AfricaCDC
Centres for Disease Control and Prevention

Safeguarding Africa's Health

Molecular Diagnostic Tests (RT-PCR) for Ebola Virus Bundibugyo Strain

RECOMMENDATIONS AS PER 22 MAY 2026

On May 17, 2026, the World Health Organization (WHO) declared the Ebola outbreak in the Democratic Republic of Congo (DRC) and Uganda as a Public Health Emergency of International Concern (PHEIC). This was followed by Africa Centres for Disease Control and Prevention (Africa CDC) declaration on 18 May 2026 as a Public Health Emergency of Continental Security (PHECS) signaling the seriousness of the situation and calling for immediate actions. Unlike previous outbreaks of Ebola Virus Disease (EVD) caused by zaire strain for which validated countermeasures have been available; there is currently lack of vaccines and therapeutics for the Bundibugyo ebolavirus strain that is driving the current outbreak. In addition, only a limited number of clinical diagnostics tests have been approved or validated for use. These gaps in effective medical countermeasures are constraining the outbreak response efforts.

In the absence of effective medical countermeasures, quality assured diagnostics used in conjunction with other outbreak control measures can play a critical role in controlling the spread of the disease. Quality assured diagnostics are therefore urgently needed to strengthen the outbreak response. Molecular real-time PCR(RT-PCR) testing remains the gold standard for the diagnosis of Ebola virus disease. Consequently, Africa CDC through the Diagnostics Advisory Committee (DAC) conducted a rapid review and assessment of available molecular diagnostic tests for Bundibugyo ebolavirus. Following this review, the DAC has produced a list of RT-PCR tests for Bundibugyo ebolavirus that have either received regulatory approval or have been laboratory validated and are currently in use in the ongoing outbreak response.

Table 1 presents the recommended RT-PCR tests for Bundibugyo ebolavirus.

Antigen Rapid Diagnostic Tests

Rapid diagnostic tests (RDTS) for viral antigen detection can play a crucial role in outbreak response through decentralization of testing and supporting timely decision-making for community level outbreak control measures. The DAC also reviewed currently available evidence on antigen based RDTs for Bundibugyo ebolavirus. The assessment criteria were informed by the WHO Target Product Profile for a simple diagnostic test for Ebola (previously used for the Zaire ebolavirus context). Based on the evidence available at the time of review, no antigen RDT currently meets the required TPP specifications for recommendation in the current outbreak response.

Biobanking Advice:

Noting the critical importance of well characterized blood specimens for full understanding of the Bundibugyo ebolavirus infection profile, the DAC reiterates the importance of careful collection and storage of blood specimens under strict biosafety and ethical conditions for biobanking purposes to facilitate further serological, immunological and molecular testing and for evaluation and validation of new diagnostics tools.

Table 1: RECOMMENDED REAL-TIME PCR (RT-PCR) TESTS FOR THE BUNDIBUGYO STRAIN OF EBOLA

Name of kit, and manufacturer	Assay target and analyte	Regulatory status	LoD or analytic metric	Comment
RealStar Ebolavirus RT-PCR Kit 1.0; Altona Diagnostics GmbH, Germany	RNA; EBOV L gene	US FDA EUA in 2020.	11–67 RNA copies/reaction (LightCycler 480 II)	Validated on serum, plasma, whole blood, urine.
RealStar Filovirus Screen RT-PCR Kit 1.0 CE; Altona Diagnostics GmbH, Germany	RNA; EBOV L gene	WHO EUL in 2019(updated in 2025), CE-IVD-D(In-Vitro Diagnostic Directive).	11–67 RNA copies/reaction (LightCycler 480 II	Validated on serum, plasma and whole blood.
Liferiver Ebola Virus RT-PCR kit; Shanghai ZJ Bio-Tech Co., China	RNA	WHO EUL in 2019.	23.9 copies/reaction 95% CI (13.4- 405.9 RNA copies/ reaction).	Validated on serum and plasma.
*RADI Ebola detection Kit; KH Medical, South Korea.	RNA; EBOV Nucleotide protein	CE IVDD	3,33 Copies/uL	Validated on serum and plasma. Clinical performance data in the DRC shows high concordance with Realstar Altona. The RADI kit operates on the RADI ONE PCR device.

*Currently in use in DRC for the laboratory diagnosis of Bundibugyo ebola virus strain.

The DAC continues to engage with partners, manufacturers, reference laboratories and African Union Member States to review new evidence and will update this list regularly. Information on molecular diagnostic tests for Bundibugyo ebolavirus may be submitted to Dr Noah Fongwen at **FongwenN@africacdc.org**