ALDATU BIOSCIENCES

Aldatu Biosciences, Inc.
313 Pleasant Street,
Watertown, MA 02472
USA

T: +1 978-709-1812
F: +1 857-232-1650
E: quality@aldatubio.com
www.aldatubio.com

Certificate of Analysis

PANDAA® Ebola (E-IVD)

Product Number	4012096
Lot Number	ABIO26-1006
Expiration Date	31 October 2027
Storage Temperature	−15 °C to −25 °C

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

Amplification and Detection Reagents

Functional testing performed by real-time RT-PCR on a QuantStudio 5 using the PANDAA EBOV Qualification Panel (product number 4121096).

Component	Lot	Test	Specification	Result
PRxB III	B26-1039	Qualification Panel functional test.	Qualification Panel met expected results per IFU.	Pass
Stop-Start RT	ENZ-1023	Qualification Panel functional test.	Qualification Panel met expected results per IFU.	Pass
Orthoebolavirus PANDAA	P26-1047	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 ≤ 25.0; Sample Adequacy Control Ct ≤ 30.0.				

Controls

Component	Lot	Test	Specification	Result
Internal Control RNA	RNA-1070	Quantification by RT-qPCR	Ct = 17.65 – 18.25	Ct = 18.01

Component	Lot	Test	Specification		Result
Positive Control	R26-1073	Functional testing by real-time PCR using PANDAA Ebola.	EBOV	Ct = 17 – 19	Ct = 17.7
			IC	Ct ≤ 25.0	Ct = 17.6
			SAC	Ct ≤ 30.0	Ct = 23.9
		Quantification by RT-qPCR using dPCR-traceable calibration.	120 – 180 copies/µL		147 copies/µL

Component	Lot	Test	Specification		Result
Negative Control	REA-1032	Functional testing by real-time PCR using PANDAA Ebola.	EBOV	No amplification	Not detected
			IC	Ct ≤ 25.0	Ct = 16.3
			SAC	Ct ≤ 30.0	Ct = 24.4
		hgDNA quantified by fluorometry.	0.08 – 0.12 ng/µL		0.09 ng/µL

Approval

Yoshi

29 October 2026

Quality Representative — Date of Release