

PACKAGE INSERT

INTENDED USE

The HBsAg AccuTrak™ 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

QHA711 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.

Cat. No. 2400-0141 1 vial per member
6 members, 2.0 mL per vial

PRECAUTIONS

Members of the HBsAg AccuTrak Qualification Panel QHA711 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.

The Package Insert for this panel in PDF form can be found at www.seracare.com.

A printed copy of the Package Insert may be requested by email at info@seracare.com or by phone at 508.244.6400.

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 package insert instructions.

INTERPRETATION OF RESULTS

Table 1 lists the HBsAg reactivity of QHA711. 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.

EXPECTED RESULTS

The HBsAg AccuTrak Qualification Panel QHA711 is formulated to produce the following reactivity:

Table 1

Panel Member ID	Antigen Subtype	HBsAg Reactivity
QHA711-01	ad	Reactive
QHA711-02	ad	Reactive
QHA711-03	neg	Nonreactive
QHA711-04	ay	Reactive
QHA711-05	ad	Reactive
QHA711-06	ay	Reactive

LIMITATIONS

QHA711 is offered for research use only. Not for use in diagnostic procedures.

For assistance, contact SeraCare Technical Support at 508.244.6400.

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