Prequalification-In vitro Diagnostics Assessment

Prequalification of In Vitro Diagnostics

WHO PROTOCOL for laboratory evaluation of HIV Oral Fluid serology assays

PQDX_154_v3.1
3. Introduction

3.1. WHO Prequalification of In Vitro Diagnostics Programme

The World Health Organization (WHO) Prequalification of In Vitro Diagnostics Programme is coordinated through the Prequalification In Vitro Diagnostics Team. The aim of the WHO Prequalification of In Vitro Diagnostics Programme is to promote and facilitate access to safe, appropriate and affordable in vitro diagnostics of good quality in an equitable manner. Focus is placed on products for high burden diseases and their suitability for use in resource-limited settings.

The WHO prequalification of in vitro diagnostics process includes three main components:

- Screening and assessment of the product dossier;
- Laboratory evaluation of the product;
- Inspection of the manufacturing site(s).

This document pertains to the objectives and processes of the laboratory evaluation component of the WHO prequalification assessment. This document intends to provide information for manufacturers and the WHO Collaborating Laboratory on the process for laboratory evaluation.

3.2. WHO laboratory evaluation of rapid diagnostic tests (RDTs) for HIV-1/2 antibodies using oral fluid

The laboratory evaluation determines the accuracy of HIV assays in comparison with established performance criteria. These characteristics include: sensitivity, specificity, negative and positive predictive values. In addition, a number of operational characteristics are assessed including the suitability for use in small laboratories or testing settings with limited infrastructure.

Rapid diagnostic tests for the detection of HIV-1/2 antibodies in oral fluid are covered in this protocol.

All assays submitted for laboratory evaluation are assessed at the Institute of Tropical Medicine (ITM) Antwerp and at the Blood Bank at Antwerp upon the instruction of WHO. The WHO HIV specimen panel comprises approximately 200 anti-HIV positive and 350 anti-HIV negative oral fluid specimens.
4. Study objectives

4.1. Overall objectives

The overall objectives are:

1. To evaluate and compare the accuracy of currently available HIV oral fluid rapid diagnostic tests (RDTs) for detection of HIV-1/2 antibodies against established performance criteria.

4.2. Specific objectives

The specific objectives of the evaluation are:

1. To determine the sensitivity and specificity of currently available HIV RDTs for the detection of HIV-1/2 antibodies in oral fluid samples as compared to a reference result (one antibody detection enzyme immunoassay (EIA), one antibody/antigen EIA and/or one HIV nucleic acid testing (NAT), performed on a matched plasma specimen).

2. To evaluate the operational characteristics of HIV oral fluid RDTs, e.g. ease of performance, inter-reader variability, reaction endpoint stability, rate of invalid runs/devices, suitability for use in extreme climates (high/low temperatures, high humidity), and suitability for use in countries with limited infrastructure (no/limited electricity, no/limited clean water, and inadequate means of biosafety disposal).

5. Study Design

5.1. Reference laboratory

The Institute of Tropical Medicine (ITM) is a National AIDS Reference Laboratory (ARL) for Belgium and has been identified as the external reference laboratory for this laboratory evaluation. ITM is a WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support and since 1985 has been actively involved in the diagnosis of HIV infection with more than 20 years of experience in evaluating HIV diagnostic products on behalf of WHO. Within the ARL, the full range of technologies for investigation of HIV viruses is available from basic serological tests to nucleic acid testing and molecular characterization.

ITM holds the following certification for quality management within the laboratory: ISO17025 (General requirements for the competence of testing and calibration laboratories) and ISO15189 (Medical laboratories — Particular requirements for quality and competence) both issued by BELAC.

Dr Katrien Fransen will act as the Principal Investigator (PI) for the work performed by ITM. The PI will be responsible to submit the protocol for institutional review board before commencing the study.

