

## DEKS

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This report contains:  
 • Cover letter  
 • Summary by methods  
 • Individual results

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 03.05.2021 - 10.05.2021

# Cystatin C, Creatinine and eGFR, 3345 DK EQA report no. 2, October 2020

## Number of participants

There are 25 laboratories registered for this scheme.  
 23 laboratories have reported 23 results for P-Cystatin C.  
 14 laboratories have been reporting P-Creatinine and 9 laboratories have calculated eGFR in addition to P-Cystatin C.

## Sample material

### Sample material **Bac (03\_2020)**

A plasma pool from patients with a normal kidney function. Expected P-Cystatin C, P-Creatinine and eGFR in the normal ranges.

### Sample material **Grm (04\_2020)**

A plasma pool from patients with a reduced kidney function. Expected high P-Cystatin C, high P-Creatinine and eGFR in the lower range.

## Target value/Target values

For P-Cystatin C the chosen target value is the overall mean for sample material *Bac*, which is 0.745 mg/L. The target value for P-Cystatin C in sample material *Grm* is 1.83 mg/L  $\pm$  0.03 (k=2). The value for *Grm* are transferred from the certified reference material ERM-DA471/IFCC and includes calculated values as mean of all, from measurements on both nephelometry and turbidimetry.

The target value for P-Creatinine in sample material *Bac* is 75.0  $\mu$ mol/L, and for samples material *Grm* is 132.3  $\mu$ mol/L.

For P-Creatinine the target values are a total mean.

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

Sample	Equation	mL/min/1.73 m <sup>2</sup>
Bac (03_2020)	2009 CKMD-EPI (Crea)	102
Bac (03_2020)	2012 CKD-EPI (Crea -CysC)	107
Bac (03_2020)	2012 CKD-EPI (Cys C)	109
Grm (04_2020)	2009 CKMD-EPI (Crea)	54
Grm (04_2020)	2012 CKD-EPI (Crea -CysC)	43
Grm (04_2020)	2012 CKD-EPI (Cys C)	36

## 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, as the difference between the overall mean and the median may only constitute a consensus decided value of the acceptance interval. For both P-Creatinine and eGFR the requirement for acceptable normal distribution across method groups is not met for the two materials (*Bac* and *Grm*). This means that we may, on a false basis, put someone outside the green acceptance range.

## Outliers

Outliers are defined as results that deviate more than 3.2 x SD in order to the target value, no outliers were found in this round. Due to a reasonable suspicion that there has been an exchange of results, for P-Creatinine and eGFR, for the two materials *Bac* and *Grm* in two of the participants, the results were excluded as manual outliers.

## 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<sup>2</sup>, though the unit in the graphic part is shortened to mL/min.

<sup>1</sup> 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".

For P-Cystatin C, the measurements for Nephelometry in material *Bac*, are lower than the target value, with a mean value of 0.679 mg/L.

*Bac* has been used three times before: 2015 (round 1), 2017 (round 1) and 2018 (round 2). See the current historic data for *Bac* and historic data from previous reports. When comparing the results for P-Cystatin C, the reference value was used as target value for results in 2015 (round 1) and 2017 (round 1), whereas in 2018 (round 2) and current round, the overall mean was used as target value.

For P-Cystatin C, the measurements for Turbidimetry in material *Grm* are higher than target value, with a mean value of 2.05 mg/L.

*Grm* has been used one time before in 2019 (round 2). See the current historic data for *Grm* and historic data from previous reports.

### eGFR:

If your LIMS system generates an automatic calculation of 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

