

AccuSet[™] Anti-HBc IgM Mixed Titer Performance Panel Modified PHE203(M) / 0805-0216

INTENDED USE

The AccuSet[™] Anti-HBc Mixed Titer Performance Panel Modified PHE203(M) / 0805-0216 is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot anti-HBc IgM 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 modified 22-member panel originating from Anti-HBc Mixed Titer Performance Panel PHE203-1.0. Panel members 1, 2, and 24 from the original 25-member panel are no longer available. Panel members are undiluted, naturally occurring plasma samples with anti-HBc IgM reactivity ranging from negative to strong positive. Each sample represents a single collection event. No preservatives were added.

Material Number:

0805-0216, 1 vial per member 22 members, 1.0 mL per vial

STORAGE

Panel members should be stored at -20 °C or colder. LGC SeraCare Life Sciences 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 Anti-HBc Mixed Titer Performance Panel Modified PHE203(M) / 0805-0216 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 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 Anti-HBc Mixed Titer Performance Panel Modified PHE203(M) / 0805-0216 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 by tests for 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 <u>www.seracare.com</u>.

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.