AccuTrak™ HIV 1/2/O/p24 Qualification Panel

QRX701 (2400-0158)

INTENDED USE

The AccuTrak™ HIV 1/2/O/p24 Qualification Panel QRX701 (2400-0158) is a panel of six members with established reactivity in anti-HIV-1, anti-HIV-2, anti-HIV-1 group O, HIV p24 antigen and combination assays. This panel may be used for training, qualifying, and re-qualifying technical personnel in the performance of tests for the detection of HIV. The panel may also be used as part of ongoing programs for lot acceptance and internal proficiency testing for HIV assays, to isolate system errors, in troubleshooting these assays, and as a component of a quality assurance program. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This panel consists of six members, manufactured from human serum or plasma, with a range of concentrations of HIV antibodies and p24 antigen. Panel members were filtered through a 0.2 micron filter. ProClin® (0.1%) was added as a preservative.

Item No. 2400-0158 1 vial per member
6 members, 3.5 mL per vial

PRECAUTIONS

Members of the AccuTrak HIV 1/2/O/p24 Qualification Panel QRX701 (2400-0158) are manufactured from human serum or plasma that is negative for HBsAg and antibodies to HCV. Anti-HIV positive material was treated with beta-propiolactone and ultraviolet irradiation. The antigen positive member was formulated using HIV 8E5. The 8E5 virus contains an intact but defective viral genome[1]. The potential for transmission of infectious agents exists, and these materials should be handled following good laboratory safety practice[2]. 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 HIV reactivity of QRX701 (2400-0158). 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 AccuTrak HIV 1/2/O/p24 Qualification Panel QRX701 (2400-0158) is formulated to produce the reactivity in Table 1.

Table 1

Panel Member ID	Reactivity
2400-0158-01	Anti-HIV-1 Low Reactive
2400-0158-02	Nonreactive
2400-0158-03	Anti-HIV-2 Low Reactive
2400-0158-04	Anti-HIV-1 group O Low Reactive
2400-0158-05	HIV p24 antigen Low Reactive
2400-0158-06	Anti-HIV-1 Mid-High Reactive

LIMITATIONS

QRX701 (2400-0158) is offered for research use only. Not for use in diagnostic procedures.

REFERENCES

1. Folks TM, Benn S, Rabson A, Theodore T, Higgan MD, Martin M, Lightfoote M, Sell K. Characterization of a continuous T-cell line susceptible to cytopathic effects of the acquired immunodeficiency syndrome associated retrovirus. Proc. Natl. Acad. Sci. 82: 4539-4543, 1985.

2. 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 SeraCare 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 info@seracare.com or by phone at 508.244.6400