

AccuSet[™] SARS-CoV-2 Performance Panel (0820-0410)

INTENDED USE

The AccuSet[™] SARS-CoV-2 Performance Panel (0820-0410) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot SARS-CoV-2 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 an 11-member panel consisting of undiluted, naturally occurring plasma samples collected from individual donors positive for SARS-CoV-2 antibodies. Each sample represents a single collection event. No preservatives were added.

Material Number: 0820-0410, 1 vial per member 10 Positive members, 1.0 mL per vial 1 Negative member, 1.0 mL per vial

STORAGE

Panel members should be stored frozen at -20°C or colder. 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. After opening, record the date opened and the expiration date on the vial. Multiple freeze-thaw cycles are not recommended and may have variable adverse effects on test results. To prevent leakage, store vials upright.

INTERPRETATION OF RESULTS

The Data Sheet for AccuSet[™] SARS-CoV-2 Performance Panel (0820-0410) 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

AccuSet[™] SARS-CoV-2 Performance Panel is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

SAFETY PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Follow Universal Precautions¹. The units that make up this panel were tested and found negative for anti-HIV, HBsAg and anti-HCV. 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 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>info@seracare.com</u> or by phone at 508.244.6400.