Roche + CDC Partnership (ASLM Webinar)
Develop Capacity and Improve Efficiencies in Laboratory Operations

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February 11, 2021
The purpose of this presentation is to provide information on tools developed in partnership with the CDC ILB to support continued scale up of HIV viral load and early infant diagnosis. These tools provide support training and implementation efforts and can contribute to improving laboratory efficiency and strengthening across the programs.

These tools will be available via the ASLM Resource Center for easier access online providing the ability to access them when it is convenient for your lab, to provide you with updates for the latest innovations to support your HIV programs and to help reduce time spent to build training, implementation or other laboratory activities.

This information is shared for your awareness of their availability, location and content and does not reflect endorsement by ASLM.
Agenda

Introduction: Partnerships
Implementing cobas® Plasma Separation Card
Building Capacity on EID DBS to Enhance Access to testing
Streamlining Verification of Assays
Summary & Questions
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Public-Private Partnership (PPP) for HIV/AIDS Response

Developing laboratory tools for viral load and EID scale up

Improved laboratory capacity and accelerated training of lab staff

Quality improvement for laboratory services, including certification courses for molecular diagnostics & QMS

“PPP contributions to laboratory systems strengthening are a model”

Developing pre-service training curricula

Collaboration with the ASLM to strengthen local capacity and to promote country ownership and sustainability


1. Shrivastava et al. BMC Health Services Research (2019); https://doi.org/10.1186/s12913-018-3744-z
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February 11, 2021

February 17, 2021
Early Infant Diagnosis Through DBS Collection

Training remains a critical component to expanding access to EID

UNAIDS Joint Statement:

Recently issued by global partners reinforced the commitment to urgently address the challenges to the early diagnosis and treatment of children living with HIV, which led to estimated death of 95,000 children in 2019¹.

Coalition of governments and global partners have, in accordance with WHO guidelines, effectively implemented EID across multiple settings, with training and capacity building of healthcare workers on DBS Collection across PMTCT sites a key intervention.

Critical success factors to ensuring accurate, timely early diagnosis include the following: i) obtaining high quality samples, ii) careful handling of specimens; and iii) maintaining accurate records.

¹ UNAIDS. Joint statement calling for urgent country scale-up of access to optimal HIV treatment for infants and children living with HIV. 22 December 2020
In collaboration with global partners, CDC has led the development of training videos covering **EID through DBS collection.**

In addition to explaining how to troubleshoot common issues, the videos outline how to:

1. **gather DBS supplies for EID**
2. **collect DBS samples**
3. **tell the difference between valid and invalid DBS;** and
4. **ensure DBS cards are properly labelled and logged.**

A pre- and post-test is available to help track progress.

In English, French and Portuguese, the videos can be accessed via **ASLM's Resources Centre** and **YouTube.**

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Summary & Questions
Limitations to Meeting Virally Suppressed Target - 95% by 2025

Barriers to plasma-quality Viral Load for patients across all settings

- Not all people live close to a major health clinic
- Infrastructure not in place to allow for optimal storage and transportation of EDTA Plasma Specimens i.e. cold chain
- Those living in rural settings have blood taken in small clinics – centrifuge required for sample handling
- DBS is an alternative sample type but a more effective solution is required
Use of DBS Can Cause Misclassification

**Ideal for EID but not VL**

Data from Vietnam shows 6% of patients misclassified using DBS

**Downward misclassification**

Believe patients failing treatment **are suppressed**

This could lead to **additional health complications** and the risk of infecting more people which both add to cost

**Upward misclassification**

Believe suppressed patient is **failing treatment**

This leads to **additional costs** associated with adherence counselling and the change to more costly second line therapy
cobas® Plasma Separation Card

An effective alternative to DBS...

- **WHO standard of <1000 cp/mL** (in plasma)
  - No other CE-marked or WHO prequalified sample collection solution matches performance

- **Superior solution compared to DBS**
  - Better performance than DBS with low misclassification rates

- **Easy handling, transport and storage**
  - Provides an easy-to-use solution to monitor patients in remote areas

- **Plasma-based sample** (gold standard)
  - Separates from whole blood
  - Stabilizes dried plasma/viral RNA under extreme heat and humidity

- **Correlation to plasma as the GOLD standard**
  - Plasma is the preferred sample type for HIV viral load testing
Design of the cobas® Plasma Separation Card

Spotting Layer

Carrier Layer

Whole blood

Filtration through membrane

Plasma
Sample Collection Process for the cobas® Plasma Separation Card

1) Sample Collection
(140μL whole blood required per spot and one spot required)

