic microbes in blood cultures, Oxoid has designed its new system to provide a straightforward method for rapid detection and recovery of micro-oganisms without the need for expensive hardware, electrical signalling, radioactive isotopes or the necessity to sub-culture at specified intervals.

The SIGNAL system

The sealed blood-culture bottle contains 84mL of broth medium under partial negative pressure. The growth indicator device which is attached after the addition of the blood to the bottle includes in its cap a 0.2 micron hydrophobic filter which ensures that the system remains at ambient pressure for sampling.

A maximum of 10mL of the patient's blood is injected aseptically through the rubber stopper of the bottle and mixed with the broth.

The system is designed for a blood broth radio of 1:8, although the system will function with smaller volumes of blood and is also suitable for paediatric use.

Following inoculation, the growth indicator device is inserted aseptically through the rubber stopper into the blood culture bottle and the outer sleeve of the device is pushed down to lock onto the neck of the bottle, to ensure that the growth indicator device is held securely and correctly in place. The system is then placed on an orbital shaker at 150 rpm for the first 24 hours at 36±1 °C and examined regularly for signs of a positive result.

If microbial growth occurs in the bottle, the consequent increase in pressure will force the infected blood broth mixture to be displaced into the growth indicator chamber. A seven day incubation period is recommended with a visual examination and manual agitation of the bottles twice daily after the initial period of 24 hours continuous shaking. Samples for sub-culturing, identification or microscopy are aseptically removed from the growth indicator chamber by unscrewing the green cap. The complete system should be autoclaved prior to disposal.

Quick results without automated equipment

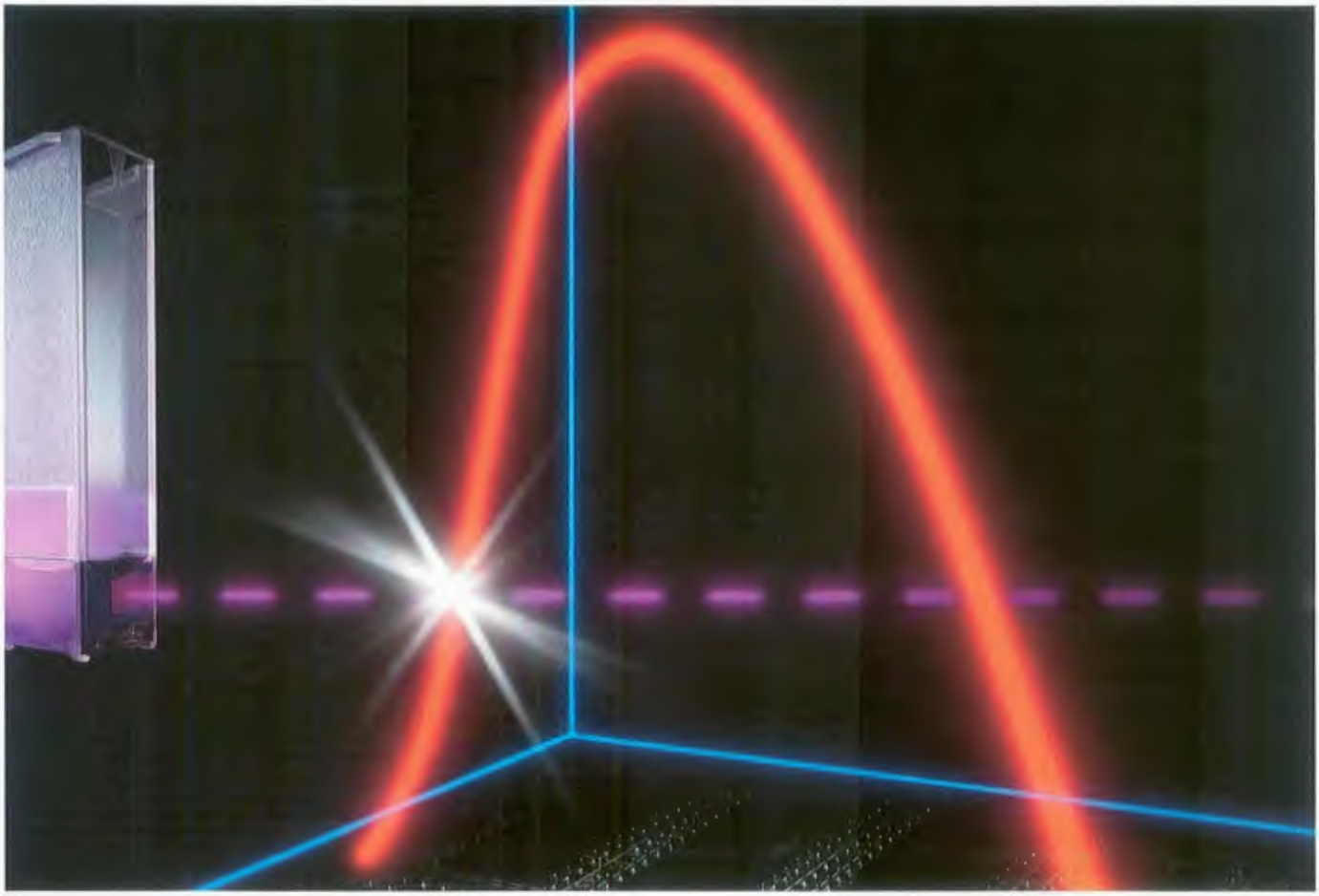
In practical terms the Oxoid SIGNAL Blood Culture System offers the laboratory the advantages of ease of handling the rapid assessment of results without requiring expensive automated equipment or the problems associated with radioactive waste disposal. As a routine, only those bottles with the blood broth mixture showing above the level of the green sleeve in the growth indicator chamber need be sampled for sub-culture and microscopy. This reduces labour and time considerations and minimises the opportunities for laboratory-induced contamination into the system. The system does however, allow easy sampling if, for example, turbidity or lysis are seen to occur in the blood broth mixture.

Growth of a wide range of micro-organisms with varying oxygen demands has been shown to be supported by the SIGNAL system, even when the volume of the blood sample or concentration of microbes per mL of blood is low. With its additional advantages of simplicity and safety, applications for SIGNAL are foreseen in any hospital microbiology department, large or small throughout the world.

Further information from ICI Ltd, phone (09) 778-219 or **circle 130 on readers reply card.**

Measurement in the third dimension

Behring TurbiTimeSystem to make Plasmaprotein determination quick and easy



A new advanced method for plasma protein determinations. The new evaluation system measures both sides of the Heidelberger-Kendall Curve by monitoring two reaction parameters simultaneously. The Behring Turbitimer and the specially adapted Turbiquant® reagents make up the TurbiTimeSystem.

Advanced technique

- Wide measuring range
- Evaluates both sides of Heidelberger-Kendall Curve
- Standard curve and control data entered via barcode-reader wand
- Bidirectional interface

Reliability

- Turbiquant® reagents pre-calibrated
- Automatic reagent identification
- Automatic temperature correction
- Quality control program

Easy handling

- User guidance by instrument dialog
- Turbiquant® reagents ready to use
- Uniform reagent volume and sample predilution

Fast operation

- Results within seconds
- Ready to start after switching on
- Automatic mixing and measurement start

Ln 00209 GB

Behring Diagnostics
Hoechst New Zealand Limited
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