5.2. Training, performance evaluation and supervision

The following issues are key to minimizing error and maximizing the value of this evaluation:

- The PI will be responsible for training the laboratory technicians on the evaluation protocol and on the performance of each assay undergoing evaluation after demonstration by the manufacturer;

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• Only those personnel who have received specific training for this evaluation will be employed in the evaluation;
• Accurate record keeping is crucial to the success of the evaluation and the PI will be responsible for ensuring that all data collected during the evaluation are recorded on the agreed data collection sheets, and are accurate and up to date;
• It is important to plan work in advance and follow standard operating procedures as prepared and controlled by ITM;
• To reduce the risk of adding an incorrect specimen to a test device/well, before starting the test run, the operator will prepare worksheets and label all tubes, dilution vessels, test devices or plates with the specimen’s unique number;
• Because objective, machine-generated, permanent results for simple/rapid diagnostic tests are not feasible, it is essential that the PI emphasizes to the operator performing the tests the need for accurate recording of results and recordkeeping;
• To minimize the risk of error, it is recommended that the results are read and recorded independently by two trained staff members. If the two readers disagrees, a third reader will act as tie-breaker reader. A consensus result will be recorded as the interpretation that occurs two out of three times.
• To allow immediate correction of erroneous recording of results (rather than differences in visual interpretation), the PI or designee should assess the results as soon as possible to allow her to return to the original test device to investigate apparently discordant readings;
• At least one representative result from both HIV positive and negative specimens will also be recorded by taking electronic images. Unexpected test results will also be digitally recorded as well an image of the instructions for use.

5.3. Safety
HIV, Hepatitis B and Hepatitis C and other blood borne pathogens are transmissible by blood and body fluids. Therefore, all types of specimens (including oral fluid, venous and capillary whole blood, serum/plasma, etc.) must be handled as potentially infectious. Appropriate precautions to minimize infectious hazards must be taken at all stages from the collection of specimens to the disposal of used materials from the laboratory. The WHO Guidelines on HIV Safety Precautions, and Guidelines for the Safe Transport of Specimens (WHO/EMC/97.3) and the ITM guidelines on laboratory safety should be carefully followed by the laboratory staff.

5.4. Storage of assays
All reagents must be stored as indicated in the instructions for use. Some assays may not need refrigeration. If refrigerated storage space is inadequate to store the entire test kit, they may be divided so that labile reagents can be refrigerated separately from the non-labile supplies. Calibrated thermometers are placed at each location where reagents and specimens are stored, i.e. ambient, refrigerator and freezer. Temperatures are recorded daily on temperature logs. The lot numbers of the test kits received/used and their expiry dates are recorded on the individual run worksheets.
Two separate production lots will be requested for evaluation, according to the following definition\(^1\) of a lot: “The amount of material that is uniform in its properties and has been produced in one process or series of processes. The material can be either starting material, intermediate material or finished product.” Furthermore, lots must be sourced from a representative production run and not produced especially for the purpose of this evaluation.

### 6. Specimens

#### 6.1. Oral fluid specimen collection and testing

**6.1.1. Collection and characterization of specimens at the ITM clinic**

Oral fluid specimens are collected using the device provided within the test kit, according to the manufacturer instructions for use (IFU). Specific precautions against eating, drinking and dental care in the time preceding the sampling will be observed for each assay under evaluation. A matched EDTA whole blood specimen is collected from the same individual for viral load testing.

Each plasma and oral fluid specimen will be assigned a unique identification number by ITM upon collection. The same WHO specimen identification number will be assigned for both oral fluid and plasma specimens with the suffix OF for the oral fluid specimen and P for the plasma specimen.

Oral fluid specimens will be collected and tested immediately, as per the manufacturer IFU. This will necessitate that oral fluid is sampled from the study participant and then taken to a separate room for the rest of the test procedure to be undertaken by a trained ITM staff member.

The aliquot of the matched plasma specimen will be processed and labeled. During the period of testing, the specimens are stored at 2 to 8 °C and this time period does not exceed one week. After the completion of testing, they are stored at -20 °C.

Specimens will be tested by an adaptation of the ITM HIV testing confirmatory algorithm using routinely for clinical purposes. Each plasma specimen will be tested on VIDAS HIV Duo Quick (bioMérieux): a CIFA for detection of HIV-1/2 antibodies and HIV-1 p24 antigen, Genscreen HIV Ag/Ab Ultra (Bio-Rad Laboratories); an EIA for detection of HIV-1/2 antibodies and HIV-1 p24 antigen in parallel. In addition, all specimens will be tested and on Genscreen HIV 1/2 v2: an EIA for detection of HIV-1/2 antibodies. All specimens will be further characterized on INNO-LIA™ HIV I/II Score (Fujirebio)) line immunoassay.

