CONSOLIDATED GUIDELINES ON

HIV TESTING SERVICES

2019

Web Annex J. Ensuring the quality of HIV testing services

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## J1. Delegating responsibilities for quality assurance activities

The responsibility for ensuring the quality of testing must be a continuum involving all tiers of the health system. Users of HTS should also insist on quality in testing services. Table J.1a details the roles and responsibilities of HTS staff.

### Table J.1a. Roles and responsibilities for all staff to ensure the quality of HIV testing

<table>
<thead>
<tr>
<th>Level</th>
<th>Where</th>
<th>Counselling</th>
<th>Testing</th>
<th>Records</th>
<th>Supplies</th>
</tr>
</thead>
</table>
| 0 Community | Outside of facilities (home-based, mobile, outreach) | Monitor own performance  
Conduct client exit interviews | Adhere to SOPs  
Run QC  
Participate in EQAs | Keep accurate and secure testing records  
Have access to SOPs for all staff | Ensure sufficient supply of test kits and supplies under appropriate conditions |
| 1 Primary | Facility-based (stand-alone, clinical, laboratories) | Monitor own performance  
Conduct client exit interviews | Adhere to SOPs  
Run QC  
Participate in EQAs | Regularly aggregate data (EQAs, NCs)  
Conduct data quality audits | Order test kits and supplies from national level  
Distribute QC specimens & EQA panels |
| 2 District | Clinical facilities, district laboratories | Monitor own performance  
Conduct client exit interviews  
Provide supportive supervision of counselling in levels 0, 1, 2  
Suggest corrective and preventive actions | Adhere to SOPs  
Run QC  
Participate in EQAs  
Provide supportive supervision of testing processes in levels 0, 1, 2  
Suggest corrective actions | | |
| 3 Provincial | Clinical facilities, provincial laboratories | Monitor own performance  
Conduct client exit interviews  
Provide supportive supervision of counselling in levels 0, 1, 2  
Suggest corrective and preventive actions | Adhere to SOPs  
Run QC  
Participate in EQAs  
Provide supportive supervision of testing processes in levels 0, 1, 2  
Suggest corrective actions | Regularly aggregate data (EQAs, NCs)  
Conduct data quality audits | Order test kits and supplies from national level  
Distribute QC specimens & EQA panels |
| 4 National | National reference laboratory | Verify national testing algorithms  
Perform lot verification testing for post-market surveillance  
Produce QC specimens and EQA panels  
Evaluate data (EQAs, NCs) from all districts/provinces; suggest corrective actions  
Develop site SOPs and job aids  
Conduct training using standardized hands-on curricula | | | |
| Ministry of health | | Ensure testing sites’ readiness for accreditation (laboratories, clinical facilities) or site registration (stand-alone sites, community programmes)  
Establish national HIV testing policy that includes QA  
Establish national QA coordination team  
Allocate resources for QA  
Procure, store and distribute test kits/supplies | | | |
| Regulatory bodies | | Set national regulatory standards for IVDs  
Set standards for accreditation/certification of testing sites  
Respond to field safety notices arising from post-market surveillance | | | |

SOP: standard operating procedure; QC: quality control; EQAS: external quality assessment scheme; NC: non-conformance; QA: quality assurance; IVDs: in vitro diagnostics
J2. WHO prequalification of in vitro diagnostics

Acknowledgement: Prat

Eligibility for WHO prequalification assessment
WHO determines whether an application for an in vitro diagnostic product will be accepted for prequalification assessment based on WHO eligibility criteria and programmatic suitability. At this point in the process, it is necessary to determine whether a product is made by the original manufacturer (not re-branded), whether it is commercially available and which regulatory version of the product has been submitted.

Applications for prequalification should be submitted in accordance with guidance in Instructions for the completion of the pre-submission form (http://www.who.int/diagnostics_laboratory/evaluations/Application/en/). Two types of prequalification assessment can take place, depending on the regulatory version submitted and evidence from a previous stringent review.

Full prequalification assessment
The full prequalification assessment process consists of the following components:
- review of a product dossier;
- performance evaluation, including operational characteristics;
- inspection of manufacturing site(s); and
- labelling review.

