

AccuTrak™ HBsAg Qualification Panel QHA711 (2400-0141)

INTENDED USE

The AccuTrak™ HBsAg Qualification Panel QHA711 (2400-0141) is a panel of six samples with established reactivity in Hepatitis B Surface Antigen (HBsAg) assays. This panel may be used for training, qualifying, and re-qualifying technical personnel in the performance of tests for the detection of HBsAg. The panel may also be used as part of ongoing programs of lot acceptance and internal proficiency testing for HBsAg 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 product consists of six members, manufactured from human serum or plasma, with a range of concentrations of HBsAg. The five reactive panel members represent dilutions of HBsAg subtype ad and HBsAg subtype ay stocks in defibrinated human plasma. The nonreactive member is made from defibrinated human plasma that is nonreactive for HBsAg. Panel members were filtered through a 0.2 micron filter. Proclin® (0.1%) was added as a preservative.

Material Number: 2400-0141, 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.

INTERPRETATION OF RESULTS

Table 1 lists the HBsAg reactivity of AccuTrak HBsAg Qualification Panel QHA711 (2400-0141). The antigen subtype is listed for reactive 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.

LIMITATIONS

The AccuTrak HBsAg Qualification Panel QHA711 (2400-0141) is offered for research use only. Not for use in diagnostic procedures.

PRECAUTIONS

Members of the AccuTrak HBsAg Qualification Panel QHA711 (2400-0141) are manufactured from human serum or plasma that is negative for antibodies to HIV 1 and 2, HCV, and HTLV. HBsAg reactive stock materials were treated with beta-propiolactone and ultraviolet irradiation. 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.

EXPECTED RESULTS

The AccuTrak HBsAg Qualification Panel QHA711 (2400-0141) is formulated to produce the following reactivity:

Table 1

Panel Member ID	Antigen Subtype	HBsAg Reactivity
2400-0141-01	ad	Reactive
2400-0141-02	ad	Reactive
2400-0141-03	neg	Nonreactive
2400-0141-04	ay	Reactive
2400-0141-05	ad	Reactive
2400-0141-06	ay	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 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.