IVDs prequalification for beginners: a detailed overview
PQDx: aim, scope and impact

- The aim of PQDx is to promote and facilitate access to safe, appropriate and affordable IVDs of good quality in an equitable manner.
- Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings.
- The findings of PQDx are used to provide independent technical information on safety, quality and performance of IVDs, principally to other UN agencies but also to WHO Member States and other interested organizations.

> The PQDx status, in conjunction with other procurement criteria, is used by UN agencies, WHO Member States and other interested organizations to guide their procurement of IVDs.
PQ Dx components

- PQ Dx undertakes a comprehensive assessment of individual IVDs through a standardized procedure aimed at determining if the product meets WHO prequalification requirements.
- The prequalification assessment process includes three components:
  > Review of a product dossier;
  > Performance evaluation including operational characteristics; and
  > Manufacturing site(s) inspection.
Who can apply for PQDx?

> Applications to PQDx are only accepted from the legal manufacturer of the product

> "Re-branding" arrangements

• WHO considers a "re-branded" product to be one that is manufactured under identical conditions at the same manufacturing site(s) as the original product. A “re-branded” product is identical in every aspect to the product manufactured by the original manufacturer, except that the product is labeled with the "re-branded" product name and purchaser identifier.

• WHO encourages joint applications by original equipment manufacturers and "re-branders".

• A condition for the prequalification assessment of a "re-branded" product is that the original product manufacturer and the "re-brander" explicitly consent to the public disclosure by WHO of this "re-branding" arrangement. Such disclosure will include the recommendation that the two products should not be used in combination within the same testing algorithm in the WHO prequalification public report.
Prequalification: decision

> Final prequalification outcome depends on:
  • Results of dossier assessment and acceptance of action plan
  • Results of inspection(s) and acceptance of action plan
  • No level 5 nonconformities outstanding for either dossier or for inspection
  • Meeting the acceptance criteria for the laboratory evaluation

> WHO PQDx Public Report is posted on WHO website and product is added to the list of WHO prequalified products

> Product is then eligible for WHO and UN procurement
PQDx Product application
The Application Process

• Manufacturers can apply at any time
• Read the WHO PQDx_007 “Overview of the Prequalification of In Vitro Diagnostics”
• Complete the Pre-Submission Form (WHO PQDx_015), using the following guidance:
  WHO PQDx_017 “Instructions for the Completion of the Prequalification of In Vitro Diagnostics Pre-submission Form.”
The Pre-Submission Form

- Used to determine whether the application will be prioritized based on
  - Prioritization criteria
  - Programmatic suitability
- Used to determine whether the product is made by the original manufacturer (not rebranded)
- Used to determine the regulatory version of the device
**Prioritization Criteria**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listed on the WHO procurement scheme and procured by UN organizations in significant levels</td>
<td>Ensure continuity of supply and quality of products procured</td>
</tr>
<tr>
<td>Assist in the diagnosis and/or monitoring of infection with HIV-1/HIV-2, the diagnosis and/or monitoring of infection with hepatitis C, and diagnosis of infection with malaria parasites, and diagnosis of infection with Human Papillomavirus for cervical cancer prevention</td>
<td>Focus on priority disease areas</td>
</tr>
<tr>
<td>Rapid test format and/or technologies that can be used at or near to point-of-care (POC)</td>
<td>Bringing testing closer to the community</td>
</tr>
<tr>
<td>Original product manufacturers</td>
<td>Ensure known supply chain; no duplication of effort, best possible prices</td>
</tr>
<tr>
<td>Few other prequalified products exist in the product category such as CD4, VL</td>
<td>Focus on unmet market / procurement needs</td>
</tr>
<tr>
<td>Adult Male Circumcision Devices</td>
<td>Focus on the needs of WHO disease programmes</td>
</tr>
</tbody>
</table>

Other criteria dependent on changing global health needs, the particular needs of WHO Member States, and the emergence of new and relevant diagnostic technologies.
Outcome of application process

