LABQUALITY

External Quality Assessment Scheme

Urine strip test B, particle count and estimation of density Round 1, 2023

Specimens

Please find enclosed a lyophilized human urine sample S001 15 mL with added chemicals, stabilized human red cells and organic particles to simulate leukocytes. The cells are only for particle counting. You will also receive 15 mL of water for sample dissolution if you have ordered it separately (3131, Urine strip test B, dissolution water, 15 mL).

Caution

Quality control sample derived from human urine must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases.

Examinations

Please see page 2.

Storage and use

After arrival the sample should be stored at +2...8 °C. Add 15 mL distilled or reagent grade water at room temperature into the bottle. If you have ordered the dissolution water (3131, à 15 mL), just pour the water from the tube carefully to the sample bottle and tap gently the remaining water drops to the sample bottle. Rotate the vessel gently at least for 1 minute and leave at room temperature for 45 minutes. Rotate the vessel gently but thoroughly at least 1 minute just before every use to ensure homogeneity; turn the vessel gently upside down at least 20 times before analysis. The analysing is done from the room temperature sample. Dissolved sample is stable for 5 days when stored at +2...8 °C.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator. SI-units should be checked before reporting the results.

If you get a <u>negative strip tests result</u>, mark it to LabScala form as <u>neg</u> and if you get an estimation of density (relative density, osmolality or creatinine) results below (<) or above (>) of your method's detection limit, please mark these results with < or > characters (eg. <5 or >100) so that the character and your numeric result are typed together without space.

"Trace" category in strip tests must be interpreted as negative.

Please do not report "zero" results, if some examination is not in use in your laboratory, just leave that result column empty.

S001



2023-03-13

INSTRUCTIONS

Product no. 3130-3131 LQ744623011/US

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **March 31, 2023**.

Inquiries

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Urine strip test B, particle count and estimation of density

Examinations

Particle counting

The erythrocytes and leukocytes should be counted with the method routinely used in the laboratory. To reach a good statistical precision, more than 200 cells should be counted for both erythrocytes and leukocytes. Microscope fields are to be selected systematically from different areas under the coverslip. With both the coverslip technique and the chamber counting more fillings may be needed to achieve an adequate total count. Final results should then be expressed as standardized particle concentrations. Check your own standardization. Conversions from HPF to unit 10⁶/L should be checked with the help of ECLM-European Urinalysis Guidelines, Scand J Clin Lab Invest, suppl 231, 2000; chapter 12.1.2., page 62. The results from the coverslip method are reported with the unit particles x 10 ⁶/L (or E6/L) as well. The conversion factor should be calculated locally; examples from the Finnish standardization are: Ocular viewfield number 18 mm, factor is 8.6, Ocular viewfield number 20 mm, factor is 7.0 and Ocular viewfield number 22 mm, factor is 5.8.

You can also report results from the automatic analyzers.

Estimation of density

Report the Relative density, Creatinine and Osmolality results.

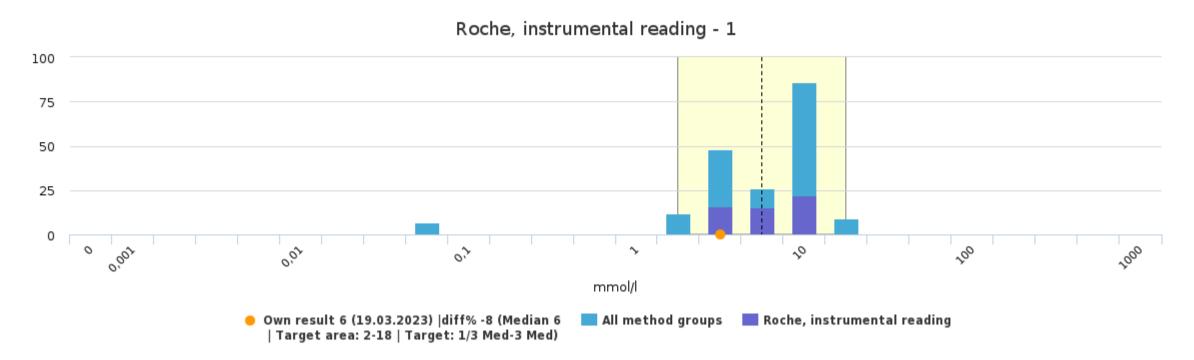
Strip tests

We ask you to mark your strip test results (U-Glucose, U-Ketones, U-Blood (erythrocytes), U-pH, U-Protein, U-Nitrite, U-Leukocytes and U-Relative Density) only as arbitrary concentrations (eg. 2+ = arbitrary concentration 14 mmol/L or if the 2+ = arbitrary concentration between 10-14 mmol/L then you should report the 10 mmol/L). For nitrite arbitrary concentration, please report the positivity limit of your method without > mark.

The strip tests Leukocytes and Erythrocytes results should not be informed as particle count results and vice versa (e.g. result 573.66 x cells x 106/L is not an arbitrary strip test result).

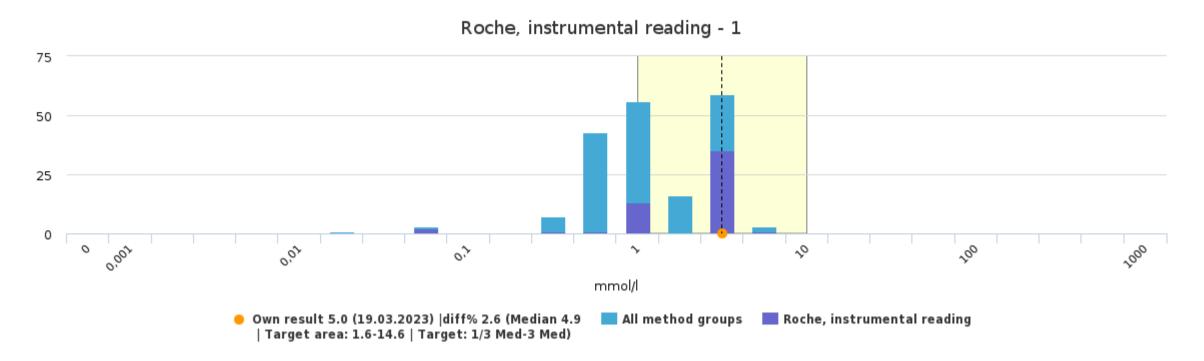
XXXX

Sample S001 | Strip tests B results | U-Glucose, mmol/l



	Median	sd	SEM	CV%	n	Target range 1/3 Med-3 Med
Roche, instrumental reading	6	5	<1	52.1	53	2 - 18
All methods	11	6	<1	59.3	188	4 - 32

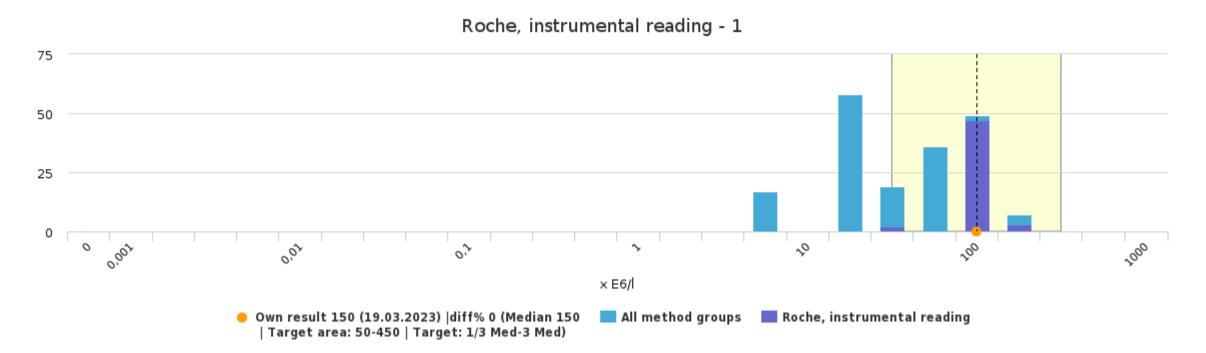
Sample S001 | Strip tests B results | U-Ketone bodies, mmol/l



	Median	sd	SEM	CV%	n	Target range 1/3 Med-3 Med
Roche, instrumental reading	4.9	1.8	0.2	47.9	53	1.6 - 14.6
All methods	1.5	1.7	0.1	68.7	188	0.5 - 4.5

