SUPPLEMENTARY MATERIAL

Conformity evaluation checklists of Panbio COVID-19 Ag Rapid Test Device for internal auditing: a quality compliance tool for ISO 15189:2012 accredited medical laboratories

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Table S1. Specific requirements for accreditation in relation to Panbio COVID-19 Ag Rapid Test Device examination kit provided by signatory members (n = 83) of the International Laboratory Accreditation Cooperation mutual recognition arrangement.

Countries (n = 83)	**Relevant specific requirements for accreditation** (n = 83)
Angola	In Angola (AGO), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Argentina	In Argentina (ARF), the Argentine Accreditation Organization (OAA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (5, pp. 8-9) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Argentine Standard IRAM-ISO 15189:2014 (6) [see Clause 4 (Management requirements) of Argentine Standard IRAM-ISO 15189:2014 (6) and Clause 5 (Technical requirements) of Argentine Standard IRAM-ISO 15189:2014 (6)] apply for accreditation. The OAA does not provide any specific requirements in relation to the maintenance of thermometer and timer (5, pp. 8-9); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4,p.36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Argentine Standard IRAM-ISO 15189:2014 (6)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Argentine Standard IRAM-ISO 15189:2014 (6)], for implementation.
Australia	In Australia (AUS), the National Association of Testing Authorities, Australia (NATA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (7) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Australian Standard AS ISO 15189—2013 (8) [see Clause 4 (Management requirements) of Australian Standard AS ISO 15189—2013 (8,pp.6-19) and Clause 5 (Technical requirements) of Australian Standard AS ISO 15189—2013 (8,pp.19-39)] apply for accreditation.

	NATA specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (9, pp. 11-12) and interval-specific check (9, pp. 11-12)] and timer [interval-specific check (9, p. 12)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Austria	In Austria (AUT), the Accreditation Austria does not provide any specific requirements in relation to the use of lateral flow immunochromatography (10) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Austrian Standard ÖNORM EN 12469:2000 (11) [see Clause 4 (Management requirements) of Austrian Standard ÖNORM EN 12469:2000 (11) and Clause 5 (Technical requirements) of Austrian Standard ÖNORM EN 12469:2000 (11)] apply for accreditation. Accreditation Austria does not provide any specific requirements in relation to the maintenance of thermometer and timer (10); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Austrian Standard ÖNORM EN ISO 15189:2012 (12)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Austrian Standard ÖNORM EN ISO 15189:2012 (12)], for implementation.
Bangladesh	In Bangladesh (BGD), the Bangladesh Accreditation Board (BAB) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (13) that affects the use of Panbio COVID-19 Ag Rapid Test Device kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2,pp.6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2,pp.19-39)] apply for accreditation. BAB does not provide any specific requirements in relation to the maintenance of thermometer and timer (13); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Belarus	In Belarus (BLR), the Belarusian State Centre for Accreditation (BSCA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (14) that affects the use of Panbio COVID-19 Ag Rapid Test Device kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2,pp.6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2,pp.19-39)] apply for accreditation. The BSCA does not provide any specific requirements in relation to the maintenance of thermometer and timer (14); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological

	traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Belgium	In Belgium (BEL), the Belgian Accreditation Body (BELAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (15) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Belgian Standard NBN EN ISO 15189:2012 (16) [see Clause 4 (Management requirements) of Belgian Standard NBN EN ISO 15189:2012 (16) and Clause 5 (Technical requirements) of Belgian Standard NBN EN ISO 15189:2012 (16)] apply for accreditation. BELAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (15); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Belgian Standard NBN EN ISO 15189:2012 (16)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Belgian Standard NBN EN ISO 15189:2012 (16)], for implementation.
Botswana	In Botswana (BWA), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Brazil	In Brazil (BRA), the General Coordination for Accreditation (CGCRE) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (17) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Brazilian Standard NBR ISO 15189:2015 (18) [see Clause 4 (Management requirements) of Brazilian Standard NBR ISO 15189:2015 (18) and Clause 5 (Technical requirements) of Brazilian Standard NBR ISO 15189:2015 (18)] apply for accreditation. The CGCRE does not provide any specific requirements in relation to the maintenance of thermometer and timer (17); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Brazilian Standard NBR ISO 15189:2015 (18)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Brazilian Standard NBR ISO 15189:2015 (18)] for implementation.
Bulgaria	In Bulgaria (BFT), the Executive Agency "Bulgarian Accreditation Service" (EA "BAS") does not provide any specific requirements in relation to the use of lateral flow immunochromatography (19) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Bulgarian Standard BDS EN ISO 15189:2012 (20) [see Clause 4 (Management

	requirements) of Bulgarian Standard BDS EN ISO 15189:2012 (20) and Clause 5 (Technical requirements) of Bulgarian Standard BDS EN ISO 15189:2012 (20)] apply for accreditation. EA “BAS” does not provide any specific requirements in relation to the maintenance of thermometer and timer (19); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer’s instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Bulgarian Standard BDS EN ISO 15189:2012 (20)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Bulgarian Standard BDS EN ISO 15189:2012 (20)], for implementation.
Canada	In Canada (CAN), the Institute for Quality Management in Healthcare (IQMH) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (21) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. IQMH does not provide any specific requirements in relation to the maintenance of thermometer and timer (21); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer’s instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Canada	In Canada (CAN), the Standards Council of Canada (SCC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (22) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SCC does not provide any specific requirements in relation to the maintenance of thermometer and timer (22); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer’s instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Chile	In Chile (CHL), the National Institute of Standardization (INN) (a national accreditation body) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (23) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Chilean Standard NCh-ISO 15189:2012 (24) [see Clause 4 (Management requirements) of Chilean Standard NCh-ISO 15189:2012 (24) and Clause 5 (Technical requirements) of Chilean Standard NCh-ISO 15189:2012 (24)] apply for accreditation. INN does not provide any specific requirements in relation to the maintenance of thermometer and timer (23); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the

	manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Chilean Standard NCh-ISO 15189:2012 (24)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Chilean Standard NCh-ISO 15189:2012 (24)], for implementation.
China	In China (CHN), the China National Accreditation Service for Conformity Assessment (CNAS) (a national accreditation body) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (25) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit. CNAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (25); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions, including recommended calibration information for implementation.
Colombia	In Colombia (COL), the National Accreditation Body of Colombia (ONAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (26) that affects the use of Panbio COVID-19 Ag Rapid Test Device kit; therefore, relevant requirements of Colombian Standard NTC-ISO 15189:2012 (27) [see Clause 4 (Management requirements) of Colombian Standard NTC-ISO 15189:2012 (27) and Clause 5 (Technical requirements) of Colombian Standard NTC-ISO 15189:2012 (27)] apply for accreditation. ONAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (26); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Colombian Standard NTC-ISO 15189:2012 (27)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Colombian Standard NTC-ISO 15189:2012 (27)], for implementation.
Comoros	In Comoros (COM), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Congo	In Congo (COG), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation.

	SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Costa Rica	In Costa Rica (CRI), the Costa Rican Accreditation Entity (ECA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (28) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2,pp.6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2,pp.19-39)] apply for accreditation. The ECA does not provide any specific requirements in relation to the maintenance of thermometer and timer (28); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Croatia	In Croatia (HRV), the Croatian Accreditation Agency (HAA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Croatian Standard HRN EN ISO 15189:2012 (29) [see Clause 4 (Management requirements) of Croatian Standard HRN EN ISO 15189:2012 (29) and Clause 5 (Technical requirements) of Croatian Standard HRN EN ISO 15189:2012 (29)] apply for accreditation. HAA does not provide any specific requirements in relation to the maintenance of thermometer and timer; therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Croatian Standard HRN EN ISO 15189:2012 (29)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Croatian Standard HRN EN ISO 15189:2012 (29)], for implementation.
Cyprus	In Cyprus (CYP), the Cyprus Organisation for the Promotion of Quality - Cyprus Accreditation Body (CYS-CYSAB) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (30) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Cyprus National Standard CYS EN ISO 15189:2012 (31) [see Clause 4 (Management requirements) of Cyprus National Standard CYS EN ISO 15189:2012 (31) and Clause 5 (Technical requirements) of Cyprus National Standard CYS EN ISO 15189:2012 (31)] apply for accreditation. CYS-CYSAB does not provide any specific requirements in relation to the maintenance of thermometer and timer (30); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment

	maintenance and repair) of Cyprus National Standard CYS EN ISO 15189:2012 (31)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Cyprus National Standard CYS EN ISO 15189:2012 (31)], for implementation.
Czech Republic	In Czech Republic (CZE), the Czech Accreditation Institute (CAI) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (32) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Czechoslovak Technical Standard ČSN EN ISO 15189:2013 (33) [see Clause 4 (Management requirements) of Czechoslovak Technical Standard ČSN EN ISO 15189:2013 (33) and Clause 5 (Technical requirements) of Czechoslovak Technical Standard ČSN EN ISO 15189:2013 (33)] apply for accreditation. CAI does not provide any specific requirements in relation to the maintenance of thermometer and timer (32); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Czechoslovak Technical Standard ČSN EN ISO 15189:2013 (33)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Czechoslovak Technical Standard ČSN EN ISO 15189:2013 (33)], for implementation.
Denmark	In Denmark (DEN), the Danish Accreditation Fund (DANAK) does not specify requirements in relation to the use of lateral flow immunochromatography (34) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Danish Standard DS/EN ISO 15189:2012 (35) [see Clause 4 (Management requirements) of Danish Standard DS/EN ISO 15189:2012 (35) and Clause 5 (Technical requirements) of Danish Standard DS/EN ISO 15189:2012 (35)] apply for accreditation. DANAK does not provide any specific requirements in relation to the maintenance of thermometer and timer (34); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Danish Standard DS/EN ISO 15189:2012 (35)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Danish Standard DS/EN ISO 15189:2012 (35)], for implementation.
Egypt	In Egypt (EGY), the Egyptian Accreditation Council (EGAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (36) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2,pp.6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2,pp.19-39)] apply for accreditation. EGAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (36); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Ethiopia	In Ethiopia (ETH), the Ethiopian National Accreditation Office (ENAO) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (37) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant

	requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2,pp.6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2,pp.19-39)] apply for accreditation. ENAO does not provide any specific requirements in relation to the maintenance of thermometer and timer (37); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Finland	In Finland (FIN), the Finnish Accreditation Service (FINAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (38) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Finnish Standard SFS-EN ISO 15189:en (39) [see Clause 4 (Management requirements) of Finnish Standard SFS-EN ISO 15189:en (39) and Clause 5 (Technical requirements) of Finnish Standard SFS-EN ISO 15189:en (39)] apply for accreditation. FINAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (38); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Finnish Standard SFS-EN ISO 15189:en (39)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Finnish Standard SFS-EN ISO 15189:en (39)], for implementation.
France	In France (FRA), the French Accreditation Committee (COFRAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (40) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of French Standard NF EN ISO 15189:2012 (41) [see Clause 4 (Management requirements) of French Standard NF EN ISO 15189:2012 (41) and Clause 5 (Technical requirements) of French Standard NF EN ISO 15189:2012 (41)] apply for accreditation. COFRAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (40); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of French Standard NF EN ISO 15189:2012 (41)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of French Standard NF EN ISO 15189:2012 (41)], for implementation.
Germany	In Germany (DEU), the German Accreditation Body (DakkS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (42) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of German Standard DIN EN ISO 15189:2014 (43) [see Clause 4 (Management requirements) of German Standard DIN EN ISO 15189:2014 (43) and Clause 5 (Technical requirements) of German Standard DIN EN ISO 15189:2014 (43)] apply for accreditation. DakkS does not provide any specific requirements in relation to the maintenance of thermometer and timer (44); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment

	maintenance and repair) of German Standard DIN EN ISO 15189:2014 (43)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of German Standard DIN EN ISO 15189:2014 (43)], for implementation.
Greece	In Greece (GRC), the Hellenic Accreditation System (ESYD) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (45) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Hellenic Standard ELOT EN ISO 15189:2012 (46) [see Clause 4 (Management requirements) of Hellenic Standard ELOT EN ISO 15189:2012 (46) and Clause 5 (Technical requirements) of Hellenic Standard ELOT EN ISO 15189:2012 (46)] apply for accreditation. ESYD does not provide any specific requirements in relation to the maintenance of thermometer and timer (45); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Hellenic Standard ELOT EN ISO 15189:2012 (46)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Hellenic Standard ELOT EN ISO 15189:2012 (46)], for implementation.
Guatemala	In Guatemala (GTM), the Guatemalan Accreditation Body (OGA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (47) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Guatemalan Standard COGUANOR NTG/ISO 15189:2012 (48, pp. 11-45) [see Clause 4 (Management requirements) of Guatemalan Standard COGUANOR NTG/ISO 15189:2012 (48, pp. 11-24) and Clause 5 (Technical requirements) of Guatemalan Standard COGUANOR NTG/ISO 15189:2012 (48, pp. 24-45)] apply for accreditation. OGA does not provide any specific requirements in relation to the maintenance of thermometer and timer (47); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Guatemalan Standard COGUANOR NTG/ISO 15189:2012 (48, pp. 29-30)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Guatemalan Standard COGUANOR NTG/ISO 15189:2012 (48, p. 29)], for implementation.
Hong Kong	In Hong Kong (HKG), the Hong Kong Accreditation Service (HKAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (49) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit. HKAS specifies recommendations in relation to the maintenance of thermometer [interval-specific calibration (50,p.19) and interval-specific check (50,p.19)] and timer [interval-specific calibration (50,p.18)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions, including recommended calibration information, for implementation.
Hungary	In Hungary (HUN), the National Accreditation Authority (NAH) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (51) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Hungarian Standard MSZ EN ISO 15189:2012 (52) [see Clause 4 (Management requirements) of Hungarian Standard MSZ EN ISO 15189:2012 (52) and Clause 5 (Technical requirements) of Hungarian Standard MSZ EN ISO 15189:2012 (52)] apply for accreditation.