- **Step 1**: Remove primary packaging
- **Step 2**: Prepare finger prick
- **Step 3**: Collect blood
- **Step 4**: Apply blood to spot
- **Step 5**: Let card dry and package for shipment

2) Sample Transport from the Field to the Laboratory
(18-45°C and up to 85% humidity (>21 days))

- **Step 1**: Put dried card into sample bag
- **Step 2**: Add desiccant
- **Step 3**: Add cards to transport bag
- **Step 4**: Ship transport bag to Centralized Laboratory
cobas® Plasma Separation Card Bundle Components
Convenient for clinics and patients, and simplifies ordering
Training and Support for cobas® Plasma Separation Card

Tools to support implementation of cobas® PSC

Roche has developed training videos, posters and presentations detailing how to use the cobas® Plasma Separation Card, specifically:

• Sample Collection Method
• Preparation for Sample Transportation
• Sample Preparation and Instrument Workflow for Roche systems (including cobas® 6800/8800 Systems, cobas® 4800 System and COBAS® AmpliPrep/COBAS® TaqMan® System)

Training material is available in English, French and Portuguese, and can be accessed via ASLM’s Resources Centre.
**Mozambique Study**

**Performance - Very low misclassification rates with cobas® PSC**

### Misclassification rates of viral load values below 1000 c/ml

- **Capillary specimen**: 0.7%
- **Venous specimen**: 0.3%
- **DBS specimen**: 5.9%

**Eliminates the interference of cell-associated viral nucleic acid**

**No over-quantification**

**Cell-associated viral nucleic acid** present in whole blood

**Over-quantification**


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Milestones in regulatory process met

**Evaluation Letter**

- **Memorandum issued in 2019 by CDC following evaluation study in South Africa**

**WHO Prequalification**

- **WHO Prequalified for cobas® 6800/8800 Systems and COBAS® AmpliPrep/COBAS® TaqMan® System**, application submitted for cobas® 4800 System
- **The Limit of Detection estimated at 489 cp/mL (95% CI: 330-1256)** for cobas Plasma Separation Card (cobas® 6800/8800 Systems)

**Verification Panels**

- In partnership with CDC development of verification panels (TBD)

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Streamlining Verification of Assays
Roche Assay Implementation Tool
Streamlining the verification of new assays for laboratories

**Planning** assistance for assay verification experiments for PCR based testing for CE-IVD or FDA approved assays*

**Data analysis** of the performance specifications required for assay verification through a web-based portal

**Report generation** of analyzed data for assessment by authorized laboratory personal for verification sign-off and compliance requirements

*Tool in current format was developed for Roche PCR based IVD assays
Roche Assay Implementation Tool
A support tool for laboratories across Africa for verification of IVDs

With the Assay Implementation Tool* labs will be able to:

• **Review** definitions of various verification terms as well as recommended guidelines on **how to perform studies** when verifying the performance of an **In Vitro Diagnostic test**

• **Input data** generated from studies performed as part of a verification process as well as **automatically calculate and produce standard graphs**

• **Document** (via .pdf format) for the laboratory’s records the runs were performed as part of a verification study, including the results, data analyses generated, as well as other details associated

* Roche has worked in collaboration with CDC ILB team to modify the tool to meet verification parameters required per CDC guidelines.
Roche Assay Implementation Tool

Accessible, easy to navigate, simple data input interface and report generation

Notes:

• Training video on using the tool (which will provide a technical overview) will be issued in parallel to the tool’s release
Streamlining Verification of Assays

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Tools to support capacity development and improve efficiencies in laboratory operations

Capacity building training materials available on ASLM Resource Center

- DBS collection for EID testing
- cobas® Plasma Separation Card (dried plasma spots), sample collection, transport and laboratory process and country implementation

Introducing a tool currently in development to help optimize laboratory operations (timing for release to be determined)

- Online, intuitive Roche Assay Implementation Tool to streamline planning and implementation of the verification process
Thank you to the contributors

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### References

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<tr>
<td>a</td>
<td>Shrivastava R et al. (2019)</td>
<td>Role of public-private partnerships in achieving UNAIDS HIV treatment targets</td>
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<td>b</td>
<td>Roche and the US President’s Emergency Plan for AIDS Relief (PEPFAR) partner to strengthen laboratories medicine training and knowledge on the African continent</td>
<td>From <a href="https://www.roche.com/media/releases/med-cor-2012-12-04.htm">https://www.roche.com/media/releases/med-cor-2012-12-04.htm</a> Accessed 5 Sept 2018</td>
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Doing now what patients need next