Abridged prequalification assessment
The rationale for abridged prequalification assessment is that a prior regulatory approval provides a level of assurance relating to the product’s quality, safety and performance in countries where it is approved, but it cannot always provide the same assurance when the product is used in other jurisdictions, including resource-limited settings. The aim of abridged prequalification assessment is to avoid duplication of effort and reduce the time taken to prequalify a product by focusing on aspects where WHO prequalification assessment brings added value. Products that have already undergone a stringent assessment by certain national authorities or their designated bodies may be eligible for an abridged WHO prequalification assessment.

The abridged prequalification assessment consists of the following components:
- performance evaluation, including operational characteristics;
- manufacturing site inspection of abridged scope; and
- labelling review.

Product dossier review
A product dossier contains documentation and data to demonstrate that the in vitro diagnostic (IVD) conforms to the Essential principles of safety and performance of medical devices and IVD medical devices, as defined by the International Medical Device Regulators Forum (IMDRF) (formerly the Global Harmonization Task Force [GHTF]). The product dossier requested by WHO should be submitted according to the Instructions for compilation of a product dossier (http://www.who.int/diagnostics_laboratory/evaluations/PQDxInfo/en/).

The WHO prequalification assessment reviews the safety and performance of IVDs specifically from the perspective of resource-limited settings, including risk assessment, robustness, stability and instructions for use. National regulatory authorities undertaking stringent review may not review these aspects in the same way as they would focus on risks in their own jurisdiction. WHO rates any non-conformity identified during the dossier review, and the manufacturer is expected to file a corrective action plan that outlines how and when such non-conformities will be addressed.

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1 World Health Organization, Prequalification Team - Diagnostics Assessment, Regulation and Prequalification Department, Geneva
**Inspection of manufacturing site(s)**

Inspection of the manufacturing site(s) is conducted to assess compliance of the manufacturer’s quality management system and manufacturing practices with international standards, such as the quality management standard ISO 13485 and other relevant international standards, and guidelines produced by the GHTF and IMDRF. WHO inspection of the manufacturing site will focus on the suitability of the implemented processes and procedures for the reliable supply of IVDs to WHO Member States. Therefore, customer-related issues that may be covered only in general terms in ISO 13485 are inspected in detail by WHO.

Under the full prequalification assessment, the initial inspection of the manufacturing site will be performed in two stages. The stage 1 inspection, usually a desk audit, will evaluate the documentation related to the quality management system to ensure readiness for the stage 2 inspection. The stage 2 inspection will comprehensively evaluate the effective implementation of the quality management system and production processes through an onsite inspection. Under the abridged prequalification assessment, a manufacturing site inspection of abridged scope will take place. WHO rates any non-conformity identified during the inspection, and the manufacturer is expected to file a corrective action plan that outlines how and when such non-conformities will be addressed.

**Independent laboratory evaluation of performance and operational characteristics**

WHO laboratory evaluations aim to assess technical and performance characteristics such as sensitivity and specificity, as well as seroconversion and low titer sensitivity relative to those of other assays of similar format.

Manufacturers send two production lots to WHO collaborating centres or other laboratories designated by WHO to conduct the evaluation testing. WHO issues a technical report of the performance and operational characteristics and determines if the assay meets WHO prequalification requirements. Specific minimum acceptance criteria are applied to each assay format (Table J.2a).

**Table J2a. Minimum acceptable performance for serology assays for WHO prequalification (2)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RDT</th>
<th>EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>&gt;99%</td>
<td>100%</td>
</tr>
<tr>
<td>Specificity</td>
<td>&gt;98%</td>
<td>&gt;98%</td>
</tr>
<tr>
<td>Inter-reader variability</td>
<td>&lt;5%</td>
<td>N/A</td>
</tr>
<tr>
<td>Invalid rate</td>
<td>&lt;5%</td>
<td>&lt;5%</td>
</tr>
</tbody>
</table>

EIA: enzyme immunoassay; RDT: rapid diagnostic test

In addition to performance, certain operational characteristics that make assays suitable for resource-limited settings are evaluated (Table J.2b).

