P0219 SeraQ Vitros Syphilis

REF P0219

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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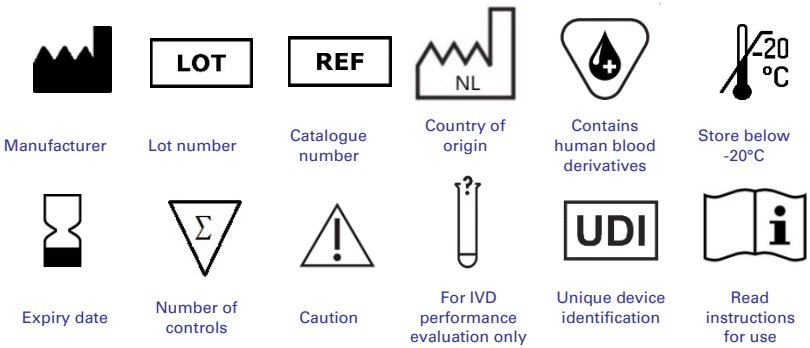
Intended Use

P0219 SeraQ Vitros Syphilis is intended to be used on QuidelOrtho VITROS® platform in diagnostic and blood screening laboratories as an external run control in combination with the assay for the detection of antibodies to *Treponema pallidum* (see Table 1). P0219 SeraQ Vitros Syphilis is a single marker dilution of an internal anti-*Treponema pallidum* standard in defibrinated plasma giving a low reactive result in the VITROS® Syphilis Assay. The run control is intended for repeated testing in consecutive runs of the immunoassays over time by trained laboratory workers. By comparison of the sample to cut off (S/CO) values found on P0219 SeraQ Vitros Syphilis run control one can monitor whether the analytical sensitivity of test runs is consistent. The run control should not be used to replace internal controls or calibrators in the test kits. 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. This product is used for performance evaluation only.

Table 1 Test kits covered by this run control

Equipment	Agent	Assay
QuidelOrtho VITROS®	*Treponema pallidum*	VITROS® Syphilis Assay

Key to Symbols Used



Principle of method

A series of SeraQ run controls have been designed for monitoring the performance of different anti-*Treponema pallidum* assays. 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*. The analytical sensitivity of test kits from different manufacturers varies and therefore for each test kit a separate single marker run control has been designed. The SeraQ run control series includes the product P0219 SeraQ Vitros Syphilis for which the composition is optimised for use with the VITROS® Syphilis test system. The P0219 SeraQ Vitros Syphilis run control is designed to generate assay response values (i.e. S/CO ratios) positioned in the low positive range of the assay. Routine use of external run controls enables laboratories to monitor day-

to-day test performance and IVD batch variation. After approval of the Notified Body a summary of the safety and performance of the P0219 SeraQ Vitros run control will be available at the EUDAMED website of the European Union[1].

Traceability of antibody concentrations

For anti-*Treponema pallidum*, an internal serum standard has been established from which reference panels and run controls are prepared by gravimetrically recorded dilution steps. No unitage has been assigned to the internal standard for anti-*Treponema pallidum* since a suitable international reference preparation is 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 standards that are used for manufacturing of the SeraQ run controls.

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 P0219 SeraQ Vitros kit formats and contents

Cat. Code	GTIN/UDI-DI code^	Quantity run control	Tube size	Claimed sample volume	Secondary packaging
P0219/01	8718719830215	60 x 2.0 mL	10 mL	1.9 mL (+overfill)	60 tube rack in box
P0219/02	8718719831731	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 P0219 SeraQ Vitros run control is 871871983P0219ES.

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 Syphilis: SYPH. The barcode of each run control tube can be read by the QuidelOrtho VITROS® instruments.

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. For each VITROS® instrument 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

P0219 SeraQ Vitros Syphilis run controls are prepared from an internal serum standard, in which the bacterium has been inactivated by refrigerated storage[2]. 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[3,4].
- 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 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.

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 Vitro system for regular donor or patient samples.
- Test on the QuidelOrtho VITROS® platform with the assays 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 on run control

As this device is in its early performance evaluation phase, test results data for this run control are not yet available. The expected values cannot be given.

Each batch of QuidelOrtho VITROS® Syphilis Assay has its own dose response curve and distribution of S/CO values on SeraQ run controls. This depends on the analytical sensitivity of the QuidelOrtho reagent batches that are in use. P0219 SeraQ Vitros Syphilis serves as an independent external run control for monitoring consistent analytical sensitivity of QuidelOrtho reagent batches over time.

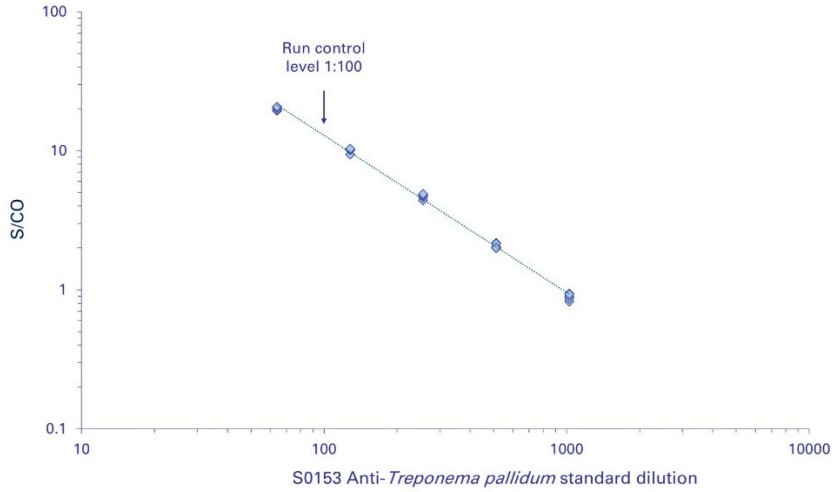
Analytical Performance Characteristics

SeraQ run controls have been designed by examination of the response curves on dilutions of the internal standards and as such relate to the analytical sensitivity of immunoassays. In the following paragraphs the essential analytical performance characteristics of SeraQ run controls are presented.

Dose response and analytical sensitivity

By analysing standard dilution series, the relationship between S/CO values and concentration of the analyte can be established[5,6]. Plotting Log transformed VITROS® S/CO values against Log concentration of analyte using linear regression analysis enables calculation of correlation coefficients. Figure 1 shows a linear dose response relation in the QuidelOrtho VITROS® Syphilis assay on logarithmic scales of dilution factor and S/CO values.

Figure 1. Dose response in QuidelOrtho VITROS® Syphilis assay. Syphilis S/CO values are plotted against dilution of anti-*Treponema pallidum* standard on logarithmic scales (r^2=0.99).



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 S/CO values and 99% predictive intervals have not yet been established.
- 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

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