

Certificate of Analysis

PANDAA® Ebola

Product Number	4011096
Lot Number	260601
Expiration Date	31 December 2026
Storage Temperature	-15 °C to -25 °C

For Research Use Only. Not for use in diagnostic procedures.

Amplification and Detection Reagents

Functional testing performed by real-time RT-PCR on a QuantStudio 5 using the PANDAA EBOV Qualification Panel (product number 4111096).

Component	Lot	Test	Specification	Result
PRxB III	260601	Qualification Panel functional test	Qualification Panel met expected results per IFU	Pass
Stop-Start RT	260501	Qualification Panel functional test	Qualification Panel met expected results per IFU	Pass
Ebolavirus PANDAA	260601	Qualification Panel functional test	Qualification Panel met expected results per IFU	Pass

Expected Qualification Panel results: Samples A–F and H–J detected; sample G not detected. Associated control criteria met: Internal Control Ct ≤ 20.0; Sample Adequacy Control Ct ≤ 25.0.

Controls

Component	Lot	Test	Specification	Result
EBOV Positive Control	260501	Functional testing performed by real-time PCR using PANDAA Ebola.	LASV Ct = 18 – 20	19.0
			IC Ct ≤ 20.0	16.5
			SAC Ct ≤ 25.0	23.3
		Copy number quantified by RT-qPCR using dPCR-traceable calibration.	120 – 180 copies/μL	139 copies/μL

Component	Lot	Test	Specification	Result
Negative Control	260501	Functional testing performed by real-time PCR using PANDAA Ebola.	LASV No amplification	Not detected
			IC Ct ≤ 20.0	16.5
			SAC Ct ≤ 25.0	23.3
		hgDNA quantified by fluorometry.	0.08 – 0.12 ng/μL	0.11 ng/μL

Approval

Quality Representative

Date of Release

This certifies that the PANDAA® Ebola lot identified above was manufactured tested in compliance with Aldatu Biosciences' ISO 13485:2016 certified quality management system procedures and met all lot release criteria.