P0267
SeraQ TPHA Syphilis V2

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 open platforms utilising the Treponema *pallidum* haemagglutination assay (TPHA) as an external run control for the detection of antibodies to Treponema *pallidum* (see Table 1) performed in diagnostic and blood screening laboratories. 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 Syhilis 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	Agent	Tests
Diverse	Treponema *pallidum*	TPHA

Key to Symbols Used

Manufacturer

Lot number

Catalogue number

Store below -20°C

For performance evaluation ony

Biological substance Category B

Expiry date

Contents

Caution

Read instructions for use

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 the TPHA tests. The P0267 SeraQ TPHA Syphilis run control is designed to generate a weak positive agglutination result in 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 0.094 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 (secondary) 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 kit formats and contents.

Cat. Code	UDI code	Quantity run control	Size vials	packing
P0267/01	8718719830932	60 x 2.0 mL	10 mL	60 vials in rack/box
P0267/02	8718719833803	10 x 2.0 mL	10 mL	10 vials in box

Materials not provided

Pipettes or pipetting devices for use in IVD test systems.

Storage Instructions

Store unopened tubes at or below -20°C. After thawing the run control tubes should be stored to 2°C to 8°C for no longer than 4 weeks.

Warning and precautions

P0267 SeraQ TPHA Syphilis V2 run controls are prepared from internal serum standards, in which the bacterium has been inactivated by cold storage.[1] Infectivity and inactivation data have been analysed to demonstrate absence of residual infectivity of Treponema *pallidum*, HBV, HCV and HIV-1 in the run controls[1]. The serum matrix in in the run controls has been tested for infectious disease markers by serologic and molecular screening methods. However, no screening procedure can offer complete assurance that products derived from human blood cannot transmit undetected infectious agents.

- 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.
- Do not use run controls beyond 4 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.

Test Procedure

- Allow a run control tube to adapt to room temperature.
- Mix the tubes thoroughly prior to use (any visible precipitate will then easily disappear).
- 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
- Store the opened tube immediately after use at 2-8 °C (see storage instructions).

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 TPHA assays on P0267 SeraQ TPHA Syphilis V2

Marker	Assay	Agglutination result	Endpoint titer (range)
Anti-Treponema *pallidum*	TPHA	Weak reactive	Dilution 1:3 (1:2 to 1:6)

Analytical Performance Characteristics

P0267 SeraQ TPHA Syphilis V2 run controls has been designed by examination of the agglutination results on dilutions of the internal standard. The expected endpoint titer in TPHA is approximately 1:3 and therefore a weak positive agglutination result is expected (Table 3).

Limitations

SeraQ run controls were designed for monitoring the analytical performance of IVD kits. They cannot be used to evaluate the diagnostic sensitivity of IVD kits. The run control must not be substituted for the mandatory controls or calibrators provided with IVD test kits for setting 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.

References

1. Van Drimmelen A.A.J., Lelie PN. Preparation of inactivated secondary viral standards: Safety assessment of quality control samples for viral serology and NAT assays in blood screening laboratories. BQC document number CE4006 (manuscript in preparation).
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 healthcare and public-safety workers. MMWR 1989; 38(S-6): 1-36.

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