**ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS**
**EXTERNAL QUALITY CONTROL PROGRAM**
**SPECIFIC PROTEINS SPECIFIC TESTS PROGRAM-INSTRUCTIONS**

**Cycle: 1**
**Lot: A2018, SKT: 2019-11 REF: KBUDÖSP**
**Program Code: ÖS**
**Store at +2–8$^0$C**

## Purpose of use
The KBUDEK Specific Protein Specific Tests External Quality Control Program is designed to enable the comparison of the performance of each laboratory participating in this program with other laboratories on a test, method and device basis.

## Privacy
KBUDEK gives great importance to the confidentiality of program participants. Each participant is identified only by a code known to them and KBUDEK. The laboratory code, user code and password are defined for each participant to input and review data on the internet. Users can change their user codes and passwords themselves.

## Tests

**Specific Proteins Specific Tests Program (Free to Specific Proteins participants)**
α-1 acid glycoprotein, α-1 antitrypsin, α-2 macroglobulin, β-2 microglobulin, Ceruloplasmin, Haptoglobin, Ig E, Prealbumin (Transthyretin), Retinol Binding Protein, Transferrin, Free Kappa Light Chain, Total Kappa Light Chain, Free Lambda Light Chain, Total Lambda Light Chain

## Safety Precautions and Warnings
WARNING: Biological source. Potentially infected material.
For external use only. Do not pipette by mouth. The procedures applied for handling laboratory reagents should also be applied for these materials. Samples were prepared by lyophilizing human serum pools. At the donor level, Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg) and Hepatitis C Virus (HCV) antibody were tested and found to be non-reactive. These tests were performed with FDA approved methods. However, since no method can guarantee the absence of infectious agents, this material should be handled and disposed of accordingly, assuming that it is capable of spreading infectious disease.
Product safety data sheets are available on request.

## Sample Preparation
Specific Protein control samples are ready to use.
Samples should be handled in the same way as patient samples. If possible, it should be taken into daily processes without the knowledge of laboratory staff.
Note: It is recommended to run the External Quality Control Samples (as repetition) once.

## Storage Conditions
**Unopened sample:** Store at +2–8°C. Stable to expiration date printed on individual vials.
**Opened sample:** It is stable for 30 days at +2°C to +8°C.
Only volume needed to measure should be removed and analyzed. The remaining sample after use should not be discharged back to original vial.

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## Working times of samples
The box contains 6 samples that are labeled for bimonthly work within a year. Information on which month it should be worked is available on the label. Each sample should be run on the date indicated on the back page of this document.

## Submission of results
The results should be entered to the system at the latest business day of the related month by using the internet code, user code and password that are reported to you via the internet at www.kbudek.com. Before entering your results, be sure to make test identifications and choose the correct test units to report the result.

## Late results
Late results do not affect the mean and standard deviation values that are already calculated and published but those values are used to calculate late results. The report contains information that the results are late. No evaluation shall be made for late results after the cycle is closed.

## Monitoring performance results
Evaluation results are published on the internet in the second week of the following month. Each participant will only be able to see their results by entering with his own laboratory code, user code and password.

## Analyzer or method changes
Any changes related with participant's analyzer, test method or unit should be updated via the website.
For current tests and methods used in the program, please refer to the program instructions published at www.kbudek.com

## Materials provided:
Specific Protein Specific Tests Control samples-6 vials – ready to use - 1 ml

## Materials required but not provided:
Automatic pipette

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Schedule

| Month | Sample Number | Recommended working date | Last date to enter results |
|---|---|---|---|
| February | 1 | 23.02.2018 | 28.02.2018 |
| April | 2 | 20.04.2018 | 30.04.2018 |
| June | 3 | 22.06.2018 | 30.06.2018 |
| August | 4 | 17.08.2018 | 31.08.2018 |
| October | 5 | 26.10.2018 | 31.10.2018 |
| December | 6 | 21.12.2018 | 31.12.2018 |

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Tests and Methods in the program

| TEST ADI | KULLANILAN YÖNTEMLER |
|---|---|
| **α-1 acid glycoprotein, α-1 antitrypsin, α-2 macroglobulin, β-2 microglobulin, , Haptoglobin, Prealbumin (Transthyretin)** | Nephelometric, end point<br>Nephelometric, fixed time, kinetic<br>Nephelometric, kinetic<br>RID<br>Turbidimetric<br>Other methods |
| **Retinol Binding Protein** | Nephelometric<br>Other methods |
| **Immunoglobulin E (Ig E)<br>Ceruloplasmin<br>Transferrin** | Nephelometric, end point<br>Nephelometric, fixed time, kinetic<br>Nephelometric, kinetic<br>RID<br>Turbidimetric<br>Luminescence (chem/electrochem) Immunoassay<br>Florescence Polarization immunoassay (FPIA)<br>Fluorimetric immunoassay (FIA)<br>Enzymatic immunoassay (EIA)<br>Other methods |
| **Free Kappa Light Chain,<br>Total Kappa Light Chain,<br>Free Lambda Light Chain,<br>Total Lambda Light Chain** | Nephelometric, end point<br>Nephelometric, fixed time, kinetic<br>Nephelometric, kinetic<br>Turbidimetric<br>Other methods |