	NAH does not provide any specific requirements in relation to the maintenance of thermometer and timer (51); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Hungarian Standard MSZ EN ISO 15189:2012 (52)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Hungarian Standard MSZ EN ISO 15189:2012 (52)], for implementation.
India	In India (IND), the National Accreditation Board for Testing and Certification Laboratories (NABL) specifies requirements in relation to the use of lateral flow immunochromatography (53,p.16) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; in addition, the medical laboratory should identify relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2,pp.6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2,pp.19-39)] for implementation. NABL specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (53,p.18)], excluding timer, for accreditation purposes; in addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation. NABL specifies requirements in relation to qualitative testing in relation to lot verification that applies to examination kits (53, p. 92).
Indonesia	In Indonesia (IDN), the National Accreditation Body of Indonesia (KAN) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (54) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Indonesian National Standard SNI ISO 15189:2012 (55, pp. 24-25)] apply for accreditation. KAN does not provide any specific requirements in relation to the maintenance of thermometer and timer (54); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Indonesian National Standard SNI ISO 15189:2012 (55, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Indonesian National Standard SNI ISO 15189:2012 (55, pp. 24-25)], for implementation.
Ireland	In Ireland (IRL), the Irish National Accreditation Board (INAB) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (56) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Irish Standard IS EN ISO 15189:2012 (57) [see Clause 4 (Management requirements) of Irish Standard IS EN ISO 15189:2012 (57) and Clause 5 (Technical requirements) of Irish Standard IS EN ISO 15189:2012 (57)] apply for accreditation. INAB does not provide any specific requirements in relation to the maintenance of thermometer and timer (56); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Irish Standard IS EN ISO 15189:2012 (57)], including recommended calibration information [see Subclause 5.3.1.4

	(Equipment calibration and metrological traceability) of Irish Standard IS EN ISO 15189:2012 (57)], for implementation.
Israel	In Israel (ISR), the Israel Laboratory Accreditation Authority (ISRAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (58) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. ISRAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (58); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Italy	In Italy (ITA), the Italian Accreditation Body (Accredia) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (59) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Italian Standard UNI EN ISO 15189:2013 (60) and Italian Standard EC 1-2014:UNI EN ISO 15189:2013 (61) [see Clause 4 (Management requirements) of Italian Standard UNI EN ISO 15189:2013 (60) and Clause 5 (Technical requirements) of Italian Standard UNI EN ISO 15189:2013 (60)] apply for accreditation. Accredia does not provide any specific requirements in relation to the maintenance of thermometer and timer (59); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Italian Standard UNI EN ISO 15189:2013 (60)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Italian Standard UNI EN ISO 15189:2013 (60)], for implementation.
Jamaica	In Jamaica (JAM), the Jamaica National Agency for Accreditation (JANAAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (62) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. JANAAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (62); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Japan	In Japan (JPN), the Japan Accreditation Board (JAB) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (63) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of

	International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. JAB does not provide any specific requirements in relation to the maintenance of thermometer and timer (63); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Jordan	In Jordan (JOR), the Jordan Accreditation & Standardization Systems - Accreditation Unit (JAS-AU) does not provide any specific requirements in relation to the use of lateral flow immunochromatography that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Jordanian Standard JS EN ISO 15189:2012 (64) [see Clause 4 (Management requirements) of Jordanian Standard JS EN ISO 15189:2012 (64) and Clause 5 (Technical requirements) of Jordanian Standard JS EN ISO 15189:2012 (64)] apply for accreditation. JAS-AU does not provide any specific requirements in relation to the maintenance of thermometer and timer; therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Jordanian Standard JS EN ISO 15189:2012 (64)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Jordanian Standard JS EN ISO 15189:2012 (64)], for implementation.
Kazakhstan	In Kazakhstan (KAZ), the National Center of Accreditation (NCA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (65) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Standard of the Republic of Kazakhstan ST RK ISO 15189-2015 (66) [see Clause 4 (Management requirements) of Standard of the Republic of Kazakhstan ST RK ISO 15189-2015 (66) and Clause 5 (Technical requirements) of Standard of the Republic of Kazakhstan ST RK ISO 15189-2015 (66)] apply for accreditation. The NCA does not provide any specific requirements in relation to the maintenance of thermometer and timer (65); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Standard of the Republic of Kazakhstan ST RK ISO 15189-2015 (66)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Standard of the Republic of Kazakhstan ST RK ISO 15189-2015 (66)], for implementation.
Kenya	In Kenya (KEN), the Kenya Accreditation Service (KENAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (67) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2,pp.6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2,pp.19-39)] apply for accreditation. KENAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (68); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of

	International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Korea	In Korea (KOR), the Korea Laboratory Accreditation Scheme (KOLAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (69) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Korean Standard KS P ISO 15189:2013 (70) [see Clause 4 (Management requirements) of Korean Standard KS P ISO 15189:2013 (70) and Clause 5 (Technical requirements) of Korean Standard KS P ISO 15189:2013 (70)] apply for accreditation. KOLAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (69); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Korean Standard KS P ISO 15189:2013 (70)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Korean Standard KS P ISO 15189:2013 (70)], for implementation.
Lesotho	In Lesotho (LSO), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Lithuania	In Lithuania (LTU), the Lithuanian National Accreditation Bureau (LA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (71) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Lithuanian Standard LST EN ISO 15189:2012 (72) [see Clause 4 (Management requirements) of Lithuanian Standard LST EN ISO 15189:2012 (72) and Clause 5 (Technical requirements) of Lithuanian Standard LST EN ISO 15189:2012 (72)] apply for accreditation. LA does not provide any specific requirements in relation to the maintenance of thermometer and timer (71); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Lithuanian Standard LST EN ISO 15189:2012 (72)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Lithuanian Standard LST EN ISO 15189:2012 (72)], for implementation.

Luxembourg	In Luxembourg (LUX), the Luxembourg Office of Accreditation (OLAS) does not provide any specific requirements in relation the use of lateral flow immunochromatography (73) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Luxembourg Standard ILNAS-EN ISO 15189:2012 (74) [see Clause 4 (Management requirements) of Luxembourg Standard ILNAS-EN ISO 15189:2012 (74) and Clause 5 (Technical requirements) of Luxembourg Standard ILNAS-EN ISO 15189:2012 (74)] apply for accreditation. OLAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (73); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Luxembourg Standard ILNAS-EN ISO 15189:2012 (74)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Luxembourg Standard ILNAS-EN ISO 15189:2012 (74)], for implementation.
Madagascar	In Madagascar (MDF), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Malawi	In Malawi (MWI), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Malaysia	In Malaysia (MYS), the Department of Standards Malaysia does not provide any specific requirements in relation to the use of lateral flow immunochromatography (75) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Malaysian Standard MS ISO 15189:2012 (76) [see Clause 4

	(Management requirements) of Malaysian Standard MS ISO 15189:2012 (76) and Clause 5 (Technical requirements) of Malaysian Standard MS ISO 15189:2012 (76)] apply for accreditation. The Department of Standards Malaysia does not provide any specific requirements in relation to the maintenance of thermometer and timer (75); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Malaysian Standard MS ISO 15189:2012 (76)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Malaysian Standard MS ISO 15189:2012 (76)], for implementation.
Mexico	In Mexico (MEX), the Mexican Accreditation Entity does not provide any specific requirements in relation to the use of lateral flow immunochromatography (77) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Mexican Standard NMX-EC-15189-IMNC-2015 (78) [see Clause 4 (Management requirements) of Mexican Standard NMX-EC-15189-IMNC-2015 (78) and Clause 5 (Technical requirements) of Mexican Standard NMX-EC-15189-IMNC-2015 (78)] apply for accreditation. Mexican Accreditation Entity does not provide any specific requirements in relation to the maintenance of thermometer and timer (77); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Mexican Standard NMX-EC-15189-IMNC-2015 (78)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Mexican Standard NMX-EC-15189-IMNC-2015 (78)], for implementation.
Moldova	In Moldova (MDA), the National Accreditation Centre of the Republic of Moldova (MOLDAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (79) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Moldovan Standard SM SR EN ISO 15189:2013 (80) [see Clause 4 (Management requirements) of Moldovan Standard SM SR EN ISO 15189:2013 (80) and Clause 5 (Technical requirements) of Moldovan Standard SM SR EN ISO 15189:2013 (80)] apply for accreditation. MOLDAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (79); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Moldovan Standard SM SR EN ISO 15189:2013 (80)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Moldovan Standard SM SR EN ISO 15189:2013 (80)], for implementation.
Mozambique	In Mozambique (MOZ), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5)(3) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance

	information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Namibia	In Namibia (NAM), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19)(2) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Netherlands	In the Netherlands (HLD), the Dutch Accreditation Council (RvA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (81) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Dutch Standard NEN-EN-ISO 15189:2012(Cor. 2014-9) (82) [see Clause 4 (Management requirements) of Dutch Standard NEN-EN-ISO 15189:2012(Cor. 2014-9) (82) and Clause 5 (Technical requirements) of Dutch Standard NEN-EN-ISO 15189:2012(Cor. 2014-9) (82)] apply for accreditation. The RvA does not provide any specific requirements in relation to the maintenance of thermometer and timer (81); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Dutch Standard NEN-EN-ISO 15189:2012(Cor. 2014-9) (82)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Dutch Standard NEN-EN-ISO 15189:2012(Cor. 2014-9) (82)], for implementation.
New Zealand	In New Zealand (NZL), the International Accreditation New Zealand (IANZ) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (83) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. IANZ specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (83, p. 31) and interval-specific check (83, pp. 31-32)] and timer [interval-specific check (83, pp. 33-34)] for accreditation purposes; in addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information

