AccuTrak™ HIV-1, HCV, HBV Nucleic Acid Qualification Panel

QCA702 (2400-0140)

INTENDED USE

The AccuTrak™ HIV-1, HCV, HBV Nucleic Acid Qualification Panel QCA702 (2400-0140) is a multi-analyte panel of five samples with established reactivity using HIV-1 RNA (Human Immunodeficiency Virus Type 1), HCV RNA (Hepatitis C Virus), and HBV DNA (Hepatitis B Virus) assays. This panel may be used for training, qualifying, and re-qualifying technical personnel in the performance of tests for the detection of HIV-1 RNA, HCV RNA and HBV DNA. The panel may also be used as part of ongoing programs of lot acceptance and internal proficiency testing for HIV-1 RNA, HCV RNA, and HBV DNA assays, to isolate system errors, and in troubleshooting performance of these assays, as a component of a quality assurance program. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The AccuTrak HIV-1, HCV, HBV Nucleic Acid Qualification Panel QCA702 (2400-0140) consists of five members, manufactured from human serum or plasma with a range of reactivity in HIV-1 RNA, HCV RNA, and HBV DNA assays. Reactive members represent dilutions of reactive stock in a nonreactive pool. Three panel members are formulated to be reactive for either HIV-1 RNA, HCV RNA, or HBV DNA individually and one member is formulated to be reactive for HIV-1 RNA, HCV RNA, and HBV DNA in combination. One panel member is nonreactive for HIV-1 RNA, HCV RNA, and HBV DNA. The nonreactive pool was filtered through a 0.2 micron filter. Sodium azide (0.09%) was added as a preservative.

Material Number: 2400-0140, 1 vial per member
5 members, 4.0 mL per vial

STORAGE

Panel members should be stored at -70°C until use. Alternatively, panels may be stored for up to 6 months at -20°C if the panels are used before the labeled expiration date. Label panels with date that -20°C storage began.

Once panel members are thawed and opened, the vials should not be used more than three times and must be used within 10 days after opening. Store vials at 2-8°C between uses.

Alterations in physical appearance may indicate instability or deterioration. Solutions that are visibly turbid should be discarded.

INTERPRETATION OF RESULTS

Table 1 lists the reactivity of AccuTrak HIV-1, HCV, HBV Nucleic Acid Qualification Panel QCA702 (2400-0140). 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

AccuTrak HIV-1, HCV, HBV Nucleic Acid Qualification Panel QCA702 (2400-0140) is offered for research use only. Not for use in diagnostic procedures.

PRECAUTIONS

Members of the AccuTrak HIV-1, HCV, HBV Nucleic Acid Qualification Panel QCA702 (2400-0140) are manufactured from human serum or plasma that is negative for antibodies to HIV-1/2 and HTLV. 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 HIV-1, HCV, HBV Nucleic Acid Qualification Panel QCA702 (2400-0140) is formulated to produce the following reactivity:

Table 1

Panel Member ID	HIV-1 RNA	HCV RNA	HBV DNA
2400-0140-01	Reactive	Nonreactive	Nonreactive
2400-0140-02	Nonreactive	Reactive	Nonreactive
2400-0140-03	Nonreactive	Nonreactive	Reactive
2400-0140-04	Reactive	Reactive	Reactive
2400-0140-05	Nonreactive	Nonreactive	Nonreactive

For assistance, contact SeraCare Technical Support at 508.244.6400.

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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.