- WHO will send a letter informing of the outcome of the prioritisation process
- The letter will provide further instruction for those applications that are prioritised
  - First payment
  - Whether the application will be eligible for an abbreviated assessment
  - If for a full assessment, how and when to submit the product dossier
Recurrent Issues

- Multiple products per pre-submission form
- Incomplete
- Unclear name of product (inconsistent)
- Unclear regulatory version
  - Product undergoing PQ assessment
  - Other versions available
- Unclear/missing performance claims including
  - Lack of confidence intervals
  - Data not consistent with IFU claims
- Unclear site(s) of manufacture and roles of different sites
- Misconception that this step constitutes part of the PQ process
Dossier
How and when to submit the dossier

• Required, on request by WHO, for applications undergoing full assessment
• Must be submitted according to WHO PQDx_018 “Instructions for Compilation of a Product Dossier”
• The first page should be the original signed Letter of Agreement
• The “Product Dossier Checklist” WHO PQDx_049 must be completed and used as a Table of Contents for the dossier documentation
  • Sample Product Dossier for a fictitious CD4 POC product available on website – example of type of documentation to be submitted in a Product Dossier
  • Additional sample product dossiers to be published
Product Dossier Requirements

• Based on best international practice (ISO, EN, GHTF, IMDRF, CLSI…)
• Follows the content of the IMDRF MA IVD ToC (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140630-rps-ivd-toc.pdf)
• Dossier must demonstrate that the IVD conforms to the Essential Principles of Safety and Performance of Medical Devices (GHTF/SG1/N41R9:2005)
• Looks into critical aspects for WHO Member States often not dealt with from a local perspective by SRAs
  • stability, risk assessment, instructions for use, etc.
WHO Dossier Screening Process for full assessment

1. Application Prioritised
   - Fees Paid
   - Dossier Requested

2. Dossier Submitted
   - Dossier Screened
   - Supplements requested

3. Round 1 Supplements Submitted
   - Rd 1 Supplements Screened
   - Supplements Submitted

4. Round 2 Supplements Received
   - Rd 2 Supplements Screened
   - Dossier ready for technical review

Joint UNICEF, UNFPA & WHO MEETING with manufacturers and suppliers
Recurrent Issues - Dossier Screening Process

- Layout and format
- No clear identification of the product being submitted to PQ in the dossier documentation and reports
- Photos of the kits components are unclear/missing
- Some sections are not documented (e.g. design changes)
- Full study reports not submitted or too summarised
- Information on training and support network not available for countries where the assay is supplied
- Certificates requested are not certified
- No inspection reports submitted
WHO Dossier Technical Review Process

- Fees Paid
- Dossier submitted to assessor

Dossier Review

- Dossier Rated
- CAP requested

CAP Rd 1 Submitted

- Cap Rd 1 Reviewed
- Revision Requested

CAP Rd 2 Submitted

- CAP Rd 2 reviewed
- Amendments requested

Amendments Submitted

- Amendments Reviewed
- Dossier Rated
- PQ Decision

Joint UNICEF, UNFPA & WHO MEETING with manufacturers and suppliers
Manufacturing site(s) Inspections
Requirements for Inspections

- Fully implemented quality management system (design & development, manufacturing including quality control, storage, distribution)
- Risk management to meet ISO 14971:2007
- Product stable to meet "harsh" conditions (hot, wet, dry, dusty)
- Products undergoing prequalification have to be in routine manufacturing
- Sufficient capacity to ensure reliable delivery
Quality Management System

> Fully implemented quality management system (design & development, manufacturing including quality control, storage, distribution)

• Meets ISO 13485:2003 requirements (note: user requirements in areas of interest)
• Competence of personnel
• Work environment (determined and established)
• Quality control processes follow risk management results, quality control plan established, performance tested according to claims in instruction for use
• Storage conditions, temperature and humidity, validated for intermediates, components and kit, real time data required
Risk Management

