P0267 SeraQ TPHA Syphilis V2

CE
0483

IVD

REF P0267

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

P0267 SeraQ TPHA Syphilis V2 is intended to be used on automated platforms utilising the *Treponema pallidum* haemagglutination or particle agglutination assays (TPHA) in diagnostic and blood screening laboratories as an external run control for the detection of antibodies to *Treponema pallidum* (see Table 1). P0267 SeraQ TPHA Syphilis V2 is a single-marker anti-*Treponema pallidum* standard dilution in defibrinated plasma giving a weak reactive agglutination result in TPHA assays. The run control is intended to be tested in consecutive runs of the agglutination assay over time. The run control should not be used to replace internal controls or calibrators in the test kits. P0267 SeraQ TPHA Syphilis V2 must not be used to replace the internal kit controls or calibrators required for the release of test results. The test result on the run control should not be used to reject the run or delay the release of test results on donor or patient samples.

Table 1 Test kits covered by this run control

Equipment	Marker	Tests
Olympus PK7300 (Beckman) or other automated platforms	Anti-*Treponema pallidum*	TPHA

Key to Symbols Used

Manufacturer

Lot number

Catalogue number

In vitro diagnostic medical device

Country of origin

Contains human blood derivatives

Store below –20 °C

Expiry date

Number of controls

Caution

CE mark with Notified Body number

Unique device identification

Read instructions for use

Positive control

Principle of method

A number of SeraQ run controls for monitoring the performance of different anti-*Treponema pallidum* assays have been designed. The run control tubes are barcoded and can be placed at random positions in sample racks of the blood screening device. The tubes are comparable in size to donor blood collection tubes. The run controls are designed to mimic naturally occurring serum specimens with low reactivity for anti-*Treponema pallidum*. This SeraQ run control series includes the product P0267 SeraQ TPHA Syphilis for which the composition is optimised for use with automated TPHA test systems of relatively high sensitivity such as on the Olympus PK7300 (Beckman). The P0267 SeraQ TPHA Syphilis run control is designed to generate a weak reactive agglutination result in the TPHA assay. Routine use of external run controls enables laboratories to monitor day-to-day test performance and IVD batch variation.

Traceability of antibody concentration

The P0267 SeraQ TPHA Syphilis V2 run control is traceable to the 1st WHO International Standard for human syphilitic plasma IgG (05/122) and contains approximately 0.15 IU/mL.

The consistent concentration of the analytes in consecutive SeraQ run control batches is guaranteed by batch release control testing against suitable reference samples kept frozen at −30 °C. These reference samples are derived from the same undiluted internal standards that are used for manufacturing of the SeraQ run controls.

Materials Provided

The run control is provided in two formats as specified in table 2 and contains 2.0 mL of P0267 SeraQ TPHA Syphilis V2 run control and 0.01% (w/v) Thimerosal as preservative.

Table 2. Description of P0267 SeraQ TPHA Syphilis kit formats and contents

Cat. Code	GTIN/UDI-DI code^	Quantity run control	Tube size	Claimed sample volume	Secondary packaging
P0267/01	8718719830932	60 x 2.0 mL	10 mL	1.9 mL (+overfill)	60 tube rack in box
P0267/02	8718719833803	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 P0267 SeraQ TPHA Syphilis run control is 871871983P0267F5.

Materials not provided

Pipetting devices in IVD test systems, a vortex instrument for thorough mixing of samples prior to use and a water bath of 37 °C for quickly thawing of run control are not provided.

Storage Instructions

Store unopened tubes at or below −20 °C. Thaw one run control tube in a water bath of 37 °C until ice clot has disappeared. After thawing, the run control tubes should be stored at 2 °C to 8 °C for no longer than four weeks.

Warning and precautions

P0267 SeraQ TPHA Syphilis V2 run control is prepared from a serum standard, which is considered to be non-infectious since *Treponema pallidum* is only transmitted by fresh blood products and is not resistant to cooling or freezing[1]. The serum matrix in the run controls has been tested for infectious disease markers by serologic and molecular screening methods. However, no screening strategy can offer complete assurance that products derived from human blood cannot transmit undetected 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[2,3].
- This product contains human plasma and traces of biological source material of non-human origin (bovine thrombin).
- The use of the run control in other assay configurations should be avoided and is not supported by the manufacturer.

