

MEETING MINUTES

Diagnostics Working Group

Date: 23 September 2026

Purpose of the Meeting

The meeting focused on diagnostic preparedness and response for the Bundibugyo virus outbreak, with particular emphasis on:

- Diagnostic capacity and outbreak updates in DRC
- WHO diagnostic guidance and Emergency Use Listing (EUL) activities
- BRIDGE Access diagnostic evaluation platform
- Remaining gaps and priorities for deployment of rapid diagnostic tests (RDTs)

Opening remarks (Noah Fongwen, Africa CDC)

An ongoing collaboration between Africa CDC, WHO, PATH, CHAI, Unitaid, and other partners through the BRIDGE-Access consortium aims to establish a harmonized platform for diagnostic evaluation and deployment not only to support the current outbreak but also to provide a sustainable framework for future outbreaks. Progress have been made to shortlist near-point of care rapid diagnostic tests and lab-based open PCR.

Main Discussion Points

1. Current outbreak and diagnostic response – Eddy Lusamaki (INRB)

Diagnostic deployment

More than 20 mobile laboratories are currently deployed in affected regions. A new confirmed case in South Ubangi prompts expansion of diagnostic capacity in western DRC. Additional surveillance activities are ongoing in North Ubangi, and other provinces receiving alerts such as Kasaï and Lomami. Samples received from these provinces all tested negative.

Sequencing and genomic surveillance

More than 700 genomes have been generated. Most available genomes originate from Ituri Province, prompting efforts to improve geographic representation and better characterize transmission and the dynamic of the outbreak. Beyond sequencing, there are now up to 100 commercial test kits either identified or in development. Some of these kits are being evaluated by INRB.

Variants

No evidence currently suggests the emergence of a new variant. A frequent mutation identified in an intergenic region is under investigation but has no known impact. Three genomes contained a GP mutation near the V82A mutation previously associated with increased transmissibility during the western Africa outbreak; however, the mutation remains rare.

Serology plans

INRB is developing ELISA-based assays and Multiplex serology assays using Luminex technology. Planned applications include studies of non-symptomatic individuals, vaccine studies, and post-exposure research.

Decentralized sequencing

Three sequencing hubs have been established, in Kinshasa, Bunia and Beni (equipment relocated from Goma because of security concerns). Expanded sequencing activities are planned in North Kivu.

2. Update on Diagnostic Access and Evaluation Initiatives – Céline Barnadas (WHO)

Laboratory scale-up

The DRC currently has 26 testing sites, with 23 reporting regularly, yielding a theoretical testing capacity exceeds 4,000 tests per day. Expansion is ongoing, including approximately 10 additional testing sites and 20 clinical laboratories. Neighboring countries are also strengthening capacity through both open PCR and near-POC platforms.

Emergency Use Listing (EUL)

Since its opening in May 2026, 33 manufacturers contacted WHO and 27 manufacturers submitted questionnaires covering 38 kits. 15 manufacturers were invited to submit dossiers. So far, four IVDs have been officially listed for BDBV nucleic acid detection. Additional products are expected to be listed following ongoing dossier reviews.

Access and forecasting

Significant efforts are underway to forecast future diagnostic needs and secure sufficient supplies of PCR and future Ag-RDT products. Forecasting activities are being coordinated with partners to support procurement planning.

Normative guidance and priorities

Current WHO guidance continues to recommend PCR as the primary diagnostic method while the use of antigen RDTs remains limited due to insufficient validation data for Bundibugyo virus. WHO is developing guidance to support testing decentralization across open PCR, near-POC molecular tests, and antigen RDTs. Priority areas include:

- Biosafety: validation and standardization of inactivation buffers and procedures.
- Development of Target Product Profiles (TPPs).
- Expansion of the EUL process to include antigen-based tests.

Discussion

- WHO confirmed that additional diagnostic products are expected to be added to the EUL as reviews are completed.
- INRB has been evaluating Bundibugyo qPCR kits, and further validation data are expected to become available shortly.

3. Update on BRIDGE Access – Gonzalo Domingo (PATH)

Overview

BRIDGE Access is a consortium coordinated by WHO, Africa CDC, and Unitaid to facilitate equitable access to specimens and generate evidence for Bundibugyo diagnostic tools.

Product selection

A total of 66 submissions were received through the initial expression of interest process, including 7 near-POC molecular tests, 11 antigen RDTs and 21 laboratory-based RT-PCR assays. Manufacturers participating in BRIDGE Access agreed to access-related commitments, including transparent pricing and preferential access for affected countries.

Evaluation activities

Three complementary activities are underway:

1. **Analytical testing.** PATH and partners are conducting analytical evaluations of Ag-RDTs, with efforts focused on measuring analytical sensitivity, supporting clinical studies, identifying reagent gaps and supporting future TPP development
1. **A retrospective clinical evaluation** conducted by INRB and Uganda CPHL approved by WHO ERC on 26 August and launched on 15 September 2026 in DRC while the Uganda component is pending local approval. This evaluation uses previously collected whole-blood specimens. It includes both PCR-positive and PCR-negative samples and evaluates diagnostic accuracy against a validated RT-PCR reference assay.
2. **A prospective clinical evaluation** currently being finalized and planned to begin later in 2026.

Study objectives

The short-term goals are to generate evidence needed for adoption of quality diagnostic tests and establish a robust evidence base for potential Ag-RDT use. The long-term goals are to develop reagents, protocols, and infrastructure to support future test development and evaluation.

Collaboration and transparency

BRIDGE Access intends to publish evaluation protocols and to create a reusable platform for future outbreak responses.

Discussion

- Selected Ag-RDTs were chosen based on manufacturer evidence suggesting they could detect Bundibugyo virus.
- Gamma irradiation will be used for viral inactivation in planned analytical studies.
- Additional evaluations using live virus are being planned by participating laboratories.

4. Discussion

Performance expectations for RDTs

Participants agreed that RDT performance remains the key determinant for deployment.

INRB emphasized that:

- Sensitivity should ideally exceed 80%, with higher performance strongly preferred.
- RDTs would primarily serve as complementary tools to molecular diagnostics.
- Availability and procurement at scale are critical operational requirements.

Development of Bundibugyo-specific antigen detection tools

Participants noted that several groups are developing Bundibugyo-specific antibodies for antigen detection, although these efforts remain in early development stages.

Safer sample collection and biosafety

Discussion focused on needle-free capillary blood collection systems (e.g., Tasso devices) combined with inactivation buffers. The potential benefits include improved biosafety and safer transport and handling.

INRB expressed strong interest in these approaches, while stressing the need to ensure that diagnostic sensitivity is not compromised.

Conclusion – Eddy Lusamaki (INRB) and Hervé Raoul (ANRS-MIE)

Participants emphasized the substantial progress achieved since the outbreak began, notably:

- Expansion of diagnostic capacity.

- Increased sequencing coverage.
- Rapid mobilization of manufacturers and evaluators.
- Launch of the BRIDGE Access evaluation platform.

The group agreed that diagnostics remain central to outbreak control and that continued collaboration, data sharing, and coordinated validation efforts will be essential to accelerate access to reliable point-of-care and laboratory diagnostic tools.

Future working-group sessions will focus on specific technical topics, and participants were encouraged to submit priority questions and discussion topics for upcoming meetings.