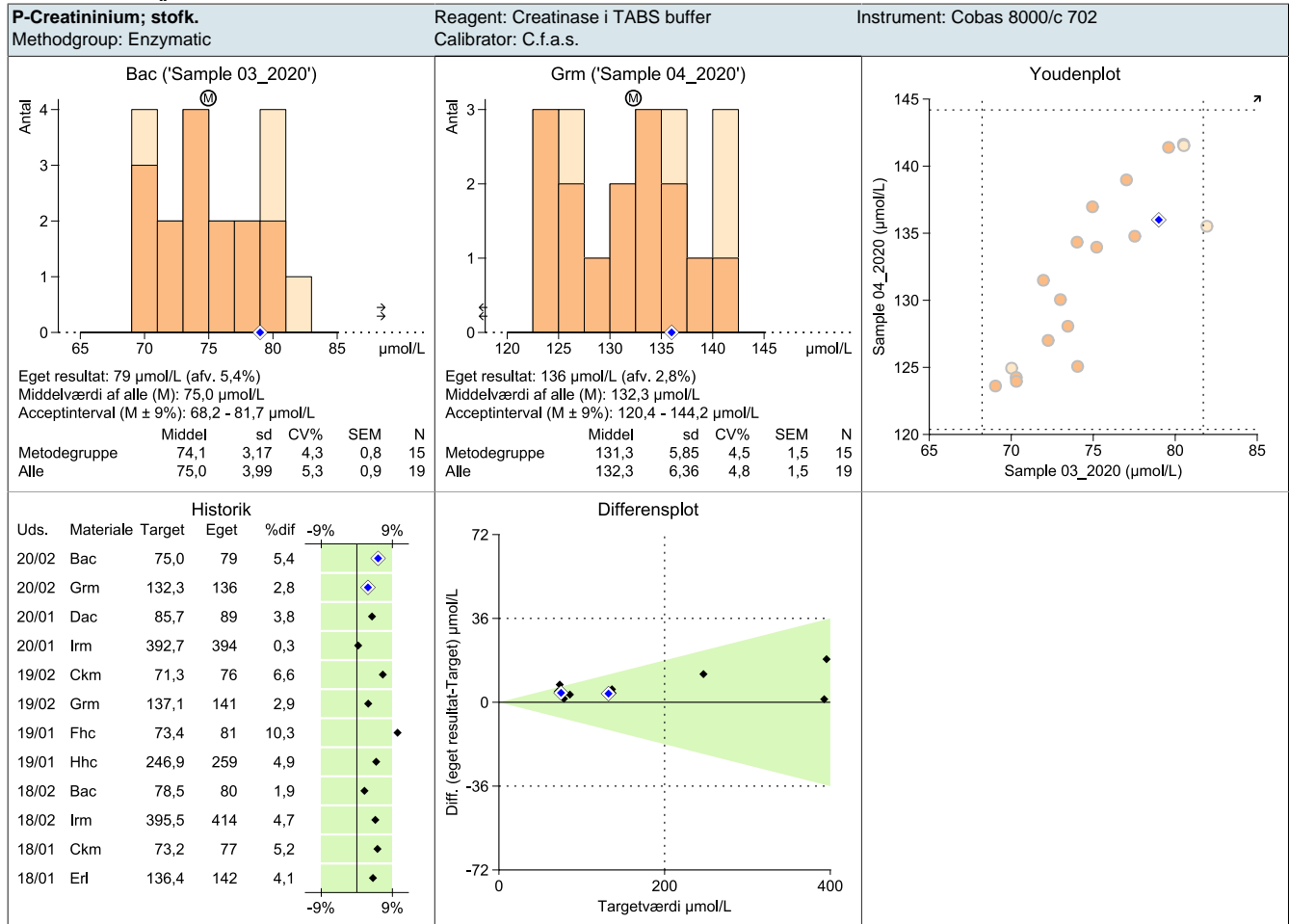
You will find a guide for reading the graphic report at <http://deks.dk/en/products/information-about-the-danish-products/interpretation-of-reports/>

