Cystatin C, Creatinine and eGFR, 3345 DK EQA report no. 2, November 2023

DEKS

Rigshospitalet - Glostrup
Valdemar Hansens Vej 1-23
Opgang 8,1.
2600 Glostrup
Denmark
☎ +45 3863 4400
www.deks.dk

Last day of analysis:
2023.10.30

Program coordinators:
Dår Kristian Kur
☎ +45 38634406
daar.kur@deks.dk
Lisbeth Nielsen
☎ +45 38634410
lisbeth.nielsen@deks.dk

Program expert:
Morten Pedersen
Chemist
DEKS
Rigshospitalet - Glostrup

This report contains:
- This letter
- Summary
- Individual results

Approved by MP
2023.11.07

Next reporting periods:
2024.04.22 – 2024.04.29
2024.10.21 – 2024.10.28

DANAK
PT Reg.No. 591
Member of EA MLA

Number of participants

There are 31 laboratories registered for this scheme.
26 laboratories have reported one or more set of results for P-Cystatin C, 20 laboratories for P-Creatinine and 20 laboratories have calculated eGFR in addition to P-Cystatin C.

Sample material

Sample material **Haeb (02_2023)**
A plasma pool from patients with a normal kidney function. Expected levels of P-Cystatin C, P-Creatinine and eGFR, in the normal range. This pool has not been used before.

Sample material **Hacb (03_2023)**
A plasma pool from patients with a reduced kidney function. Expected levels of P-Cystatin C and P-Creatinine in the high range, and eGFR in the lower range. This pool has not been used before.

Target values

The target values for P-Cystatin C and P-Creatinine are the over-all mean values for the respective material.

The target values for eGFR for the different method groups are based on 50-year-old white male (85 kg) and are calculated from the overall mean value of P-Cystatin C and/or P-Creatinine for the respective sample material. The acceptance intervals (±11.4 %) for the different method groups are shown in grey (Table 1):

Table 1. Target value (T) and accept interval (A) for eGFR in mL/min/1.73 m^2, for each sample and the different method groups (CKD-EPI formula variants).

Sample	Method group/formula	T	A
Haeb (03_2023)	2009 CKD-EPI (Crea)	105	(93.2 – 117.2)
Haeb (03_2023)	2012 CKD-EPI (Crea-CysC)	109	(97.0 – 121.9)
Haeb (03_2023)	2012 CKD-EPI (Cys C)	110	(97.7 – 122.9)
Haeb (03_2023)	2021 CKD-EPI (Crea)	109	(96.2 – 121.0)
Hacb (04_2023)	2009 CKD-EPI (Crea)	11	(9.3 – 11.7)
Hacb (04_2023)	2012 CKD-EPI (Crea-CysC)	10	(8.5 – 10.7)
Hacb (04_2023)	2012 CKD-EPI (Cys C)	10	(8.9 – 11.1)
Hacb (04_2023)	2021 CKD-EPI (Crea)	11	(9.9 – 12.5)

Statistics

Mean, SD and CV% are calculated for all results as well as for the method groups. In the graphic part, the acceptance interval is calculated from the overall mean value (M) or reference value (R) (only applicable to pools from patients with a reduced kidney function, produced before 2021), which assumes that the results are normally distributed. For each quantity, it is examined whether the results deviate to an unacceptable degree from the normal distribution, by looking at the difference between the overall mean and the median in relation to the width of the acceptance interval.
For P-Cystatin C the requirement for acceptable normal distribution across method groups is not met for the sample material *Haeb*. This means that we may, on a false basis, place someone outside the acceptance range.

Outliers

Outliers are defined as results that deviate more than 3.6 x SD relative to the target value.
Two outliers are found in this round. The results are not included in the calculations.

Acceptance interval

The acceptance limit for P-Cystatin C is 11.4 %, calculated as total error from biological variation. The intra-individual variation is 8.6 % and the between-individuals variation is 15 % (ref. 1).
The acceptance limit for P-Creatinine of 8.9 % is calculated from biological variation based on the intra-individual variation being 6 % and the between-individuals variation 14.7 % (ref. 2).
The acceptance limit for eGFR is 11.4 % (the same as for P-Cystatin C).

