Instructions for Use

RealLine Internal Control

INTERNAL CONTROL SAMPLE FOR TESTING OF THE RELIABILITY OF EXTRACTION AND DETECTION OF DNA/RNA FROM CLINICAL SAMPLES

In vitro Diagnostics

CE

RealLine Internal Control	**VBC8881**	**250 tests**
valid from:	**September 2019**	

BIORON Diagnostics GmbH
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RealLine Internal Control

Explanation of symbols used in labeling

IVD	*In vitro* diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Contains sufficient for <n> tests
	Use-by-date
	Temperature limit
	Consult instructions for use
	Keep away from sunlight
	Manufacturer

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1. INTENDED USE

The **RealLine Internal Control** sample kit is designed for the control of the efficiency of DNA / RNA isolation and of the absence of PCR inhibitors in samples when kits of the **RealLine** series intended for detection of DNA / RNA are combined with DNA / RNA extraction kits that do not belong to the **RealLine** series.

Application: for clinical laboratory diagnostics.

The kit is intended for analysis of 250 samples.

2. PRINCIPLE OF METHOD

The extraction of nucleic acids from the specimens is performed together with preliminarily added Internal Control sample (**IC**) with subsequent amplification of selected DNA fragments and the detection of PCR products in real-time.

The use of **IC** prevents generation of false negative results associated with possible loss of NA during specimen preparation and indicates whether PCR inhibitors are present in the reaction mixture. IC should be added to each specimen (including control samples) prior to NA extraction procedure. The amplification and detection of IC does not influence the sensitivity or specificity of the target DNA PCR.

3. KIT CONTENT

Internal control sample (IC), lyophilized	6 vials
Recovery Solution for Control samples (RSC)	2 vials, 4 ml each
Dilution solution (Specimen Diluent)	4 vials, 15 ml each
The kit also includes screw caps for vials with IC	6

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4. SPECIFICATIONS AND PERFORMANCE EVALUATION

4.1. Detectability of IC NA was determined with the use of Standard Reference Panel, comprising four serum samples that went through the extraction process by a “RealLine Extraction 100” together with Internal Control sample. To control the detection of IC DNA a CE-marked “RealLine Mycoplasma hominis” assay kit was used. To control the detection of IC RNA a CE-marked “RealLine TBEV” assay kit was used.
Detectability equaled 100 % provided that all samples were determined as valid (IC is detected in the range Ct 26-30).

4.2. Detectability of IC (in the range Ct 26-30) preliminary added to 120 clinical samples of serum, plasma, cerebrospinal fluid, epithelial swabs equaled 100% (range 97.5 % - 100 %, with a confidence level of 90 %).

5. LIMITATIONS

The **RealLine Internal Control sample IC** is **just** functioning with RealLine Pathogen Kits from BIORON Diagnostics GmbH.

6. WARNING AND PRECAUTIONS

- For in vitro use only.
- The kits must be used by skilled personnel only.
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents.
- Every workspace must be provided with its own set of variable-volume pipettes, necessary auxiliary materials and equipment. It is prohibited to relocate them to other workspaces.
- Never use the same tips for different samples.
- Do not pool reagents from different lots or from different vials of the same lot.
- Dispose unused reagents and waste in accordance with country, federal, state and local regulations.
- Do not use the kit after the expiration date at the side label of the kit.

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7. ADDITIONAL MATERIALS AND DEVICES REQUIRED BUT NOT SUPPLIED

- Laminar safety box;
- Refrigerator;
- Half-automatic variable-volume single-channel pipettes;
- Disposable medical non-sterile powder-free gloves;
- Disposable pipette tips with aerosol barrier;
- Biohazard waste container;
- Equipment and materials required for work with NA extraction kit.

8. PREPARATIONS OF THE KIT COMPONENTS

8.1 Prior to use take the kit out of the refrigerator, and keep the at (18 – 25) °C for at least 30 minutes.

8.2 Open the vial with IC, remove the plastic cap and resin stopper into the biohazard waste container. Place the removed cap and cork into a disinfection solution.

Add 1 ml of **Recovery Solution for Control samples** (RSC) into a vial with IC, close tightly with the plastic cap provided in the kit.

Mix carefully, keep for 15 min at (18 - 25) °C, and then mix thoroughly.

Store diluted IC at (2 – 8) °C for no more than 1 month.

8.3 Prepare the Positive Control sample (PC) from the PCR kit of the “RealLine” series to be used in the assay.

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9. PROCEDURE

Extraction of Nucleic Acids from Clinical Specimens:

9.1. Prior the NA extraction procedure, add **20 µl** IC to each specimen intended for the extraction (including control samples).

9.2. Run the NA extraction procedure according the Instruction manual to the extraction kit till the elution stage.

9.3. At the elution stage add **200 µl** of Specimen diluent solution from the RealLine Internal Control sample kit to each tube. If necessary, the elution volume can be increased to 600 µl.

9.4. Carry out the elution procedure according to the Instruction manual for the extraction kit used. Specimens are ready for PCR.

Explanations for the Detection of the IC:

For each sample the program should detect the increase of the amplification signal of the IC DNA in the channel **FAM** (*Green*) and determine IC **Ct**.

Calculate (IC **Ct**)$_{av}$ as an average IC **Ct** of all analyzed samples (including PC and NC). IC **Ct** values that differ by more than 2 from the (IC **Ct**)$_{av}$ should be discarded. Recalculate the (IC **Ct**)$_{av}$ for the remaining values after the screening. A repeated analysis of this samples, starting with the DNA isolation step, is necessary.

10. STORAGE AND TRANSPORTATION

- Store the kit at (2 - 8) °C in the manufacturer's packing.
- Transport at (2 - 8)°C; transportation up to 25 °C for 10 days is allowed.
- Do not freeze the kit.
- Do not pool reagents from different lots or from different vials of the same lot.
- Strictly follow the Instruction manual for reliable results.
- Do not use kits with damaged packages and get in contact with BIORON Diagnostics GmbH.

For further technical information: **Techsupport@bioron.de**

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