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\(^1\)ISO 18113-1:2009 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
Figure 1 - Testing algorithm for characterization of the WHO HIV specimen reference panel (serum/plasma specimens)

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6.1.2. **Collection and characterization of specimens at the Belgian Blood Transfusion Service**

Oral fluid specimens are collected using the device provided within the test kit according to the IFU while the blood donation of the study participant is being collected. Specific precautions against eating, drinking and dental care in the time preceding the sampling will be observed for each assay under evaluation. As per usual procedures, an additional matched plasma (EDTA as anticoagulant) specimen will be collected for screening of the blood donation.

Each oral fluid specimen will be assigned a unique identification number by ITM upon collection. The blood transfusion service will organize the link between the blood donation identification and the oral fluid specimen. Oral fluid specimens will be collected and tested immediately, as per the manufacturer IFU.

Specimens sourced from the Belgian Blood Service will be tested as per the BTS HIV testing algorithm using routinely for blood screening. Each plasma specimen will be tested by the HIV O Plus (Abbott, the Architect HIV Ag/Ab Combo (Abbott) and the MPX-NAT HIV. Only specimens that are non-reactive on all assays (serology and NAT testing) will be considered HIV seronegative and included in the study.

6.1.3. **Composition of the WHO HIV oral fluid specimen testing panel**

The overall panel will consist of approximately 200 anti-HIV positive specimens and 350 anti-HIV negative specimens. Of the 200 anti-HIV positive specimens, 150 will be collected from individuals that are antiretroviral therapy (ART) naive, and 50 anti-HIV positive specimens will be collected from individuals who are currently on ART. The main reason for including HIV infected patients on ARV in the study population is based on the available literature suggesting that individuals infected with HIV-1 and/or HIV-2, who are receiving highly active antiretroviral therapy (HAART), may have undetectable levels of antibodies to HIV-1 and/or HIV-2. Such patients may give false non-reactive test result on some assays. During data analysis the sub-population who are on ART will be clearly identified and separated from the overall results (see section 7.3).

**Table 1 - WHO HIV Oral Fluid Specimen Evaluation Panel**

<table>
<thead>
<tr>
<th></th>
<th>HIV positive specimens (HIV clinic)</th>
<th>HIV negative specimens (Blood Centre)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART naive</td>
<td>150</td>
<td>350</td>
<td>500</td>
</tr>
<tr>
<td>On ART</td>
<td>50</td>
<td>N/A</td>
<td>50</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>200</td>
<td>350</td>
<td>550</td>
</tr>
</tbody>
</table>

6.2. **External quality control specimen**

See section 6 for further details.
7. Laboratory testing

7.1. Review of instructions of use

Each assay under evaluation is used strictly in accordance with the instructions for use (IFU) issued by the manufacturer. ITM will send a copy of the IFU to WHO upon delivery of the test kits and prior to the commencement of the laboratory evaluation.

The IFU must be reviewed against the IFU submitted to WHO as part of the dossier assessment for the prequalification assessment. If the IFU has been updated since dossier submission, WHO technical officer-in-charge of laboratory evaluation will inform WHO technical officer-in-charge of dossier assessment of any ramifications for dossier assessment prior to the laboratory evaluation commencing.

Any specific procedural aspects of the IFU that should be reinforced or clarified, such as use of specimen transfer device included within the test kit, will be communicated by email to ITM, prior to commencement of the evaluation.

7.2. Sequence of testing

The WHO HIV oral fluid specimen reference panel is run in order that approximately one half of the specimen panel will be run with the one lot and the other half of the panel with the other lot. The specimens of the WHO HIV oral fluid specimen reference panel will be tested in singular.

For the purpose of evaluating RDTs, a ‘test run’ is defined as a consecutive run of simple/rapid tests of the same production lot performed during the same ‘session’. A ‘testing session’ might be considered to be a morning or afternoon.

7.3. Recording test results

All test results are recorded on standardized test result worksheets and then entered in a Microsoft Excel spreadsheet for further data analysis. For subjectively read assays such as RDTs or line immunoassay, the intensity of band/line/spot is additionally entered into the data collection sheet. The intensity rating system reads as described in Table 2.

