

SARS-CoV-2 External Control Kit (ATCC® MP-32™)

Product description

A ready-to-use external control kit comprising six vials of a positive control and six vials of a negative control. The positive control is composed of a single-use preparation of heat-killed SARS-CoV-2 strain 2019-nCoV/USA-WA1/2020 provided at 20,000 copies/mL. The virus particles have been modified via heat inactivation to render them non-infectious. The negative control is composed of single-use WI-38 cells provided at 70,000 cells/mL.

Positive Control (heat-inactivated SARS-CoV-2): 6 x 1.0 mL; 20,000 copies/mL

Negative Control (WI-38 cells): 6 x 1.0 mL; 70,000 cells/mL

Intended use

The SARS-CoV-2 External Control Kit is intended for use as external positive and negative quality run controls in evaluating the performance of in vitro laboratory nucleic acid testing procedures designed to detect the presence of SARS-CoV-2 RNA. This product enables laboratories to determine limit-of-detection variances, variability within lot-to-lot performances, operator variation, and the identification of systemic errors within the nucleic acid testing protocol design.

Warnings and precautions

- This product is intended for in vitro analytical testing.
- This product contains inactivated microorganisms and materials of human and animal origin. The inactivation was verified using a standard microbiological growth protocol. Safe practices suggest that the controls be considered potentially infectious and to use universal precautions when handling.
- Product may be handled under biosafety level (BSL) 1 conditions. ATCC determines the BSL of material based on our risk assessment as guided by the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL), U.S. Department of Health and Human Services Publication No. (CDC) 21-1112. It is the user's responsibility to understand the hazards associated with the product per user's organization's policies and procedures as well as any other applicable regulations as enforced by your local or national agencies
- This product is not intended to replace manufacturer controls provided for a device.
- Quality control materials should be used in accordance with local and national regulations and accreditation requirements.
- Fetal bovine serum used in the manufacture of this product meets applicable U.S. Department of Agriculture (USDA) requirements for abattoir sourced animals, traceability, and country of origin. The serum was collected at USDA-licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante- and post-mortem at the abattoir as required by the USDA.
- This product is for single-use only.

Recommended storage conditions

- SARS-CoV-2 External Control Kit test materials must be stored frozen (-20°C or colder).

Instructions for use

- 1 Remove frozen vials of the MP-32™ positive control and/or negative control from -20°C storage (according to the number of tests to be performed) and place them in a tube rack at room temperature. Store the remaining vials at -20°C or colder.
- 2 Allow the vials to come completely to room temperature (18°–25°C); this will take approximately 30-60 minutes.
- 3 Immediately before use, mix the vials thoroughly by rapidly inverting the vials five (5) times. Tap the vial several times on the bench or briefly centrifuge to remove any liquid caught in the cap before opening.
- 4 Process according to manufacturer's instructions for nucleic acid testing procedures.
- 5 Discard after use.

Limitations

- FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.
- This product is not intended to replace the manufacturer's controls provided with the assay.


Expected Values


- End user must independently evaluate the product to establish acceptance criteria for demonstrating acceptable assay performance.
- Expected results are listed in Table 1.


Table 1

Assay target	MP-32™ Positive Control	MP-32™ Negative Control
SARS-COV-2 N	POS	NEG

For assistance, contact ATCC customer support at tech@atcc.org or your local distributor

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