Results and comments

Calculations of mean of all can be seen in the "Summary report for metodegruppe".

P-Cystatin C

There is a good agreement between the mean value of Nephelometry and Turbidimetry method group for the normal sample material *Haeb* (0.771 mg/L vs. 0.78 mg/L). The main bulk of participants' results comes from Turbidimetry. Eight results are outside the acceptance interval for Turbidimetry.
Nephelometry mean value is also in good agreement with Turbidimetry method group for sample material, *Hacb*, from patients with reduced kidney function (4.96 vs. 4.82 mg/L). None of the results are outside the acceptance interval for both method groups.

P-Creatinine

There is generally good agreement between the mean value of Enzymatic and Jaffe method group for both sample material, although the mean value for Jaffe is higher, but not significantly higher than the target value for the normal sample material *Haeb*. For *Haeb*, 3 and 2 results for the respective method group, are outside the acceptance interval.

eGFR

Most of the eGFR results are reported using the *2009 CKD-EPI (Crea)* formula (n=13).
Using the *2009 CKD-EPI (Crea)* formula, 3 and 1 result for the respective sample material are outside the acceptance interval of the target value (Table 1).
For those laboratories using the *2012 CKD-EPI (Crea-CysC)* formula (n=3), 2 and 1 result for the respective sample material are outside the acceptance interval and for those using *2012 CKD-EPI (CysC)* formula (n=5), 2 results are outside for the normal sample material *Haeb*.
Those laboratories should check their performance carefully.

All individual results are seen in the graphic part.
The unit is mL/min/1.73 m^2, though the unit in the graphic part is shortened to mL/min.
If your LIMS system generates an automatic calculation of eGFR, you must control if the variant of the CKD-EPI formula used is the same as the one that

you have reported. If not, the target value and the accept interval can be different.

Scientific method

The Danish scientific societies recommend automatic reporting of eGFR whenever a P-Cystatin C or a P-Creatinine is ordered by the clinicians. This automatic reporting helps to identify asymptomatic kidney dysfunction at an earlier stage.

Interpretation of reports

You will find a guide for reading the graphic report at https://deks.dk/en/products/information-about-the-deks-programs/interpretation-of-reports/

Yours sincerely

Lisbeth Nielsen and Dår Kristian Kur

References

1. Reinhard M, Erlandsen EJ & Randers E. Biological variation of cystatin C and creatinine. Scand J Clin Lab Invest 2009;69(8):831-836.
2. Ricos C. *et al.* Current databases on biologic variation: pros, cons and progress. Scand J Clin Lab Invest 1999;59:491-500.

Component	Mean	Sd	CV	sem	N	Outliers
P-Creatininium; stofk. Sample 'Hacb'						
Alle	509	12,07	2,37	2,57	22	0
Enzymatic	510	11,33	2,22	2,67	18	0
Jaffe reaction	508	16,96	3,34	8,48	4	0
P-Creatininium; stofk. Sample 'Haeb'						
Alle	69	5,36	7,76	1,142	22	0
Enzymatic	67,8	5,1	7,53	1,203	18	0
Jaffe reaction	74,6	1,863	2,5	0,931	4	0
P-Cystatin C; massek. Sample 'Hacb'						
Alle	4,83	0,214	4,44	0,0413	27	1
Nephelometry immunoassay	4,96	0,477	9,62	0,338	2	1
Turbidimetry	4,82	0,1971	4,09	0,0394	25	0
P-Cystatin C; massek. Sample 'Haeb'						
Alle	0,779	0,0878	11,28	0,0169	27	1
Nephelometry immunoassay	0,771	0,0417	5,41	0,0295	2	1
Turbidimetry	0,78	0,091	11,67	0,0182	25	0
P-eGFR; (Glomerular filtration) vol.hast. Sample 'Hacb'						
Alle	10,73	0,674	6,29	0,1406	23	0
2009 CKD-EPI (Crea)	10,75	0,595	5,54	0,1651	13	0
2012 CKD-EPI (CysC- Crea)	11,04	1,322	11,97	0,763	3	0
2012 CKD-EPI (CysC)	10,31	0,447	4,33	0,1999	5	0
2021 CKD-EPI (Crea)	11,1	0,1414	1,274	0,1	2	0
P-eGFR; (Glomerular filtration) vol.hast. Sample 'Haeb'						
Alle	107,7	12,1	11,23	2,52	23	0
2009 CKD-EPI (Crea)	103,8	7,66	7,38	2,12	13	0
2012 CKD-EPI (CysC- Crea)	118,2	25,1	21,2	14,47	3	0
2012 CKD-EPI (CysC)	110,9	13	11,72	5,81	5	0
2021 CKD-EPI (Crea)	109	0,0707	0,0649	0,05	2	0

