

External Quality Assessment (EQA)

Hematology – Monthly Program

Ref 444 Pack Size 12 x 2 ml

Instructions for Use

The usual precautions in the laboratory for potential hazardous samples apply for these samples. The blood donations used for production were tested to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV.

Intended Use

The NHS-NEQAS Hematology (Monthly) Program is specifically designed to offer an independent and confidential assessment of individual laboratory performance. It also facilitates a comparative analysis of the methods employed by various participating laboratories

Product Description

This product contains human erythrocytes, leukocytes, platelets and preservatives suspended in EQA Sample.

Storage and Stability

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once opened and stored tightly capped at 2 to 8°C, this product will be stable for 48 hours.

Exception:

- Protect tubes from OVERHEATING and FREEZING.
- This product is shipped under refrigerated conditions.

Detailed testing instructions:

Before testing, it's essential to open the vial carefully by removing the cap. The EQA Sample should be treated the same as patient specimen and run in accordance with the instructions accompanying the instrument, kit and reagent being used.

Gloves should be put on before opening the container and should be kept on throughout the period specimens are handled. Replace gloves if contaminated, or if their ability to function as a barrier is compromised.

Ensure that the specimens reach room temperature before testing. Gently invert the vials 4-5 times to ensure homogeneity, without the use of a mechanical mixer. Roll the tube back and forth for 30 seconds (without shaking) until the red cells are completely suspended.

Transfer the specimen to a sample cup by inverting the vial. After sampling, promptly replace the cap and return the specimen vials to the refrigerator within 30 minutes of use. It's vital to guarantee minimal exposure to room temperature.

Limitations

- 1) This product should not be used past the expiration date.
- 2) This product is not intended for use as a standard.
- 3) After mixing, the sample should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish. This is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. Do not use the sample if deterioration is suspected.
- 4) The performance of this product is assured only if it is properly stored and used as described in the insert.
- 5) Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

Reporting Information

The program entails a monthly presentation of results obtained for each analyte from the analysis of samples with unknown concentrations. While entering the results, please select the appropriate instrument, method, and reagent from the drop-down menu. If any of them is not listed, contact us, and we will guide you. Ensure the accuracy of all reporting codes by reviewing the online result form; results cannot be changed once submitted.

Timing of Assays

Each sample result online submission date is updated in the calendar on the nhs-neqas.com website. There are twelve samples to be assayed over a twelve-month period, with one sample every month.

Deadline for Data Submission

Please check nhs-neqas.com website for further information regarding the date of result submission.

Reports and Certificates:

The data will be evaluated by NHS-NEQAS, and individual laboratory reports can be retrieved online via our website. The report of every round will be available within two days after deadline of result submission.

Confidentiality:

We highly value participant confidentiality. Each laboratory is uniquely identified by a code known only to NHS-NEQAS and the participant. Results from sample analysis should not be disclosed to colleagues from other laboratories before the testing period concludes.



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The samples are intended for use as quantitative control material for External Quality Assessment (EQA) in medical laboratories for the following analytes:

- Haematocrit (HCT)
- Mean Cell Haemoglobin Concentration (MCHC)
- Platelets (PLT)
- Plateletcrit (PCT)

- Haemoglobin (Hb)
- Mean Cell Volume (MCV)
- Red Blood Cell Count (RBC)
- Total White Blood Cell Count (WBC)
- Mean Cell Haemoglobin (MCH)
- Mean Platelet Volume (MPV)
- Red Blood Cell Distribution Width (RDW)

Warning <u>1</u>

This product contains biological source material and should be treated as potentially infectious. Each human donor unit used in its manufacturing has been rigorously tested for evidence of infection due to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV), with non-reactive or negative results. However, it may contain other human source materials for which there are no approved tests. Therefore, it should be handled with the same precautions used with patient specimens, following good laboratory practice.



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Reference No: NHS/QC/Clinical/IFU/444

Handle as Biohazard Material