	[see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
North Macedonia	In North Macedonia (MKD), the Institute for Accreditation of the Republic of North Macedonia (IARNM) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (84) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. The IARNM does not provide any specific requirements in relation to the maintenance of thermometer and timer (84); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Macedonian Standard MKC EN ISO 15189:2013 (85)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Macedonian Standard MKC EN ISO 15189:2013 (85)], for implementation.
Norway	In Norway (NOR), Norwegian Accreditation (NA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (86) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Norwegian Standard NS-EN ISO 15189:2012 (87) [see Clause 4 (Management requirements) of Norwegian Standard NS-EN ISO 15189:2012 (87) and Clause 5 (Technical requirements) of Norwegian Standard NS-EN ISO 15189:2012 (87)] apply for accreditation. NA specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (88) and interval-specific check (88)], excluding timer; therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Norwegian Standard NS-EN ISO 15189:2012 (87)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Norwegian Standard NS-EN ISO 15189:2012 (87)], for implementation.
Philippines	In the Philippines (PHL), the Philippine Accreditation Bureau (PAB) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (89) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Philippine National Standard PNS ISO 15189:2012 (90) [see Clause 4 (Management requirements) of Philippine National Standard PNS ISO 15189:2012 (90,pp.6-19) and Clause 5 (Technical requirements) of Philippine National Standard PNS ISO 15189:2012 (90,pp.19-39)] apply for accreditation. PAB does not specify any specific requirements in relation to the maintenance of thermometer and timer (89); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Philippine National Standard PNS ISO 15189:2012 (90, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Philippine National Standard PNS ISO 15189:2012 (90, p. 24)], for implementation.
Poland	In Poland (POL), the Polish Centre for Accreditation (PCA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (91) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements

	of Polish Standard PN EN ISO 15189:2013-5 (92) [see Clause 4 (Management requirements) of Polish Standard PN EN ISO 15189:2013-5 (92) and Clause 5 (Technical requirements) of Polish Standard PN EN ISO 15189:2013-5 (92)] apply for accreditation. PCA does not provide any specific requirements in relation to the maintenance of thermometer and timer (91); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Polish Standard PN EN ISO 15189:2013-5 (92)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Polish Standard PN EN ISO 15189:2013-5 (92)], for implementation.
Portugal	In Portugal (PRT), the Portuguese Institute for Accreditation (IPAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (93) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Portugal Standard NP EN ISO 15189:2012 (94) [see Clause 4 (Management requirements) of Portugal Standard NP EN ISO 15189:2012 (94) and Clause 5 (Technical requirements) of Portugal Standard NP EN ISO 15189:2012 (94)] apply for accreditation. IPAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (93); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Portugal Standard NP EN ISO 15189:2012 (94)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Portugal Standard NP EN ISO 15189:2012 (94)], for implementation.
Romania	In Romania (ROU), the Romanian Accreditation Association (RENAR) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (95) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Romanian Standard SR EN ISO 15189:2013 (96) [see Clause 4 (Management requirements) of Romanian Standard SR EN ISO 15189:2013 (96) and Clause 5 (Technical requirements) of Romanian Standard SR EN ISO 15189:2013 (96)] apply for accreditation. RENAR does not provide any specific requirements in relation to the maintenance of thermometer and timer (95); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Romanian Standard SR EN ISO 15189:2013 (96)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Romanian Standard SR EN ISO 15189:2013 (96)], for implementation.
Serbia	In Serbia (SRB), the Accreditation Body of Serbia (ATS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (97) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Serbian Standard SRPS EN ISO 15189:2012 (98) [see Clause 4 (Management requirements) of Serbian Standard SRPS EN ISO 15189:2012 (98) and Clause 5 (Technical requirements) of Serbian Standard SRPS EN ISO 15189:2012 (98)] apply for accreditation. ATS does not provide any specific requirements in relation to the maintenance of thermometer and timer (97); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of

	International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Serbian Standard SRPS EN ISO 15189:2012 (98)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Serbian Standard SRPS EN ISO 15189:2012 (98)], for implementation.
Seychelles	In Seychelles (SYC), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Singapore	In Singapore (SGP), the Singapore Accreditation Council (SAC) specifies requirements in relation to the use of lateral flow immunochromatography that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SAC specifies recommendations in relation to the maintenance of thermometer [interval-specific check (99,p.16)] and timer [interval-specific check (99, p. 17)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Slovakia	In Slovakia (SVK), the Slovak National Accreditation Service (SNAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (100) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of European Standard EN ISO 15189:2012 (101) [see Clause 4 (Management requirements) of European Standard EN ISO 15189:2012 (101) and Clause 5 (Technical requirements) of European Standard EN ISO 15189:2012 (101)] apply for accreditation. SNAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (100); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of European Standard EN ISO 15189:2012 (101)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of European Standard EN ISO 15189:2012 (101)], for implementation.

Slovenia	In Slovenia (SVN), the Slovenian Accreditation (SA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (102) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Slovenski Standard SIST EN ISO 15189:2013 (103) and Slovenski Standard SIST EN ISO 15189:2013/AC101:2015 (104) [see Clause 4 (Management requirements) of Slovenski Standard SIST EN ISO 15189:2013 (103) and Clause 5 (Technical requirements) of Slovenski Standard SIST EN ISO 15189:2013 (103)] apply for accreditation. SA does not provide any specific requirements in relation to the maintenance of thermometer and timer (102); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Slovenski Standard SIST EN ISO 15189:2013 (103)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Slovenski Standard SIST EN ISO 15189:2013 (103)], for implementation.
South Africa	In South Africa (ZAF), the South African National Accreditation System (SANAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (105) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SANAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (105); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Spain	In Spain (ESP), the Spanish National Accreditation Body (ENAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (106) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Spanish Standard UNE-EN ISO 15189:2013 (107) [see Clause 4 (Management requirements) of Spanish Standard UNE-EN ISO 15189:2013 (107) and Clause 5 (Technical requirements) of Spanish Standard UNE-EN ISO 15189:2013 (107)] apply for accreditation. ENAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (106); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Spanish Standard UNE-EN ISO 15189:2013 (107)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Spanish Standard UNE-EN ISO 15189:2013 (107)], for implementation.
Sri Lanka	In Sri Lanka (LKA), the Sri Lanka Accreditation Board for Conformity Assessment (SLAB) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (108) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5