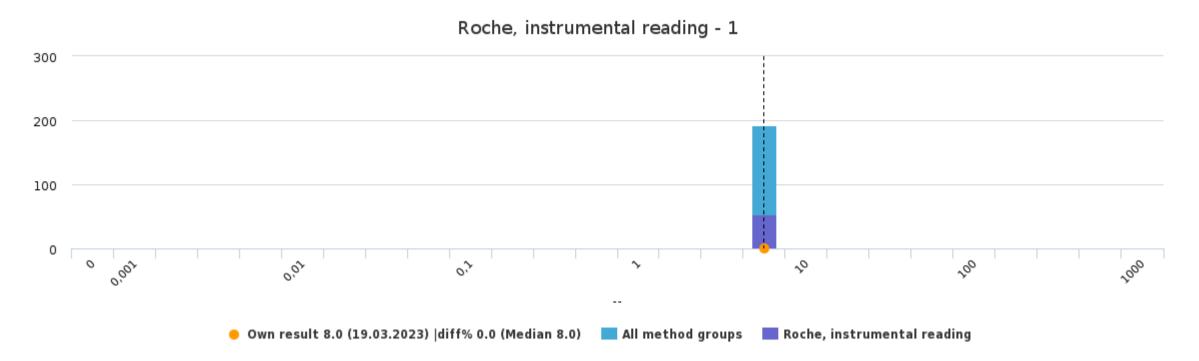
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Sample S001 | Strip tests B results | U-Erythrocytes, x E6/l



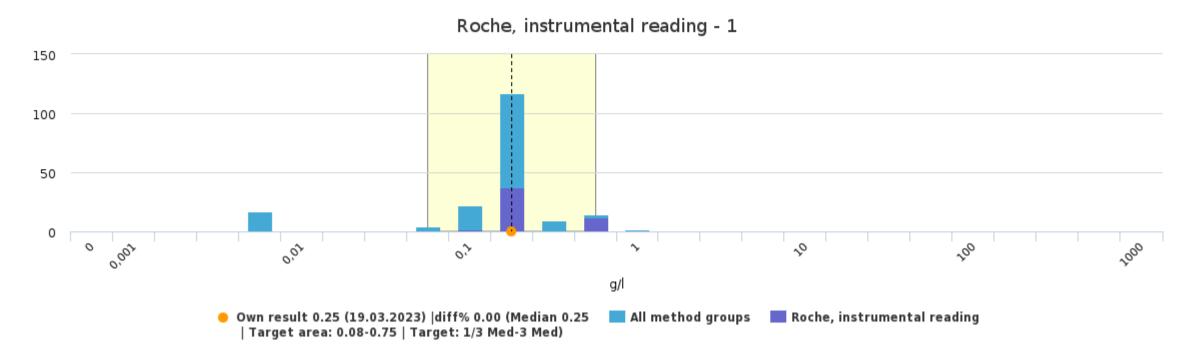
	Median	sd	SEM	CV%	n	Target range 1/3 Med-3 Med
Roche, instrumental reading	150	<1	<1	<0.1	52	50 - 450
All methods	50	54	4	75.9	186	17 - 150

Sample S001 | Strip tests B results | U-pH, --



	Median	sd	SEM	CV%	n
Roche, instrumental reading	8.0	<0.1	<0.1	0.9	53
All methods	7.5	0.4	<0.1	4.7	192

Sample S001 | Strip tests B results | U-Protein, g/l



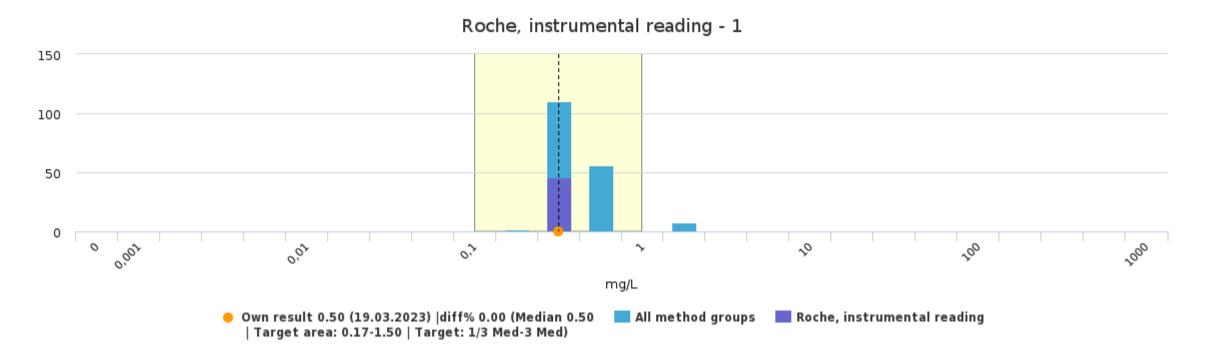
	Median	sd	SEM	CV%	n	Target range 1/3 Med-3 Med
Roche, instrumental reading	0.25	0.22	0.03	61.7	52	0.08 - 0.75
All methods	0.25	0.17	0.01	61.6	185	0.08 - 0.75

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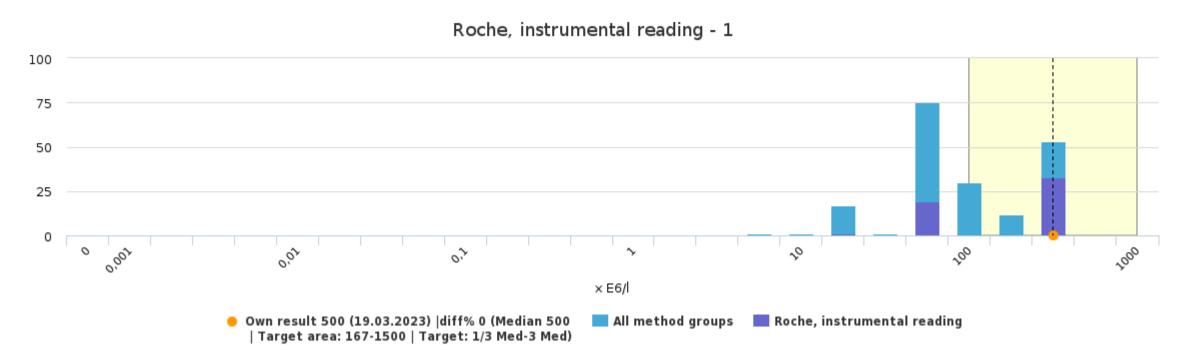
Sample S001 | Strip tests B results | U-Nitrite, mg/L



	Median	sd	SEM	CV%	n	Target range 1/3 Med-3 Med
Roche, instrumental reading	0.50	<0.01	<0.01	<0.1	46	0.17 - 1.50
All methods	0.50	0.16	0.01	28.6	180	0.17 - 1.50

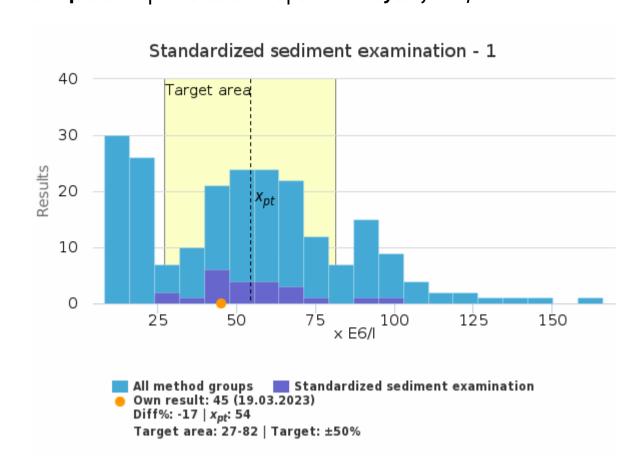
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Sample S001 | Strip tests B results | U-Leukocytes, x E6/l

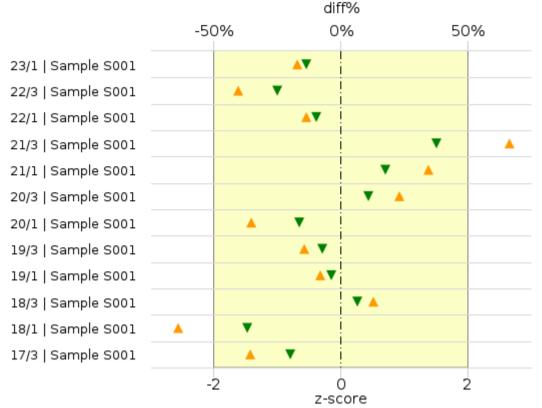


	Median	sd	SEM	CV%	n	Target range 1/3 Med-3 Med
Roche, instrumental reading	500	199	27	57.3	53	167 - 1500
All methods	105	188	14	90.2	190	35 - 315

