Cystatin C, Creatinine and eGFR, 3345 DK EQA report no. 2, November 2021

DEKS

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Test period:
25.10.2021 - 04.11.2021
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This report contains:
- Cover letter
- Summery by methods
- Individual results

Approved by MP
11.11.2021

Next reporting period

02.05.2022 – 09.05.2022

DANAK
PT Reg.No. 591
Member of EA MLA

Number of participants

There are 29 laboratories registered for this scheme.
24 laboratories have reported one or more set of results for P-Cystatin C. 14 laboratories have been reporting P-Creatinine and 12 laboratories have calculated P-eGFR in addition to P-Cystatin C.

Sample material

This round differs from the other rounds with two normal sample materials were the concentration of P-Cystatin C is different.

Sample material **Fhc (03_2021)**
A plasma pool from patients with a normal kidney function. Expect P-Cystatin C, P-Creatinine and P-eGFR in the normal range. This pool has been used one time before in 2019 (round 1). See the current historic data for *Fhc* and historic data from previous reports.

Sample material **Bac (04_2021)**
A plasma pool from patients with a normal kidney function. Expect P-Cystatin C, P-Creatinine and P-eGFR in the normal ranges. This pool has been used four times before: 2015 (round 1), 2017 (round 1), 2018 (round 2) and 2020 (round 2). See the current historic data for *Bac* and historic data from previous reports.

Target values

The target value for P-Cystatin C in sample material *Fhc* is 1.13 mg/L ± 0.04 mg/L (k=2). The target value for *Fhc* is transferred from the certified reference material ERM-DA471/IFCC as a mean of two transferred values: one using nephelometry and one using turbidimetry.
For P-Cystatin C in sample material *Bac*, the chosen target value is the overall mean, which is 0.747 mg/L.
For P-Creatinine the target value is the overall mean values for the respective materials.

For P-eGFR the target is calculated from the reference value of *Fhc* and the overall mean of *Bac* for P-Cystatin C and consensus mean for P-Creatinine.

Sample	Equation	mL/min/1.73 m^2
Fhc (03_2021)	2009 CKMD-EPI (Crea)	101
Fhc (03_2021)	2012 CKD-EPI (Crea -CysC)	83
Fhc (03_2021)	2012 CKD-EPI (Cys C)	69
Bac (04_2021)	2009 CKMD-EPI (Crea)	100
Bac (04_2021)	2012 CKD-EPI (Crea -CysC)	108
Bac (04_2021)	2012 CKD-EPI (Cys C)	113

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 reference value (R) or overall mean value (M), 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-eGFR the requirement for acceptable normal distribution across method groups is not met for the *Fhc* sample material. This means that we may, on a false basis, place someone outside the green acceptance range.

Outliers

Outliers are defined as results that deviate more than 3.2 x SD relative to the target value, no outliers were found in this round.

Acceptance interval

The acceptance limit for P-Cystatin C is 12 % calculated as total error from biological variation. The intra-individual variation is 8.6 % and the between-individuals variation is 15 %.
The acceptance limit for P-Creatinine of 9 % is calculated from biological variation based on the intra-individual variation being 6% and the between-individuals variation 15 % (ref. 1).
The acceptance limit for eGFR is 12 % (the same as for P-Cystatin C).
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.

[1] *Reinhard M, Erlandsen EJ & Randers E, Biological variation of cystatin C and creatinine. Scand J Clin Lab Invest 2009;69(8):831-836.*

Results and comments

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

Cystatin C

As in the previous round, the measurements for the Turbidimetry method group (1.262 mg/L for *Fhc* and 0.755 mg/L for *Bac*) are higher than the target values in both samples. For *Fhc*, Immuno MALDI (1.08 mg/L) is, lower than the target value. For Nephelometry (1.12 mg/L) there is a good agreement with the reference value of 1.13 mg/L. This was not the case in 2019 (round 2) for Nephelometry (1.17 mg/L) in sample material *Fhc*.

For *Bac*, the measurements for Immuno MALDI (0.66 mg/L) and Nephelometry (0.702 mg/L) are lower than the turbidimetry method group (0.755 mg/L). A similar distribution was found, in the two previous rounds.

Creatinine

No comments.

eGFR

If your LIMS system generates an automatic calculation of P-eGFR, you must control whether it is the CKD-EPI formula or another variant. In such circumstances the value can be different.

Scientific method

The Danish scientific societies recommend automatic reporting of eGFR whenever a Cystatin C or a Creatinine is ordered by the clinicians. This automatic reporting has revealed illness in kidneys otherwise not being found.

