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NOPAM

Presentation

The concept for the program:

Patient medians and flagging rates are normally stable over time, and any change is usually due to pre-analytical or analytical instability or error.

Background

- Noklus took over and has been running a program based on the patient median (the Percentiler) and the flagging rate (the Flagger) since 2019
- The Percentiler/Program was a part of a project called *The Empower project* where patient medians and frozen single-donation samples were analyzed and compared
(The Empower project – a new way of assessing and monitoring test comparability and stability, De Grande, L.A., Goossens, K., Van Uytfanghe, K., Stockl, D., Thienpont, L.M., Clin Chem Lab Med 2015; 53(8):1197-1204)
- June 1st 2024 Noklus launch **Noklus Patient Median (NOPAM)**, this is a new patient-based EQA-program that will replace both the Percentiler- and Flagger program.

NOPAM compared to percentiler and flagger

NOPAM	Percentiler and flagger
Data: country, patient population, sample material, sample conditions, methods, manufacturer, instrument model, instrument type, reagent lot-number	Data: Manufacturer, instrument model, instrument type
Results: patient median, percentage of results below and above the reference range, number of results the calculations are calculated from	Results: patient median, percentage of results below and above the reference range, number of results the calculations are calculated from
Charts (for participants): Monthly overview of laboratory instruments, Differences between instrument groups, Daily median values of instruments, Group overview - variation over time	Charts (for participants): Moving median
Calculations and statistics: medians, number of results, 10 th and 90 th percentile, lower quartile, upper quartile, average, MAD and SD	Calculations and statistics: medians, bias, CV
Analyte specific warnings	
Facilitated for EQA-providers	
Facilitated for manufacturers	

*MAD is the median absolute deviation

Daily results sent to NOPAM

- Participating laboratories calculate, and report instrument-specific medians based on patient results. The total number of patient results is also reported. It is recommended to calculate medians from an out-patient population.
- Participating laboratories calculate, and report instrument-specific percentage of patient results above and below the reference limit.
- Reagent lot-numbers can also be registered, and the lot-number can be in the daily report or added manually by the participant.

Information
about
the participating
laboratory registered

Data:

Country

Patient population

Sample material

Fasting / all results

Method

Reagent lot-number

Manufacturer

Instrument model

Instrument type

Locally used factors

A daily result report example

Lab.	Execution day	Instrument	Requester ward	Test	Unit	Median	Number	% < REF	% > REF	Assay lot id
Laboratory ID	01.07.2023	ARC-T3	External	S_ALAT	U/L	25.46	43	0.00 %	33.33 %	50159UD00
Laboratory ID	01.07.2023	ARC-T3	External	S_ALB	g/L	29.81	39	100.00 %	0.00 %	46167UD00
Laboratory ID	01.07.2023	ARC-T3	External	S_ALP	U/L	77.06	13	0.00 %	33.33 %	53995UN22
Laboratory ID	01.07.2023	ARC-T3	External	S_ASAT	U/L	91.99	41	0.00 %	100.00 %	49192UD00
Laboratory ID	01.07.2023	ARC-T3	External	S_BIL	umol/L	7.87	21	0.00 %	0.00 %	62807UQ09
Laboratory ID	01.07.2023	ARC-T3	External	S_CA	mmol/L	2.33	45	0.00 %	0.00 %	35579UN22
Laboratory ID	01.07.2023	ARC-T3	External	S_CRP	mg/L	5.56	34	0.00 %	0.00 %	30197Y600
Laboratory ID	01.07.2023	ARC-T3	External	S_GGT	U/L	47.66	27	0.00 %	33.33 %	47518UD00

This is an example of how laboratories can send their results. The result report starts with a unique laboratory code. Then the date, instrument code, the code for the patient population, analyte code, unit, median value, number of results on which the median value is based, percentage of results below the lower reference limit, percentage of results above the upper reference limit and the reagent lot-number.

