

AccuSet[™] Syphilis Mixed Titer Performance Panel 0820-0514

INTENDED USE

The AccuSet[™] Syphilis Mixed Titer Performance Panel 0820-0514 is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot syphilis test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is a 20-member panel consisting of undiluted, naturally-occurring plasma samples. Panel members represent bleeds from multiple individuals that demonstrate varying levels of reactivity for non-treponemal reagins and treponemal antibodies. Each sample represents a single collection event. One sample is included as a non-reactive sample and is negative for all syphilis related test methods. No preservatives were added.

Material Number:

0820-0514, 1 vial per member 20 members, 1.0 mL per vial

STORAGE

Panel members should be stored frozen at -20 °C or colder. LGC SeraCare recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

INTERPRETATION OF RESULTS

The Data Sheet for The AccuSet Syphilis Mixed Titer Performance Panel 0820-0514 is available at <u>www.seracare.com</u>. The Data Sheet lists results for panel members generated using commercially-available screening, monitoring, and confirmatory test methods. Tests were performed at LGC SeraCare or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Information regarding specific test methods is available on the data sheet. Data Sheets are updated when new data are available.

LIMITATIONS

The AccuSet Syphilis Mixed Titer Performance Panel 0820-0514 is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC SeraCare Life Sciences does not claim that others can duplicate test results exactly.

PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Follow Universal Precautions¹. Some panel members were found positive for syphilis infection. The units that make up this panel were tested and found negative for anti-HIV, anti-HCV, and HBsAg. This does not ensure the absence of these or other human pathogens.

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.

REFERENCES

 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 SeraCare 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 <u>CDx-Info@LGCGroup.com</u> or by phone at 508.244.6400.