Interpretation of reports

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

Yours sincerely

Dår Kristian Kur and Lisbeth Nielsen

Component	Mean	Sd	CV	sem	N	Outliers
P-Creatininium; stofk. Sample 'Bac'						
Alle	78,2	3,6	4,6	0,9	16	0
Enzymatic	78,2	2,59	3,32	0,719	13	0
Jaffe reaction	78	7,53	9,65	4,35	3	0
P-Creatininium; stofk. Sample 'Fhc'						
Alle	75,6	3,42	4,53	0,884	15	0
Enzymatic	76	3,04	4	0,876	12	0
Jaffe reaction	74,2	5,26	7,08	3,03	3	0
P-Cystatin C; massek. Sample 'Bac'						
Alle	0,747	0,0573	7,67	0,01124	26	0
Immuno MALDI	0,66				1	0
Nephelometry immunoassay	0,702	0,0877	12,49	0,062	2	0
Turbidimetry	0,755	0,0529	7	0,01102	23	0
P-Cystatin C; massek. Sample 'Fhc'						
Reference Target	1,13					
Alle	1,243	0,1039	8,35	0,0208	25	0
Immuno MALDI	1,08				1	0
Nephelometry immunoassay	1,12	0,0707	6,31	0,05	2	0
Turbidimetry	1,262	0,0949	7,52	0,0202	22	0
P-eGFR; (Glomerular filtration) vol.hast. Sample 'Bac'						
Alle	101,5	10,62	10,47	2,95	13	0
2009 CKD-EPI (Crea)	101,7	9,17	9,02	2,9	10	0
2012 CKD-EPI (CysC- Crea)	96,6	22,2	23	15,68	2	0
2012 CKD-EPI (CysC)	109				1	0
P-eGFR; (Glomerular filtration) vol.hast. Sample 'Fhc'						
Alle	94,2	18,71	19,87	5,19	13	0
2009 CKD-EPI (Crea)	103,6	10,33	9,97	3,44	9	0
2012 CKD-EPI (CysC- Crea)	85,8	4	4,67	2,83	2	0
2012 CKD-EPI (CysC)	60	7,07	11,79	5	2	0

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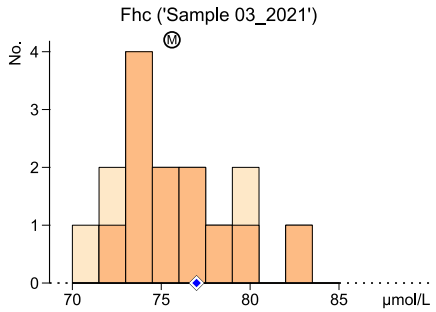
Udsendelse 2 - 2021. Laboratorie nr. 500, resultat id. 500

Metodesæt 1 ()

P-Creatininium; stofk.
Methodgroup: Enzymatic

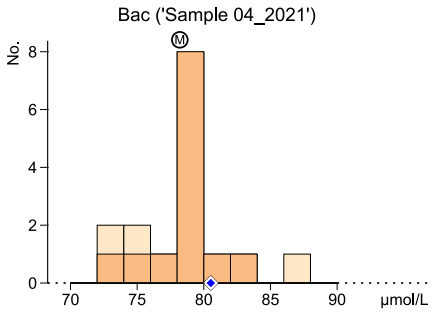
Reagent: ECREA
Calibrator: Atellica CH Chem CAL

Instrument: Atellica



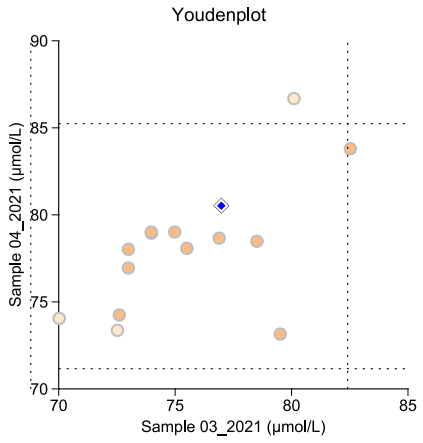
Own result: 76,986 μmol/L (dev. 1,8%)
Mean of all (M): 75,6 μmol/L
Acceptance interval (M ± 9%): 68,8 - 82,4 μmol/L