3345 DK - Cystatin C, creatinin og/and eGFR - EKSEMPEL RAPPORT

Udsendelse 2 - 2023. Laboratorie nr. 500, resultat id. 500

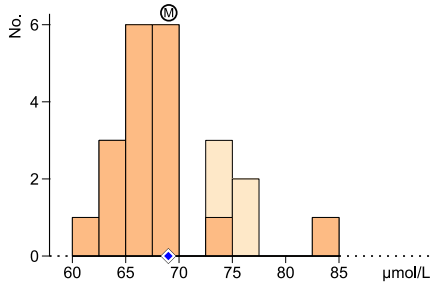
Metodesæt 2 ()

P-Creatininium; stofk. - NPU18016
Methodgroup: Enzymatic

Reagent: CREP2
Calibrator: C.f.a.s.

Instrument: Cobas 8000/c 702

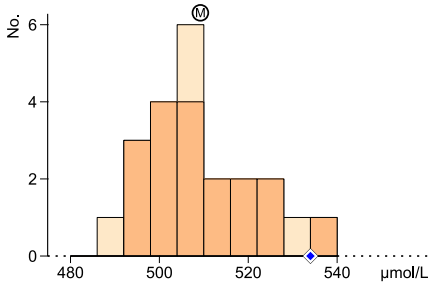
Haeb ('03_2023')



Own result: 69 µmol/L (dev. -0,1%)
Mean of all (M): 69,0 µmol/L
Acceptance interval (M ± 8,9%): 62,9 - 75,2 µmol/L

	Mean	sd	CV%	SEM	N
Method group	67,8	5,10	7,5	1,2	18
All	69,0	5,36	7,8	1,1	22

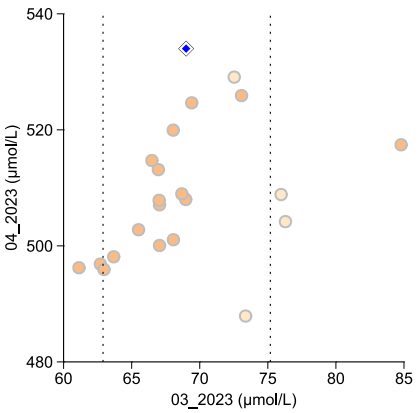
Hacb ('04_2023')



Own result: 534 µmol/L (dev. 4,9%)
Mean of all (M): 509 µmol/L
Acceptance interval (M ± 8,9%): 464 - 555 µmol/L

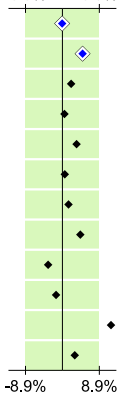
	Mean	sd	CV%	SEM	N
Method group	510	11,33	2,2	2,7	18
All	509	12,07	2,4	2,6	22

