

POCT Respiratory Virus EQA

INTENDED USE

Weqas POCT Respiratory Virus EQA samples are for in vitro diagnostic use as External Quality Assessment material for testing of SARS-CoV-2 Ag, Influenza A, Influenza B and RSV on devices that use Nucleic Acid Amplification Testing methods.

SUMMARY

External Quality Assessment (EQA), or proficiency Testing (PT) is an essential part of providing quality laboratory diagnostic services, and participation in EQA is required for laboratory accreditation to ISO 15189 and ISO 17025. EQA is the inter laboratory comparison and performance evaluation that extends throughout all phases of the healthcare diagnostic testing cycle.

PRODUCT DESCRIPTION

The base material is a phosphate buffered solution spiked with inactivated SARS-CoV-2, inactivated Influenza A/B & RSV. The material is dispensed into 1mL aliquots and stored at -20°C until dispatch, and will thaw in transit.

STORAGE AND STABILITY

The samples should be assayed on the day you receive them. If you are unable to assay the samples immediately upon receipt, please store at 2-8°C. Samples stored at 2-8°C prior to analysis must be brought to ambient temperature (18-30°C) and assayed within 30 minutes.

Samples are stable for 14 days at 2-8°C.

STORAGE AND PROCEDURE FOR BATCHED SAMPLES

The samples should be stored at -20°C on receipt. At the start of the return window for each distribution thaw the relevant samples at ambient temperature (18-30°C) and assay as described in PROCEDURE.

PROCEDURE

Please ensure sample is mixed thoroughly.

1. Mix the sample well by inverting 10 times – ensure there are no air bubbles in the sample.
2. Wear gloves and handle the sample as if it were a normal patient sample.
3. Carefully remove the lid from the sample.

For Cobas Liat Users:

- Transfer EQA sample to instrument using pipette provided in the test kit and follow manufacturer's instructions.

For Abbott ID NOW users:

SARS-CoV-2 Ag

- Select 'SWAB' sample.
- Dip the swab in the EQA sample and swirl for at least 5 seconds to absorb as much sample as possible.
- Add the swab to the sample receiver and follow instrument instructions.

Influenza A/B/RSV

- Transfer EQA sample to instrument using pipette provided in test kit.
- Please follow the test procedure in the 'Instructions for use' leaflet in the kit, supplied by the manufacturer (following procedure for 'sample eluted in transport media' for ID-NOW users).

LIMITATIONS OF PROCEDURE

The *POCT Respiratory Virus* EQA samples should be analysed according to the instructions within this document. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.

The *POCT Respiratory Virus* EQA samples supplied require storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents and the use of correct procedures.

ANALYTES COVERED

The Weqas *POCT Respiratory Virus* EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte
SARS-CoV-2 Ag
Influenza A
Influenza B
RSV

! CAUTION !

1. For in vitro diagnostic use only.
2. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens.