

PACKAGE INSERT

INTENDED USE

The HIV 1/2/O/p24 Qualification Panel QRX701 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 antibodies to HIV-1, HIV-2 and HIV-1 group O, and HIV p24 antigen. The panel may also be used as part of ongoing programs of lot acceptance and internal proficiency testing for these assays, to isolate system errors and in troubleshooting, as a component of a quality assurance program. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

QRX701 consists of six members manufactured from human serum or plasma with a range of reactivity for antibodies to HIV-1, HIV-2 and HIV-1 group O and for HIV p24 antigen. Panel members were formulated with various reactivities: two for anti-HIV-1, one for anti-HIV-2, one for anti-HIV-1 group O, one for HIV p24 antigen and one nonreactive. Panel members were filtered through a 0.2 micron filter. Proclin® (0.1%) was added as a preservative.

Cat. No. QRX701-3.5 1 vial per member
6 members, 3.5 mL per vial

PRECAUTIONS

Members of the HIV 1/2/O/p24 Qualification Panel QRX701 are manufactured from human serum or plasma that is negative for HBsAg and antibodies to HCV. Anti-HIV positive members were 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. 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.

This package insert (PI) in PDF form can be found at www.seracarepanels.com

A printed PI may be requested by email at info@seracare.com or by phone at 508.244.6400

INTERPRETATION OF RESULTS

Table 1 describes the anti-HIV-1, anti-HIV-2 and anti-HIV-1 group O reactivity, and HIV p24 antigen reactivity of QRX701.

Specific levels of reactivity (absorbance readings, 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 HIV 1/2/O/p24 Qualification Panel QRX701 is formulated to produce the following reactivity:

Table 1

Panel Member ID	Reactivity
QRX701-01	Anti-HIV-1 Low Reactive
QRX701-02	Nonreactive
QRX701-03	Anti-HIV-2 Low Reactive
QRX701-04	Anti-HIV-1 group O Low Reactive
QRX701-05	HIV p24 antigen Low Reactive
QRX701-06	Anti-HIV-1 Mid-High Reactive

LIMITATIONS

QRX701 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.

For assistance, contact SeraCare Technical Support at 508.244.6400.

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