Youdenplot

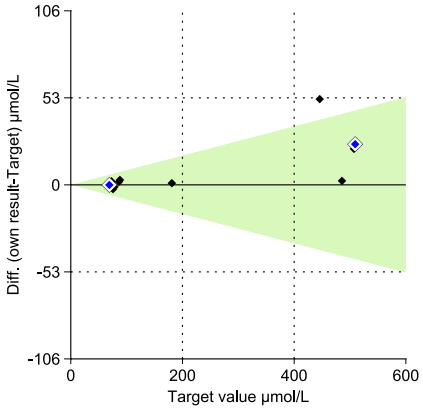


History

Round	Material	Target	Own	%dif
23/02	Haeb	69,0	69	-0,1
23/02	Hacb	509,2	534	4,9
23/01	Dac	86,2	88	2,1
23/01	Gkol	485,6	488	0,5
22/02	Dac	88,0	91	3,4
22/02	Gkml	181,0	182	0,6
22/01	Ckm	71,9	73	1,5
22/01	Hacb	507,1	529	4,3
21/02	Fhc	75,6	73	-3,4
21/02	Bac	78,2	77	-1,5
21/01	Jhc	445,8	498	11,7
21/01	Ckm	72,8	75	3,0



Difference plot



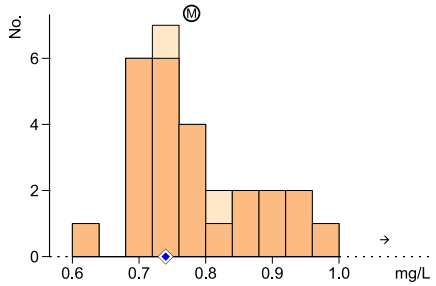
Metodesæt 1 ()

P-Cystatin C; massek.
Methodgroup: Turbidimetry

Reagent: Multigent Cystatin C
Calibrator: MULTIGENT Cystatin C Calibrator

Instrument: Architect

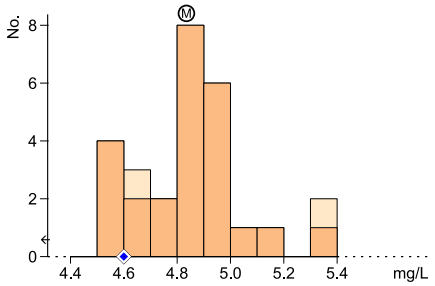
Haeb ('03_2023')



Own result: 0,74 mg/L (dev. -5,0%)
Mean of all (M): 0,779 mg/L
Acceptance interval (M ± 11,4%): 0,690 - 0,868 mg/L

	Mean	sd	CV%	SEM	N
Method group	0,780	0,09	11,7	0,0	25
All	0,779	0,09	11,3	0,0	27

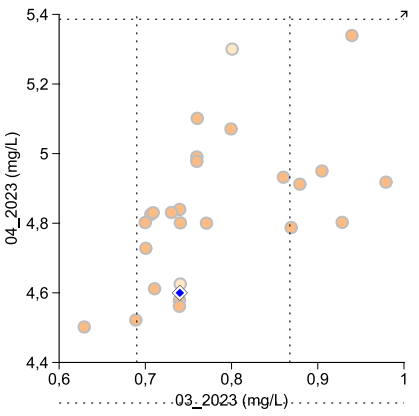
Hacb ('04_2023')



Own result: 4,60 mg/L (dev. -4,9%)
Mean of all (M): 4,83 mg/L
Acceptance interval (M ± 11,4%): 4,28 - 5,39 mg/L

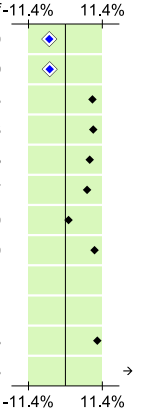
	Mean	sd	CV%	SEM	N
Method group	4,82	0,20	4,1	0,0	25
All	4,83	0,21	4,4	0,0	27

