



POCT Glucose & Ketone

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INTENDED USE

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

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 sterile animal serum, with added dyes, and an antibiotic added to maintain sterility. The serum is dispensed and stored at 2-8°C until dispatch.

STORAGE AND STABILITY

At $2-8^{\circ}\text{C}$ the samples are stable for 6 weeks in the unopened container.

At ambient temperature (18-30°C) the samples are stable for 4 weeks in the unopened container.

At -20° C the samples are stable for 1 year in the unopened container.

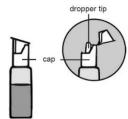
Once opened, the EQA samples are stable for 1 day at 2-8°C.

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) prior to use.

PROCEDURE

Each POCT Co-ordinator will receive multiple samples for each POCT site / operator. 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.
- Hold the sample with cap facing up and flick the cap firmly several times to make sure that no liquid remains inside the dropper tip.
- 3. Open the flip cap by lifting the cap.



- 4. Gently squeeze the bottle to form a small drop onto a non-absorbent surface e.g. back of a gloved hand.
- 5. Inoculate the strip as per manufacturer's instructions.
- 6. Record the results according to your organisational policy.
- After each use, be sure to wipe the dropper tip and inside of cap to keep them clean. Recap the dropper bottle tightly.
- 8. 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.

LIMITATIONS OF PROCEDURE

The *POCT Glucose* and *Ketone 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 Glucose* and *Ketone 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 Glucose* and *Ketone EQA* samples cover a relevant pathological and analytical range for the analytes below:

Analyte	
Glucose	
Ketone	

! CAUTION!

Animal source material.

The base material is sterile animal serum from certified healthy donor animals.

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.