

PANDAA[®] LASV Qualification Panel

Instructions for Use

PANDAA[®] LASV Qualification Panel is for Research Use Only (RUO)

NOT FOR RESALE

RUO

For research use only

REF

2121096



-15 °C to -25 °C



Contents sufficient for 10 × 20 reactions



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Overview

Intended Use (RUO)

The PANDAA LASV Qualification Panel is a panel of synthetic, non-infectious RNA for use exclusively with the PANDAA® Lassa Virus (Aldatu Biosciences, catalog # 2021096) *in vitro* real-time RT-PCR assays for the amplification and detection of Lassa virus (LASV) RNA. This Qualification Panel may be used for training technical personnel in the PANDAA® Lassa Virus assay, internal proficiency testing as a component of a quality assurance program, and for qualifying real-time PCR instruments for use with the PANDAA® Lassa Virus assay.

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

Contents and Storage

Product Description

The PANDAA LASV Qualification Panel includes ten (10) samples **made from synthetic, non-infectious RNA**. Nine (9) positive panel members covering the target regions for the PANDAA assays in the Lassa virus genome of seven LASV isolates. The negative panel member (sample G) consists of the synthetic, non-infectious RNA from the equivalent genomic region of LCMV (lymphocytic choriomeningitis mammarenavirus), a closely related mammarenavirus. Synthetic RNA is prepared in a background of Internal Control RNA and human genomic DNA.

Each Qualification Panel sample is provided at 200 µL and 10 µL is used in a 20 µL PANDAA reaction.

Label	LASV Isolate	Lineage	Conc. (copies/µL)	Copies/Reaction
A	LP/Pinneo	I	5 cp/µL	50 cp/rxn
B	Josiah	IV	5 cp/µL	50 cp/rxn
C	Soromba-R	V	5 cp/µL	50 cp/rxn
D	Togo	VII	5 cp/µL	50 cp/rxn
E	KAK-428	VI	5 cp/µL	50 cp/rxn
F	Nig08-04	II	5 cp/µL	50 cp/rxn
G	LCMV *	-	500 cp/µL	5,000 cp/rxn
H	Nig08-A18	III	5,000 cp/µL	50,000 cp/rxn
I	Nig08-A18	III	500 cp/µL	5,000 cp/rxn
J	Nig08-A18	III	5 cp/µL	50 cp/rxn

* **Note:** LCMV (lymphocytic choriomeningitis mammarenavirus) is a mammarenavirus closely related to LASV and acts as a specificity negative control for the PANDAA LASV Qualification Panel.

Storage and Stability

The PANDAA LASV Qualification Panel is shipped on dry ice, and the kit components will arrive frozen. All components should be stored between $-15\text{ }^{\circ}\text{C}$ and $-25\text{ }^{\circ}\text{C}$ upon arrival. After thawing, the Qualification Panel samples can be stored between $2\text{ }^{\circ}\text{C}$ and $8\text{ }^{\circ}\text{C}$ for up to 72 hours. More than two freeze-thaw cycles should be avoided to ensure preserve sample integrity.

PANDAA LASV Qualification Panel Step-by-Step Instructions

Before Beginning

To prepare the PANDAA mastermix, follow all steps in the instructions for use for the PANDAA Lassa Virus assay.

Running the Qualification Panel

Run each Qualification Panel sample in four replicates alongside four replicates each of the PANDAA Lassa Virus kit Positive and Negative Controls.

In total, you will run 48 samples (12×4), which uses one half of a PANDAA assay kit.

- 1. Prepare samples:** Spin the sample tubes briefly to collect drops that may have formed on the sides of the tubes. Gently vortex the sample tubes and spin briefly again.
- 2. Add sample or controls:** Add $10\text{ }\mu\text{L}$ Qualification Panel sample, Positive Control, or Negative Control into the top of the mastermix in each well / tube. **Do not pipette up and down to mix.**
 - Refer to the sample loading plate maps on page 6.
- 3. Seal and spin (plate only):** Seal the plate with optical adhesive film or cap the reaction tubes. If using a 96-well plate, spin the plate briefly before loading into the real-time PCR instrument.