Table 2 - Results legend for data collection sheets for subjectively read assays

<table>
<thead>
<tr>
<th>Scoring index</th>
<th>Intensity reading scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Negative</td>
</tr>
<tr>
<td>1</td>
<td>Very Weak, but Definitely Reactive</td>
</tr>
<tr>
<td>2</td>
<td>Medium to Strong Reactivity</td>
</tr>
<tr>
<td>7</td>
<td>Debris</td>
</tr>
</tbody>
</table>

Visual interpretation of results of subjectively read assays is made independently by two readers (without the knowledge of the other set of results) and entered onto the data collection sheets.
These results are compared by the operator carrying out the assay so that any mistakes may be identified and rectified immediately. Should recording errors be identified, both the original and corrected result are recorded and initialied by the reader. When the three readers interpret the results differently from each other, the consensus is recorded as that interpretation which occurs two out of three times. In cases where all three interpretations are different, the result is recorded as indeterminate.

A technician’s appraisal is made of each assay under evaluation and is completed by the operator performing the testing. It includes questions about the ease of the procedure, reading of results, clarity of IFU, as well as room to record any specific difficulties encountered during the evaluation.

8. Quality control and interpretation of test results

8.1. Test kit controls
If available, manufacturer-supplied positive and negative test kit controls will be run as indicated in the IFU at the commencement of each testing session for RDTs. Where positive and negative test kit controls are not supplied by the manufacturer, as will be the case for many rapid diagnostic tests, the external quality control specimen (oral fluid) will act at the control specimen, see later section 6.3.

8.2. Internal control lines for rapid diagnostic tests
Generally, RDTs contain a control band, line or spot to determine that the test device is operating correctly. Most control bands/lines/spots will become visible with the addition of reagent (i.e. buffer) only. However, some RDTs will contain a control band/line/spot that becomes visible with addition of specimen (i.e. presence of IgG). It is imperative that the exact nature of the control band/line/spot is ascertained and recorded in the report. An experiment is performed to verify this point, if not explicitly mentioned in the IFU.

8.3. External quality control specimen
ITM supplies an external quality control (QC) specimen which is tested in singular at the beginning of each test session for RDTs. See definition of testing session in section 5.1. The QC specimen represents a lowly reactive HIV positive specimen, and thus may be different for different assays and different assay formats. The QC specimen (oral fluid) is made by ITM or acquired commercially, depending on the assay under evaluation.

8.4. Proficiency panels
For assays under evaluation that have already been evaluated on the WHO specimen reference panel for serum/plasma, proficiency will have already been established. For other assays, a proficiency panel (serum/plasma) must be run successfully for each assay by each operator before the evaluation commences.

8.5. Limits of acceptability
All results on test kits controls and QC specimens are entered on the data collection sheets. Should the test kit controls or the QC specimen not give results within the expected ranges, evaluation testing on that assay is suspended until the cause has been identified and a satisfactory solution identified. Such problems must be communicated immediately to WHO and recorded on the data
sheets. The PI is responsible for carefully checking all data entry forms for legibility, accuracy and completeness.

8.6. Interpretation of results
The interpretation of results for each assay under evaluation is made strictly according to the manufacturers’ instructions in the IFU. Invalid test results are recorded on the data collection sheets including where the control line does not appear or in any other way the test result is invalid as defined by the IFU. For test results that are indeterminate according to the IFU, the results are recorded on data collection sheets.

9. Analysis of data

9.1. Invalid test devices
The number of invalid devices is recorded as the number of invalid test results as a percentage of the total number of devices used for the evaluation.

Invalid results may mean invalid test results as defined by the instructions for use such as where the control line/band/spot does not appear or invalid due to obviously defective test device or defective transfer pipette. Specimens that do not flow along or through the membrane will also be noted.

9.2. Inter-reader variability
The inter-reader variability is calculated when assay readings must be performed without any objective reading instruments i.e. RDTs. Two persons independently interpret each test result. The inter-reader variability is expressed as the percentage of specimens for which initial test results are differently interpreted (i.e. reactive or non-reactive or indeterminate) by the independent readers.

9.3. Performance characteristics from WHO specimen testing panel
The following methods are used to calculate the performance characteristics for each assay under evaluation and is closely linked to the reference testing results gained during specimen panel characterization.