Sample S001 | Particle count | U -Leukocytes, x E6/l



Standardized sediment examination - 1 - History



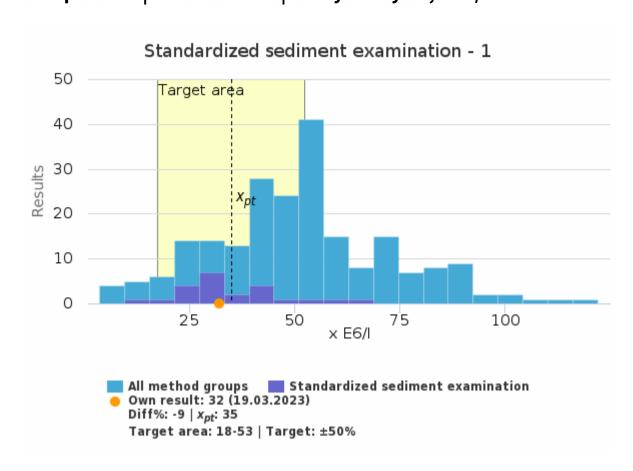


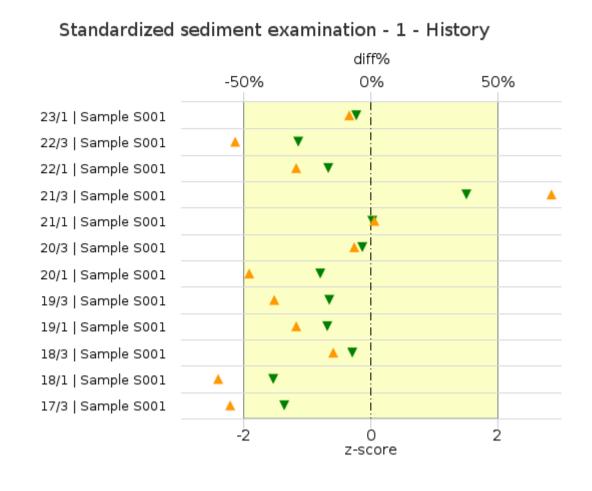
	^X pt	sd	SEM	CV%	n
Standardized sediment examination	54 x E6/l	17	4	31.8	23
All methods	52 x E6/l	29	2	56.2	219

Round	Sample	^X pt	Result	diff%	z-score
23/1	Sample S001	54	45	-17%	-0.54
22/3	Sample S001	64	38	-40%	-1.01
22/1	Sample S001	59	51	-13%	-0.39
21/3	Sample S001	69	115	67%	1.50
21/1	Sample S001	67	90	34%	0.70
20/3	Sample S001	63	77	23%	0.44
20/1	Sample S001	68	44	-35%	-0.65
19/3	Sample S001	68	58	-14%	-0.30
19/1	Sample S001	69	64	-8%	-0.15
18/3	Sample S001	68	77	13%	0.26
18/1	Sample S001	73	26	-64%	-1.47
17/3	Sample S001	70	45	-36%	-0.79

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Sample S001 | Particle count | U -Erythrocytes, x E6/l



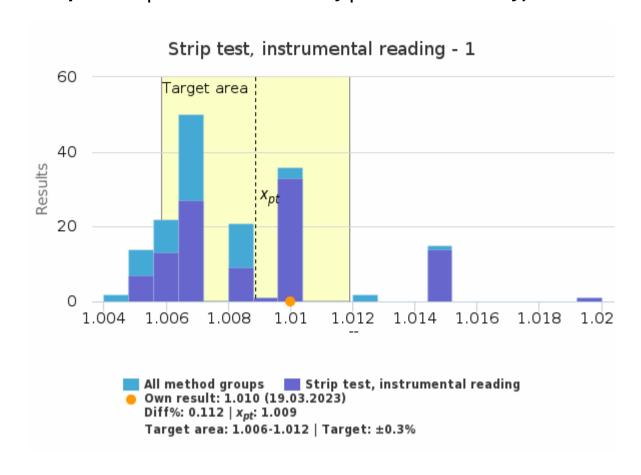


	x _{pt}	sd	SEM	CV%	n
Standardized sediment examination	35 x E6/l	13	3	38.0	23
All methods	51 x E6/l	21	1	40.7	218

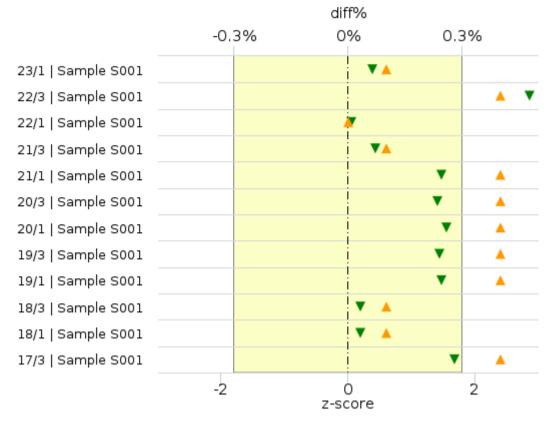
Round	Sample	x _{pt}	Result	diff%	z-score
23/1	Sample S001	35	32	-9%	-0.23
22/3	Sample S001	56	26	-53%	-1.14
22/1	Sample S001	54	38	-29%	-0.67
21/3	Sample S001	53	90	71%	1.50
21/1	Sample S001	50	51	1%	0.03
20/3	Sample S001	48	45	-7%	-0.13
20/1	Sample S001	58	30	-48%	-0.79
19/3	Sample S001	52	32	-38%	-0.66
19/1	Sample S001	45	32	-29%	-0.69
18/3	Sample S001	31	26	-15%	-0.30
18/1	Sample S001	33	13	-60%	-1.54
17/3	Sample S001	29	13	-55%	-1.37

diff% ▼ z-score

Sample S001 | Estimation of density | U-Relative density, --









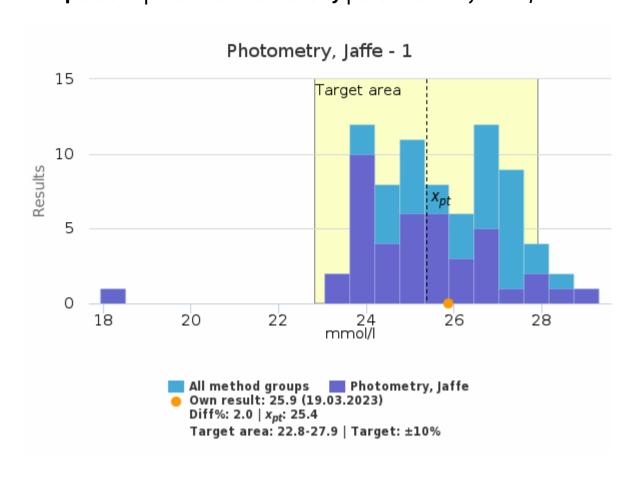
	^x pt	sd	SEM	CV%	n
Strip test, instrumental reading	1.009	0.003	<0.001	0.3	105
All methods	1.008	0.003	<0.001	0.3	164

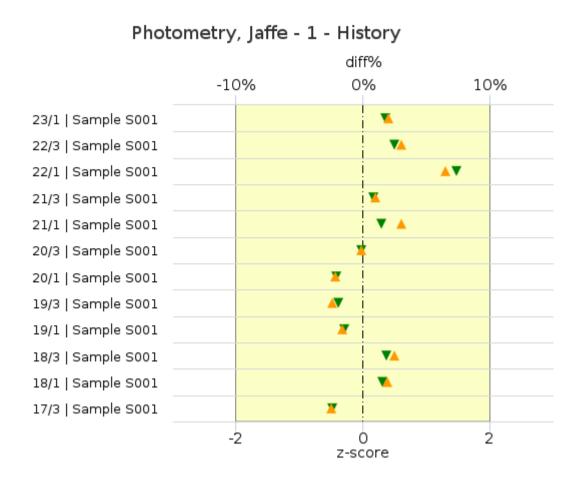
Round	Sample	^X pt	Result	diff%	z-score
23/1	Sample S001	1.009	1.010	0.112%	0.38
22/3	Sample S001	1.009	1.020	1.048%	2.86
22/1	Sample S001	1.010	1.010	0.022%	0.06
21/3	Sample S001	1.009	1.010	0.147%	0.43
21/1	Sample S001	1.009	1.015	0.577%	1.48
20/3	Sample S001	1.010	1.015	0.489%	1.41
20/1	Sample S001	1.010	1.015	0.536%	1.56
19/3	Sample S001	1.010	1.015	0.516%	1.45
19/1	Sample S001	1.010	1.015	0.534%	1.47
18/3	Sample S001	1.009	1.010	0.064%	0.19
18/1	Sample S001	1.009	1.010	0.066%	0.20
17/3	Sample S001	1.009	1.015	0.571%	1.68

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Sample S001 | Estimation of density | U-Creatinine, mmol/l







	^X pt	sd	SEM	CV%	n
Photometry, Jaffe	25.4 mmol/l	1.4	0.2	5.7	42
All methods	25.7 mmol/l	1.4	0.2	5.4	76

Round	Sample	x _{pt}	Result	diff%	z-score
23/1	Sample S001	25.4	25.9	2.0%	0.36
22/3	Sample S001	25.9	26.6	3.0%	0.50
22/1	Sample S001	25.9	27.6	6.5%	1.48
21/3	Sample S001	23.6	23.9	1.0%	0.17
21/1	Sample S001	23.1	23.8	3.0%	0.29
20/3	Sample S001	24.6	24.6	-0.1%	-0.03
20/1	Sample S001	25.0	24.5	-2.2%	-0.42
19/3	Sample S001	17.6	17.1	-2.4%	-0.38
19/1	Sample S001	17.0	16.7	-1.6%	-0.29
18/3	Sample S001	18.4	18.9	2.5%	0.37
18/1	Sample S001	18.3	18.7	1.9%	0.31
17/3	Sample S001	18.6	18.1	-2.5%	-0.48

Report info

Participants

212 participants from 16 countries.