Qualification Panel Sample Loading Plate Map (96-well Plate)

Load samples in the configuration shown in Figure 1.

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	B	C	D	E	F	G	H	I	J	POS	NEG
B	A	B	C	D	E	F	G	H	I	J	POS	NEG
C	A	B	C	D	E	F	G	H	I	J	POS	NEG
D	A	B	C	D	E	F	G	H	I	J	POS	NEG
E												
F												
G												
H												

Figure 1: Loading map for 96-well plate.

Qualification Panel Sample Loading Map (Optical Reaction Tubes)

Mic optical reaction tubes are pre-packed into a loading rack. Follow the loading rack map in Figure 2 for mastermix and sample loading.

Follow Table 1 for sample loading for the Mic (Bio Molecular Systems) and Rotor-Gene Q (Qiagen). Sample A should be loaded into rotor positions 1–4 with samples B through J then loaded sequentially. The Positive Control should be loaded in positions 41–44 and the Negative Control in positions 45–48.

	1	2	3	4	5	6
A	A	C	E	G	I	POS
B	A	C	E	G	I	POS
C	A	C	E	G	I	POS
D	A	C	E	G	I	POS
E	B	D	F	H	J	NEG
F	B	D	F	H	J	NEG
G	B	D	F	H	J	NEG
H	B	D	F	H	J	NEG

Figure 2: Loading rack map for Mic reaction tubes.

Sample	Rotor Position
A	1–4
B	5–8
C	9–12
D	13–16
E	17–20
F	21–24
G	25–28
H	29–32
I	33–36
J	37–40
POS	41–44
NEG	45–48

Table 1: Rotor loading

Real-Time PCR Protocol

Follow the Instructions for Use for the PANDAA Lassa Virus kit (Aldatu Biosciences, catalog # 2021096). Refer to Appendix B of the Instructions for Use for detection channel settings for compatible real-time PCR instruments.

Use the real-time PCR template provided by Aldatu Biosciences, available to download from www.aldatu.bio/qpcr-templates.

Data Analysis

Real-Time PCR Analysis Parameters

Refer to Appendix B of the PANDAA Lassa Virus Instructions for Use for instrument-specific analysis settings, including threshold settings for determination of Ct values for the PANDAA Lassa Virus, Internal Control, and Sample Adequacy Control targets. For technical assistance, contact Aldatu Biosciences Technical Support at support@aldatubio.com.

Expected Results

Label	LASV Isolate	Expected Results
A	LP/Pinneo	Detected
B	Josiah	Detected
C	Soromba-R	Detected
D	Togo	Detected
E	KAK-428	Detected
F	Nig08-04	Detected
G	LCMV	Not Detected
H	Nig08-A18	Detected
I	Nig08-A18	Detected
J	Nig08-A18	Detected
Positive Control	Nig08-A18	Detected
Negative Control	-	Not Detected

Customer and Technical Support

Email: support@aldatubio.com

Address: Aldatu Biosciences
313 Pleasant Street
Watertown, MA 02472
USA

Disclaimers

This Qualification Panel is for Research Use Only and is not intended for use in diagnostic procedures.

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Patents

The PANDAA technology is covered by US Patent No. 10,100,349 and European Patent Application No. 3052656 owned by the President and Fellows of Harvard College and exclusively licensed to Aldatu Biosciences, Inc.

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Explanation of Symbols



For Research Use Only



Catalog number



Batch number



Storage temperature range



Use-by date



Contents sufficient for n reactions



Consult Instructions for Use



Contents of the PANDAA® LASV Qualification Panel



Manufacturer

The logo for ALDATU BIOSCIENCES is displayed in white on a dark blue background. The word "ALDATU" is written in a large, bold, sans-serif font. A horizontal line passes through the middle of the letters "A", "L", "D", "A", and "T". To the left of the "A", there are three curved lines that sweep upwards and to the right, suggesting motion or a biological process. Below "ALDATU", the word "BIOSCIENCES" is written in a smaller, all-caps, sans-serif font, with wide letter spacing.

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al • da • tu [ɒl - də - tu]: to become something different