Risk management to meet ISO 14971:2007

- Risk management for product realisation (design, manufacturing, storage, transportation), user and patient
- Risk management file
- Risk management plan
- Risk analysis
- Risk evaluation and control
- Residual risk acceptable?
Product Stability

> Product stable to meet "harsh" conditions (hot, wet, dry, dusty)
  • Transportation studies (simulate "worst" conditions)
  • Long term stability at limiting conditions
  • In-use stability studies (open vial)
  • Data to support all claims available on-site
  • Note: product labelling (component, kit and shipping box)
Routine Manufacturing

• Transfer from R&D to production completed
• Established and evaluated suppliers
• Validated processes (acceptance ranges determined, in-process controls established)
• Trained personnel (requirements determined, training plan, records)
• Standard batch sizes
• Established "out-of-specification" process
• Batch manufacturing records established (include all manufacturing information, full traceability of material and equipment)
Guidance Documents

> WHO Guidance

- Overview of the prequalification of diagnostics assessment process (PQDx_007)
- Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics (PQDx_014)
- Abbreviated prequalification assessment (PQDx_173)

> International Guidance

- GHTF.SG4.(99)28 Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements (including supplements 1,2, 4 and 6). Note: 10.2.1 and 10.2.3 in this document further describe audit team competency criteria
Guidance Documents

> International Guidance

- GHTF/SG4(pd1)/N33R16:2007 Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports
Guidance Documents

> IMDRF guidance
  • Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations
  • Medical Device Regulatory Audit Reports
  • MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization
  • Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
  • Competence and Training Requirements for Auditing Organizations
  • Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations
  • Clarification of the Term “Legal Entity” for MDSAP Recognition Purposes
  • MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes
International Standards

- ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 19011:2011 Guidelines for quality and/or environmental management systems auditing.
- ISO 14971:2007 Medical devices - Application of risk management to medical devices
- Note: EN ISO 14971:2012 applies only to manufacturers placing devices on the market in Europe and contains useful annexes; the body of the standard is identical to ISO 14971:2007 ISO 9000:2005 Quality management systems - Fundamentals and vocabulary
International Standards

- ISO 15223-1:2012 Symbols to be used with medical device labels, labelling and information supplied—Part 1 General requirements
- …
Onsite Inspections

> Application (Pre-submission form)
> Dossier review (QM documentation part)
> Inspection Cycle:
  • Evaluation of readiness for inspection (stage 1)
    > Desktop of additional documentation (Certificates, recent audit reports, quality procedures, SOP, summary of sold product...)
    > Stage 1 inspection (1 inspector day to inspect state of QMS implementation, facility, competence of staff, critical suppliers incl. outsourced activities, internal audit and management commitment / review)
  • Initial (Stage 2) Inspection
  • Follow up (confirm implementation of CAP); onsite inspection, if required
  • Re-Inspection (risk based, after 3-5 years)
Performance Evaluations
Performance evaluation process

**Preparation**
- Successful dossier screening
- Identification WHO collaborating Centers
- Protocol is sent to the WCC and the manufacturer
- Ethical approval by the WCC
- Delivery of kits to the WCC

**Testing**
- WHO verify the Instruction for Use
- Manufacturer demonstration at the WCC
- Testing using approved protocol and manufacturer
- Draft lab evaluation report sent to WHO

**Report**
- WHO review the submitted draft report and submit to the manufacturer
- Mx submit comments to WHO within 30 days
- WHO send the final report to the Mx
Performance evaluation

> Limited assessment of the clinical performance claims
  > Initial sensitivity and specificity (HIV, HBV, HCV, Syphilis)
  > Accuracy: trueness and precision (CD4 and HIV viral load)
  > Operational characteristics: inter-reader variability and invalid rates (RDT)

> Intended settings low and middle income countries (appropriate plasma panels)
## Specimen panels used

