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RealStar®
Ebolavirus Qualification Panel 1.0

Verification and Validation Material for the RealStar® Ebolavirus RT-PCR Kit 1.0

For Research Use Only

Version 02/2015

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Product No.: 5810-QP

10 x 140 µl


Store at -25°C ... -15°C


February 2015


altona Diagnostics GmbH • Mörkenstraße 12 • D-22767 Hamburg

INS-5810QP-EN-01

Content

The RealStar® Ebolavirus Qualification Panel 1.0 is a five member verification and validation panel representing three different concentrations (low, medium, and high) of an *in-vitro* transcript (IVT) comprising the target sequence of the RealStar® Ebolavirus RT-PCR Kit 1.0, diluted in buffer AE + 10 µg/mL polyA RNA.

It can be used for the verification and validation of the RealStar® Ebolavirus RT-PCR Kit 1.0 for the detection of Ebolavirus-specific RNA in combination with the QIAamp® Viral RNA Mini Kit.

For research use only. Not for use in diagnostic prodcedures.

1. Panel Components

Lid Color	Yellow	Yellow	Yellow	Yellow	Yellow
Component QPM*	Ebola QPM 1	Ebola QPM 2	Ebola QPM 3	Ebola QPM 4	Ebola QPM 5
Quantitative Concentration [copies/µl]	32	160	32	3,200	160
Number of Vials	2	2	2	2	2
Volume [µl/Vial]	140	140	140	140	140

* The RealStar® Ebolavirus Qualification Panel 1.0 contains 5 different Qualification panel members (QPM).

2. Storage

- The RealStar® Ebolavirus Qualification Panel 1.0 is shipped on dry ice. The components of the kit should arrive frozen. If one or more components are not frozen upon receipt, or if tubes have been compromised during shipment, contact altona Diagnostics GmbH for assistance.
- All components should be stored at -15°C to -25°C upon arrival.
- Always check the expiration date and do not use the panel members beyond the expiration date.
- Repeated thawing and freezing of the panel members should be avoided, as this might affect the stability of the IVT.
- Storage at +4°C should not exceed a period of two hours.

3. Material and Devices required but not provided

- Nuclease-Free Water (not DEPC-Treated), Life Technologies (Cat. No 4387936) or equivalent
- Ebolavirus-negative human EDTA plasma

4. Test Principle

The RealStar® Ebolavirus Qualification Panel 1.0 provides a set of samples for an in-house qualification of the workflow comprising the RealStar® Ebolavirus RT-PCR Kit 1.0 and the manual sample preparation QIAamp® Viral RNA Mini Kit. It can be used to monitor all steps of the workflow and contains 5 samples (provided in separate tubes) with high, medium and low concentrations of an Ebolavirus specific IVT which should be subjected directly to the extraction procedure. The panel has to be taken through all steps of the assay. Each box contains two sets of the panels to allow repeated testing. It is recommended to use at least one Negative Process Control (NPC) together with the Panel Members of the RealStar® Ebolavirus Qualification Panel 1.0. This can be either Ebolavirus-negative human EDTA-plasma or nuclease-free water (refer to “Material required but not provided”).

5. Limitations and Precautions

- The RealStar® Ebolavirus Qualification Panel 1.0 should only be used in combination with the RealStar® Ebolavirus RT-PCR Kit 1.0.
- The results from the RealStar® Ebolavirus Qualification Panel 1.0 are not to be used for the diagnosis of Ebola disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent Ebola disease or its sequelae.
- Good laboratory practice is essential for proper performance of the RealStar® Ebolavirus Qualification Panel 1.0.
- Appropriate panel member storage and processing procedures are required for the integrity of the RealStar® Ebolavirus Qualification Panel 1.0. Improper storage of panel members may lead to false negative results.
- The RealStar® Ebolavirus Qualification Panel 1.0 must not be used directly for RT-PCR analysis with the RealStar® Ebolavirus RT-PCR Kit 1.0. Appropriate nucleic acid extraction using the QIAamp® Viral RNA Mini Kit must be conducted prior to the analysis with the RealStar® Ebolavirus RT-PCR Kit 1.0.

- When using the RealStar® Ebolavirus Qualification Panel 1.0 with the RealStar® Ebolavirus RT-PCR Kit 1.0 the panel members should be included directly into the extraction procedure and be taken through the entire test procedure.
- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR.
- Use of this product is limited to specified laboratories and clinical laboratory personnel who have been trained on authorized instruments
- The presence of RT-PCR inhibitors may cause false negative or invalid results.
- Avoid microbial and nuclease (DNase/RNase) contamination of the components of the RealStar® Ebolavirus Qualification Panel.
- Always use DNase/RNase-free disposable pipette tips with aerosol barriers.
- Always wear protective disposable powder-free gloves when handling RealStar® Ebolavirus Qualification Panel 1.0 components.
- Use separated and segregated working areas for (i) specimen preparation, (ii) reaction set-up and (iii) amplification/detection activities. Workflow in the laboratory should proceed in unidirectional manner. Always wear disposable gloves in each area and change them before entering different areas.
- Dedicate supplies and equipment to the separate working areas and do not move them from one area to another.
- Store panel members separated from all other components of the RealStar® Ebolavirus RT-PCR Kit 1.0 to avoid contamination.
- Do not open the reaction tubes/plates from the qualification runs post amplification to avoid contamination with amplicons.
- Perform thorough cleaning of PCR areas after handling the amplification panels so to not contaminate subsequent diagnostic PCR samples.
- Do not use components of the RealStar® Ebolavirus Qualification Panel 1.0 that have passed their expiration date.
- Discard sample waste according to your local safety regulations.

6. Instructions for Use

All panel members planned to be used should be thawed completely, mixed (by pipetting or gentle vortexing) and centrifuged briefly before use.

It is recommened to include at least one Negative Process Control (Ebolavirus negative human EDTA plasma or Nuclease-Free Water (not DEPC-Treated)) in each run.

RNA Extraction using the QIAamp® Viral RNA Mini Kit
Please refer to the instructions for use of the RealStar® Ebolavirus RT-PCR Kit 1.0.

PCR analysis using the RealStar® Ebolavirus RT-PCR Kit 1.0
Please refer to the instructions for use of the RealStar® Ebolavirus RT-PCR Kit 1.0.

7. Technical Assistance

For customer support, please contact our Technical Support:

e-mail: support@altona-diagnostics.com

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8. Trademarks and Disclaimers

RealStar® (altona Diagnostics GmbH); QIAamp® (QIAGEN).

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For research use only! Not for use in diagnostic procedures.

Not available in all countries. For information about availability in your country please contact:

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9. Explanation of Symbols

Product number

Batch code


Contains sufficient for “n” tests/reactions (rxns)


Temperature limitation


Version


Use until


Caution


Consult instructions for use


Manufacturer

Notes