Report info

Your own result should be compared to others using the same method.

Particle count and Estimation of density parts assigned values (x_{nt}, target values) are means of the results where results deviating more than +/- 3*standard deviation from the

median are removed. Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

In strip tests B part the assigned values (Med, target values) are median of the results where results deviating more than +/- 3*standard deviation from the median are removed.

The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM).

In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method. Results reported with < or > -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" LabScala User instructions (top right corner? Help link).

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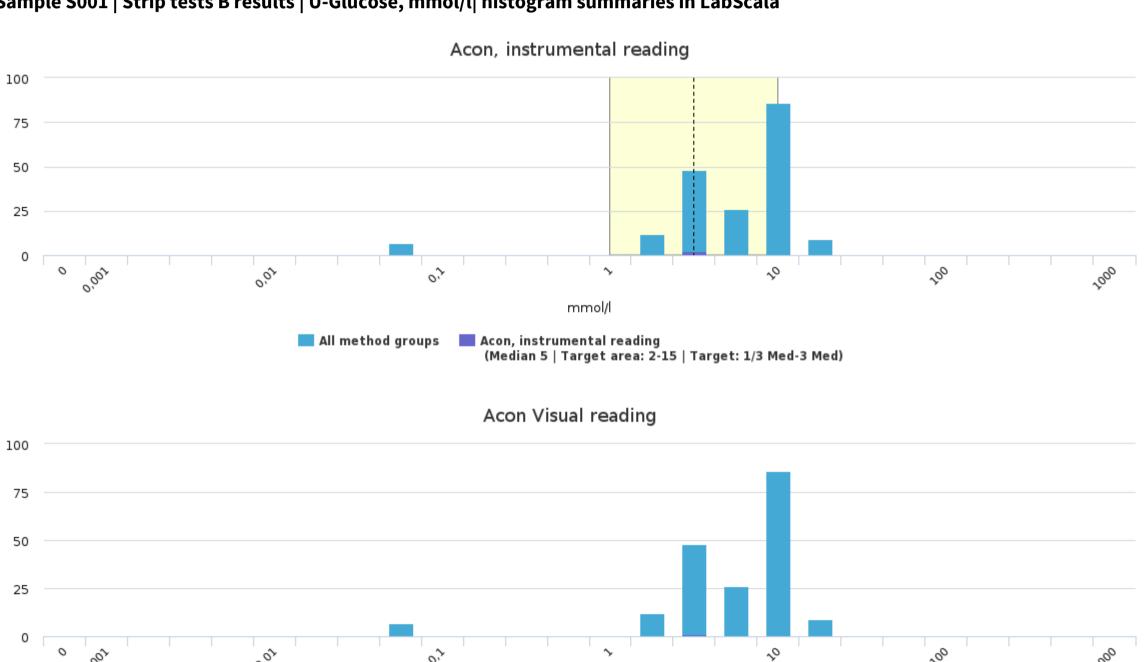
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Sample S001 | Strip tests B results | U-Glucose, mmol/l

Methodics	Median	sd	CV%	SEM	min	max	Outliers	n
Acon, instrumental reading	5	<1	<0.1	<1	5	5	-	2
Acon Visual reading	-	-	-	-	6	6	-	1
AMP diagnostics, instrumental reading	-	-	-	-	6	6	-	1
Arkray, instrumental reading	-	-	-	-	8	8	-	1
Dirui, instrumental reading	-	-	-	-	6	6	-	1
Dirui visual reading	-	-	-	-	10	10	-	1
Erba Lachema, instrumental reading	17	7	50.1	4	6	17	-	3
Iris Diagnostics, instrumental reading	11	2	22.1	<1	6	11	-	11
Macherey-Nagel, instrumental reading	8	<1	<0.1	<1	8	8	-	3
Menarini, instrumental reading	8	<1	<0.1	<1	8	8	-	2
Mindray, instrumental reading	-	-	-	-	14	14	-	1
Roche, instrumental reading	6	5	52.1	<1	6	17	-	53
Roche visual reading	11	8	71.8	6	6	17	-	2
Siemens, instrumental reading	6	5	71.6	<1	0	14	1	56
Siemens visual reading	21	10	46.6	7	14	28	-	2
Sysmex, instrumental reading	14	4	31.8	<1	6	14	-	32
Urit Medical Electronic, instrumental reading	-	-	-	-	14	14	-	1
Yeongdong, instrumental reading	14	8	40.3	3	11	28	-	8
77 Elektronika, instrumental reading	28	10	53.9	4	8	28	-	7
All	11	6	59.3	<1	0	28	-	188

Sample S001 | Strip tests B results | U-Glucose, mmol/l| histogram summaries in LabScala