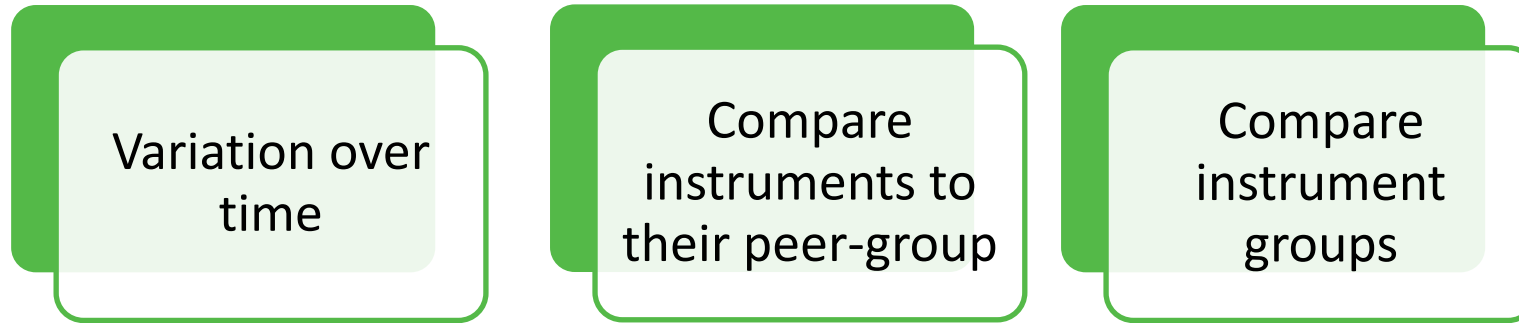
Analyte specific warnings for the moving patient median

- 1. MEDIAN:** If **the slope for the smoothed curve** (11 days bandwidth) for the patient median reported for one instrument is above a certain value (analyte specific) for more than three consecutive days, the participant will have a warning.
- 2. MEDIAN:** If **the monthly median value** calculated as the median of all patient medians reported for one instrument deviates more than X % (the X-value is analyte specific and entered by admin users) from the **median value for the previous 12 months** for the same instrument, the participant will have a warning.
- 3. MEDIAN:** If the **monthly median value** for one instrument deviates more than X % (the X-value is analyte specific and entered by admin users) from **the peer group** (instrument model group), the participant will have a warning.
4. There are also warnings for the percentage of results below and above the reference range.

Analytes included in NOPAM

25-Hydroxyvitamin D	Albumin	ALP	ALT	AST
Bilirubin (total)	BUN	Ca	Cholesterol	Cl
Creatinine	CRP	Ferritin	Folate (B9)	FT4
GGT	Glucose	Hb	HbA1c	HDL-cholesterol
IgA	IgG	IgM	K	LDL-cholesterol
LDH	MCV	Mg	Na	Phosphate
PLT	Protein (total)	PSA	PTH	RBC
Triglycerides	TSH	Urea	Uric acid	Vitamin B12
WBC				

How can the results be used?



The results can be used for the laboratories to see their variation over time and to compare their instruments, compare their instruments to their instrument group and to compare different instrument groups.

Results

Statistics

- Monthly overview of laboratory instruments
- Differences between instrument groups
- Daily median values of instruments
- Group overview - variation over time

