

AccuPlex™ Monkeypox

Positive Reference Material Kit

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 LGC 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 CDx-Info@LGCGroup.com, or call us at +1.508.244.6400.

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



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AccuPlex™ Monkeypox Positive Reference Material Kit

NAME AND INTENDED USE

AccuPlex™ Monkeypox Positive Reference Material Kit is formulated for use with test methods that can detect Monkeypox virus, the causative agent of Monkeypox disease. The reference materials are designed to support Monkeypox test verification at installation and can also be utilized for long-term performance monitoring. 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 contains recombinant Adenovirus. There are 5 vials of positive controls that contain recombinant virus particles with sequences comprising J2R (G2R_G), F8L (E9L-NVAR), F3L (MPXV_F3L) and N3R of the virus genome. The sequences are based on the Genbank accession number ON585038.1 USA.

The recombinant viruses used to produce the AccuPlex Monkeypox reference material are replication defective and heat-treated. However, handle AccuPlex products and all human blood products as though they can transmit infectious agents.

The product is formulated in viral transport media that consists of Tris-buffered saline, with added glycerol, anti-microbial agents and human proteins. **This material must go through extraction, similar to the patient sample.**

Item No.: 0505-0347
Positive: 5 x 1.5 mL vials

WARNINGS AND SAFETY PRECAUTIONS

For Research Use only. Not for use in diagnostic procedures.

Use Centers for Disease Control (CDC) recommended universal precautions for handling AccuPlex Monkeypox reference material 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.

STORAGE INSTRUCTIONS

This product should be stored at 2-8 °C during regular use. It may also be initially stored at -20 °C, but subsequently maintain thawed material at 2-8 °C. Do not expose to multiple freeze thaw cycles. Each vial can be used multiple times up until the date of expiry.

INSTRUCTIONS FOR USE

Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous suspension. AccuPlex reference materials should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. AccuPlex Monkeypox reference material must go through an extraction process prior to detection. Process the product according to the instructions for unknown samples provided by the test kit or the laboratory's standard operating procedures. AccuPlex reference materials must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

INTERPRETATION OF RESULTS

Levels of reactivity for the AccuPlex reference material may vary with different types of tests and different test kit lots. This product contains targeted formulations of 5,000 copies/mL for positive members as measured using reverse transcription digital PCR. Each positive member is also confirmed positive on a Monkeypox PCR test. Note that the positive reference material may contain traces of RNase P and therefore generate a positive RNase P result due to the presence of a human plasma component in the product matrix; it is not designed or intended to be used as an RNase P reference material.

LIMITATIONS OF THE PROCEDURE

AccuPlex Monkeypox reference material 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 Monkeypox reference material have been established only for amplified nucleic acid and sequencing tests for RNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

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.

Table 1. This product is tested at release using the following assays. Results are for information only, not assigned values.

Assay Manufacturer/Test Name	Product Component	Result
Laboratory Developed Test using PCR Primers and Probes using US CDC acceptance criterion	AccuPlex™ Monkeypox Positive Molecular Reference Material Kit	Positive (5,000 copies/mL)

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400.