	Mean	sd	CV%	SEM	N
Method group	76,0	3,04	4,0	0,9	12
All	75,6	3,42	4,5	0,9	15



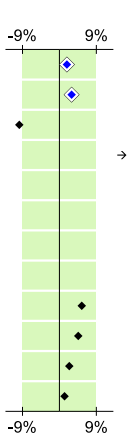
Own result: 80,525 μmol/L (dev. 3,0%)
Mean of all (M): 78,2 μmol/L
Acceptance interval (M ± 9%): 71,2 - 85,2 μmol/L

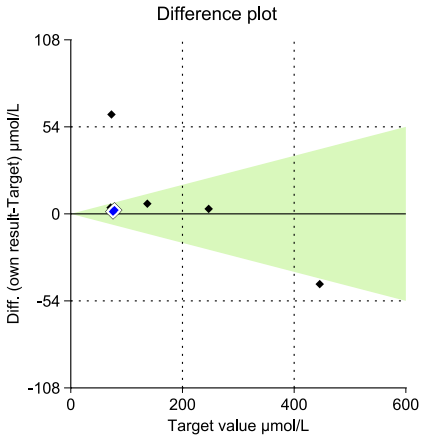
	Mean	sd	CV%	SEM	N
Method group	78,2	2,59	3,3	0,7	13
All	78,2	3,60	4,6	0,9	16



History

Round	Material	Target	Own	%dif
21/02	Fhc	75,6	76,986	1,8
21/02	Bac	78,2	80,525	3,0
21/01	Jhc	445,8	402,18	-9,8
21/01	Ckm	72,8	134,50	84,7
20/02	Bac			
20/02	Grm			
20/01	Dac			
20/01	Irm			
19/02	Ckm	71,3	75,2	5,4
19/02	Grm	137,1	143,35	4,6
19/01	Fhc	73,4	75,2	2,4
19/01	Hhc	246,9	250	1,2



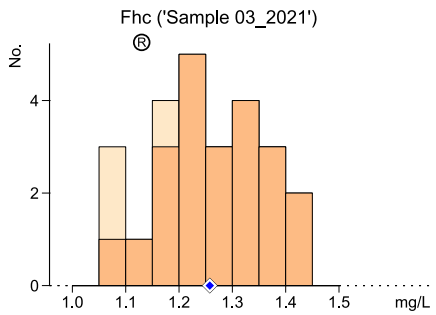


Metodesæt 2 ()

P-Cystatin C; massek.
Methodgroup: Turbidimetry

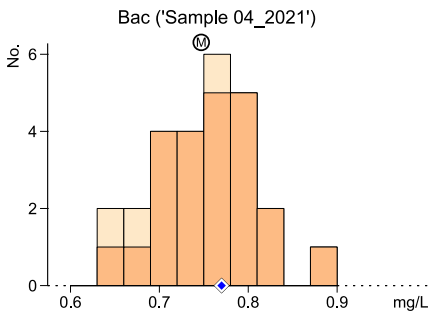
Reagent: Tina-Quant
Calibrator: Calibrator C.f.a.s. Cystatin C

Instrument: Cobas c 701



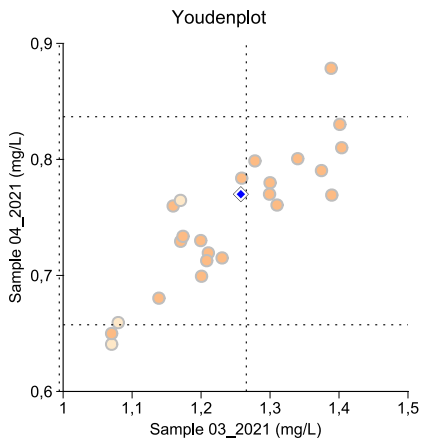
Own result: 1,2577 mg/L (dev. 11,3%)
Reference value (R): 1,13 mg/L
Acceptance interval (R ± 12%): 0,994 - 1,266 mg/L

	Mean	sd	CV%	SEM	N
Method group	1,262	0,09	7,5	0,0	22
All	1,243	0,10	8,4	0,0	25



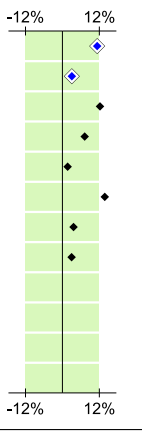
Own result: 0,77 mg/L (dev. 3,1%)
Mean of all (M): 0,747 mg/L
Acceptance interval (M ± 12%): 0,657 - 0,837 mg/L

