NHS NEQAS
*Excellence in Quality*

# External Quality Assessment (EQA)

## Coagulation – Monthly Program

| | | | | |
|---|---|---|---|---|
| Ref | 641a-CO | 6 Analytes ~ | Pack Size | 12 x 2 ml |
| | 641b-CO | 17 Analytes | | 12 x 2 ml |

**Intended Use**

The NHS-NEQAS Coagulation (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 labs.

**Instructions for Use**

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

**Product Description**

This product is prepared from human source material with added constituents and preservatives. This product is a pooled, citrated human plasma with added stabilizers and preservative.

**Storage and Stability**

This product will be stable until the expiration date when stored unopened at 2 to 8°C.

After opening and at 15 to 22 °C the product is stable as follows:

- All Analytes: 8 hours and Protein S (Functional): 4 hours

This product is shipped under ambient conditions.

**Exception:**

- If there is evidence of microbial contamination or turbidity in the product, discard the vial.

**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. Invert several times to ensure homogeneity.

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.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

**Limitations**

1) Reconstituted material should be discarded after use. Sample should not be frozen.
2) This product should not be used past the expiration date.
3) This product is not intended for use as a standard.
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5) Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.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 is 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 each 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:

- APTT ~
- PT (Including INR) ~
- TT ~
- Fibrinogen ~
- Antithrombin III ~
- D-dimer ~
- Factor II
- Factor V
- Factor VII
- Factor VIII
- Factor IX
- Factor X
- Factor XI
- Factor XII
- Plasminogen
- Protein C
- Protein S

**Warning** ⚠

This product contains biological source material and should be treated as potentially infectious. Each human donor unit used in the manufacturing of this product 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. Human source materials reactive for viral hepatitis markers and antibodies to retroviruses used to produce this product have been treated to inactivate infectious agents. However, it may contain other human source materials for which there are no approved tests. Therefore, it should be handled with the same precautionsused with patient specimens, following good laboratory practice. It is recommended that this product and all human specimens be handled in accordance with Biosafety Level 2 practices.

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Reference No: NHS/QC/Clinical/IFU/641-V1

Handle as Biohazard Material