SEROQAS® External Quality Control

BIOCHEMISTRY

IVD CE

REF 100 CC12 12 x 3 mL 2C°  8C°  EXP 2018-12-31 LOT 10018XX

www.serocon.com www.kayentrading.ae

INTENDED USE

SEROQAS Biochemistry External Quality Program is designed to provide an independent and confidential external assessment of individual laboratory performance together with a simultaneous comparison of the methods currently in use in those laboratories.

SUMMARY OF REPORTS

The basis of the Program is in certain periods presentation of the results obtained for each analyte by the analysis of a sample with unknown concentrations.

For each parameter, the results of all institutions are calculated by the median method. The results of the values that include ± 2SD distances from this center are shown in the distribution graph.

All institutions see their value on the left of the chart.

Values entered by other institutions can be examined without specifying the name of the institution, adhering to the principle of confidentiality.

The median, the lower limit, the upper limit, the value obtained for the institution, the bias and the standard deviation values for each parameter are presented to the user as a table.

For each parameter, Levey-Jenings graphs are given at 3-month intervals.

REAGENT

This product is prepared from human serum, plasma or whole blood with added chemicals, constituents of human origin, therapeutic drugs and stabilizers. This product is provided in lyophilized form for increased stability.

WARNING

Biological source material.

Treat as potentially infectious.

Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material

should be considered potentially infectious and handled with the same precautions used with patient specimens.

PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used. Using a volumetric pipet or equivalent, reconstitute each vial with 3.0 mL of distilled or deionized water. Replace the stopper and allow this product to stand for approximately 15 minutes swirling occasionally.

Before sampling, allow this product to reach room temperature (18 to 25°C). Gently swirl the vial several times to ensure homogeneity. After each use, promptly replace the stopper and return to 2 to 8°C storage.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact sales office or technical services.

STORAGE AND STABILITY

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

Reconstituted and Refrigerated: After reconstituting and storing tightly capped at 2 to 8°C, this product will be stable as follows:

- All analytes: 3 days

Reconstituted and Frozen: When reconstituted and stored tightly capped at -20 to -70°C, this product will be stable as follows:
- All analytes: 90 days
Once thawed, do not refreeze this product. Discard the remaining material. This product is shipped under ambient conditions.

LIMITATIONS

1. This product should not be used past the expiration date.

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

3. This product is not intended for use as a standard.

TIMING OF ASSAYS

There are twelve samples to be assayed during the course of the twelve-month period, one sample every month (four samples each quarter to work on four-month programs). Each sample is labeled with the date by which results should be submitted to SEROCON. The samples are analyzed by the last day of the month according to the program and entered into the system. Entry of results will not be allowed after the closing date of the program.

REPORTING RESULTS

After your username and password are confirmed by SEROCON, you can login to the system. When entering results, each institution will log in using the program for their device and method. Method change can be made through the program. Laboratories that make changes in the application methods may switch to the different methods opened on their behalf. The results will be announced from the second week of the next month.

CONFIDENTIALITY

SEROCON maintains a high respect for participant confidentiality. To protect the identity of a participant, each laboratory is identified by a unique code known only to SEROCON and the participant.