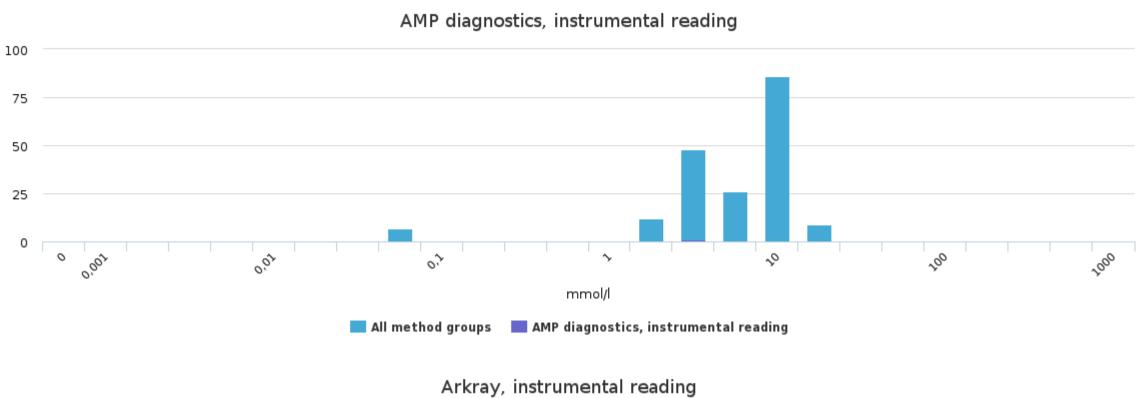
mmol/l

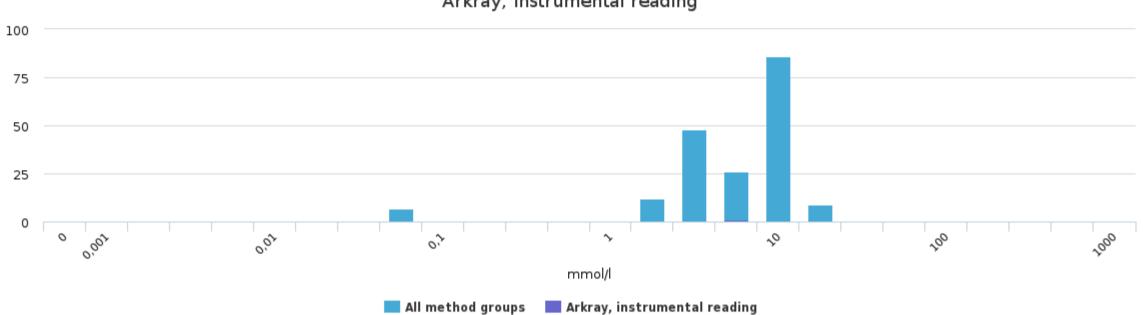
All method groups Acon Visual reading

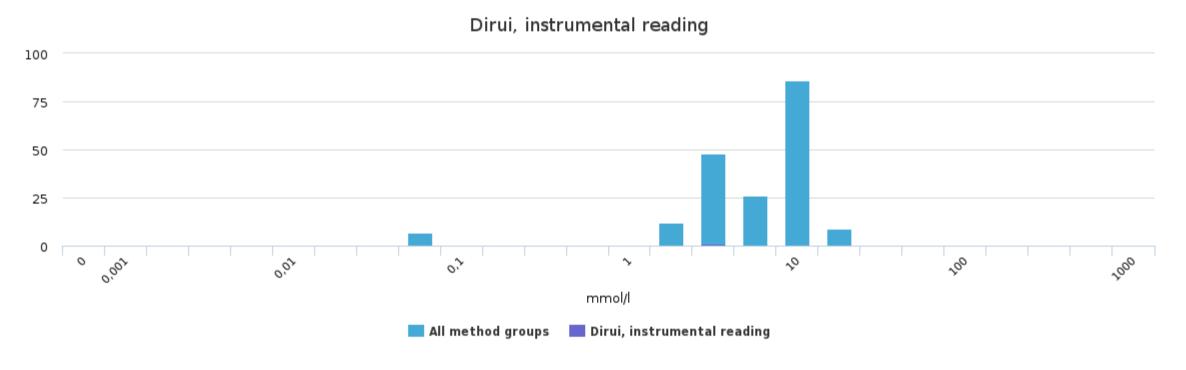
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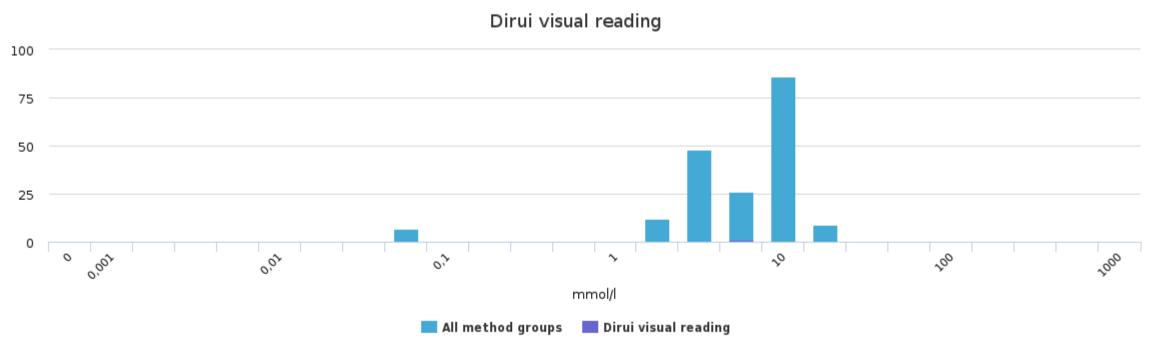
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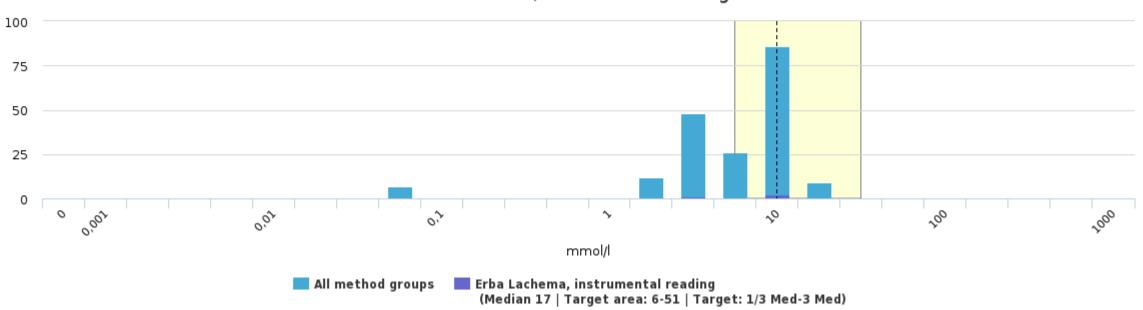




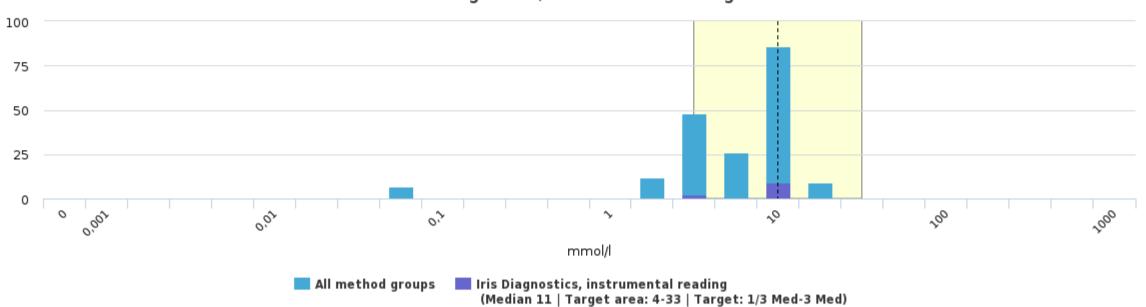
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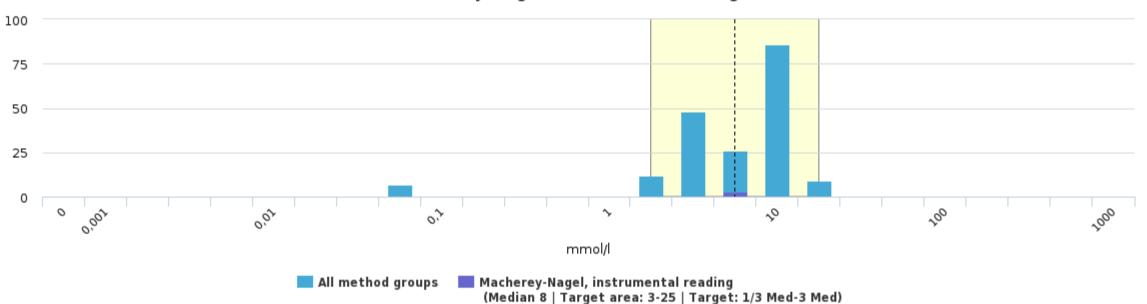




