P0048
ViraQ Negative

CE
0483

IVD

REF P0048

The kit insert contains a detailed protocol and should be read carefully before testing the run control to ensure optimal performance

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Intended Use

P0048 ViraQ Negative is intended to be used as external negative control for nucleic acid amplification technology (NAT) blood screening assays for the detection of HBV-DNA, HCV-RNA, HIV-1/2 RNA, HEV-RNA, HAV-RNA, Parvovirus B19-DNA, and WNV-RNA (Table 1 and 2). P0048 ViraQ Negative has been prepared from pooled plasma that was tested for the absence of these markers in the Roche cobas assays. The negative control helps laboratories to ensure absence of contamination and non-specific reactivity in the assays. P0048 Negative controls should not be used to replace the negative control in the test kits. The test result on the negative control should not be used to reject the run or delay the release of test results on donor samples.

Table 1. Assays and platforms covered by P0048 ViraQ Negative run control

Assay (manufacturer)	Platform	Test environment
Procleix® assays (Grifols)	Procleix® Panther®	Blood screening
cobas® assays (Roche)	cobas® 5800/6800/8800	

Key to Symbols Used

Manufacturer

Lot number

Catalogue number

In vitro diagnostic medical device

Country of origin

Expiry date

Number of controls

Caution

CE mark with Notified Body number

Unique device identification

Store below –30 °C

Negative control

Contains human blood derivatives

Read instructions for use

Principle of method

P0048 ViraQ Negative control has been carefully formulated to mimic human plasma specimens. P0048 ViraQ Negative control has been designed to assess assay specificity for the analytes and NAT methods listed in Table 2. The P0048 ViraQ Negative control is supplied in barcoded tubes which can be placed at random position in the sample racks of the NAT instruments and be tested as regular donor specimens. The controls are filled off in volumes for single use.

Table 2. Analytes confirmed to be nonreactive in NAT blood screening assays

Analyte	Assay
HBV-DNA, HCV-RNA, HIV1/2-RNA	cobas MPX, cobas MPX E, Procleix Ultrio Elite, Procleix UltrioPlex E
HEV-RNA	cobas HEV, cobas MPX E, Procleix HEV, Procleix UltrioPlex E
HAV-RNA, parvovirus B19-DNA	cobas DPX, Procleix Parvo/HAV
WNV-RNA	cobas WNV, Procleix WNV, Procleix UltrioPlex W, Procleix ArboPlex

Kit Contents (materials provided)

The run control contains human plasma without preservatives and is provided in two formats as detailed in Table 3.

Table 3. Description of P0048 ViraQ Negative control# kit formats and contents.

Platform	Cat. Code	GTIN/UDI-DI code^	Quantity	Tube size	Sample volume	Secondary packing
cobas®	P0048/01	8718719830482	60 tubes	10 mL	1.5 mL (+overfill)	Rack in box
	P0048/02	8718719832073	10 tubes	10 mL	1.5 mL (+overfill)	Plastic zip bag
Procleix®	P0048/03	8718719830697	60 tubes	10 mL	1.4 mL (+overfill)	Rack in box
	P0048/04	8718719830703	10 tubes	10 mL	1.4 mL (+overfill)	Plastic zip bag

^ Global Trade Item Number = Unique Device Identification - Device Identifier (UDI-DI) code,
# Global Model Number (GMN) = Basic UDI-DI code for P0048 is 871871983P0048EP

To facilitate automation the run control is presented in a polypropylene tube with screw cap comparable in size to vacutainer tubes used for donor sample collection. In addition, the label includes a barcode identifying the product and sequential batch number. The barcode of each run control tube of the P0048/01 and P0048/02 product variants is unique and can be read by the automated cobas systems, whereas the barcodes on the P0048/03 and P0048/04 variants are suitable for the Panther instruments.

Materials required but not supplied

The test kits and liquid handling devices by the NAT manufacturer as specified in Table 1, a water bath of 37 °C for quickly thawing of run control and a vortex instrument for thorough mixing of samples are not provided.

Storage instructions

The run controls should be stored at or below −30 °C for a maximum of five years after preparation of the run control batch and not be used after the expiry date. Once thawed the run control samples should be used within 8 hours. During this period, when the run control is not in use, store sample at 2-8 °C. Do not refreeze the controls after thawing to prevent formation of cryoprecipitates. Any control sample that appears cloudy or contains precipitates after thawing and mixing should be discarded.

Warning and precautions

The negative control is prepared from human blood plasma that tested negative for the viral nucleic acid markers listed in Table 2 as well as for the serologic markers HBsAg,

anti-HCV, anti-HIV 1/2, anti-HTLV I/II, and anti-*Treponema pallidum*. No test method can offer complete assurance that products derived from human blood cannot transmit (unknown) infectious agents. The run control should only be used by trained laboratory workers who are aware of the potential risk of infectious agents in human plasma samples and take the necessary precautions. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials[1,2]. In case of a serious incident related to the use of the run control, report it immediately to BioQControl's technical support group (tel: +31 (0)72 2020 730; e-mail: info@bioqcontrol.com) and to the competent authority of the country/EU Member State where the incident occurred.

- Do not pipette by mouth.
- Use personal protective equipment, including lab coats, gloves and safety glasses.
- Do not eat, drink or smoke in areas where the run control is handled.
- Disinfect spills using a 0.5% hypochlorite solution (1:10 v/v household bleach) or equivalent disinfectant.
- Dispose unused or spilled materials according to the normal practices for biological waste disposal in your institution.
- If precipitates are visible, mix the run controls for 2 minutes thoroughly.
- Once thawed, do not re-freeze and thaw the run control samples to avoid formation of cryoprecipitates that could alter reactivity or cause pipetting errors in the automated sampling systems.
- Store run controls in an upright position.

Reagent preparation

- Thaw the run control quickly in a water bath at 37 °C.
- Mix gently during thawing until contents are just thawed.
- Immediately after the ice clot has disappeared remove the run control tube from the water bath.
- Before testing allow the run control tube to adapt to room temperature.
- Mix the run control tube thoroughly prior to use with a vortex instrument.
- Give a short spin in a centrifuge to remove liquid before releasing screw cap from vial.
- Minimise the time from thawing until testing of the control samples.
- Test run control sample within 8 hours after thawing.
- After thawing when not in use, store run control tube at 2-8 °C.

Expected assay results on run control

All test results on the negative control in the assays specified in Tables 1 and 2 should be found nonreactive. Reactive results, which are likely to be a random event, need further investigation. However, repeat reactivity may be indicative for contamination in NAT instruments or test samples, or by other systematic errors.

Limitations

- P0048 ViraQ Negative control cannot be used to evaluate the analytical or diagnostic specificity of NAT blood screening assays
- P0048 ViraQ Negative control must not be substituted for the mandatory negative controls provided with NAT test kits for calculating the cut-off and/or criteria for releasing test results.

- It cannot be guaranteed that 100% nonreactive results will always be found on P0048 ViraQ Negative control in NAT blood screening assays. Therefore, a reactive result on the negative control should not be used for a decision to accept or reject the test run.

References

1. Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other blood borne pathogens in health-care settings. MMWR 1988; 37:377-388.
2. Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.

Revision history

Date	Version	Description of change
September 2026	V1.0	First version

Biologicals Quality Control B.V.
Droogmakerij 31h
1851 LX, Heiloo
The Netherlands

Telephone: +31-72-2020730
E-mail: info@bioQControl.com
Internet: www.bioQControl.com

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