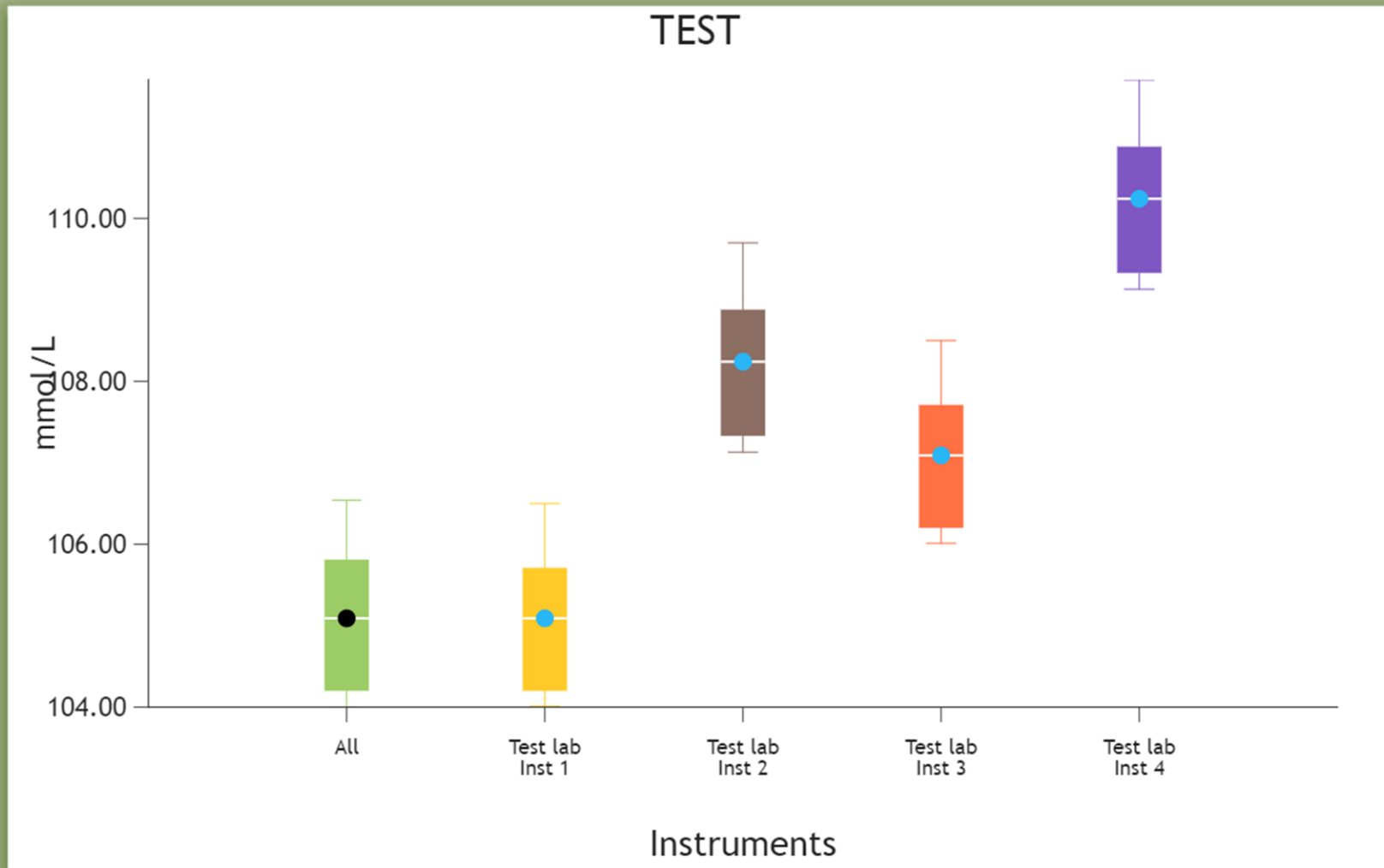
1. Monthly overview of laboratory instruments

2. Differences between instrument groups

3. Daily median values of instruments

4. Group overview – variation over time

Monthly overview of laboratory instruments



This is an example of one laboratory sending results for four instruments

In this example, the results for instrument 2, 3 and 4 are factorized to illustrate how factors affects the instrument results.

