

Bio  QC Control

**P0267**  
**SeraQ TPHA Syphilis**



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 is intended to be used on open platforms utilising the *Treponema pallidum* haemagglutination assay (TPHA) test 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 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. The product is intended for In Vitro Diagnostic (IVD) performance evaluation only.

**Table 1 Test kits covered by this run control**

Equipment	Agent	Tests
Diverse	<i>Treponema pallidum</i>	TPHA

## Key to Symbols Used



Manufacturer



Lot number



Catalogue number



Store below -20°C



Device for performance evaluation



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 results in TPHA assay. Routine use of external run controls enables laboratories to monitor day-to-day test performance and IVD batch variation.

## Traceability of antigen and antibody concentration

No unitage could be assigned to the internal standard for anti-*Treponema pallidum* since international reference preparations are not available. 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**

Ten (10) polypropylene tubes (10 mL) with screw caps, each contains 5.0 mL of P0267 SeraQ TPHA Syphilis run control and 0.01% (w/v) Thimerosal as preservative.

### **Materials not provided**

Pipettes or pipetting devices for use in IVD test systems.

### **Storage Instructions**

Store unopened tubes at or below -20°C. After use, the run control tubes should be stored to 2°C to 8°C (< 1 month).

### **Warning and precautions**

P0267 SeraQ TPHA Syphilis run controls are prepared from internal serum standards, in which the bacterium has been inactivated by cold storage.<sup>1</sup> 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<sup>1</sup>. The serum matrix 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<sup>2,3</sup>
- 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 of 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 one month 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 manufacturers 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 is a weak positive agglutination result (Table 2)

Table 2. Expected agglutination results in TPHA assays on P0267 SeraQ TPHA Syphilis

Marker	Assay	Agglutination result	Endpoint titer (range)
Anti- <i>Treponema pallidum</i>	TPHA	Weak reactive	Dilution 1:4 (1:2 to 1:8)

## Analytical Performance Characteristics

P0267 SeraQ TPHA Syphilis 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 1:4 and therefore a weak positive agglutination results is expected (Table 2).

## 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 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.

## 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. BOC 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 health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.

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