

Certificate of Analysis

PANDAA® Lassa Virus

Product Number	2021096
Lot Number	260301
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 LASV Qualification Panel (product number 2121096).

Component	Lot	Test	Specification	Result
PRxB II	260201	Qualification Panel functional test	Qualification Panel met expected results per IFU	Pass
Stop-Start RT	LOT-ENZ-1019	Qualification Panel functional test	Qualification Panel met expected results per IFU	Pass
Lassa Virus PANDAA	260201	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
Positive Control	260201	Functional testing performed by real-time PCR using PANDAA Lassa Virus.	LASV Ct = 19 – 21	Ct = 20.1
			IC Ct ≤ 20.0	Ct = 16.7
			SAC Ct ≤ 25.0	Ct = 21.4
		Copy number quantified by RT-qPCR using dPCR-traceable calibration.	120 – 180 copies/μL	150 copies/μL

Component	Lot	Test	Specification	Result
Negative Control	260201	Functional testing performed by real-time PCR using PANDAA Lassa Virus.	LASV No amplification	Not detected
			IC Ct ≤ 20.0	Ct = 15.2
			SAC Ct ≤ 25.0	Ct = 21.5
		hgDNA quantified by fluorometry.	0.08 – 0.12 ng/μL	0.10 ng/μL

Approval

Quality Representative

Date of Release

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