

HCV RNA Genotype AccuTrak™

Qualification Panel

2400-0182

INTENDED USE

The HCV RNA Genotype AccuTrak™ Qualification Panel (2400-0182) is a panel of nine members with established reactivity in Hepatitis C (HCV) Genotype assays. This panel may be used by clinical laboratories, diagnostic manufacturers, and researchers to develop, evaluate, or troubleshoot HCV genotype assays for the detection of HCV genotypes one through six. It may also be used for assay validation, verifying lot changes, internal proficiency testing, or as a component of an ongoing quality assurance program. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The HCV RNA Genotype AccuTrak Qualification Panel consists of nine members, eight positive and one negative for HCV RNA, manufactured from human plasma. The positive members were formulated by diluting HCV RNA positive plasma samples from eight different HCV genotypes into HCV RNA negative pooled plasma. The negative member was formulated from an HCV RNA negative pool. Sodium Azide (0.09%) was added as a preservative.

Item No. 2400-0182 1 vial per member
 9 members, 1.2 mL per vial

STORAGE

Panel members should be stored at -70°C or colder. Once thawed and opened vials should not be reused. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

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.

INTERPRETATION OF RESULTS

The Data Sheet for the HCV RNA AccuTrak Qualification Panel is available at www.seracare.com. The Data Sheet contains information regarding specific test methods. Table 1 lists the expected HCV genotype and RNA target concentration for each panel member. Specific levels of reactivity will vary among different laboratories and test methods. The HCV RNA Genotype AccuTrak Qualification Panel is formulated to produce the reactivity in Table 1.

Table 1

Panel Member ID	Expected Genotype	Target Concentration
2400-0183	1a	3×10^3 to 1.75×10^5 IU/mL
2400-0184	1b	3×10^3 to 1.75×10^5 IU/mL
2400-0185	2a	3×10^3 to 1.75×10^5 IU/mL
2400-0186	2b	3×10^3 to 1.75×10^5 IU/mL
2400-0187	3	3×10^3 to 1.75×10^5 IU/mL
2400-0188	4	3×10^3 to 1.75×10^5 IU/mL
2400-0189	5	3×10^3 to 1.75×10^5 IU/mL
2400-0190	6	3×10^3 to 1.75×10^5 IU/mL
2400-0191	Negative	Negative

LIMITATIONS

The HCV RNA Genotype AccuTrak Qualification Panel is offered for research use only. Not for use in diagnostic procedures.

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