

HK23 Biochemistry

Product code 2237 DK

Lot. No. 202307

Purpose

HK23 Biochemistry is an external human quality control material (EQA-material), for long-term quality testing of the laboratory's examination ability of clinical biochemical measurands, in relation to accuracy and precision.

Material

HK23 Biochemistry is a freeze-dried human serum produced by Aalto Scientific, Ltd.

To obtain suitable concentrations of various measurands, the material has been spiked.

Proteins and enzymes are all enriched with humanely purified material, thereby minimizing matrix effects.

Different analysis methods and instruments therefore should be comparable.

The fact that all components are humane, unlike most other commercial EQA materials, is an essential quality parameter.

Measurands

HK23 Biochemistry, component list with indicative concentrations.

Komponent	IUPAC-kode ¹	Vejledende koncentration	Enhed
Alanin transaminase [ALAT] *	NPU19651	97	U/L
Albumin	NPU19673	43	g/L
Alkaline phosphatase *	NPU19655	119	U/L
Alpha-1-antitrypsin	NPU19692	1,66	g/L
Amylase *	NPU53974	65	U/L
Amylase, pancreatic type	NPU19653	32	U/L
Aspartat transaminase [ASAT]	NPU19654	142	U/L
Bilirubin(conjugated)	NPU17194	15	µmol/L
Bilirubins *	NPU01370	22	µmol/L
Calcifediol+25-Hydroxyergocalciferol	NPU10267	46	mmol/L
Calcium *	NPU01443	2,44	mmol/L
Calcium-ion(frit) (pH = 7,40)	NPU04144	1,42	mmol/L
Calcium-ion(frit) (pH aktuel)	NPU01446	1,42	mmol/L
Carbamide *	NPU01459	8,1	mmol/L
Chloride *	NPU01536	118	mmol/L
Cholesterol + ester *	NPU01566	4,8	mmol/L
Cholesterol + ester, i HDL	NPU01567	1,5	mmol/L
Cholesterol + ester, i LDL *	NPU01568	2,8	mmol/L
Chorionic Gonadotropin, hCG	NPU01572	22 - 49 ²	IU/L
Cobalamin *	NPU01700	530	pmol/L
Cortisol *	NPU03247	248	nmol/L

* : Concentrations have been updated based on the participants reported results

¹ The stated IUPAC-codes are suggested, as many measurands have several NPU-numbers

² Depending of the method

Komponent	IUPAC-kode ¹	Vejledende koncentration	Enhed
C-reaktivt protein [CRP]	NPU01423	26	mg/L
Creatininium *	NPU18016	110	µmol/L
Creatin kinase, total [CK] *	NPU19656	201	U/L
Creatin kinase MB [CKMB]	NPU19750	2,60	µg/L
Cystatine C	NPU19748	0,58	mg/L
Estradiol *	NPU01972	0,21	nmol/L
Ferritin *	NPU19763	241	µg/L
Folate	NPU02070	26	nmol/L
Follitropin [FSH] *	NPU04014	7,2	IU/L
Gamma-Glutamyltransferase [GGT] *	DNK05119	155	U/L
Glucose *	NPU02192	6,6	mmol/L
Haptoglobin	NPU19788	1,6	g/L
Homocysteine *	NPU04073	9,0	µmol/L
Hydrogen-ion (pH 37 °C)	NPU03995	7,40	
Immunglobulin A *	NPU19795	2,3	g/L
Immunglobulin E	NPU02482	264	kIU/L
Immunglobulin G *	NPU19814	10,4	g/L
Immunglobulin M *	NPU19825	0,92	g/L
Iron *	NPU02508	20	µmol/L
Lactat dehydrogenase [LD] *	NPU19658	200	U/L
Lutropin [LH] *	NPU02618	6,0	IU/L
Magnesium	NPU02647	0,98	mmol/L
Myoglobin	NPU19865	24	µg/L
Natrium *	NPU03429	144	mmol/L
Orosomucoïd	NPU19873	0,89	g/L
Phosphate *	NPU03096	1,13	mmol/L
Potasium ion *	NPU03230	4,3	mmol/L
Progesterone *	NPU03242	1,9	nmol/L
Prolactin	NPU18014	209	mIU/L
Prostate-specific antigen	NPU08669	0,44	µg/L
Protein *	NPU03278	74	g/L
Testosterone	NPU03543	15,5	nmol/L
Thyroid-peroxidase Ab	NPU20041	60	kIU/L
Thyrotropin [TSH]	NPU03577	2,0	mIU/L
Thyroxine [T4]	NPU03578	109	nmol/L
Thyroxine(free) [T4 free] *	NPU03579	14,0	pmol/L
Transferrin *	NPU26470	3,1	g/L
Triglyceride *	NPU04094	1,44	mmol/L
Triiodthyronine [T3]	NPU03624	1,3	nmol/L
Triiodthyronine(free) [T3 free]	NPU03625	3,50	pmol/L
Urate *	NPU09356	313	µmol/L
Zinc	NPU03768	12	µmol/L

* : Concentrations have been updated based on the participants reported results

Only the above components have been measured.

