AccuTrak™ Anti-HIV 1/2 Qualification Panel

QRZ761 (2400-0160)

INTENDED USE

The AccuTrak™ Anti-HIV 1/2 Qualification Panel QRZ761 (2400-0160) is a panel of six members with established reactivity in anti-HIV 1/2 (Human Immunodeficiency Types 1 and/or 2) assays. This panel may be used for training, qualifying, and re-qualifying technical personnel in the performance of tests for the detection of anti-HIV 1/2. The panel may also be used as part of ongoing programs for lot acceptance and internal proficiency testing for anti-HIV 1/2 assays, to isolate system errors, and in troubleshooting these assays. 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 reactivity in anti-HIV 1/2 EIA assays. Four panel members were formulated with various reactivities for anti-HIV-1, one member was formulated with reactivity for anti-HIV-2, and the nonreactive member was formulated from anti-HIV 1/2 negative pools. Panel members were filtered through a 0.2 micron filter. Proclin® (0.1%) was added as a preservative.

Material Number: 2400-0160, 1 vial per member
6 members, 1.0 mL per vial

PRECAUTIONS

Members of the AccuTrak Anti-HIV 1/2 Qualification Panel QRZ761 are manufactured from human serum or plasma that is negative for HBsAg and antibodies to HCV and HTLV. Anti-HIV positive stock materials were treated with beta-propiolactone and ultraviolet irradiation. The potential for transmission of infectious agents exists. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling human specimens[1]. 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-HIV reactivity of AccuTrak Anti-HIV 1/2 Qualification Panel QRZ761. Specific levels of reactivity (absorbance reading or signal to cutoff ratios) will vary among different laboratories and test methods. Procedures for lot acceptance, training and troubleshooting must be established by each laboratory.

EXPECTED RESULTS

The AccuTrak Anti-HIV 1/2 Qualification Panel QRZ761 is formulated to produce the following reactivity:

Table 1

Panel Member ID	Anti-HIV 1/2 Reactivity
2400-0160-01	HIV 1 Reactive
2400-0160-02	HIV 2 Reactive
2400-0160-03	HIV 1 Reactive
2400-0160-04	Nonreactive
2400-0160-05	HIV 1 Reactive
2400-0160-06	HIV 1 Reactive

LIMITATIONS

The AccuTrak Anti-HIV 1/2 Qualification Panel QRZ761 (2400-0160) is offered for research use only. Not for use in diagnostic procedures.

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.