

AccuPlex™ HCV Genotype 5

About this package insert

Thank you for your interest in this AccuPlex™ product. This package insert consists of two pages.

The first page contains the product name, the SeraCare logo, and contact information.

The second page contains the complete package insert text. If the package insert you view or print does not contain two pages, or if you experience any problems, please email us at info@seracare.com, or call us at +1.508.244.6400.

A printed package insert will be sent to you upon request.



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NAME AND INTENDED USE

AccuPlex™ HCV Genotype 5 reference material 0505-0059 is formulated for use with test methods that can detect hepatitis C genotype 5. AccuPlex virus products are non-replicative recombinant viruses that are intended to assess the performance of the full process of a molecular test. AccuPlex can be used to evaluate test proficiency and accuracy through the full process because they are encapsulated viruses which require extraction and amplification. *For Research Use Only. Not for use in diagnostic procedures.*

PRODUCT DESCRIPTION

This product is a recombinant Sindbis virus that contains sequences encompassing the entire hepatitis C genotype 5 viral genome. The sequences contained in this product are based on the Genbank accession number NC_009826. The recombinant viruses used to produce the AccuPlex HCV Genotype 5 reference material are replication defective and heat-treated. However, handle AccuPlex products and all human blood products as though they can transmit infectious agents.

Material Number: 0505-0059, 1 x 1.0mL vial

STORAGE INSTRUCTIONS

This product should be stored frozen at -70 °C or colder. SeraCare recommends that the product be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

INTERPRETATION OF RESULTS

Levels of reactivity for the AccuPlex HCV Genotype 5 reference material may vary with different types of tests and different test kit lots. This product contains a targeted formulation of 5.0E+07 copies/mL which is above the established range of most HCV molecular assays and thus a dilution is required to establish quantitation.

LIMITATIONS OF THE PROCEDURE

AccuPlex HCV Genotype 5 reference materials must not be substituted for the control reagents provided with manufactured test kits. Test procedures and interpretation of results provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. AccuPlex materials are not calibrators and should not be used for assay calibration. Performance characteristics for AccuPlex HCV Genotype 5 reference material have been established only for amplified nucleic acid tests for RNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

WARNINGS AND PRECAUTIONS

Use Centers for Disease Control (CDC) recommended universal precautions for handling AccuPlex HCV Genotype 5 and human specimens¹. Do not pipette by mouth; do not smoke, eat or drink in areas where specimens are being handled. Clean any spillage by immediately wiping with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

EXPECTED RESULTS

Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers and different laboratories. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory. Each laboratory should establish its own range of acceptable values.

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 Technical Support at +1 508.244.6400.