	(Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SLAB specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (108, p. 27) and interval-specific check (108, p. 27)], excluding timer (108), for accreditation purposes; in addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)] for implementation.
Swaziland	In Swaziland (SWZ), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies srequirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Sweden	In Sweden (SWE), the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (109) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Swedish Standard SS-EN ISO 15189:2012 (110) [see Clause 4 (Management requirements) of Swedish Standard SS-EN ISO 15189:2012 (110) and Clause 5 (Technical requirements) of Swedish Standard SS-EN ISO 15189:2012 (110)] apply for accreditation. SWEDAC does not provide any specific requirements in relation to the maintenance of thermometer and timer (109); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Swedish Standard SS-EN ISO 15189:2012 (110)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Swedish Standard SS-EN ISO 15189:2012 (110)], for implementation.
Switzerland	In Switzerland (CHE), the Swiss Accreditation Service (SAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (111) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Swiss Standard SN EN ISO 15189:2013 (112) The SAS does not provide any specific requirements in relation to the maintenance of thermometer and timer (111); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Swiss Standard SN EN ISO 15189:2013

	(112)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Swiss Standard SN EN ISO 15189:2013 (112)], for implementation.
Taiwan	In Taiwan (TWN), the Taiwan Accreditation Foundation (TAF) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (113) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit. TAF does not provide any specific requirements in relation to the maintenance of thermometer and timer (113); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions, including recommended calibration information, for implementation.
Tanzania, United Republic of	In the United Republic of Tanzania (TZA), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Thailand	In Thailand (THA), the Bureau of Laboratory Quality Standards (BLQS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (114) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. The BLQS does not provide any specific requirements in relation to the maintenance of thermometer and timer (114); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Turkey	In Turkey (TUR), the Turkish Accreditation Agency (TURKAK) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (115) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of Turkish Standard TS EN ISO 15189:2012 (116) [see Clause 4 (Management requirements) of Turkish Standard TS EN ISO 15189:2012 (116) and Clause 5 (Technical requirements) of Turkish Standard TS EN ISO 15189:2012 (116)] apply for accreditation. TURKAK does not provide any specific requirements in relation to the maintenance of thermometer and timer (115) ; therefore, the medical

	laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of Turkish Standard TS EN ISO 15189:2012 (116)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Turkish Standard TS EN ISO 15189:2012 (116)], for implementation.
United Arab Emirates	In the United Arab Emirates (ARE), the Emirates International Accreditation Centre (EIAC) does not any specific requirements in relation to the use of lateral flow immunochromatography (117) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. EIAC specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (117,p.36)] and timer [interval-specific calibration (117,p.37)] for accreditation purposes. in addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
United Kingdom	In the United Kingdom (GBR), the United Kingdom Accreditation Service (UKAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (118) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of British Standard BS EN ISO 15189:2012 (119) [see Clause 4 (Management requirements) of British Standard BS EN ISO 15189:2012 (119, pp. 6-19) and Clause 5 (Technical requirements) of British Standard BS EN ISO 15189:2012 (119, pp. 19-39)] apply for accreditation. UKAS specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (120) and interval-specific check (120)], excluding timer (118), for accreditation purposes; in addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of British Standard BS EN ISO 15189:2012 (119, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of British Standard BS EN ISO 15189:2012 (119, p. 24)], for implementation.
United States	In the United States (USA), the American Association for Laboratory Accreditation (A2LA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (121) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. A2LA specifies requirements in relation to the maintenance of thermometer [calibration (122, p. 6)] and timer [calibration (122, p. 6)] for accreditation purposes; in addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including

	recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
United States	In the United States (USA), Perry Johnson Laboratory Accreditation (PJLA) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (123) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. PJLA does not provide any specific requirements in relation to the maintenance of thermometer and timer (123); therefore, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
United States	In the United States (USA), the ANSI National Accreditation Board (ANAB) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (124) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. ANAB specifies requirements in relation to the maintenance of thermometer [calibration (124, pp. 6-7)] and timer [calibration (124, pp. 6-7)] for accreditation purposes; in addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Viet Nam	In Viet Nam (VNM), the Bureau of Accreditation does not provide any specific requirements in relation to the use of lateral flow immunochromatography (125) that affects the use of Panbio COVID-19 Ag Rapid Test Device kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. Bureau of Accreditation specifies requirements in relation to the maintenance of thermometer [interval-specific calibration (125, p. 34)] and timer [interval-specific calibration (125, p. 34)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Zambia	In Zambia (ZMB), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements

	of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.
Zimbabwe	In Zimbabwe (ZWE), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of lateral flow immunochromatography (1) that affects the use of Panbio COVID-19 Ag Rapid Test Device examination kit; therefore, relevant requirements of International Standard ISO 15189:2012 (2) [see Clause 4 (Management requirements) of International Standard ISO 15189:2012 (2, pp. 6-19) and Clause 5 (Technical requirements) of International Standard ISO 15189:2012 (2, pp. 19-39)] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of thermometer [calibration (3, p. 5) and check (3, p. 6)] and timer [calibration (3, p. 5) and check (3, p. 6)] for accreditation purposes. In addition, the medical laboratory should identify relevant maintenance information [see Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019 (4, p. 36)] from the manufacturer's instructions [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012 (2, pp. 24-25)], including recommended calibration information [see Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012 (2, p. 24)], for implementation.