The material is human freeze-dried serum and as such is expected to contain several additional components than those mentioned in the table.

Safety

The material must be handled with the same precautions as patient samples.

The used donor plasma has individually tested negative for hepatitis B, hepatitis C and HIV.

Volume

HK23 Biochemistry is delivered in boxes of 8 vials. Each vial should be reconstituted with 5 mL water, see the section 'Preparation'.

Storage and Stability

Freeze-dried material:

DEKS store freeze-dried HK23 Biochemistry below -20 °C.

The laboratory should after receipt store the material in a freezer at -20 °C or colder, where the shelf-life is a minimum of 4 years.

The material can, however, be stored in a fridge at 2-8 °C for up to 1 year³.

Reconstituted material

In a fridge at 2-8 °C the stability is 7 days. Some measurands have limited stability in the fridge after reconstitution⁴.

In the freezer below -20 °C the measurands are generally stable for at least a month with a few exceptions. It has previously been observed that aliquoting and freezing in vials can lead to changed values compared to freshly reconstituted material. DEKS assumes that the type and size of the vials affect the stability.

Shipment

HK23 Biochemistry is shipped from DEKS at ambient temperature with ordinary mail.

Preparation

HK23 Biochemistry is moved from freezer to fridge 1-7 days prior to reconstitution, as it is assumed that the fridge temperature allows proteins and enzymes to "re-fold" better into an active conformation.

HK23 Biochemistry is to be reconstituted with cold (2-8 °C) sterile, distilled or demineralized water following this guide:

Reconstitution without weighing:

- Take HK23 Biochemistry out of the fridge.
- Unscrew the cap and add 5,00 mL fresh sterile, distilled or demineralized cold water with a pipette.
- Replace the cap and mix the content of the glass in a turning device for half an hour.

Reconstitution including weighing:

- Take HK23 Biochemistry out of the fridge and dry condensation off the outside.
- Weigh the glass with a 2 decimals precision (a gram).
- Unscrew the cap and add 5 mL fresh sterile, distilled or demineralized cold water.
- Replace the cap and mix the content of the glass in a turning device for half an hour.
- The glass is weighed again after condensation is dried off (b gram).
- Check that b gram, minus a gram lies within the permitted limit $5,00 \pm 0,30$ gram. If not, the test results are multiplied with the factor: $F = (b-a + 0,30) / 5,30$.

³ The glucose concentration is however not consistent when stored in a fridge: it drops with approximate 1 % per year at 2-8°C.

⁴ Alkaline phosphatase, Creatinkinase (CK) and, lactate dehydrogenase (LD) can change activity at storage in fridge after reconstitution. The stability of Folate may be reduced. DEKS recommend reconstitution with cold water (2-8 °C) and use of the material the same day. Here CK will keep its activity and alkaline phosphatase maintains a stable, reproduceable activity. Please note (if the reconstituted material is not used right away) that the alkaline phosphatase will not reach maximum activity until at least two days later.

Use in the Laboratory

HK23 Biochemistry can be used in the laboratory as an external long-term control. By participating in the corresponding external quality assurance program (EQA-program), program code 2011 DK, your results are compared in a monthly report with results from other laboratories who measure HK23 Biochemistry. The EQA-program is an independent evaluation based on the participating laboratories measuring HK23 Biochemistry an adequate number of times per month and report the mean value and the standard deviation. The material can be supplemented with other EQA-materials: HK Special (heart- and cancer markers), HK HbA1c and HK F-Haemoglobin.

HK23 HK Biochemistry can also with advantage be used to document the quality of results from approved series of analysis.

Data Processing

By participating in the EQA-Program 2011 DK, it is possible to report results from HK23 Biochemistry every month and have these processed in a monthly report. DEKS make a monthly report containing histograms and calculations showing your laboratory's results compared to all the other laboratories' mean values and standard deviations. The report also contains an accumulated overview of the results from the past 12 months, both for your laboratory and for all the other laboratories, so your general concentration level can be monitored over time. Even though, only a few laboratories report on a specific measurand, the program makes it possible for you to follow your laboratory's concentration level and imprecision during the approximate 4 years the material is available. In the report consensus values are used for the specific method groups and for all laboratories' reported results.

At www.deks.dk you can find the latest updated package insert and more useful information about HK.

Inquiries

Any questions should be directed to:

- Karin Heidemann, karin.heidemann@deks.dk
- Morten Pedersen, morten.pedersen@deks.dk

Revision history

Version	Year-Month	Ændring
01	2024-02-08	Package Insert created
02	2024-06-01	The components Antitrypsin, Bilirubin(conjugated), Myoglobin and Prolactin added
03	2024-06-20	The components Creatine kinase MB, Orosomuroid, Prostate-specific antigen, Testosterone, Thyroid-peroxidase Ab, thyroxineand Triiodothyronine (free) added.

Concentrations for components marked with * have been updated based on the participants reported results.