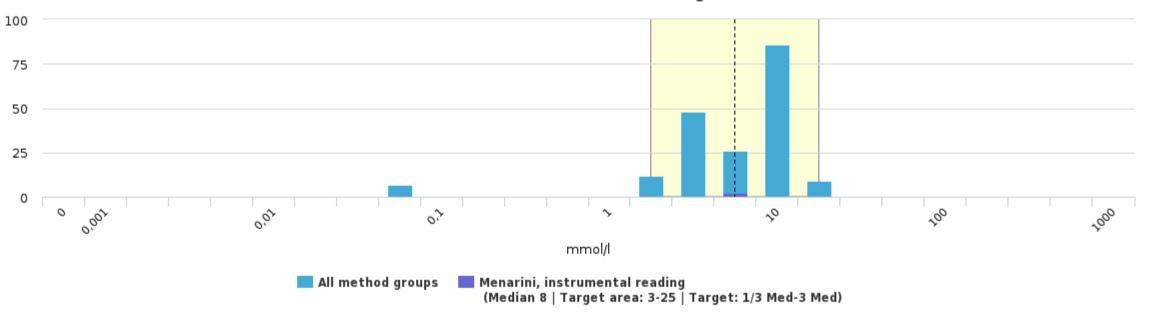
Iris Diagnostics, instrumental reading



Macherey-Nagel, instrumental reading



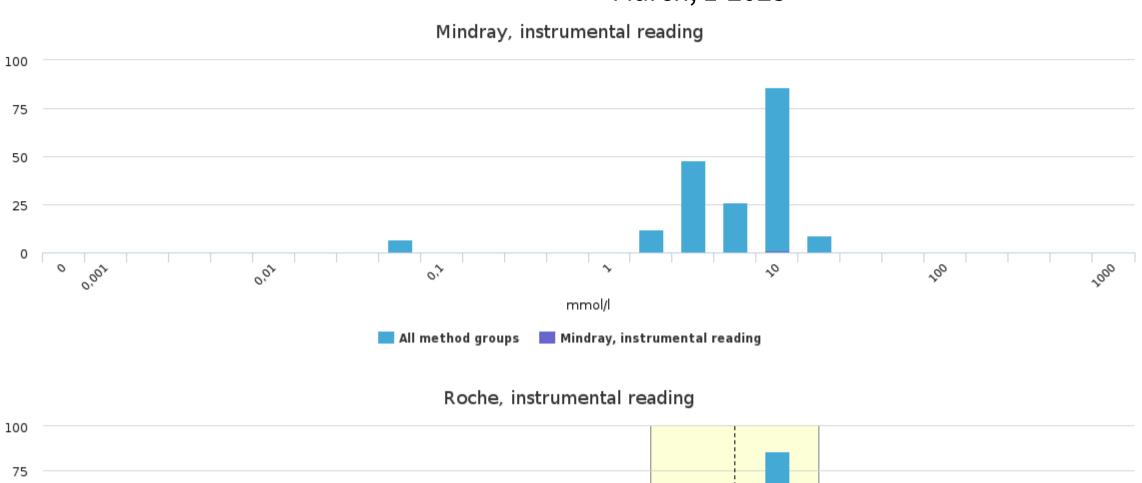
Menarini, instrumental reading

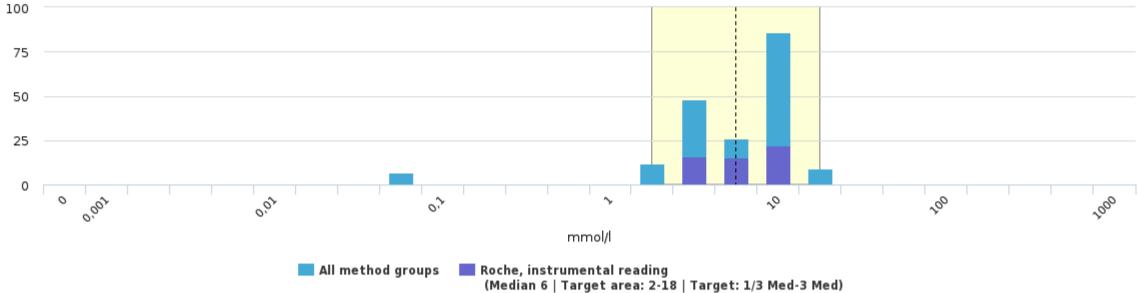


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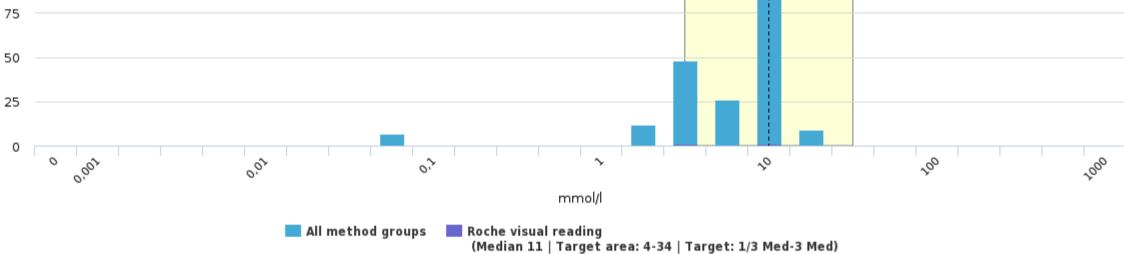
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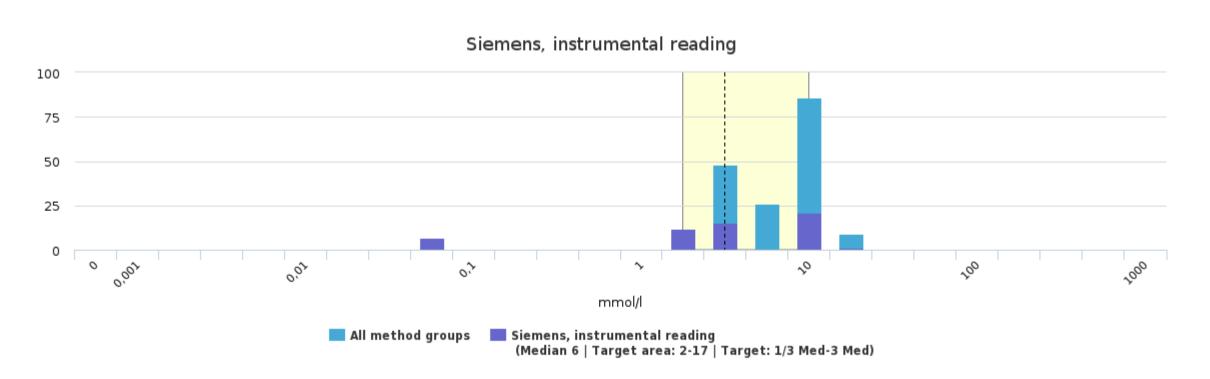








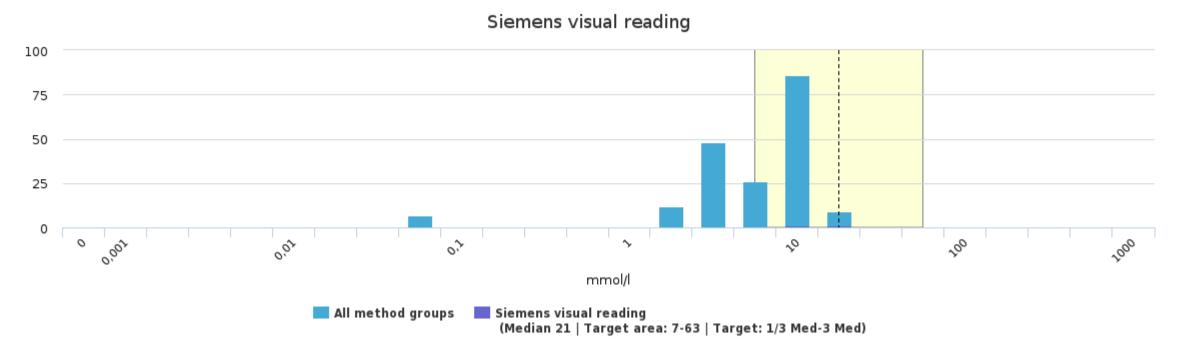


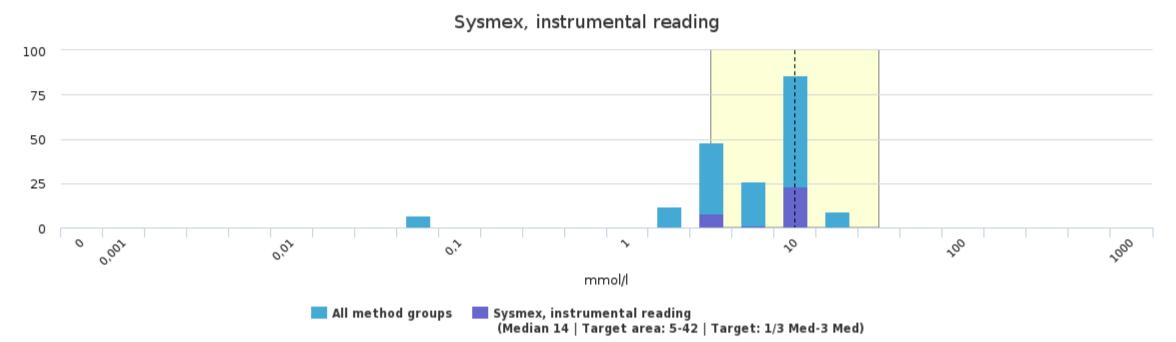


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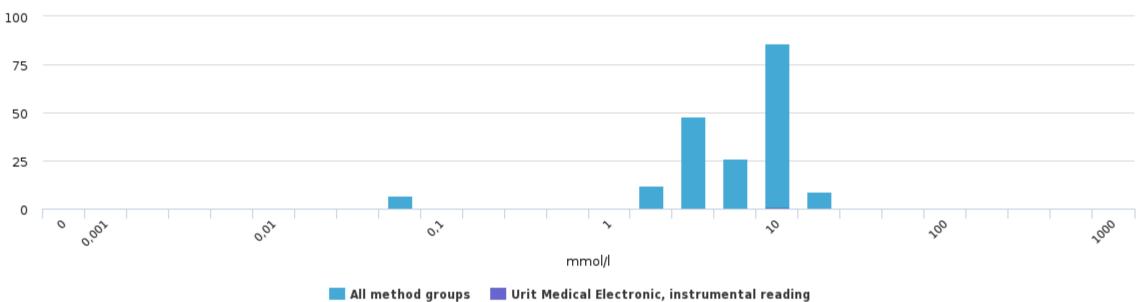
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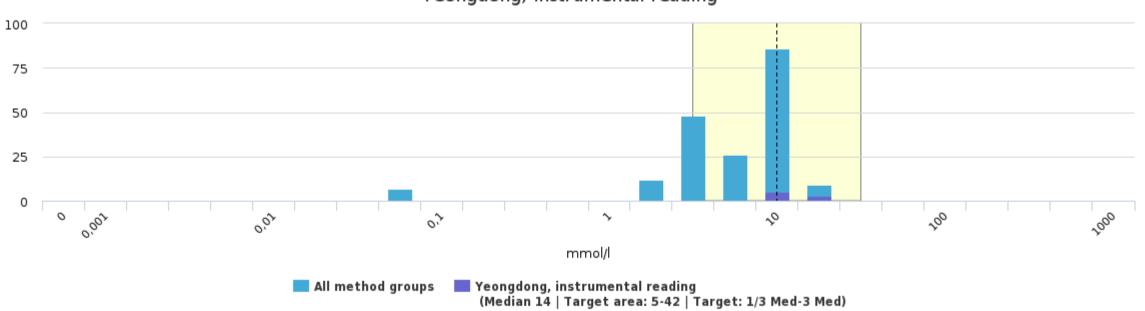