Instrument 1: Original results







Instrument 2: $\times 1,03$

Instrument 3: $+2$

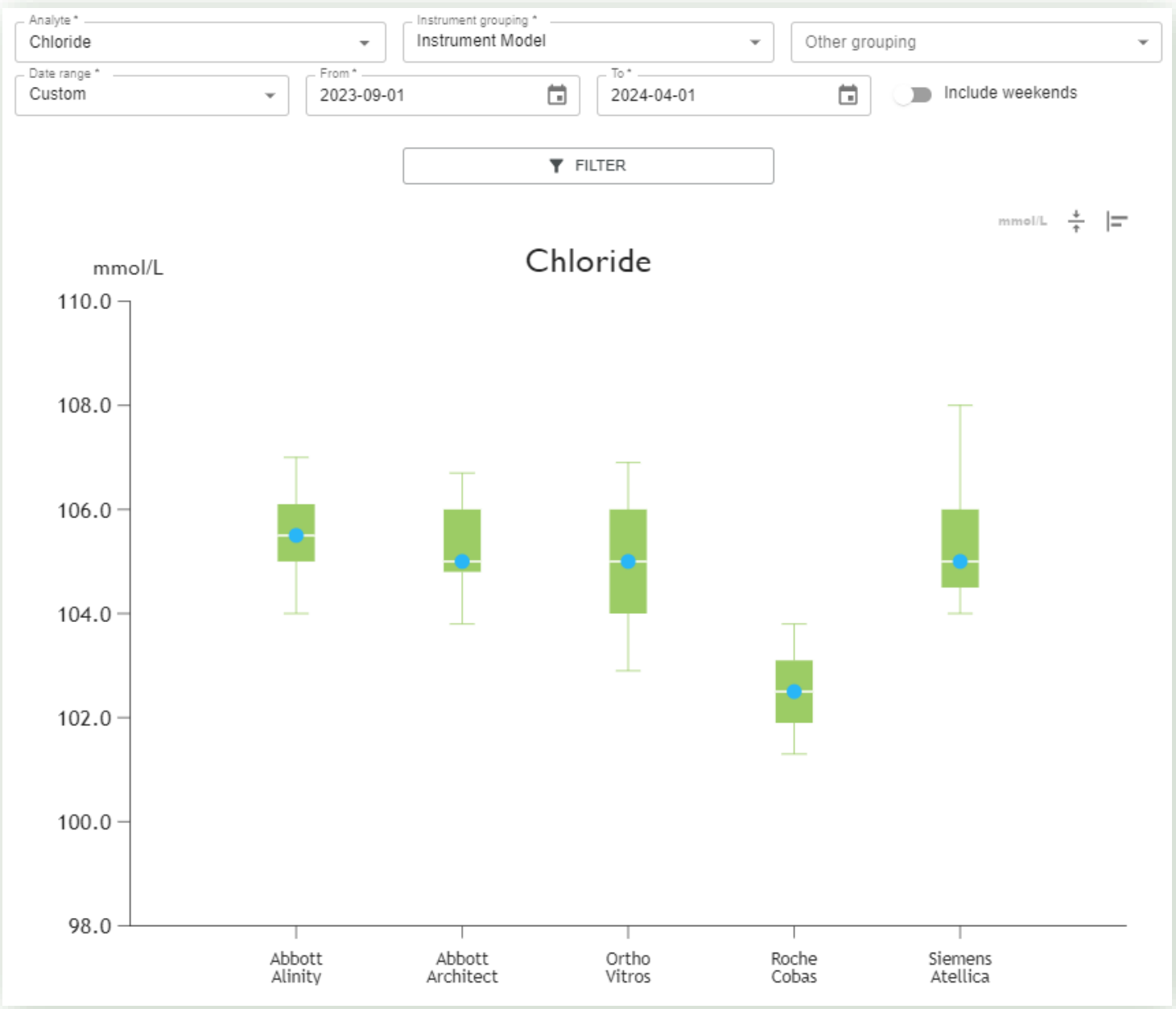
Instrument 4: $\times 1,03 +2$

For all group calculations, the factors are removed.

Monthly overview of laboratory instruments - Corresponding results

Statistics								
Filter	Instrument code	Number of results	Median	Minimum	Maximum	Lower quartile	Upper quartile	Show/Hide
<input type="checkbox"/>	All	84	104.54	99.78	105.98	103.85	104.85	
<input type="checkbox"/>	Test lab - Inst 1	21	104.54	99.78	105.98	103.85	104.85	
<input type="checkbox"/>	Test lab - Inst 2	21	107.67	102.77	109.16	106.97	108.00	
<input type="checkbox"/>	Test lab - Inst 3	21	106.54	101.78	107.98	105.85	106.85	
<input type="checkbox"/>	Test lab - Inst 4	21	109.67	104.77	111.16	108.97	110.00	