<table>
<thead>
<tr>
<th>Assays</th>
<th>HIV serology</th>
<th>HIV serology (oral fluid)</th>
<th>Combined HIV/Syphilis serology</th>
<th>CD4 technologies</th>
<th>HIV viral load/EID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen type</td>
<td>Plasma or serum</td>
<td>Linked plasma/serum and oral fluid</td>
<td>Plasma or serum</td>
<td>Whole blood</td>
<td>Plasma/Dried blood spots/whole blood</td>
</tr>
<tr>
<td>Study type</td>
<td>Retrospective</td>
<td>Prospective clinic settings</td>
<td>Retrospective</td>
<td>Prospective clinic settings</td>
<td>Retrospective/Prospective</td>
</tr>
<tr>
<td>Panels type</td>
<td>Characterized panels</td>
<td>Consecutive plasma + OF fresh exudates</td>
<td>Characterized panels</td>
<td>Consecutive fresh whole blood</td>
<td>Characterized panels</td>
</tr>
<tr>
<td>Regional distribution</td>
<td>African, Asia, American, European</td>
<td>African, Asia, American, European</td>
<td>African, Asia, American, European</td>
<td>At least two regions</td>
<td>African, Asia, American, European</td>
</tr>
</tbody>
</table>

Seek ethical clearance for conducting the studies
Other Performance evaluation

HIV:
> Serocoversion sensitivity
> Lot-lot variation
> Mixed titre
> WHO reference panel
> p24 panel
## Pass/Fail performance criteria

<table>
<thead>
<tr>
<th>Assay</th>
<th>Initial sensitivity</th>
<th>Final specificity</th>
<th>Inter-reader viability</th>
<th>Invalid rates</th>
<th>Trueness</th>
<th>Precision</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV EIA, p24</td>
<td>100%</td>
<td>≥ 98%</td>
<td>≤5%</td>
<td>≤5%</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Anti-HIV RDTs p24</td>
<td>≥ 99%</td>
<td>≥ 98%</td>
<td>≤5%</td>
<td>≤5%</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Anti-HCV EIA</td>
<td>100%</td>
<td>≥ 98%</td>
<td>≤5%</td>
<td>≤5%</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Anti-HCV RDTs</td>
<td>≥ 98%</td>
<td>≥ 97%</td>
<td>≤5%</td>
<td>≤5%</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>HBsAg EIA, RDT</td>
<td>100%</td>
<td>≥ 98%</td>
<td>≤5%</td>
<td>≤5%</td>
<td>N/A</td>
<td>N/A</td>
<td>LoD???</td>
</tr>
<tr>
<td>Anti trep</td>
<td>&gt;85%</td>
<td>≥ 98%</td>
<td>≤5%</td>
<td>≤5%</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>CD4</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Bias &lt;10%</td>
<td>CV &lt;10%</td>
<td></td>
</tr>
</tbody>
</table>
Post PQ Activities
What happens after PQ

> Post-market surveillance is a WHO post-qualification activity which includes reactive and proactive measures, through complaint reporting and post-shipment/pre-distribution lot testing.

> Post-qualification also includes mandatory manufacturer notification of changes to the product or the quality management system.
Changes to a Prequalified IVD

- As part of the life cycle of an IVD, changes to a product, its manufacture and the QMS under which it is produced may become necessary.
- A critical part of a manufacturer’s QMS is a system to design, validate and implement changes, and to determine their potential to impact on the product quality, safety and/or performance.
- Changes applied to an IVD must be made in compliance with the requirements for control of design change according to ISO 13485.
Changes to a Prequalified IVD

> Guidance for manufacturers for reporting changes to a prequalified IVD:

- Changes to the prequalified product or the manufacturing process
- Changes to the Quality Management System (QMS)
- And/or other reportable administrative changes
Determining the impact of a change

> Cause of the change!