**Table J.2b. Operational characteristics and examples for RDTs and EIAs (2)**

<table>
<thead>
<tr>
<th>Operational characteristic</th>
<th>RDT</th>
<th>EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Items required but not provided with test kits (consumables, equipment)</td>
<td>Lancets, alcohol swabs, cotton wool</td>
<td>Deionized water, reagent troughs, washer, incubator, reader</td>
</tr>
<tr>
<td>Time to first result</td>
<td>3 minutes if immunofiltration, 15 minutes if immunochromatographic</td>
<td>2 hours</td>
</tr>
<tr>
<td>Throughput per operator per hour</td>
<td>20</td>
<td>90</td>
</tr>
<tr>
<td>Stability/shelf-life for storage</td>
<td>2–30 °C</td>
<td>2–8 °C</td>
</tr>
<tr>
<td>In-use stability, including at room temperature</td>
<td>Use immediately</td>
<td>Up to 4 weeks</td>
</tr>
<tr>
<td>Specific specimen preparation steps</td>
<td>N/A</td>
<td>1 step</td>
</tr>
<tr>
<td>Number of steps required to perform the test procedure</td>
<td>1 step if immunochromatographic, 3 steps if immunofiltration</td>
<td>4 steps</td>
</tr>
</tbody>
</table>

EIA: enzyme immunoassay; RDT: rapid diagnostic test
Labelling review
Product labelling is considered a critical element of the evidence submitted for prequalification assessment. Labelling is reviewed for clarity, correctness, and consistency with the information submitted in the product dossier and in the technical documentation. It is also reviewed for consistency with international guidance and requirements, and suitability for the target user group in WHO Member States.

Final decision on prequalification
The final WHO prequalification assessment outcome depends on:
1. results of the product dossier review and acceptance of the corrective action plan, if required;
2. results of inspection of the manufacturing site(s); and acceptance of the corrective action plan, if required;
3. meeting the minimum acceptance criteria on the laboratory evaluation.

When a positive prequalification decision has been made, WHO issues a public report, and the product is added to the list of WHO-prequalified IVDs. It is therefore eligible for WHO and United Nations (UN) procurement. In the post-qualification stage, the manufacturer has specific obligations such as mandatory reporting of vigilance events, notification of reportable changes and annual reporting.

Further reading
J3. Post-market surveillance for in vitro diagnostics

Overview
The purpose of post-market surveillance of IVDs is to protect individual and public health through vigilance for adverse events related to in vitro diagnostics (IVDs) placed on the market. Post-market monitoring activities ensure that manufacturers are aware of any event that may affect the quality, safety or performance of their product. Post-market surveillance is ultimately the responsibility of the manufacturer who must detect, evaluate and assess any residual risks and, as appropriate, take risk-mitigation measures.

Other critical enablers and stakeholders for post-market surveillance of IVDs are:
- quality control monitoring by IVD end-users (who report complaints to the manufacturer);
- market surveillance by national regulatory authorities (which ensure that complaints are followed up by the manufacturer, assist end-users to respond to field safety notices and oversee lot verification testing);
- testing of IVDs by national testing laboratories (which, under the auspice of the regulatory authority, conduct for-cause lot testing to assist with documentation of complaints and lot verification testing to detect product issues, both before and after distribution to end-users).

Fig. J.3a shows the components of post-market surveillance.

Fig. J.3a. Proactive and reactive measures for post-market surveillance of in vitro diagnostics (3)

EQA: external quality assessment; QC: quality control; IVD: in vitro diagnostic; PMS: post-market surveillance

A centralized collection of post-market data by WHO on certain categories of IVDs enables coordinated action in WHO Member States and ensures traceability of information. These post-market data include results from pre-distribution and post-distribution lot verification testing as well as complaints and the effectiveness of corrective action. Regulators and users submit these post-market data to WHO in the form of lot testing reports and IVD complaint forms. National regulatory authorities, procurers and implementing partners, such as nongovernmental organizations, are notified of certain reports of adverse events through vigilance information exchange.

Other actions that WHO might take on post-market information include:
- information exchange with national regulatory authorities on post-market surveillance;
- information exchange with manufacturers on post-market surveillance;
- publishing post-market surveillance information on WHO’s website;
- additional surveillance of the IVD concerned;
• removal of the product from the list of WHO-prequalified IVDs, if needed;
• inspection of the manufacturing site to ensure that corrective or preventive action has been implemented following any complaint.

