CMV DNA AccuTrak™ Qualification Panel 2400-0201



INTENDED USE

The CMV DNA AccuTrak™ Qualification Panel (2400-0201) is a nine member panel with established reactivity in CMV (Cytomegalovirus) DNA assays. It is intended for use by clinical laboratories, diagnostic manufacturers, and researchers to develop, evaluate, or troubleshoot CMV DNA 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 performance issues. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The CMV DNA AccuTrak Qualification Panel consists of nine members: seven positive members with varying concentrations of CMV DNA, one negative member prepared from the diluent, and one vial of diluent to perform additional dilutions as desired. The positive members were manufactured by diluting cultured CMV in CMV DNA negative diluent. The diluent was prepared from normal human plasma that was filtered through a 0.2 micron filter. Each member contains a preservative (0.09% sodium azide).

Item No. 2400-0201 1 vial per member

9 members, 2.0 mL per vial

STORAGE

Panel members should be stored at -70°C or colder. Once thawed and opened, vials should not be reused. 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 instructions. Thaw the panel at room temperature and mix by gentle inversion before using.

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INTERPRETATION OF RESULTS

The Data Sheet for the CMV DNA AccuTrak Qualification Panel is available at www.seracare.com. The Data Sheet contains information regarding specific test methods. Specific levels of reactivity will vary among different laboratories and test methods.

LIMITATIONS

The CMV DNA AccuTrak Qualification Panel is offered 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.

PRECAUTIONS

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

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