- Actions taken related to concerns arising from post market surveillance, including adverse events, recalls or complaints
- Development of state of the art
- Changes to a manufacturing process, facility or equipment
- Changes to the design or composition of the prequalified IVD
- Changes to the organization of the manufacturer
- Changes to the intended use and/or test procedure
- Changes necessitating new clinical and/or analytical data that raise new issues of safety and performance
Determining the impact of a change

> **Impact of the change**

- Introduces new hazards that have not been previously addressed
- Adversely affects the risk associated with existing hazards
- Alters the details of any of the information submitted for prequalification (related to dossier, manufacturing site(s) inspection, or laboratory evaluation), such as the intended use and/or compliance with the Essential Principles
- Affects the continued compliance of the QMS with the relevant standards
Process for reporting a change

- Reporting to WHO:
  *Let us know in advance!*

- Assessment of submitted PQDx Change Report Forms and documentation:
  *Information undergoes full technical review*

- Outcome of assessment of the change report:
  *Outcome of the assessment is communicated to the manufacturer and where a change is accepted by WHO, the manufacturer can implement the change*
Case study on post-market surveillance (complaint reporting)
WHO post-market surveillance of IVDs

Any class of IVD

Proactive PMS
- Lot verification testing
  - Pre-distribution
  - Post-distribution

Reactive PMS
- Evaluation of EQA/QC data
  - Complaint
    - Possible Field Safety Corrective Action
      - Possible issuance of Field Safety Notice

Joint UNICEF, UNFPA & WHO MEETING with manufacturers and suppliers
What end-users should look for

- **When test result was incorrect**
  - Recently diagnosed HIV+ individual is re-tested & found to be HIV-
  - EQA data shows incorrect test result across multiple testing sites for the same assay

- **Intuition! When something doesn't seem right**
  - Any differences in the product, e.g. changes to the IFU, packaging looks damaged
  - For RDTs
  - Slow migration, incomplete migration, streaks, high background
  - Running out of test devices or buffer more quickly than usual
Examples of complaints related to IVDs

<table>
<thead>
<tr>
<th>Serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>An individual is diagnosed as HIV+ after transfusion of a blood product. The blood donation was screened as negative by an HIV-1/2 RDT.</td>
</tr>
<tr>
<td>A HIV+ individual reporting for ART initiation was re-tested to confirm their HIV diagnosis. The re-testing results are HIV negative.</td>
</tr>
<tr>
<td>A healthcare worker operating a small instrument-based test at POC couldn't remove a cartridge and inserted a knife into the instrument and was electrocuted, resulting in death.</td>
</tr>
</tbody>
</table>
## Examples of complaints related to IVDs

<table>
<thead>
<tr>
<th>Moderate</th>
</tr>
</thead>
<tbody>
<tr>
<td>The invalid rate for an RDT exceeds 5%, for any reason.</td>
</tr>
</tbody>
</table>

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher than usual background which may or may not obscure reading window and prevent reading of results.</td>
</tr>
</tbody>
</table>

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater than expected discrepant rate between assay 1 and assay 2, suspected reduced specificity of assay 2.</td>
</tr>
</tbody>
</table>
## Examples of complaints related to IVDs

### Mild

<table>
<thead>
<tr>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The packaging of a single use device is labelled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, obvious damage is observed and the device is not used.</td>
<td></td>
</tr>
<tr>
<td>A component labelled as lyophilized is found to be fluid, this is discovered by the user prior to use. Entire test kit must be discarded</td>
<td></td>
</tr>
<tr>
<td>Control line does not appear, test result is invalid and new device is used.</td>
<td></td>
</tr>
<tr>
<td>Desiccant has changed colour/density. Device is discarded and a new device used.</td>
<td></td>
</tr>
</tbody>
</table>
Case study

- Quikkeeze™ HIV RDT has been distributed to 5000 testing sites in one country

- All implementing partners use a joint national forecast to decide how many test kits should be purchased for the year

- 20% of the testing sites have contacted central medical stores to say they have a stock-out of test kits
Case study cont'd