Table 3 - 2 x 2 table for calculation of performance characteristics

<table>
<thead>
<tr>
<th>Results of assay under evaluation</th>
<th>Results of reference testing</th>
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</thead>
<tbody>
<tr>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>True positives</td>
<td>a</td>
</tr>
<tr>
<td></td>
<td>False positives</td>
</tr>
<tr>
<td></td>
<td>b</td>
</tr>
<tr>
<td>army</td>
<td>a+b</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>False negatives</td>
<td>c</td>
</tr>
<tr>
<td></td>
<td>d</td>
</tr>
<tr>
<td>True negatives</td>
<td>c+d</td>
</tr>
</tbody>
</table>
9.3.1. Sensitivity
Sensitivity is the ability of the assay under evaluation to detect correctly specimens that contain HIV-1/2 antibodies (reference results positive).

Thus sensitivity is the number of true positive specimens identified by the assay under evaluation as positive (a), divided by the number of specimens identified by the reference assays as positive (a+c), expressed as a percentage.

\[
\text{Sensitivity} = \frac{a}{a + c}
\]

9.3.2. Specificity
Specificity is the ability of the assay under evaluation to detect correctly specimens that do not contain HIV-1/2 antibodies (reference results negative). Thus specificity is the number of true negative specimens identified by the assay under evaluation as negative (d), divided by the number of specimens identified by the reference assays as negative (b+d), expressed as a percentage.

\[
\text{Specificity} = \frac{d}{b + d}
\]

9.3.3. Confidence intervals
The 95% confidence intervals are calculated for both sensitivity and specificity in order to assess the level of uncertainty introduced by sample size, etc. Exact 95% confidence intervals for binomial proportions were calculated from the F-distribution. [Armitage, 2002; Kirkwood, 2003]

9.3.4. Positive predictive value (PPV)
The probability that when the test is reactive that the specimen does contain HIV-1/2 antibodies. PPVs were calculated using the formula.

\[
\text{PPV} = \frac{\text{(prevalence)(sensitivity)}}{\text{(prevalence)(sensitivity)} + (1 - \text{prevalence})(1 - \text{specificity})}
\]

9.3.5. Negative predictive value (NPV)
The probability that when the test is negative that a specimen does not contain HIV-1/2 antibodies. NPVs were calculated using the formula.

\[
\text{NPV} = \frac{(1 - \text{prevalence})(\text{specificity})}{(1 - \text{prevalence})(\text{specificity}) + (\text{prevalence})(1 - \text{sensitivity})}
\]
The probability that a test result will accurately determine the true infection status of a person being tested varies with the prevalence of HIV infection in the population from which the person comes. In general, the higher the prevalence of HIV infection in the population, the greater the probability that a person testing positive is truly infected (i.e., the greater the positive predictive value [PPV]). Thus, with increasing prevalence, the proportion of individuals testing false-positive decreases; conversely, the likelihood that a person whose test result is negative is truly uninfected (i.e., the negative predictive value [NPV]), decreases as prevalence increases. Therefore, as prevalence increases, so does the proportion of individuals testing false-negative.

The PPV and NPV are calculated at a prevalence of 0.1%, 1% and 5%.

In addition, a sub-analysis of the performance of the assays in individuals infected with HIV-1 and/or HIV-2 who are on highly active antiretroviral therapy (HAART) will be conducted separately. Samples giving false non-reactive results in this sub analysis will be removed from the final analysis of the performance of the assays. However, this will be mentioned in the final report as a limitation of the assay and the manufacturer will be advised to include such information in the IFU for users to be aware.

9.4. Indeterminate results
Specimens which are found to be indeterminate (grey zone) by the criteria stated in the IFU will be recorded as such, and excluded from the denominator and numerator for the sensitivity and specificity estimates.

9.5. Discrepant results
Due to the nature of the prospective sampling for this study, it will not be possible to collect additional specimens from those individuals with specimens giving results discrepant from the expected reference results.

9.6. Technician’s appraisal
The technical aspects of the assay under evaluation is assessed by the technician who performed the testing. These assessments, along with other selected assay characteristics, contribute to an overall appraisal of each assay’s suitability for use in small laboratories. To enable comparison between assays, a scoring system is used to rate specified operational characteristics.

