

Anti-HTLV I/II AccuTrak™

Qualification Panel

QRP713 (2400-0181)

INTENDED USE

The Anti-HTLV I/II AccuTrak™ Qualification Panel, QRP713 (2400-0181) is a six member panel of samples with established reactivity in anti-HTLV I/II (Human T-Lymphotropic Virus Types I and/or II) assays. It is intended for use by clinical laboratories, diagnostic manufacturers, and researchers to develop, evaluate, or troubleshoot anti-HTLV I/II serological test methods. The panel may be used for assay validation, method comparison, verifying lot changes, internal proficiency testing, operator training, or whenever there are indications of possible assay deterioration. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The Anti-HTLV I/II AccuTrak Qualification Panel consists of six members manufactured from human serum or plasma, with a range of reactivity in anti-HTLV I/II assays. Three panel members were formulated with various reactivities for anti-HTLV I, two panel members were formulated with various reactivities for anti-HTLV II, and one nonreactive member was formulated from anti-HTLV I/II negative pools. Panel members were filtered through a 0.2 micron filter and ProClin® (0.1%) was added as a preservative.

Item No. QRP713 1 vial per member
2400-0181 6 members, 1.5 mL per vial

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 turbid should be discarded.

INSTRUCTIONS FOR USE

Each panel member should be tested following the same procedure used for unknown samples according to test manufacturer's instructions. Allow the panel to reach room temperature and mix by gentle inversion before using.

INTERPRETATION OF RESULTS

The Anti-HTLV I/II AccuTrak Qualification Panel has been formulated to produce the following reactivity:

Table 1

Panel Member ID	Anti-HTLV I/II Reactivity
QRP713-01	HTLV I Reactive
QRP713-02	Nonreactive
QRP713-03	HTLV I Reactive
QRP713-04	HTLV II Reactive
QRP713-05	HTLV I Reactive
QRP713-06	HTLV II Reactive

LIMITATIONS

The Anti-HTLV I/II AccuTrak Qualification Panel is provided for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly. Specific levels of reactivity will vary among different laboratories and test methods.

PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Use the CDC recommended Universal Precautions for handling this product¹. 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.

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 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