P0322
SeraQ Negative

CE
0483

IVD

REF P0322

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

Table of contents

Intended Use....3
Key to Symbols Used....3
Principle of method....3
Kit Contents (materials provided)....4
Materials required but not supplied....4
Storage instructions....4
Warning and precautions....4
Reagent preparation....5
Expected assay results on negative control....6
Limitations....6
References....6
Revision history....7

Intended Use

P0322 SeraQ Negative is intended to be used as external negative control in serologic assays for the detection of HBsAg, anti-HBc, anti-HBs, anti-HCV, anti-HIV1/2, HIV p24 antigen, anti-HTLV I/II and anti-*Treponema pallidum* (Table 1). P0322 SeraQ Negative has been prepared from defibrinated plasma pools tested for the absence of these markers in the Abbott Alinity assays. The negative control helps laboratories to ensure absence of nonspecific reactivity in the assays. P0322 SeraQ 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 or patient samples.

Table 1. Assays and platforms covered by P0322 SeraQ Negative run control

Assay (manufacturer)	Platform	Test environment
Alinity® assays (Abbott)	Alinity s, Alinity i	Blood screening & diagnostic testing
ARCHITECT® assays (Abbott)	ARCHITECT®	
Elecsys® assays (Roche)	cobas® e	
VITROS® assays (QuidelOrtho)	VITROS®	
LIAISON® assays (Diasorin)	LIAISON®	
BIO-RAD assays (BIO-RAD)	EVOLIS®	
Murex assays (Murex)	Various	
TPHA assays (various)	Olympus, Erytra	

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 –20 °C

Negative control

Contains human blood derivatives

Read instructions for use

Principle of method

P0322 SeraQ Negative control has been carefully formulated to mimic human serum specimens. P0322 SeraQ Negative control has been designed to assess immunoassay specificity for the following analytes:

- HBsAg
- Anti-HBc
- Anti-HBs
- Anti-HCV
- Anti-HIV1/2
- HIV p24-antigen
- Anti-HTLV I/II
- Anti-*Treponema pallidum*

The P0322 SeraQ Negative control is supplied in barcoded tubes which can be placed at random position in the sample racks of the automated test systems and be tested as regular donor or patient specimens.

Kit Contents (materials provided)

The run control contains human serum and 0.01% (w/v) Thimerosal as preservative and is provided in two formats as detailed in Table 2.

Table 2. Description of P0322 SeraQ Negative kit formats and contents

Cat. Code	GTIN/UDI-DI code^	Quantity run control	Tube size	Claimed sample volume	Secondary packaging
P0322/01	8718719831618	60 x 2.0 mL	10 mL	1.9 mL (+overfill)	60 tube rack in box
P0322/02	8718719833865	10 x 2.0 mL	10 mL	1.9 mL (+overfill)	10 tubes in bag

^ Global Trade Item Number = Unique Device Identification - Device Identifier (UDI-DI) code

The basic UDI-DI code (or Global Model Number (GMN)) of the P0322 SeraQ Negative control is 871871983P0322EL.

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, sequential batch number and Neg. The barcode of each run control tube can be read by the lab instruments.

Materials required but not supplied

The test kits and liquid handling devices of the manufacturers 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 −20 °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 four weeks. 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

P0322 SeraQ Negative is prepared from human blood plasma that tested negative for blood borne viruses. The defibrinated plasma pools are tested for the serological markers

listed above as well as for HBV-DNA, HCV-RNA and HIV-1/2 RNA in the Roche cobas MPX assay. 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 serum samples and take the necessary precautions. 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.

- SeraQ run controls should be handled with the normal preventive measures in a serology laboratory[1,2].
- This product contains human plasma and traces of biological source material of non-human origin (bovine thrombin).
- Wear disposable gloves when handling samples.
- Do not eat drink, smoke or apply cosmetics in areas where specimens are handled.
- Do not pipette by mouth.
- If skin or mucous membrane exposure occurs, immediately wash the area with copious amounts of water.
- 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 using a vortex instrument.
- Do not use run controls beyond four-week storage at 2-8 °C.
- Store run controls in an upright position.
- Validation of the diagnostic test results must be based on the specifications set by the manufacturer of the test kit and not be influenced by the test result on the run control.
- Do not pool residual volumes from different tubes or usage periods. Pooling may combine materials with different evaporation levels and matrix effects that compromise assay performance. These matrix effects increase as residual volumes decrease.
- Cap tubes immediately after use and return to storage at 2-8 °C to minimize evaporation.

Reagent preparation

- For first use of the run control thaw the tube quickly in a water bath at 37 °C.
- Mix gently during thawing until contents are just thawed.
- Immediately after 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.
- Place the run control tube at the specified positions in the sample racks of the test system for regular donor or patient samples.
- Test on the platform with the assays mentioned in Table 1 according to the manufacturer's instructions.
- Recap and store the opened tube immediately after use at 2-8 °C (see storage instructions).

Expected assay results on negative control

All test results on the negative control in the assays for detection of HBsAg, anti-HBc, anti-HBs, anti-HCV, anti-HIV1/2, HIV p24 antigen, anti-HTLV I/II and anti-*Treponema pallidum* 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 of test samples or other systematic errors.

Limitations

- P0322 SeraQ Negative control cannot be used to evaluate the analytical or diagnostic specificity of serologic assays
- P0322 SeraQ Negative control must not be substituted for the mandatory negative controls provided with serologic 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 P0322 SeraQ Negative control in serologic 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

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