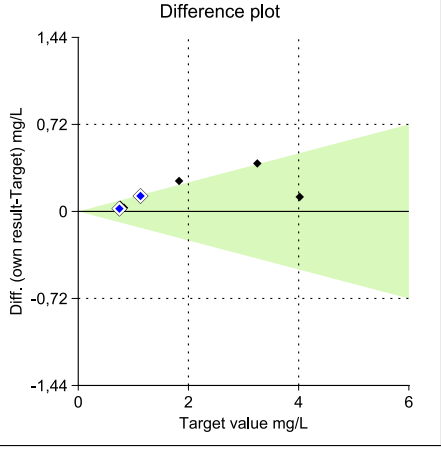
	Mean	sd	CV%	SEM	N
Method group	0,755	0,05	7,0	0,0	23
All	0,747	0,06	7,7	0,0	26



History

Round	Material	Target	Own	%dif
21/02	Fhc	1,130	1,2577	11,3
21/02	Bac	0,747	0,77	3,1
21/01	Jhc	3,250	3,647	12,2
21/01	Ckm	0,760	0,815	7,2
20/02	Bac	0,745	0,758	1,7
20/02	Grm	1,830	2,082	13,8
20/01	Dac	0,830	0,86	3,6
20/01	Irm	4,020	4,14	3,0
19/02	Ckm			
19/02	Grm			
19/01	Fhc			
19/01	Hhc			





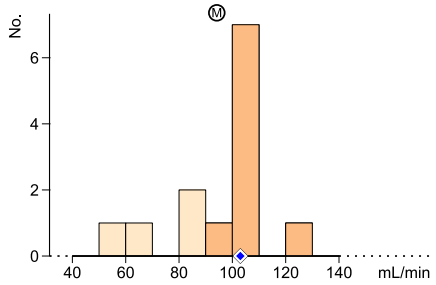
Metodesæt 2 ()

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

Reagent: Spærret
Calibrator: Spærret

Instrument: Spærret

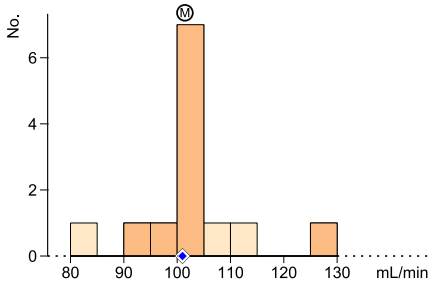
Fhc ('Sample 03_2021')



Own result: 103 mL/min (dev. 9,4%)
Mean of all (M): 94,2 mL/min
Acceptance interval (M ± 12%): 82,9 - 105,5 mL/min

	Mean	sd	CV%	SEM	N
Method group	103,6	10,33	10,0	3,4	9
All	94,2	18,71	19,9	5,2	13

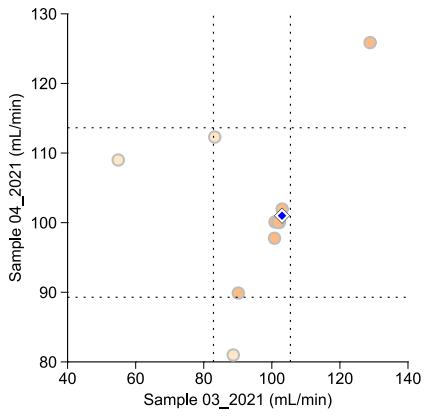
Bac ('Sample 04_2021')



Own result: 101 mL/min (dev. -0,5%)
Mean of all (M): 101,5 mL/min
Acceptance interval (M ± 12%): 89,3 - 113,6 mL/min

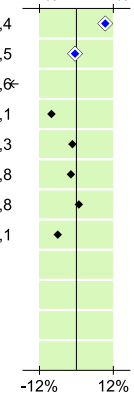
	Mean	sd	CV%	SEM	N
Method group	101,7	9,17	9,0	2,9	10
All	101,5	10,62	10,5	2,9	13

Youdenplot



History

Round	Material	Target	Own	%dif
21/02	Fhc	94,16	103	9,4
21/02	Bac	101,46	101	-0,5
21/01	Jhc	14,59	11	-24,6
21/01	Ckm	111,02	102	-8,1
20/02	Bac	103,35	102	-1,3
20/02	Grm	51,93	51	-1,8
20/01	Dac	91,28	92	0,8
20/01	Irm	14,90	14	-6,1
19/02	Ckm			
19/02	Grm			
19/01	Fhc			
19/01	Hhc			



Difference plot