Further reading

Practical guidance on post-market surveillance by end-users of rapid diagnostic tests (RDTs)

1. When to report a complaint?

When any of the following has or might have occurred:

<table>
<thead>
<tr>
<th>Happened to the client</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death of the patient, end-user or any other person</td>
</tr>
<tr>
<td>Serious deterioration in the health of the patient, end-user or any other person</td>
</tr>
<tr>
<td>A false-negative test result</td>
</tr>
<tr>
<td>A series of false-positive test results (more than 2)</td>
</tr>
<tr>
<td>Non-reproducible results</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Happened to the test kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packaging (e.g. foil pouch, buffer vial/bottle, desiccant, shipping container) – damaged, defective, suspect tampered</td>
</tr>
<tr>
<td>Labelling (e.g. pouch label, instructions for use) – insufficient, illegible, missing</td>
</tr>
<tr>
<td>Components (e.g. specimen transfer device) – defective, incorrect or missing</td>
</tr>
<tr>
<td>Increased rate of invalid or unreturnable test results</td>
</tr>
</tbody>
</table>

Please note that this is not an exhaustive list. Any issue that you suspect might affect the result should be reported.

2. What to report?

Document exactly what happened, including the following:
• When and where did you receive the test kit?
• How did you store the test kit until you used it?
• What day did you open the packaging to conduct the test?
• What was the lot number and expiry date? Take a photograph of the labelling, if possible.
• For complaints regarding false-negative and false-positive results, state how this was determined, for example, by providing testing results on other products.
• Describe exactly what happened. Include photos, if relevant.

3. Who to report to?

Report as soon as you can so that the manufacturer can start their investigation.
• Contact the manufacturer of the test kit through your local distributor; their contact details can be found in the product’s instructions for use.

2 Note:
Guidance from International Medical Device Regulators Forum (IMDRF) states that when protection against a fault functions correctly, it does not need to be reported but WHO recommends that these events be reported.

3 Refer to International Medical Device Regulators Forum (IMDRF) terminologies for categorized adverse event reporting: terms, terminology structure and codes. IMDRF, 2017 [IMDRF/AE WG/N43FINAL].

4 You may report to the legal manufacturer or any of their economic operators (authorized representative, supplier, distributor, agent, etc.).
• Contact your national regulatory authority (if WHO prequalified, report to WHO).

*Use a standardized complaint form such as [http://www.who.int/diagnostics_laboratory/postmarket/en/](http://www.who.int/diagnostics_laboratory/postmarket/en/)*

4. What next?

**Assist with the manufacturer’s investigation**

- Retain the test kit, any consumables such as the test device, the buffer vial, and its packaging including the labelling, and store at the recommended storage conditions.
- Send back a sample of the affected lot(s) and/or patient specimen(s) to the manufacturer via a local distributor.
- Ensure that any specific lot that is suspected to be the cause is marked as “do not use” and placed in a quarantine zone, so that no other individual may be tested with it until the lot is ruled out as the root cause.

**Act on field safety notices issued by the manufacturer to affected customers**

Follow up on the manufacturer’s corrective action(s) following the complaint:

- There may be certain changes to the product or the labelling such as the test procedure.
- There may be a recall of the affected product, usually restricted to certain lots of the product.
- Ensure that you are aware of the most recent version of the field safety notice.

**Where do I find information on current product issues for IVDs?**

For Australia, Canada, the European Union, Japan, Singapore, the USA: [http://www.imdrf.org/safety/safety.asp](http://www.imdrf.org/safety/safety.asp)

For WHO-prequalified IVDs: [http://www.who.int/diagnostics_laboratory/procurement/complaints/en/](http://www.who.int/diagnostics_laboratory/procurement/complaints/en/)

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**Post-market surveillance case study**

**Event.** Individuals were tested using an HIV RDT in a cross-sectional surveillance study in key populations and found to be HIV-negative. Some study participants later disclosed that they were HIV-positive. False-negative RDT results were identified for three individuals.

