ALDATU BIOSCIENCES

REF 4111096

PANDAA® EBOV Qualification Panel

Instructions for Use

PANDAA® EBOV Qualification Panel is for Research Use Only (RUO)

NOT FOR RESALE

RUO For research use only

REF 4111096

−15 ˚C to −25 ˚C

Contents sufficient for 10 × 20 reactions

Aldatu Biosciences, Inc.
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Overview

Intended Use (RUO)

The PANDAA EBOV Qualification Panel is a panel of synthetic, non-infectious RNA for use exclusively with the PANDAA® Ebola (Aldatu Biosciences, catalog # 4011096) *in vitro* real-time RT-PCR assays for the amplification and pan-species detection of ebolavirus RNA. This Qualification Panel may be used for training technical personnel in the PANDAA® Ebola assay, internal proficiency testing as a component of a quality assurance program, and for qualifying real-time PCR instruments for use with the PANDAA® Ebola assay.

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

Contents and Storage

Product Description

The PANDAA EBOV Qualification Panel includes ten (10) samples made from synthetic, non-infectious RNA. Nine (9) positive panel members covering the target regions for PANDAA assays in the genome of seven ebolavirus isolates. The negative panel member (sample G) consists of the synthetic, non-infectious RNA from the equivalent genomic region of Marburg virus a closely related filovirus. 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	Virus	Species	Isolate	Conc.	Copies/Reaction
A	Bundibugyo virus	*Orthoebolavirus bundibugyoense*	Butalya-811250	5 cp/µL	50 cp/rxn
B	Reston virus	*Orthoebolavirus restonense*	Pennsylvania	5 cp/µL	50 cp/rxn
C	Sudan virus	*Orthoebolavirus sudanense*	Boniface	5 cp/µL	50 cp/rxn
D	Taï Forest virus	*Orthoebolavirus taiense*	Pauléoula-CI	5 cp/µL	50 cp/rxn
E	Ebola virus	*Orthoebolavirus zairense*	Makona	5 cp/µL	50 cp/rxn
F	Sudan virus	*Orthoebolavirus sudanense*	Gulu	5 cp/µL	50 cp/rxn
G	Marburg virus *	*Orthomarburgvirus marburgense*	Musoke	500 cp/µL	5,000 cp/rxn
H	Ebola virus	*Orthoebolavirus zairense*	Mayinga	5,000 cp/µL	50,000 cp/rxn
I	Ebola virus	*Orthoebolavirus zairense*	Mayinga	500 cp/µL	5,000 cp/rxn
J	Ebola virus	*Orthoebolavirus zairense*	Mayinga	5 cp/µL	50 cp/rxn

* **Note:** Marburg virus is a filovirus closely related to ebolaviruses and acts as a specificity negative control for the PANDAA EBOV Qualification Panel.

Storage and Stability

The PANDAA® EBOV Qualification Panel is shipped on dry ice, and the kit components will arrive frozen. All components should be stored between −15 °C and −25 °C upon arrival. **After thawing, the Qualification Panel samples can be stored between 2 °C and 8 °C for up to 72 hours.** More than two freeze-thaw cycles should be avoided to ensure preserve sample integrity.

PANDAA EBOV Qualification Panel Step-by-Step Instructions

Before Beginning

Follow all steps in the instructions for use for the PANDAA® Ebola assay to prepare the PANDAA mastermix.

Running the Qualification Panel

Run each Qualification Panel sample in four replicates alongside four replicates each of the PANDAA® Ebola assay 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 µL 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 Ebola kit (Aldatu Biosciences, catalog # 4011096). 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 Ebola Instructions for Use for instrument-specific analysis settings, including threshold settings for determination of Ct values for the Ebolavirus, Internal Control, and Sample Adequacy Control targets. For technical assistance, contact Aldatu Biosciences Technical Support at support@aldatubio.com.

Expected Results

Label	Virus	Isolate	Expected Result
A	Bundibugyo virus	Butalya-811250	Detected
B	Reston virus	Pennsylvania	Detected
C	Sudan virus	Boniface	Detected
D	Taï Forest virus	Pauléoula-CI	Detected
E	Ebola virus	Makona	Detected
F	Sudan virus	Gulu	Detected
G	Marburg virus	Musoke	Not Detected
H	Ebola virus	Mayinga	Detected
I	Ebola virus	Mayinga	Detected
J	Ebola virus	Mayinga	Detected
Positive Control	Ebola virus	Mayinga	Detected
Negative Control	-	-	Not Detected

Customer and Technical Support

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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.

Copyright

Explanation of Symbols

RUO	For Research Use Only
REF	Catalog number
LOT	Batch number
	Storage temperature range
	Use-by date
	Contents sufficient for n reactions
	Consult Instructions for Use
Cont.	Contents of the PANDAA® EBOV Qualification Panel
	Manufacturer

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