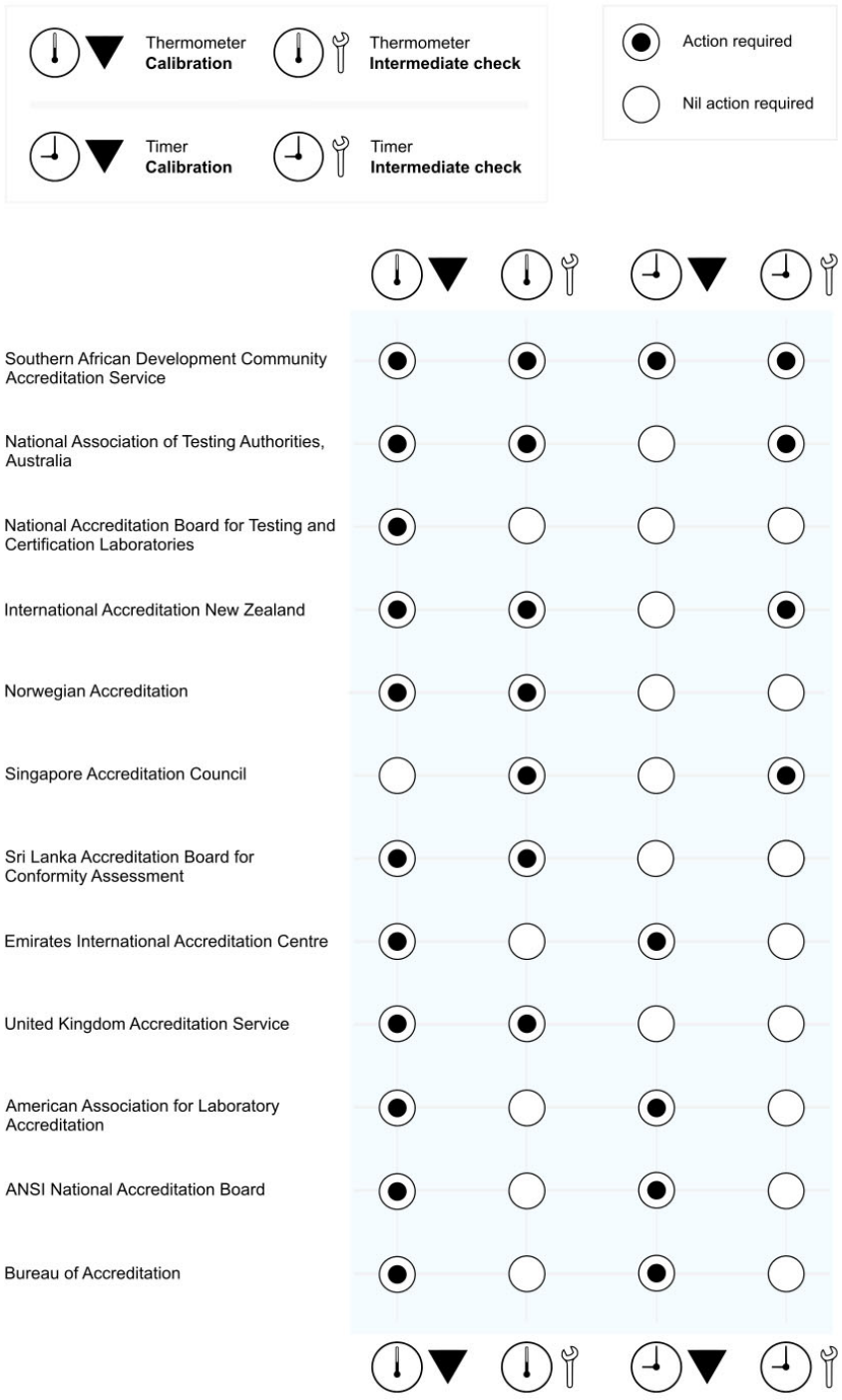

Figure S1. Specific requirements for accreditation analysis of calibration and intermediate check of thermometer and timer. Specific actions are set by 12/83 (14.4 %) accreditation bodies for medical laboratories to perform.

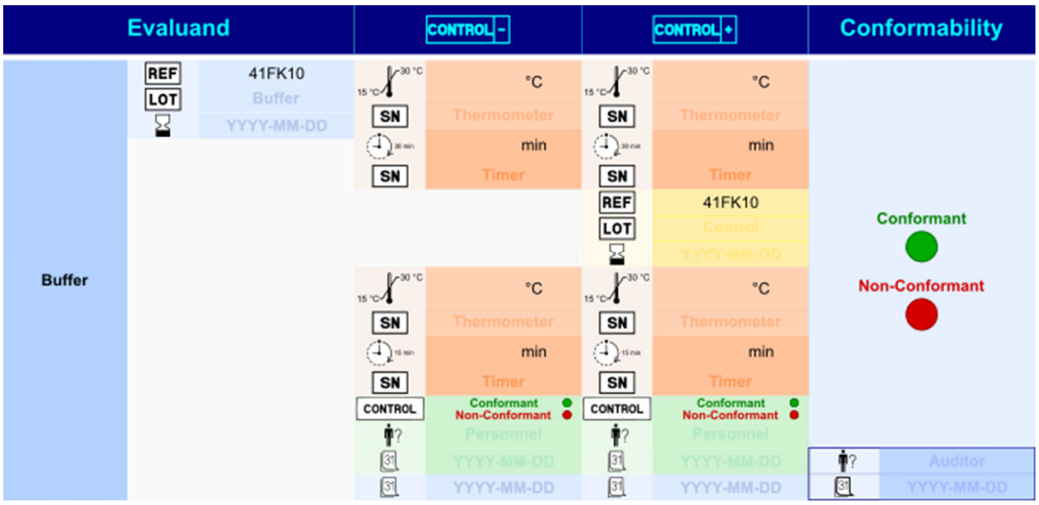

Figure S2. Panbio COVID-19 Ag Rapid Test Device examination kit conformity evaluation checklist for buffer acceptance testing.

NOTE. The first column entitled 'Evaluand' requires the internal auditor to enter the following information from records concerning buffer: 'Batch code' [Symbol ISO 7000-2492 (2004-01)] and 'Use by date' [Symbol ISO 7000-2607 (2004-01)] in the blue-shaded area.

The second column entitled 'Negative control' [Symbol ISO 7000-2495 (2004-01)] requires the internal auditor to enter the following information from records: the treatment condition (condition prior to performing the test) 'Temperature limit' [Symbol ISO 7000-0632 (2014-06)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; 'Programmable start' [Symbol ISO 7000-5132 (2002-10)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the treatment condition (reaction with test device) 'Temperature limit' [Symbol ISO 7000-0632 (2014-06)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; 'Programmable start' [Symbol ISO 7000-5132 (2002-10)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control's grade of either 'Conformant' or 'Non-Conformant', the 'Date' [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel's 'Person identification' [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the 'Date' [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The third column entitled 'Positive control' [Symbol ISO 7000-2496 (2004-01)] requires the internal auditor to enter the following information from records: the treatment condition (condition prior to performing the test) 'Temperature limit' [Symbol ISO 7000-0632 (2014-06)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; 'Programmable start' [Symbol ISO 7000-5132 (2002-10)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; 'Batch code' [Symbol ISO 7000-2492 (2004-01)] and 'Use by date' [Symbol ISO 7000-2607 (2004-01)] of the buffer in the yellow-shaded area; the treatment condition (reaction with test device) 'Temperature limit' [Symbol ISO 7000-0632 (2014-06)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; 'Programmable start' [Symbol ISO 7000-5132 (2002-10)] and 'Serial number' [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control's grade of either 'Conformant' or 'Non-Conformant', the 'Date' [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel's 'Person identification' [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the 'Date' [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The fourth column entitled 'Conformability' requires the internal auditor to indicate: the grade of either 'Conformant' or 'Non-Conformant' in the blue-shaded area; and the internal auditor's 'Person identification' [Symbol IEC 60417-5664 (2002-10)] and the 'Date' [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed in the blue-bordered, blue-shaded area. An acceptable conformity is achieved when valid records are obtained in the first, second and third columns.