**Root cause.** The manufacturer investigated and found that the test procedure given in the instructions for use was susceptible to use error due to the type of specimen transfer device used.

**Correction.** The manufacturer changed the type and source of the specimen transfer device, then offered it for use with the product.

**Corrective action.** The manufacturer revised the standard operating procedure for incoming quality control of consumables by the addition of functional testing against a specification.
J4. How to organize external quality assessment

External quality assessment (EQA) is an interlaboratory comparison to verify if testing services, such as HIV testing services (HTS), can provide the correct status to the client. EQA provides objective evidence of quality, i.e. that assays are performed accurately, results are reproducible, and that errors are detected and corrected to avoid misdiagnosis (or misclassification).

EQA may take the form of an observational visit, usually by the site supervisor or district health management team to observe testing practices. The supervisor should be trained and competent in the principles of quality management and testing practices. These visits should occur at least annually but preferably every three to six months.

EQA may take the form of participation in an EQA scheme, also known as proficiency testing, whereby a panel of blinded specimens are sent to a testing site and tested according to the usual procedures. The final status assigned (and test results) is reported back to the EQA scheme provider for analysis.

For HTS, EQA panels can be serum/plasma specimens that are clinically collected; however, large volumes of specimens are necessary, which is impractical for most programmes. An alternative is to use the dried tube specimen (DTS) methodology, which allows for sera (mixed with green dye so the pellet can be visualized) to be allowed to dry in the bottom of the tube /4/. This approach provides a practical means to prepare specimens for distribution to outlying laboratories and testing services.

It is crucial that any set of activities for EQA includes provision for the follow up of any unacceptable EQA results with corrective actions.

WHO has published guidance on how to organize national EQA programmes. There are two approaches: (1) nongovernmental organizations provide EQA services; or (2) a relevant national institution with an interest and competency in EQA provides EQA services. These two strategies are not mutually exclusive and may coexist within a national EQA programme. The national EQA programme must cover public and private testing services to ensure a common standard for generating evidence that quality requirements have been fulfilled.

The EQA organizing centre(s) must have the required competence to run an EQA programme, as described in ISO/IEC 17043 Conformity assessment – general requirements for proficiency testing (5). If the national reference laboratory is designated for providing EQA services, it must participate in an international EQA scheme at least twice per year. The EQA organizing centre(s) have an extremely important role in supporting poorly performing testing services to improve. Therefore, distribution of EQA panels alone is insufficient.

WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites
English: (https://apps.who.int/iris/bitstream/handle/10665/250117/9789241549677-eng.pdf?sequence=1)

EQA providers that ship worldwide, including to resource-limited settings (not an exhaustive list):
- College of American Pathologists, USA (http://www.cap.org/web/home/lab/proficiency-testing)
- National Institute of Communicable Diseases, South Africa (http://www.nicd.ac.za/)
- National Serology Reference Laboratory, Australia (http://www.nrl.gov.au/Our+Services/NRL+Quality+Assurance)
- Randox International Quality Assessment Scheme (https://www.randox.com/external-quality-assessment/)
- Réseaux Africain de Recherche sur le Sida, Laboratoire de Virologie Bactériologie, Senegal (http://www.rarslbv.org/)
- Royal Australian College of Pathologists (http://www.rcpaqap.com.au/serology/)
- UK National External Quality Assessment Scheme http://www.ukneqas.org.uk/content
J5. Principles for preparation of quality control specimens for end-user monitoring

Quality control (QC) refers to a material or mechanism which, when used with or as part of an assay, monitors the analytical performance of that assay. It may monitor the entire assay or only one aspect of it. Test kit controls supplied by the manufacturer (as positive and negative controls), or internal quality controls that are integrated within the assay (or test device) are typical forms of QC. However, increasingly, internal QC for RDTs comprises a control line that appears when any type of liquid is added, and therefore does not assure that adequate specimen has been added. Certain regulatory agencies have a requirement that test kit controls be provided with RDTs supplied within their jurisdiction. However, these test kit controls often have different storage requirements and stability compared to the components of the assay, and thus are usually supplied separately.