Youdenplot

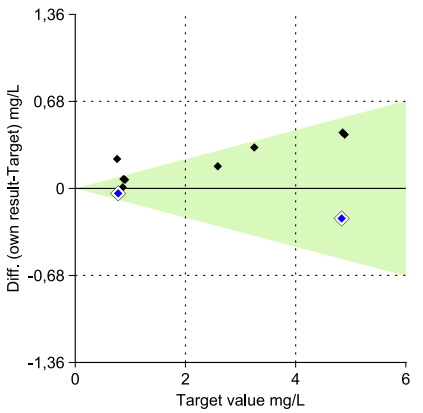


History

Round	Material	Target	Own	%dif
23/02	Haeb	0,779	0,74	-5,0
23/02	Hacb	4,835	4,60	-4,9
23/01	Dac	0,877	0,95	8,3
23/01	Gkol	4,890	5,31	8,6
22/02	Dac	0,902	0,97	7,5
22/02	Gkml	2,587	2,76	6,7
22/01	Ckm	0,862	0,87	1,0
22/01	Hacb	4,853	5,29	9,0
21/02	Fhc			
21/02	Bac			
21/01	Jhc	3,250	3,57	9,8
21/01	Ckm	0,760	0,99	30,3



Difference plot



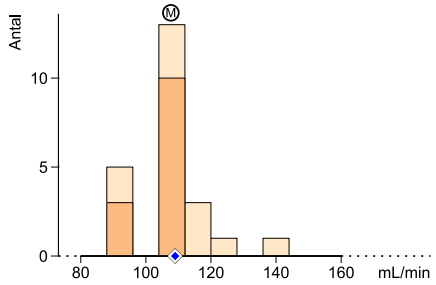
Metodesæt 2 ()

P-eGFR; (Glomerular filtration) vol.hast.
Methodgroup: 2009 CKD-EPI (Crea)

Reagent: Spærret
Calibrator: Spærret

Instrument: Spærret

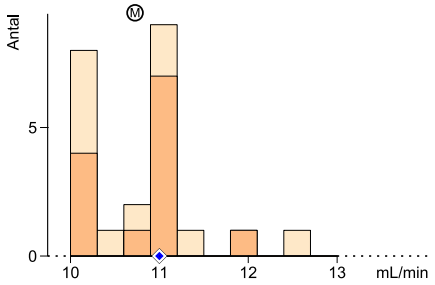
Haeb ('03_2023')



Eget resultat: 109 mL/min (afv. 1,2%)
Middelværdi af alle (M): 107,7 mL/min
Acceptinterval (M ± 11,4%): 95,4 - 120,0 mL/min

	Middel	sd	CV%	SEM	N
Metodegruppe	103,8	7,66	7,4	2,1	13
Alle	107,7	12,10	11,2	2,5	23

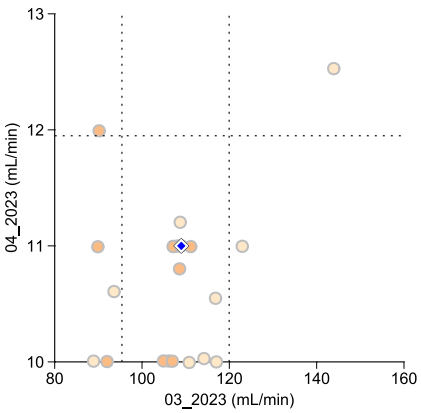
Hacb ('04_2023')



Eget resultat: 11 mL/min (afv. 2,6%)
Middelværdi af alle (M): 10,73 mL/min
Acceptinterval (M ± 11,4%): 9,50 - 11,95 mL/min

	Middel	sd	CV%	SEM	N
Metodegruppe	10,75	0,60	5,5	0,2	13
Alle	10,73	0,67	6,3	0,1	23

Youdenplot



Historik

Uds.	Materiale	Target	Eget	%dif
23/02	Haeb	107,68	109	1,2
23/02	Hacb	10,73	11	2,6
23/01	Dac	98,65	93	-5,7
23/01	Gkol	11,49	11	-4,2
22/02	Dac	88,73	88	-0,8
22/02	Gkml	34,83	38	9,1
22/01	Ckm	104,14	133	27,7 →
22/01	Hacb	10,75	19	76,8 →
21/02	Fhc	94,16	129	37,0 →
21/02	Bac	101,46	126	24,2 →
21/01	Jhc	14,59	19,3	32,3 →
21/01	Ckm	111,02	131,2	18,2 →

Differensplot