- 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 weeks 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.
- Matrix effects may reduce reactivity in assays with a relatively high input volume when residual volumes in the run control tubes become low, even within the 4-week storage period. Use fresh tubes when volumes are low and monitor results carefully toward the end of the usage period.
- 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.

Test Procedure

- 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.
- For automated test systems, place the run control tube at the specified positions in the sample racks for regular donor or patient samples. Otherwise, pipet run controls manually as with regular test specimens at the target position in test plates.
- Test in the TPHA assay as 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).

Performance Characteristics

The P0267 SeraQ TPHA Syphilis V2 run control has been designed by examination of the agglutination results on dilutions of the internal standard. The expected endpoint titer in TPHA is approximately 1:4 (1:2 to 1:8) and therefore a weak positive agglutination result is expected (Table 3). SPC values between 5 and 10 were consistently observed for two months when testing P0267 SeraQ TPHA Syphilis V2 in the TPHA assay on the Olympus PK7300 platform. This confirmed the claim of in-use stability for at least one month when run control tubes are stored at 2-8°C.

Expected assay response values

The expected result for the P0267 SeraQ TPHA Syphilis V2 is a weak positive agglutination result (Table 3).

Table 3. Expected agglutination results in a sensitive TPHA assay on P0267 SeraQ TPHA Syphilis V2 run control such as on Olympus PK7300 platform

Marker	Assay	Agglutination result	Endpoint titer (range)
Anti-*Treponema pallidum*	TPHA	Weak reactive^	Dilution 1:4 (1:2 to 1:8)

^with expected SPC values between 4-12 on Olympus PK7300 platform

Interpretation of Results

Subsequent test runs can be analysed by appropriate statistical approaches on the Olympus SPC values obtained on the external control samples. A software system (DataQ Analytics) is available via the website www.bioqcontrol.com for entering SPC values and generating a statistical report with calculations for preparing a Levey-Jennings Chart. Knowing the 95% and 99% predictive intervals for generating a Levey-Jennings chart one can use Nelson rules[4] to interpret values outside the predictive limits and for identifying trends and aberrant results. The statistical report generated by the DataQ Analytics system (on the website www.bioqcontrol.com) identifies these trends and outliers for the laboratory requesting the report.

Limitations

- SeraQ run controls were designed for monitoring the analytical performance of serologic test systems. They cannot be used to evaluate the diagnostic sensitivity of the assays.
- The run control must not be substituted for the mandatory controls or calibrators provided with IVD test kits for calculating the cut off and/or criteria for releasing test results.
- The response values on the run controls should not be used to release or reject the test run but can be used as an aid in the assessment of analytical performance.
- The expected SPC values on the run control in the Olympus PK7300 have been established with only one P0267 SeraQ run control batch and a limited number of TPHA reagent lots. It cannot be guaranteed that SPC values obtained with new TPHA reagent lots and run control batches will always fall within these limits.
- Although the batch-to batch composition of SeraQ run controls is consistent, some variation in the measurable potency of the serum standards in the run control batches cannot be avoided due to matrix effects and other manufacturing variables.

References

1. Lelie PN. Van Drimmelen A.A.J. Preparation of inactivated viral standards: Safety assessment of quality control samples for viral serology and NAT assays in blood screening laboratories. BioQControl document number CE4006. www.bioqcontrol.com
2. Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37:377-388.
3. 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.
4. Nelson LS, "The Shewhart Control Chart—Tests for Special Causes". Journal of Quality Technology 1984;16, no. 4: 238-239

Revision history

Date	Version	Description of change
August 2026	V3.0	Contact information added for reporting serious incidents in chapter “Warnings and precautions”. Symbol for positive control added. Expected performance data added in Olympus PK7300 test system and option for using DataQ Analytics for statistical analysis added

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