9.7. Report preparation
The data analysis and report drafting is carried out by ITM and sent to WHO in a timely manner. WHO verifies the draft report and sends to the authorized contact designated by the manufacturer for comment. The company has one month right of reply. The final report is prepared after one month has elapsed. The WHO scientist ensures that the comments of the authorized contact are reviewed and any outstanding issues are resolved before final publication. The final report is prepared and disseminated by WHO. A copy of the final report is sent to the authorized contact designated by the manufacturer and ITM.
10. Materials and supplies

10.1. Data collection sheets
All data will be reported to WHO/PQ-diagnostics on the following forms:

A. Data collection Microsoft Excel spreadsheet for the RDTs
   - Anti-HIV-1/2 non-discriminatory detection
B. Technician’s appraisal worksheet

10.2. Supplies
The manufacturers of products will provide the products and any equipment necessary for the evaluation free of charge.

11. Roles and responsibilities

11.1. Responsibilities of ITM
1. Act as repository for the matched plasma specimens WHO HIV oral fluid specimen testing panel;
2. Conducting the laboratory evaluation in accordance with internationally recognized best practice;
3. Preparation of QC specimens and proficiency panels;
4. Preparation of draft report on laboratory evaluation;
5. Advising WHO on operational characteristics of assays evaluated.

All source data, data analysis records and all correspondence are retained and archived for a period of at least ten years.

11.2. Responsibilities of WHO
1. Technical advice to the PI;
2. Technical and administrative management of the laboratory evaluation;
3. Procurement and delivery of supplies/assays;
4. Verification of the draft report, seeking of comments from manufacturer;
5. Preparation and dissemination of the final report;
6. Formal contacts with authorized contacts of the manufacturers.

Any publication by WHO of the results of these evaluations and the WHO recommendations derived therefrom will, however, be accompanied by the following disclaimer:

The mention of specific companies or of certain manufacturers’ products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

WHO and the Institute of Tropical Medicine, Antwerp, Belgium, do not warrant or represent that the evaluations conducted with the HIV test kits referred to in this document are accurate, complete and/or error-free. WHO and the Institute of Tropical Medicine disclaim all responsibility...
for any use made of the data contained herein, and shall not be liable for any damages incurred as a result of its use. This document must not be used in conjunction with commercial or promotional purposes.

12. References


World Health Organization Guidelines on HIV Safety Precautions, and Guidelines for the Safe Transport of Specimens (WHO/EMC/97.3)

International Standards

EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
ISO 17025 (General requirements for the competence of testing and calibration laboratories)
ISO15189 (Medical laboratories — Particular requirements for quality and competence)
13. Other documents required

Evaluation Protocols
SOP_PQDX_030 Protocol for laboratory evaluation of HIV serology assays
SOP_PQDX_044 Protocol for specimen acquisition for laboratory evaluation (serum/plasma)

Work Instructions
SOP_PQDX_072 PQT work instruction for laboratory testing at WHO Collaborating Centre
SOP_PQDX_073 PQT work instruction for specimen panels storage and characterization at WHO Collaborating Centre
SOP_PQDX_074 PQT work instruction for data entry and analysis
SOP_PQDX_075 PQT work instruction for report preparation and dissemination
SOP_PQDX_076 PQT work instruction for specimen acquisition for laboratory evaluation (serum/plasma specimens)

Master Templates
SOP_PQDX_164 PQT Report Template for HIV oral Fluid simple/rapid assays

Standard Letters
SOP_PQDX_163 WHO standard letter for HIV Oral fluid serology laboratory evaluation protocol
SOP_PQDX_077 PQT standard letter to request test kits: ITM
SOP_PQDX_081 Standard letter for draft report
SOP_PQDX_083 Standard letter for final report (simple/rapid assays)

14. DOCUMENT REVISION HISTORY

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<th>Effective date</th>
<th>Reason for revision</th>
<th>Prepared by</th>
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<td>14 March 2014</td>
<td>First release</td>
<td>Anita Sands</td>
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<tr>
<td>2.0</td>
<td>20 June 2014</td>
<td>Included comments from ITM and corrected the OF collection procedure to agree with IFUs</td>
<td>Willy Urassa</td>
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<tr>
<td>3.0</td>
<td>1 July 2015</td>
<td>Adopt PQT SOP format</td>
<td>Willy Urassa</td>
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