AccuTrak™ Syphilis Qualification Panel

QSS701 (2400-0163)

INTENDED USE

The AccuTrak™ Syphilis Qualification Panel QSS701 (2400-0163) is a panel of six members with established reactivity in syphilis assays. This panel may be used for training, qualifying, and re-qualifying technical personnel in the performance of tests for the detection of syphilis. The panel may also be used as part of ongoing programs of lot acceptance and internal proficiency testing for syphilis assays, to isolate system errors, and in troubleshooting these assays, as a component of a quality assurance program. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This panel consists of six members, manufactured from human serum or plasma, with a range of reactivity in syphilis assays. Five panel members are formulated with various reactivities for syphilis. The nonreactive member is formulated from defibrinated human plasma that is nonreactive for syphilis. Panel members are filtered through a 0.2 micron filter. Proclin® (0.1%) is added as a preservative.

Item No. 2400-0163 — 1 vial per member
6 members, 2.0 mL per vial

PRECAUTIONS

Members of the AccuTrak Syphilis Qualification Panel QSS701 (2400-0163) are manufactured from human serum or plasma that is negative for HBsAg and antibodies to HIV 1 and 2, HCV, and HTLV. The potential for transmission of infectious agents exists, and these materials should be handled following good laboratory safety practice. Do not pipette by mouth. Do not smoke, eat or drink in areas where specimens are handled. These materials should be disposed of in a manner that will inactivate pathogenic agents.

STORAGE

Panel members should be stored at 2-8°C until use. Once opened, panel members should be stored at 2-8°C and discarded after 60 days. Alterations in physical appearance may indicate instability or deterioration. Solutions that are visibly turbid should be discarded.

INSTRUCTIONS FOR USE

Each panel member should be tested following the same procedure used for unknown samples, according to the test manufacturer's package insert instructions.

INTERPRETATION OF RESULTS

Table 1 lists the syphilis reactivity of the QSS701 (2400-0163) panel members. Specific levels of reactivity will vary among different laboratories and test methods. Procedures for lot acceptance, training, and troubleshooting must be established by each laboratory.

EXPECTED RESULTS

The AccuTrak Syphilis Qualification Panel QSS701 (2400-0163) is formulated to produce the following reactivity:

Table 1

Panel Member ID	Syphilis Reactivity
QSS701-01	Reactive
QSS701-02	Reactive
QSS701-03	Reactive
QSS701-04	Reactive
QSS701-05	Reactive
QSS701-06	Nonreactive

LIMITATIONS

QSS701 (2400-0163) is offered for research use only. Not for use in diagnostic procedures.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact LGC Clinical Diagnostics at 508.244.6400.

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at CDx-Info@LGCGroup.com or by phone at 508.244.6400.