



ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS
EXTERNAL QUALITY CONTROL PROGRAM

HbA1c PROGRAM - INSTRUCTIONS

Cycle: 9

Lot: Hb2018, SKT: 2020-04, REF: KBUDHBA

Program Code: Hb

Store at +2 – 8°C



Purpose of use

The KBUDEK HbA1c 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.

Test

HbA1c

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

The bottle specified for each month on the label must be dissolved with 0.5 ml of distilled water at +15°C to +25 °C. Wait for at least 15 minutes with lid closed and mix slowly until all is dissolved. Do not create foam. Do not shake. Do not use an injector to dilute! We recommend that you dissolve using an automatic pipette of the same volume.

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: After reconstitution, it is stable for 30 days at +2°C to +8°C (**Do not freeze!**). Only volume needed to measure should be removed and analyzed. The remaining sample after use should not be discharged back to original vial. Stored specimens should be mixed before reuse.

Working times of samples

The box contains 12 (twelve) labeled samples, one for each month, to be studied in a year, respectively. 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. Late results are not included in the End of Cycle Reports.

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.

Device or method changes

Any changes related with participant's device, 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:

HbA1c Control samples -12 vials – lyophilised - 0.5 ml

Materials required but not provided:

Automatic pipette
Distilled water



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Schedule

Month	Sample Number	Recommended working date	Last date to enter results
January	1	25.01.2018	31.01.2018
February	2	22.02.2018	28.02.2018
March	3	22.03.2018	31.03.2018
April	4	19.04.2018	30.04.2018
May	5	24.05.2018	31.05.2018
June	6	21.06.2018	30.06.2018
July	7	26.07.2018	31.07.2018
August	8	16.08.2018	31.08.2018
September	9	20.09.2018	30.09.2018
October	10	25.10.2018	31.10.2018
November	11	22.11.2018	30.11.2018
December	12	20.12.2018	31.12.2018

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Tests and Methods in the program

TEST	Methods
Hemoglobin A1C	HPLC/LPLC Other Methods