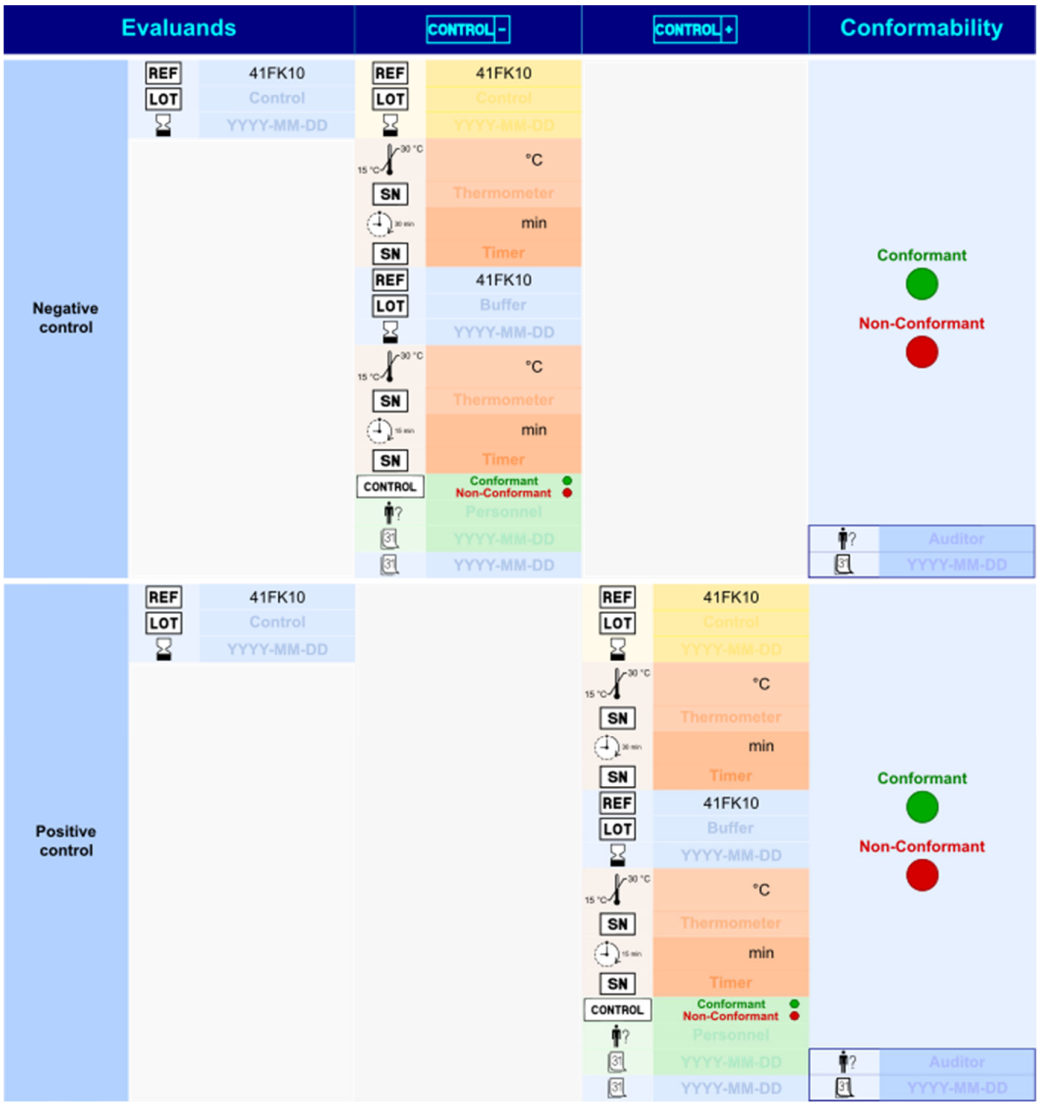

Figure S3. Panbio COVID-19 Ag Rapid Test Device examination kit conformity evaluation checklist for negative control and positive control acceptance testing.

NOTE. The first column entitled ‘Evaluands’ requires the internal auditor to enter the following information from records concerning negative control and positive control: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] in the blue-shaded area.

The second column entitled ‘Negative control’ [Symbol ISO 7000-2495 (2004-01)] requires the internal auditor to enter the following information from records: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the negative control in the yellow-shaded area; the treatment condition (condition prior to performing the test) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the buffer in the blue-shaded area; the treatment condition (reaction with test device) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control’s grade of either ‘Conformant’ or ‘Non-Conformant’, the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The third column entitled ‘Positive control’ [Symbol ISO 7000-2496 (2004-01)] requires the internal auditor to enter the following information from records: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the positive control in the yellow-shaded area; the treatment condition (condition prior to performing the test) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the buffer in the blue-shaded area; the treatment condition (reaction with test device) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498

(2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control’s grade of either ‘Conformant’ or ‘Non-Conformant’, the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The fourth column entitled ‘Conformability’ requires the internal auditor to indicate: the grade of either ‘Conformant’ or ‘Non-Conformant’ in the blue-shaded area; and the internal auditor’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed in the blue-bordered, blue-shaded area. An acceptable conformity is achieved when valid records are obtained in the first, second and third columns.

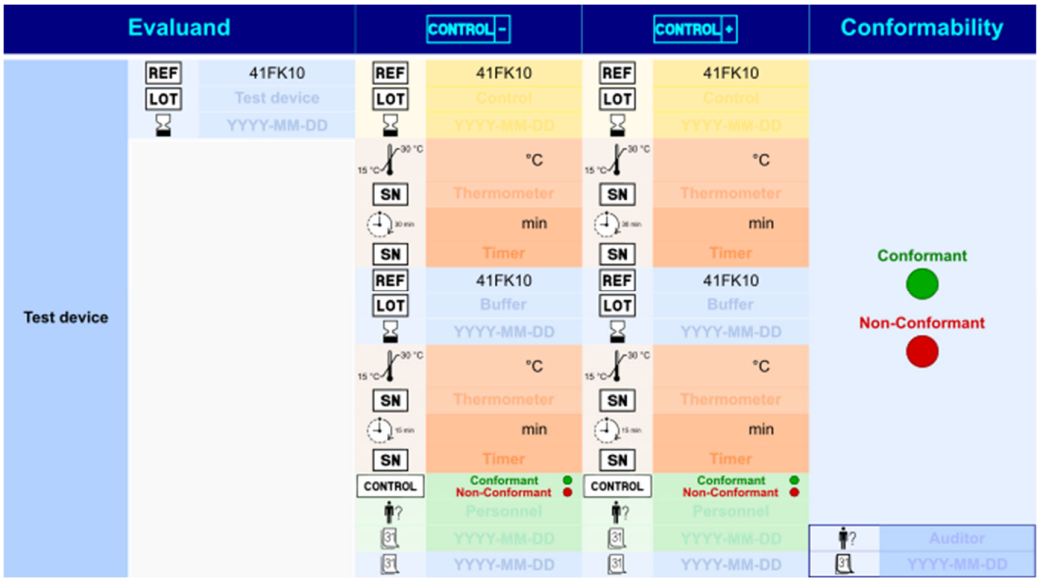

Figure S4. Panbio COVID-19 Ag Rapid Test Device examination kit conformity evaluation checklist for test device acceptance testing.

NOTE. The first column entitled ‘Evaluand’ requires the internal auditor to enter the following information from records concerning test device: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] in the blue-shaded area.

The second column entitled ‘Negative control’ [Symbol ISO 7000-2495 (2004-01)] requires the internal auditor to enter the following information from records: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the negative control in the yellow-shaded area; the treatment condition (condition prior to performing the test) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the buffer in the blue-shaded area; the treatment condition (reaction with test device) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control’s grade of either ‘Conformant’ or ‘Non-Conformant’, the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The third column entitled ‘Positive control’ [Symbol ISO 7000-2496 (2004-01)] requires the internal auditor to enter the following information from records: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the positive control in the yellow-shaded area; the treatment condition (condition prior to performing the test) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the buffer in the blue-shaded area; the treatment condition (reaction with test device) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control’s grade of either ‘Conformant’ or ‘Non-Conformant’, the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The fourth column entitled ‘Conformability’ requires the internal auditor to indicate: the grade of either ‘Conformant’ or ‘Non-Conformant’ in the blue-shaded area; and the internal auditor’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)]

and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed in the blue-bordered, blue-shaded area. An acceptable conformity is achieved when valid records are obtained in the first, second and third columns.

