

AccuTrak™ Dengue Synthetic RNA Qualification Panel

2400-0220

INTENDED USE

The AccuTrak™ Dengue Synthetic RNA Qualification Panel 2400-0220 is intended to be used by diagnostic manufacturers, researchers and clinical laboratories to develop, validate, or troubleshoot quantitative and qualitative dengue nucleic acid detection assays. This panel may also be used as part of a laboratory quality assurance program for lot acceptance testing, internal proficiency testing, and technical personnel training. These materials are intended as whole process controls and will go through specimen extraction. For research use only and is not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The product is a 4-member panel of dengue synthetic RNA assembled as a set representing Dengue Serotypes 1,2,3 and 4. A 1 mL vial of each serotype is provided in the panel. Each member is prepared from RNA transcripts representing the entire genomic RNA for each serotype. The product is formulated in a proprietary matrix and contains no substances which at their given concentration are considered to be hazardous to health or the environment as per GHS Classification, in accordance with 29 CFR 1910 (OSHA HCS) Regulation (EC) No 1272/2008.

Material Number: 2400-0220, 1 vial per member
4 members, 1.0 mL per vial

STORAGE

Panel members should be stored frozen at -70°C or colder. Do not use this product beyond the expiration date. Avoid contamination when opening and closing the vial. Limit the number of freeze-thaws this product is exposed to by creating single-use aliquots in low nucleic acid binding tubes, if necessary. This product does not have an open vial stability claim.

INTERPRETATION OF RESULTS

Table 1 lists the target reactivity of the AccuTrak Dengue Synthetic RNA Qualification Panel 2400-0220 members. Specific levels of reactivity levels will vary among different laboratories and test methods. Procedures for lot acceptance, training and troubleshooting must be established by each laboratory.

LIMITATIONS

AccuTrak Dengue Synthetic RNA Qualification Panel 2400-0220 is offered for research use only. Not for use in diagnostic procedures.

PRECAUTIONS

Follow Universal precautions¹.
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.

EXPECTED RESULTS

Table 1 lists target concentrations for each member of the AccuTrak Dengue Synthetic RNA Qualification Panel.

Table 1:

| Panel Member | Dengue Serotype | Target cp/mL * |
|--------------|-----------------------------------|----------------|
| 1 | DENV-1 strain Hawaii (1944) | 50,000 |
| 2 | DENV-2 strain New Guinea C (1944) | 50,000 |
| 3 | DENV-3 strain H87 (1956) | 50,000 |
| 4 | DENV-4 strain H241 (1956) | 50,000 |

*Formulated based on digital PCR quantitation

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.