Considering the above-mentioned issues with achieving optimal QC for RDTs, an external quality control specimen (a low antibody titre biological specimen) can be used to challenge the performance of the assay. In practice, these types of specimens are difficult to acquire as naturally occurring specimens, and so it is acceptable to use a biological specimen that has been diluted in a suitable matrix to mimic a low-reactive specimen.

Alternatively, quality control specimens may be commercially purchased.

External QC specimens are prepared by taking a strongly reactive HIV-positive specimen and diluting it in base matrix (defibrillated plasma) or normal human serum. The diluent should be safe and free of other analytes such as antibodies to HCV (anti-HCV) and hepatitis B surface antigen (HBsAg). It is preferable to make large volumes of external QC specimens and then store in small aliquots, until required.

Acceptance criteria. QC results are determined to be acceptable when the results of the external QC specimen are compared with the expected reference result (band/line intensity).

Trend monitoring. It is critical that QC results are recorded, analysed and any trends that might require occurrence management identified. For more information on occurrence management, see Chapter 8 of the Consolidated guidelines on HIV testing services.

Test kit controls should be run according to the manufacturer’s instructions for use, and external QC specimens should be run:
- once weekly, preferably at the beginning of the week;
- for any new operator (including trained staff members who have not conducted testing for some time);
- for each new lot of test kits;
- for each new shipment of test kits;
- when any environmental conditions (e.g. temperature and humidity) fall outside the range recommended by the manufacturer; and
- for-cause testing.

WHO is developing specific guidance on the preparation of QC specimens for RDTs.

Further reading


J6. Generic job aid for an HIV rapid diagnostic test

Wonderful HIV-1/2 RDT\(^5\) is an immunochromatographic RDT for the discriminatory detection of HIV-1 and HIV-2 antibodies in human serum or plasma and capillary or venous whole blood specimens.

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**Key information**
- **Shelf-life:** 18 months
- **Storage conditions:** 2–30 °C
- **Volume of specimen needed:**
  - 25 µL (serum/plasma)
  - 50 µL (whole blood)
- **Time to test one specimen:** 16 min

**Equipment required but not supplied**
- personal protection equipment, such as gloves, lab coat or gown
- timer
- appropriate biohazard waste containers
- for capillary blood collection:
  - lancet, cotton wool, alcohol swab
- for venous blood collection:
  - venepuncture apparatus and appropriate blood collection tubes

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**Test procedure**

1) Remove the test device from the protective foil pouch.

2) Label the test device with a specimen ID number.

3a) For serum or plasma specimens:
   - Using the precision pipette, apply 1 drop (25 µL) of specimen to the specimen well (S).
   - Read the results at 15 min. Do not read after 30 min.

3b) For venous whole blood (venepuncture) specimens:
   - Using the dropper provided within the test kit, apply 2 drops (50 µL) of specimen to the specimen well (S).
   - Then add 2 drops (50 µL) of buffer to the same specimen well (S).
   - Read the results at 15 min. Do not read after 30 min.

3c) For capillary whole blood (finger-stick) specimens:
   - Clean the fingertip with an alcohol swab, place the lancet off-centre and puncture the fingertip. Wipe away the first drop of blood with cotton wool.
   - Using the capillary tube, pour the specimen until the fill line. Apply 50 µL of the specimen to the specimen well (S).
   - Then add 2 drops (50 µL) of buffer to the same specimen well (S).
   - Read the results at 15 min. Do not read after 30 min.

4) Interpret the results as follows:

**Reactive for HIV-1 antibodies.** Two coloured lines appear, one in the control region “C” and one in the test region “T1”.

**Reactive for HIV-2 antibodies.** Two coloured lines appear, one in the control region “C” and one in the test region “T2”.

**Reactive for HIV-1/2 antibodies.** Three coloured lines appear, one in the control region “C” and one each in test regions “T1” and “T2”.

**Non-reactive for HIV-1 & HIV-2.** One coloured line appears in the control region “C”. No coloured lines appear in either of the test regions “T1” or “T2”.

**Invalid.** No control line appears in the control region “C”, irrespective of whether coloured lines appear in either of the test regions “T1” or “T2”; OR high background colour precludes reading of the test and control lines; OR the specimen is not seen to migrate along the test strip.

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\(^5\) This is a fictional product.
References