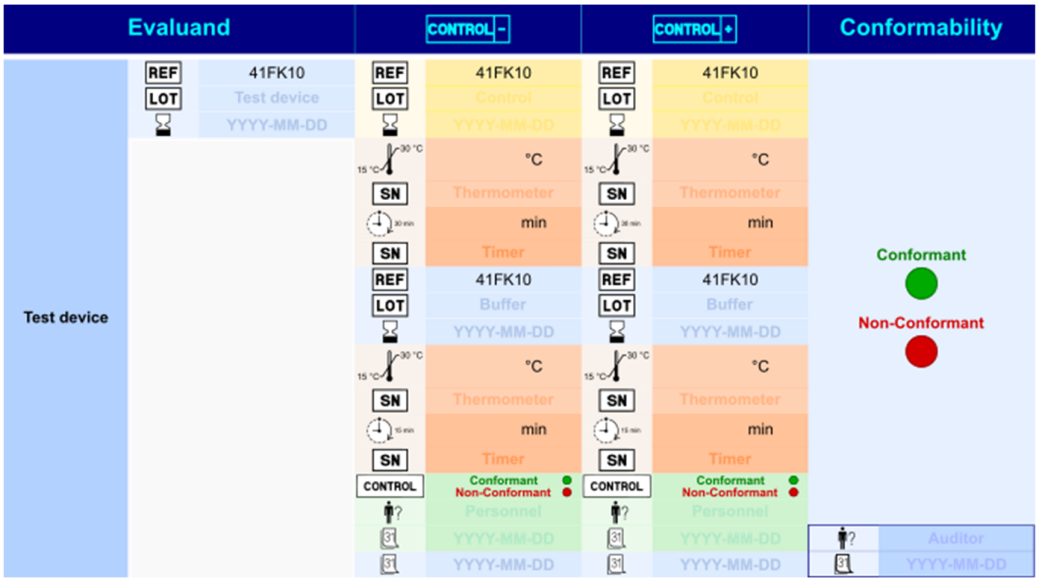

Figure S5. Panbio COVID-19 Ag Rapid Test Device examination kit conformity evaluation checklist in antigen testing for SARS-CoV-2. This checklist evaluates the reactivity of SARS-CoV-2 antigen and treatment with specified conditions of incubation and duration as well as reference equipment for monitoring the conditions.

NOTE. The first column entitled ‘Evaluand’ requires the internal auditor to enter the following information from records concerning the test device: ‘Batch code’ [symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [symbol ISO 7000-2607 (2004-01)] in the blue-shaded area.

The second column entitled ‘Negative control’ [Symbol ISO 7000-2495 (2004-01)] requires the internal auditor to enter the following information from records: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the negative control in the yellow-shaded area; the treatment condition (condition prior to performing the test) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the buffer in the blue-shaded area; the treatment condition (reaction with test device) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control’s grade of either ‘Conformant’ or ‘Non-Conformant’, the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The third column entitled ‘Positive control’ [Symbol ISO 7000-2496 (2004-01)] requires the internal auditor to enter the following information from records: ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the positive control in the yellow-shaded area; the treatment condition (condition prior to performing the test) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; ‘Batch code’ [Symbol ISO 7000-2492 (2004-01)] and ‘Use by date’ [Symbol ISO 7000-2607 (2004-01)] of the buffer in the blue-shaded area; the treatment condition (reaction with test device) ‘Temperature limit’ [Symbol ISO 7000-0632 (2014-06)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the thermometer in the light orange-shaded area; ‘Programmable start’ [Symbol ISO 7000-5132 (2002-10)] and ‘Serial number’ [Symbol ISO 7000-2498 (2004-01)] of the timer in the dark orange-shaded area; the internal procedural control’s grade of either ‘Conformant’ or ‘Non-Conformant’, the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed and the personnel’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] in the green-shaded area; and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] the activity was performed in the blue-shaded area.

The fourth column entitled ‘Conformability’ requires the internal auditor to indicate: the grade of either ‘Conformant’ or ‘Non-Conformant’ in the blue-shaded area; and the internal auditor’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed in the blue-bordered, blue-shaded area. An acceptable conformity is achieved when valid records are obtained in the first, second and third columns.

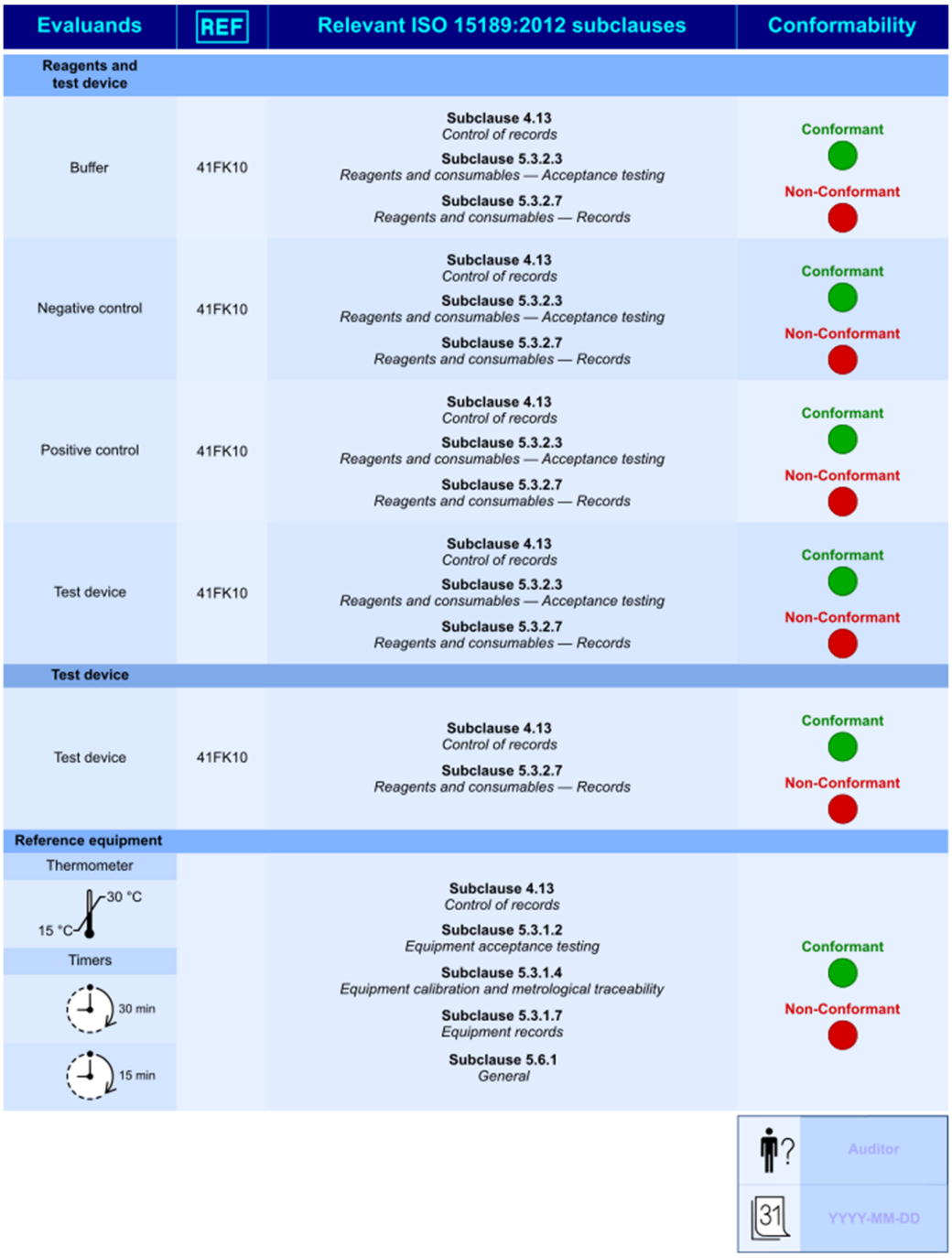

Figure S6. Interpretation checklist of Panbio COVID-19 Ag Rapid Test Device examination kit conformity evaluation checklists. Final results can be presented for review on completion of compilation of results.

NOTE. The fourth column entited ‘Conformability’ requires the internal auditor to indicate: the grade of either ‘Conformant’ or ‘Non-Conformant’ in the blue-shaded area; and the internal auditor’s ‘Person identification’ [Symbol IEC 60417-5664 (2002-10)] and the ‘Date’ [Symbol IEC 60417-5662 (2002-10)] that the evaluation was performed in the blue-bordered, blue-shaded area. An acceptable result is applied when the grade of ‘Conformant’ is applied in the Panbio COVID-19 Ag Rapid Test Device examination kit conformity evaluation checklists (Figures S2 to S5).

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