

HK19 Biochemistry, Human long-term EQA-serum Control material

Product code 2226 DK

Lot. Nr. 201808

Purpose

HK19 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

HK19 Biochemistry is a freeze-dried human serum produced by Aalto Scientific, Ltd.

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

Measurands

HK19 Biochemistry replaces HK18 Biochemistry. Please contact DEKS if you require further information about measurands and indicative concentrations at the following mail: deks@deks.dk

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

HK19 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 HK19 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 year¹.

Reconstituted material:

In a fridge at 2-8 °C the stability is 7 days. Some measurands have limited stability in the fridge after reconstitution².

In the freezer below -20 °C the measurands are generally stable for at least a month with a few exceptions³.

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

² Ferritin, T3 og Free T3 is only stable for up to 5 days. Bilirubin is only stable for 24 hours. Creatinkinase (CK), alkaline phosphatase, lactate dehydrogenase (LD) and acid phosphatase can change activity at storage in fridge after reconstitution. The stability of cortisol and folate is maybe also 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.

³ It has previously been observed that aliquoting and freezing in vials can lead to changed values compared to freshly reconstituted material.

Shipment

HK19 Biochemistry is shipped from DEKS at ambient temperature with ordinary mail.

Preparation

HK19 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.

HK19 Biochemistry is to be reconstituted with cold (2-8 °C) sterile, distilled or demineralized water following this guide:

Reconstitution without weighing:

- Take HK19 Biochemistry out of the fridge.
- Unscrew the cap and add 5,00 mL fresh sterile, distilled or demineralized cold water with a pipette or syringe.
- Replace the cap and mix the content of the glass in a turning device for half an hour.

Reconstitution including weighing:

- Take HK19 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 5,00 mL fresh sterile, distilled or demineralized cold water with a pipette or syringe.
- 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: $F = (b-a + 0,30) / 5,30$.

HK19 Biochemistry, measurand list with indicative concentrations

Measurand	IUPAC-code ⁴	Indicative concentration	Unit
Active B12	NPU27125	140	pmol/L
Alanine transaminase (ALAT)	NPU19651	99	U/L
Albumin (66 458)	NPU19673	44,2	g/L
Alkaline phosphatase	NPU19655	129	U/L
Amylase	NPU53974	64	U/L
Amylase, pancreatic type	NPU19653	27	U/L
Antitrypsin	NPU19692	1,5	g/L
ApoA1	NPU30480	1,5	g/L
ApoB	NPU19215	0,8	g/L
Aspartate transaminase (ASAT)	NPU19654	145	U/L
Bilirubin	NPU01370	21,20	µmol/L
Bilirubin, Conjugated	NPU17194	7,0	µmol/L
Calcifediol+25-Hydroxyergocalciferol	NPU10267	55	nmol/L
Calcium (II), total	NPU01443	2,41	mmol/L
Calcium ion (free)	NPU01446	1,32	mmol/L
Calcium ion (free) (pH = 7,40)	NPU04144	1,03	mmol/L
Carbamide	NPU01459	7,9	mmol/L
Chloride	NPU01536	109	mmol/L
Cholesterol + ester	NPU01566	4	mmol/L
Cholesterol + ester, HDL	NPU01567	1	mmol/L
Cholesterol + ester, LDL	NPU01568	2	mmol/L
Chorionic Gonadotropin, hCG	NPU01572	50	IU/L
Cobalamin	NPU01700	525	pmol/L
Cortisol	NPU03247	229	nmol/L
C-reactive protein (CRP)	NPU19748	24,7	mg/L

⁴ The stated IUPAC-codes are suggested, as many measurands have several NPU-numbers.

