

Anti-HCV AccuTrak™ Qualification Panel QHV712 (2400-0148)

PACKAGE INSERT

INTENDED USE

The Anti-HCV AccuTrak™ Qualification Panel QHV712 (2400-0148) is a panel of six members with established reactivity in anti-HCV (Hepatitis C Virus) assays. This panel may be used for training, qualifying, and re-qualifying technical personnel in the performance of tests for the detection of anti-HCV. The panel may also be used as part of ongoing programs of lot acceptance and internal proficiency testing for Anti-HCV 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

QHV712 consists of six members, manufactured from human serum or plasma, with a range of reactivity in Anti-HCV assays. Five panel members are formulated with various reactivities for Anti-HCV. The nonreactive member is formulated from defibrinated human plasma that is nonreactive for Anti-HCV. Panel members are filtered through a 0.2 micron filter. ProClin® (0.1%) was added as a preservative.

Cat. No. 2400-0148 1 vial per member
 6 members, 1.0 mL per vial

PRECAUTIONS

Members of the Anti-HCV AccuTrak Qualification Panel QHV712 are manufactured from human serum or plasma that is negative for HBsAg and antibodies to HIV 1 and 2, and HTLV. Anti-HCV positive stock materials are treated with beta-propiolactone and ultraviolet radiation. This does not ensure the absence of pathogens, 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.

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 Anti-HCV reactivity of the QHV712 panel 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

Anti-HCV AccuTrak Qualification Panel QHV712 is formulated to produce the following reactivity:

Table 1

Panel Member ID	Anti-HCV Reactivity
QHV712-01	Weakly Reactive
QHV712-02	Highly Reactive
QHV712-03	Nonreactive
QHV712-04	Moderately Reactive
QHV712-05	Weakly Reactive
QHV712-06	Moderately Reactive

LIMITATIONS

QHV712 is offered for research use only. Not for use in diagnostic procedures.

For assistance, contact SeraCare Technical Support at 508.244.6400.

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.

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