

AccuTrak™ Anti-HBc Qualification Panel QHG711 (2400-0145)

INTENDED USE

The AccuTrak™ Anti-HBc Qualification Panel QHG711 (2400-0145) is a six member panel with established reactivity in tests for antibody to Hepatitis B Core Antigen (anti-HBc). It is intended for use by clinical laboratories, diagnostic manufacturers, and researchers to develop, evaluate, or troubleshoot anti-HBc test methods. The panel may be used for assay validation, method comparison, verifying lot changes, internal proficiency testing, operator training, or whenever there are indications of possible assay deterioration. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The AccuTrak Anti-HBc Qualification Panel QHG711 (2400-0145) consists of six members, manufactured from human serum or plasma, that have a range of concentrations of anti-HBc. Five panel members were formulated with various reactivities for anti-HBc. The nonreactive member was formulated from an anti-HBc negative pool. Panel members were filtered through a 0.2 micron filter. ProClin® (0.1%) was added as a preservative.

Material Number: 2400-0145, 1 vial per member
6 members, 2.0 mL per vial

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 instructions. Mix by gentle inversion before using.

INTERPRETATION OF RESULTS

Table 1 lists the anti-HBc activity of QHG711. 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.

LIMITATIONS

The AccuTrak Anti-HBc Qualification Panel QHG711 (2400-0145) 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.

PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Use the CDC recommended Universal Precautions for handling this product¹. 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.

EXPECTED RESULTS

The AccuTrak Anti-HBc Qualification Panel QHG711 (2400-0145) is formulated to produce the following reactivity:

Table 1

Panel Member ID	Anti-HBc Reactivity
QHG711-01	Nonreactive
QHG711-02	Reactive
QHG711-03	Reactive
QHG711-04	Reactive
QHG711-05	Reactive
QHG711-06	Reactive

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 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 info@seracare.com or by phone at 508.244.6400.