- District management teams each visited one testing site in their district to observe testing practices

- In some sites, the invalid rate was higher than expected
- 15% invalid rate instead of 3%

- Further investigation showed that three particular lots were delivered to these sites only
Complaints: how to document

- Usual records kept at testing sites
  - Assay name
  - Lot number, expiry date
  - Version number and language of IFU
  - Operator

- Any additional testing results to support the investigation

- Accurate denominator data
  - How many tests performed per assay per site in total
  - How many invalid test results per assay per site

- What type of invalid results
  - Absence of control line
  - High background
  - Incomplete migration
  - Lack of buffer

Joint UNICEF, UNFPA & WHO MEETING with manufacturers and suppliers
Complaints: how to report

- Verify
  - Storage conditions
  - Any breaches of packaging
  - Changes to desiccant
  - IFU matches SOP/training

- Send
  - To manufacturer for all categories of complaints
  - To WHO and your NRA, for any serious or moderate adverse event
Example Field Safety Notice

Product name: Quickeze HIV Rapid Test™
Product code: 12345-50
Manufacturer name: Perfecto Engineering

FSN identifier: 2015/01
Type of action: Advice to users – recall of certain lots (9876QR, 9875QR, 9874QR)
Date: 07 September 2015

Attention: National HIV programme managers and their implementing partners, procurement agencies, national regulatory authorities for IVDs
Example Field Safety Notice cont'd

Details on affected IVD:
A rapid diagnostic test (RDT) for diagnosis of HIV-1/2 called Quickeeze HIV Rapid Test™ manufactured by Perfecto Engineering showed a higher than expected rate of invalid test results for certain lots.

Description of the problem:
In September 2015, Perfecto Engineering was alerted to high rate of invalid test results for Quickeeze HIV Rapid Test™ product code 12345-50, distributed in the country of Prequaland.

Three lots of Quickeeze HIV Rapid Test™ 9876QR, 9875QR, 9874QR were found to be affected. An investigation was conducted and the root cause was identified. It is not likely that this same problem will have affected any other lots of Quickeeze HIV Rapid Test™.
Example Field Safety Notice cont'd

Action to be taken by end-users, procurers and implementing partners:

- **Quarantine** any remaining stock of lot numbers 9876QR, 9875QR, 9874QR
- **Send a notification** to Perfecto Engineering via email (perfecto@engineering.co)

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please be aware of this notice and comply with documented evidence to assist the manufacturers in their forthcoming Field Safety Corrective Actions.

Contact person for further information:
Mr David PERFECTO, Regulatory Affairs, Perfecto Engineering
e-mail: david@engineering.co
For complaints reported to WHO

> Expect manufacturer to submit an initial investigation report within 15 days to WHO

WHO will review

– Processes for
  • Dealing with nonconforming product (e.g. root cause analysis);
  • Corrective actions taken; and
  • Application of risk management principles.
– What contributed to this nonconformance (product failure)?
– Was the complaint handling procedure adequate?
– Were the appropriate personnel involved?
Procedure for complaint handling

User notifies complaint

Complaint notified through WHO IVD complaint form

WHO reviews information in complaint form

Sufficient information, complaint proceeds

WHO sends complaint form to manufacturer

Insufficient information, additional information requested

Manufacturer plans/conducts investigation

Manufacturer submits investigation report to WHO

Manufacturer submits FSCA report to WHO

Manufacturer submits draft FSN to WHO, for review/approval

Manufacturer issues FSN to affected users

WHO ensures national IVD focal point is informed

WHO informs relevant stakeholders

Manufacturer submits final investigation report to WHO

Inadequate investigation, clarification(s) requested

WHO ensures national IVD focal point is informed

Joint investigation report to UMINING with manufacturers and suppliers
Contact us

> Contact us by email
diagnostics@who.int

> Sign up to our mailing list
By emailing diagnostics@who.int

> Check our website
http://www.who.int/diagnostics_laboratory/evaluations/en/