Differences between instrument groups



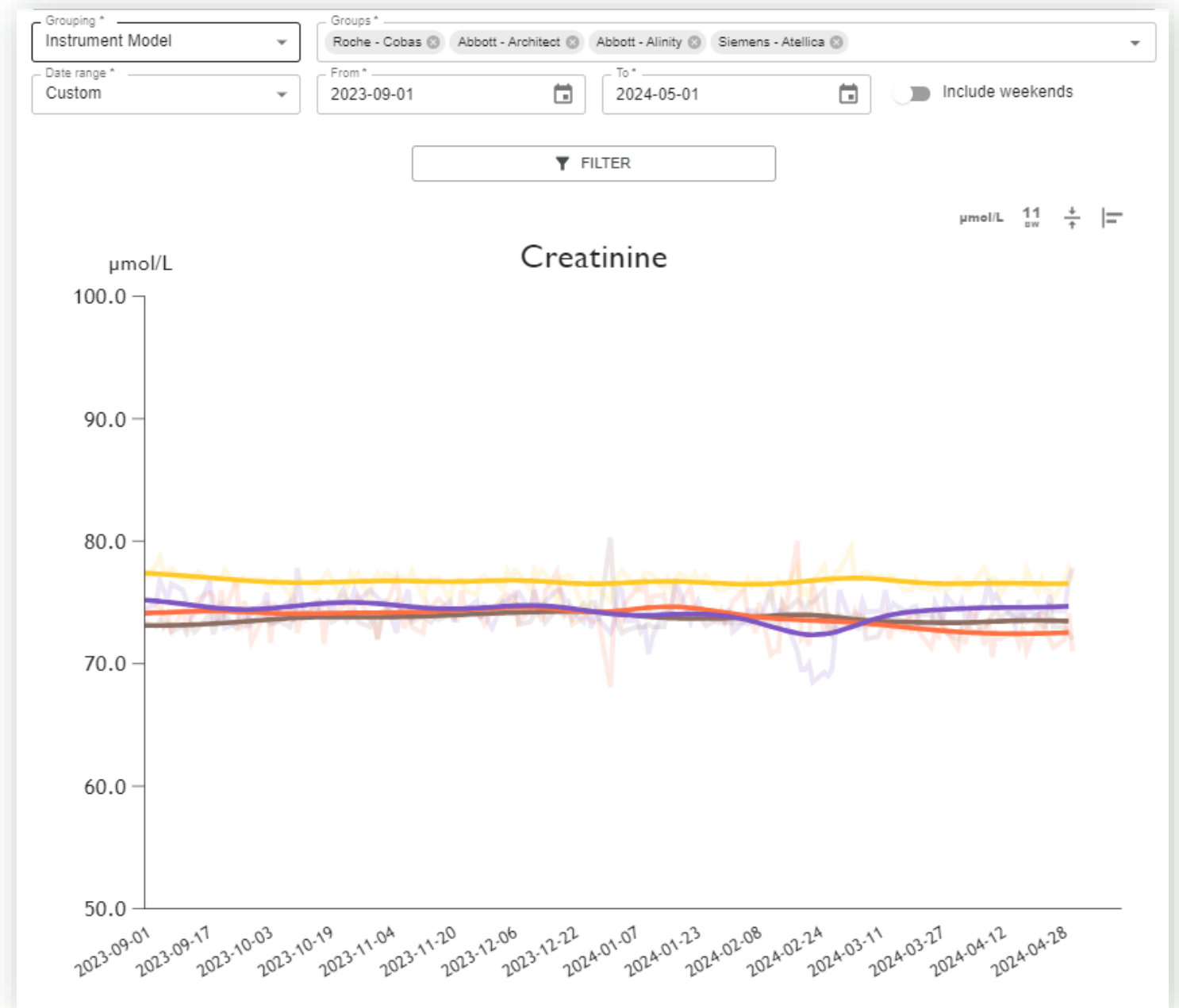
Differences between instrument groups – corresponding data

Instrument group name	Number of results	Median	Min - Max	10th - 90th percentile	Lower quartile	Upper quartile
Abbott - Alinity	2894	105.5	91.3 - 118	104 - 107	105	106.1
Abbott - Architect	5229	105	89 - 113	103.8 - 106.7	104.8	106
Ortho - Vitros	915	105	96.4 - 111.3	102.9 - 106.9	104	106
Roche - Cobas	32744	102.5	5 - 123.9	101.3 - 103.8	101.9	103.1
Siemens - Atellica	1777	105	84 - 125.4	104 - 108	104.5	106

Daily median values of instruments – corresponding data

		Number of results	Median	MAD	Laboratory median	All median	Show/Hide
	Instrument 1	221	4.94	0.122	4.96	4.63	
	Instrument 2	225	4.96	0.130	4.96	4.63	
	Instrument 3	237	4.98	0.150	4.96	4.63	
	Instrument group	9140	5.03	0.060	-	-	

Group overveiw – variation over time



Group overview – variation over time – corresponding data

Statistics							
	Instrument Model	Number of results	Median	Average	MAD	SD	Show/Hide
	Roche - Cobas	37632	76.9	76.7	0.45	0.74	
	Abbott - Architect	6648	73.7	73.7	0.45	0.88	
	Abbott - Alinity	3790	74.0	73.8	1.00	1.54	
	Siemens - Atellica	3327	74.3	74.3	0.80	1.51	

NOPAM for EQA-providers and manufacturers



ACCESS TO RESULTS FOR LABORATORIES
PARTICIPATING VIA THE EQA-
ORGANISATION



ACCESS TO RESULTS FOR ALL
INSTRUMENT-GROUPS AND GROUPS
WITH FIVE OR MORE PARTICIPANTS

We have made a separate access for EQA-providers and one for manufacturers. EQA-providers will have access to detailed information about laboratories participating via their EQA-organization and both manufacturers and EQA-providers can have access to results for instrument groups for groups with five or more participating laboratories.

NOPAM support team

If you are interested in participating in the program,
please contact us:

- Eva Rønneseth (eva.ronneseth@noklus.no) Program coordinator
- Anne Elisabeth Solsvik (anne.elisabeth.solsvik@noklus.no) Program manager