Measurand	IUPAC-code ⁴	Indicative concentration	Unit
Creatine kinase, total	NPU19656	230	U/L
Creatininium	NPU18016	115	µmol/L
Cystatine C	NPU23745	1,19	mg/L
Estradiol	NPU01972	0,97	nmol/L
Ferritin	NPU19763	402,3	µg/L
Folate	NPU02070	16,7	nmol/L
Follitropin (FSH)	NPU04014	5,8	IU/L
Gamma-Glutamyltransferase (GGT)	DNK05119	128	U/L
Glucose	NPU02192	6,63	mmol/L
Haptoglobin (86018)	NPU19788	1,4	g/L
Homocysteine (total)	NPU04073	8,6	µmol/L
Hydrogen ion (pH 37 °C)	NPU03995	7,02	
Immunoglobulin A	NPU19795	2	g/L
Immunoglobulin G	NPU19814	11	g/L
Immunoglobulin G1	NPU19817	7,8	g/L
Immunoglobulin G2	NPU19818	2,8	g/L
Immunoglobulin G3	NPU19819	0,3	g/L
Immunoglobulin G4	NPU19820	0,5	g/L
Immunoglobulin M	NPU19825	1	g/L
Iron	NPU02508	21	µmol/L
Lactate dehydrogenase	NPU19658	165	U/L
Lipoprotein Lipase	DNK05195	-	U/L
Lithium ion	NPU02613	0,87	mmol/L
Lutropin (LH)	NPU02618	5,7	IU/L
Magnesium (II)	NPU02647	1,0	mmol/L
Myoglobin	NPU19865	0,37	µg/L
Orosomucoïd	NPU19873	1,0	g/L
Phosphate	NPU03096	1,3	mmol/L
Potassium ion	NPU03230	4,08	mmol/L
Progesterone	NPU03242	3,88	nmol/L
Prostata specific antigen (PSA)	NPU08669	0,30	µg/L
Sexual-hormone-binding-globulin (SHBG)	NPU03419	43,5	nmol/L
Sodium ion	NPU03429	141	mmol/L
Solute, osmolality	NPU03433	321	µmol/g
SuPAR (Urokinase plasminogen activator surface receptor(soluble))	NPU58996	2,15	ng/mL
Testosterone, total	NPU03543	10	nmol/L
Thyroid peroxidase antibody	NPU20041	38	KIU/L
Thyrotropin (TSH)	NPU03577	1,3	mIU/L
Thyroxine(free), T4 free	NPU03579	12,9	pmol/L
Thyroxine, T4	NPU03578	86	nmol/L
Transferrin	NPU26470	3	g/L
Triacylglycerol lipase	NPU57165	33	U/L
Triglyceride	NPU04094	1	mmol/L
Triiodothyronine(frit), T3 free	NPU03625	2,6	pmol/L
Triiodothyronine, T3	NPU03624	1,1	nmol/L
Urate	NPU09356	300,0	µmol/L
Zinc (II)	NPU03768	19	µmol/L

Use in the Laboratory

HK19 Biochemistry Human long-term control, 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 HK19 Biochemistry. The EQA-program is an independent evaluation based on the participating laboratories measuring HK19 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 H (heart- and

cancer markers), HK Drug (drugs) and HK F-Haemoglobin.

HK19 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 HK19 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 5 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	2018-10	Package Insert created.
02	2019- 01	Adjustment of a few indicative concentrations.
03	2019- 03	Updating the measurand list and the indicative concentrations in relation to the middle values reported to date.
04	2019- 04	Updating the measurand list with indicative concentrations of suPAR (turbidometry)
05	2019- 05	Updating some of the NPU-codes. Added indicative concentrations for GGT and konj. Bilirubin. The sign < > has been changed to writing and a few misspellings has been changed.
06	2020-01	Updating the measurand list with the indicative concentrations of ApoA1, ApoB, Active B12 and SHBG, and linguistic corrections.
07	2020-05	Updating the measurand list with the indicative concentrations of IgG1-4.
08	2020-07	Updating the measurand list with the indicative concentrations of Calcium-ion(free), Calcium-ion(free) (pH = 7,40) and Triacylglycerol lipase. Removed indicative concentration from Lipoprotein Lipase as the values reported were in fact Lipase.
09	2020-11	The unit for Cystatin C was incorrectly stated to $\mu\text{mol} / \text{L}$ and has therefore been changed to mg / L
10	2021-10	HK Calcifediol Human Long-term control removed from the section "Use in the laboratory"