Yours sincerely

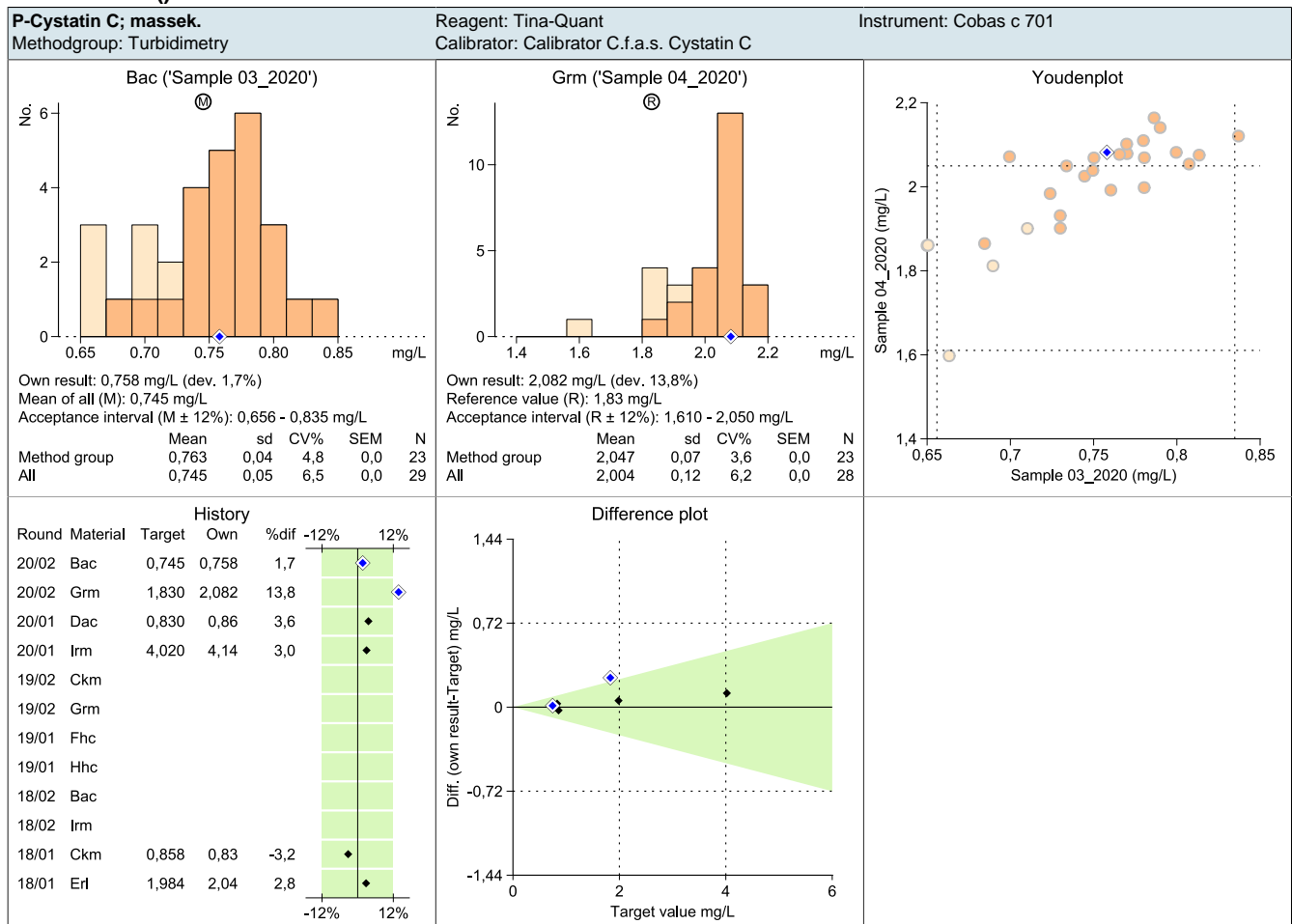
Dår Kristian Kur and Nanna Larsen

Component	Mean	Sd	CV	sem	N	Outliers
<b>P-Creatininium; stofk. Sample 'Bac'</b>						
<i>Alle</i>	75	3,99	5,32	0,915	19	2
Enzymatic	74,1	3,17	4,27	0,818	15	2
Jaffe reaction	78,2	5,53	7,06	2,76	4	0
<b>P-Creatininium; stofk. Sample 'Grm'</b>						
<i>Alle</i>	132,3	6,36	4,81	1,46	19	2
Enzymatic	131,3	5,85	4,45	1,51	15	2
Jaffe reaction	135,9	7,82	5,76	3,91	4	0
<b>P-Cystatin C; massek. Sample 'Bac'</b>						
<i>Alle</i>	0,745	0,0488	6,54	0,00905	29	0
Nephelometry immunoassay	0,679	0,028	4,13	0,01143	6	0
Turbidimetry	0,763	0,0363	4,76	0,00757	23	0
<b>P-Cystatin C; massek. Sample 'Grm'</b>						
<i>Alle</i>	2	0,1246	6,22	0,0235	28	0
Nephelometry immunoassay	1,805	0,1212	6,72	0,0542	5	0
Turbidimetry	2,05	0,0739	3,61	0,01542	23	0
<b>P-eGFR; (Glomerular filtration) vol.hast. Sample 'Bac'</b>						
<i>Alle</i>	103,4	12,27	11,87	3,88	10	2
2009 CKD-EPI (Crea)	101,6	13,24	13,03	4,68	8	2
2012 CKD-EPI (CysC- Crea)	110,5	0,707	0,64	0,5	2	0
<b>P-eGFR; (Glomerular filtration) vol.hast. Sample 'Grm'</b>						
<i>Alle</i>	51,9	9,84	18,94	3,11	10	2
2009 CKD-EPI (Crea)	54,5	9,25	16,95	3,27	8	2
2012 CKD-EPI (CysC- Crea)	41,5	0,707	1,704	0,5	2	0

**Metodesæt 1 ( )**



**Metodesæt 2 ( )**



**Metodesæt 1 ( )**

