



POCT Lipid EQA

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INTENDED USE

Wegas *POCT Lipid EQA* samples are for in-vitro diagnostic use as an external quality assessment material for testing of Lipid.

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

0.5mL volume supplied in sterile plastic tubes. The material has been prepared from human serum, with an antibiotic added to prolong stability. The serum is dispensed and stored at -70°C until dispatch.

STORAGE AND STABILITY

Unopened samples are stable for two (2) weeks in a refrigerator at 2-8°C.

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 until analysis. Samples stored at 2-8°C prior to analysis must be brought to ambient temperature (18-30°C) and assayed within 60 minutes.

PROCEDURE

The samples should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used.

- 1. Mix the sample well by gently inverting 5 to 6 times then gently swirling the vial for 5 to 10 seconds ensure there are no air bubbles in the sample.
- 2. Wear gloves and handle the sample as a normal patient sample.
- 3. Carefully remove the lid from the sample.
- 4. Follow the manufacturers' instructions on dosing the strip/cartridge.
- Cobas b101 users: Use the pastette provided to load sample onto disc. Squeeze the bulb of the pastette and release slowly to draw up sample. Ensure there are no air bubbles in sample. Squeeze bulb of pastette to release sample onto disc.
- 6. Record the results according to your organisational nolicy
- 7. Safely dispose of excess sample in accordance with local waste policy guidelines.
- The ward/operational site trainer should ensure that as many authorised users as possible participate in the scheme.

Always wear gloves to avoid contamination.

STORAGE AND PROCEDURE FOR BATCHED SAMPLES

The samples should be stored at -70°C on receipt. At the start of the return window for each distribution thaw the relevant samples at room temperature for 24 hours and assay as described in PROCEDURE.

LIMITATIONS OF PROCEDURE

The *POCT Lipid 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 Lipid EQA* requires 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 Lipid EQA* samples cover a relevant pathological and analytical range for the analytes listed below.

Analyte
Cholesterol
Triglycerides
HDL
Glucose

! CAUTION !

Human source material. Treat as potentially infectious.

Each unit of whole blood used in the manufacture of this product has been tested and found to be non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag.

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.