Yeongdong, instrumental reading

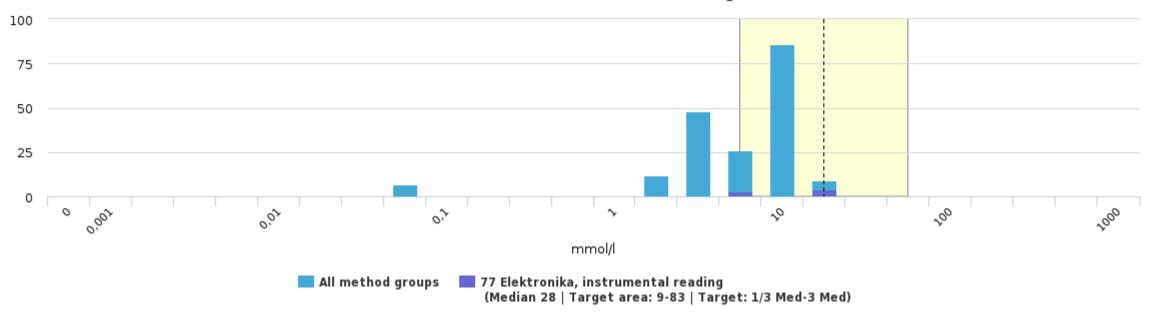


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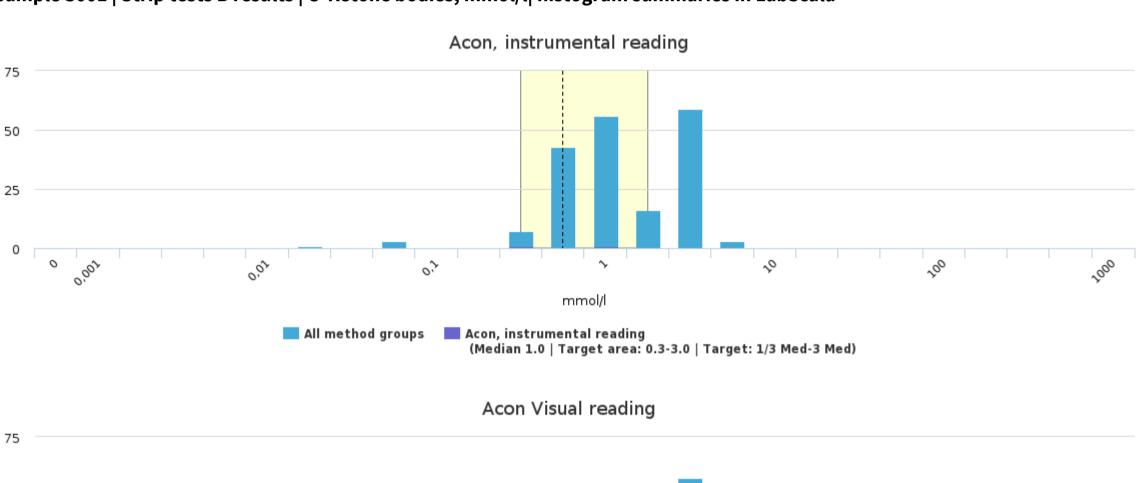


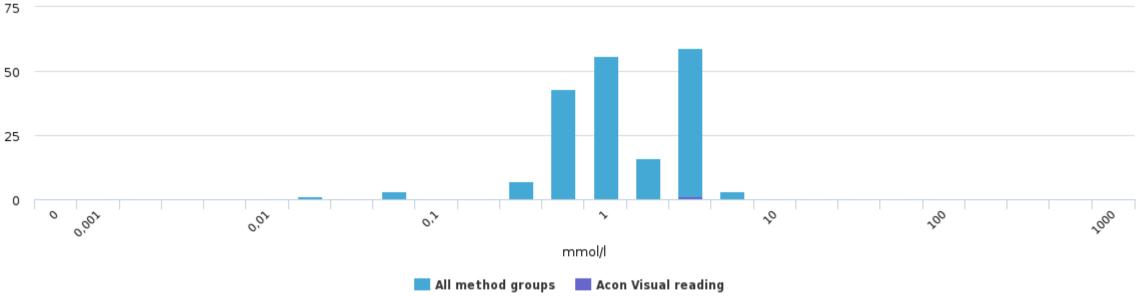


Sample S001 | Strip tests B results | U-Ketone bodies, mmol/l

Methodics	Median	sd	CV%	SEM	min	max	Outliers	n
Acon, instrumental reading	1.0	0.7	70.7	0.5	0.5	1.5	-	2
Acon Visual reading	-	-	-	-	3.9	3.9	-	1
AMP diagnostics, instrumental reading	-	-	-	-	1.5	1.5	-	1
Arkray, instrumental reading	-	-	-	-	5.9	5.9	-	1
Dirui, instrumental reading	-	-	-	-	3.9	3.9	-	1
Dirui visual reading	-	-	-	-	1.5	1.5	-	1
Erba Lachema, instrumental reading	1.5	<0.1	2.3	<0.1	1.5	1.6	-	3
Iris Diagnostics, instrumental reading	2.0	0.4	23.6	0.1	1.0	2.0	-	11
Macherey-Nagel, instrumental reading	2.4	<0.1	<0.1	<0.1	2.4	2.4	-	3
Menarini, instrumental reading	1.5	<0.1	<0.1	<0.1	1.5	1.5	-	3
Mindray, instrumental reading	-	-	-	-	8.0	8.0	-	1
Roche, instrumental reading	4.9	1.8	47.9	0.2	0.1	7.0	-	53
Roche visual reading	4.9	2.0	50.2	1.0	1.0	5.0	-	4
Siemens, instrumental reading	1.5	1.2	66.2	0.2	0.0	4.0	-	54
Siemens visual reading	-	-	-	-	3.9	3.9	-	1
Sysmex, instrumental reading	1.0	0.8	60.3	0.1	0.1	2.9	-	32
Urit Medical Electronic, instrumental reading	-	-	-	-	1.5	1.5	-	1
Yeongdong, instrumental reading	4.9	2.0	59.3	0.7	1.0	5.0	-	8
77 Elektronika, instrumental reading	1.5	<0.1	1.0	<0.1	1.5	1.5	-	7
All	1.5	1.7	68.7	0.1	0.0	5.9	2	188

Sample S001 | Strip tests B results | U-Ketone bodies, mmol/l| histogram summaries in LabScala

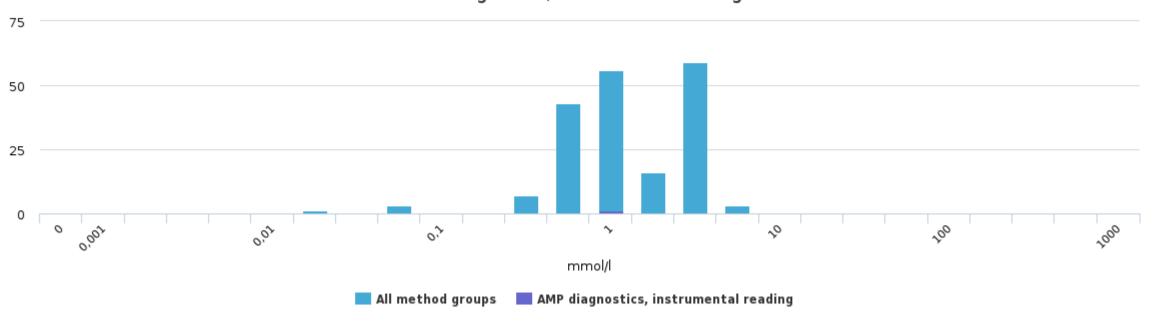




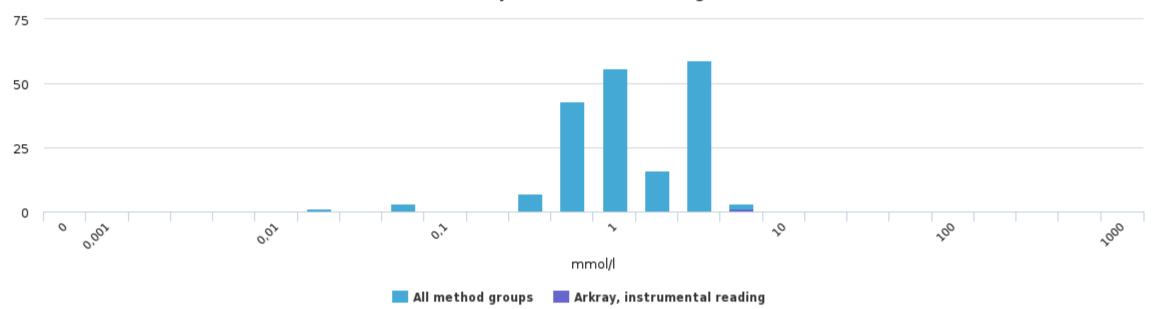
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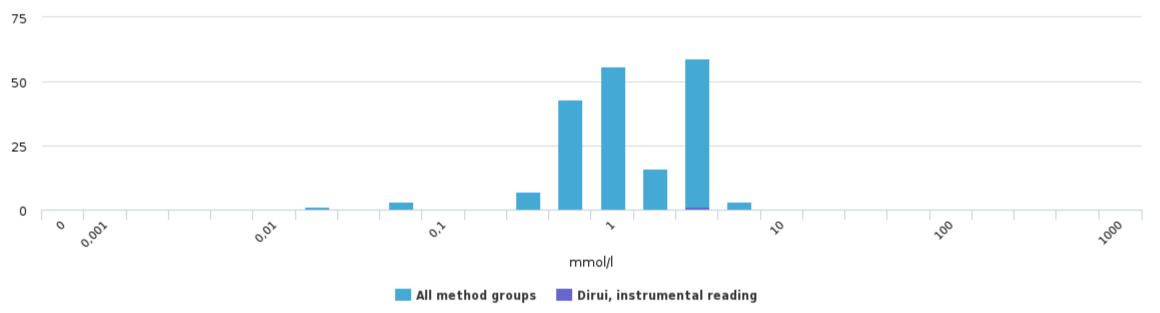




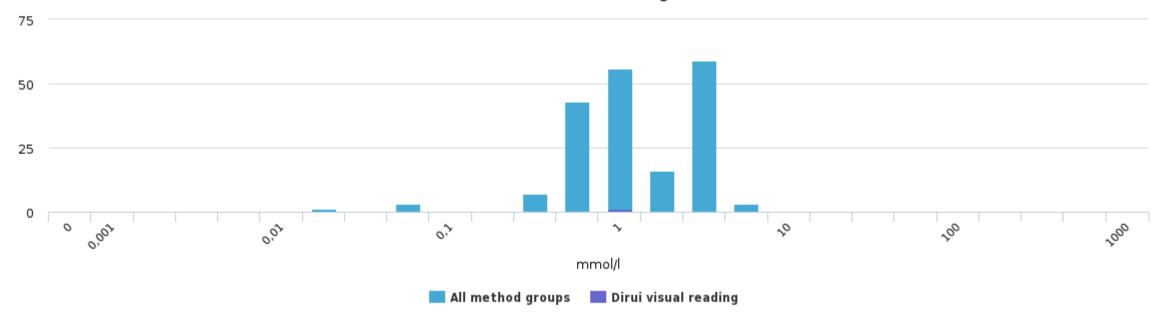
Arkray, instrumental reading



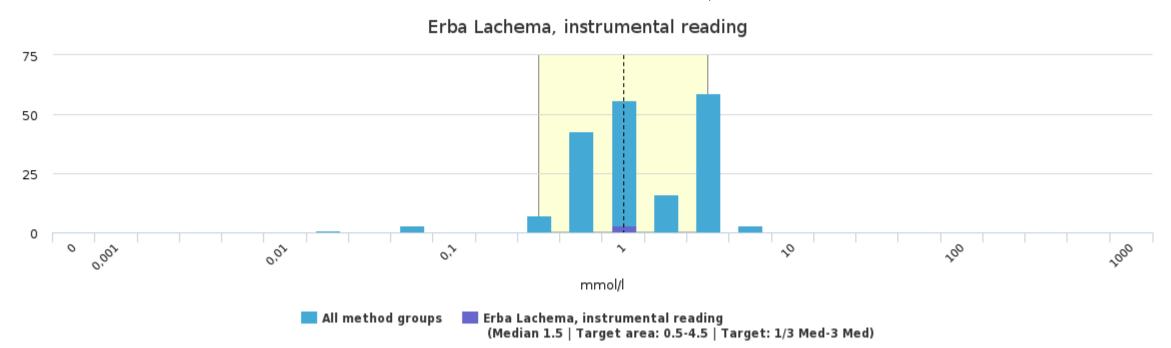
Dirui, instrumental reading

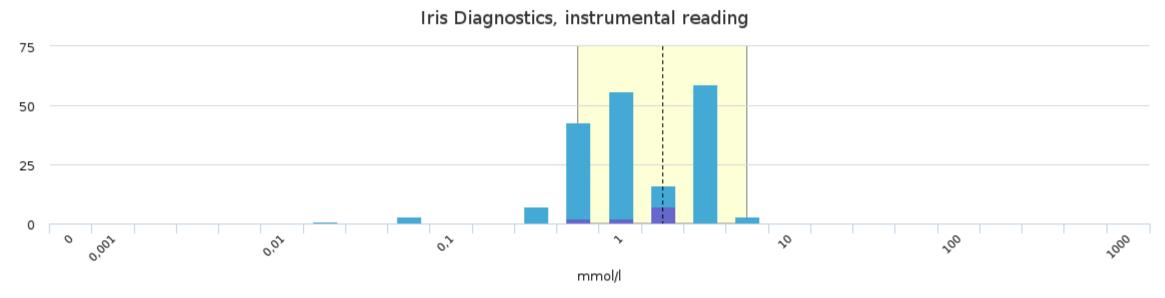


Dirui visual reading

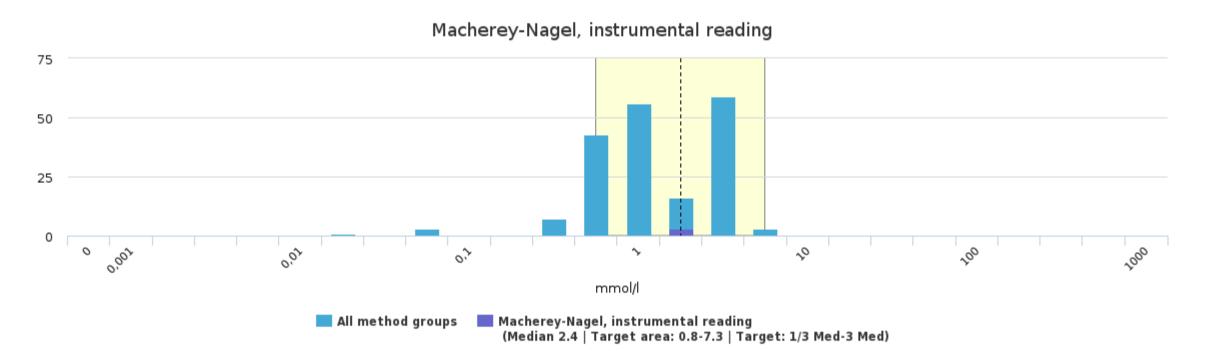


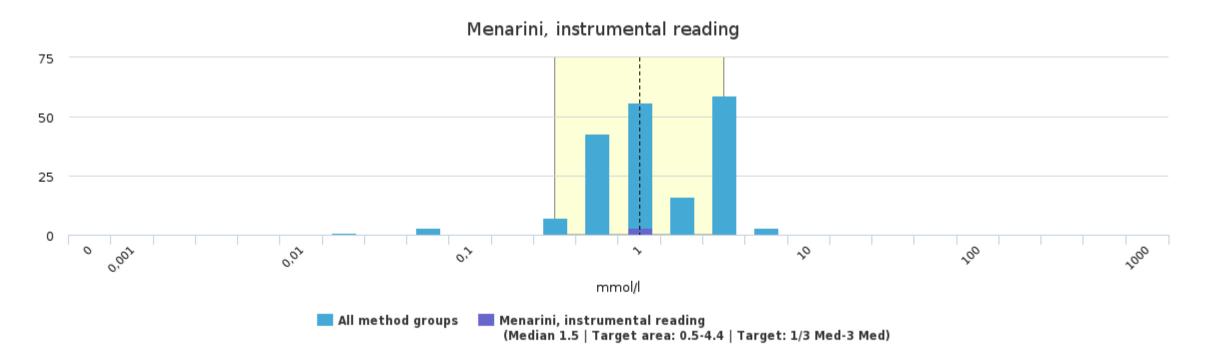
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All method groups Iris Diagnostics, instrumental reading (Median 2.0 | Target area: 0.7-5.9 | Target: 1/3 Med-3 Med)

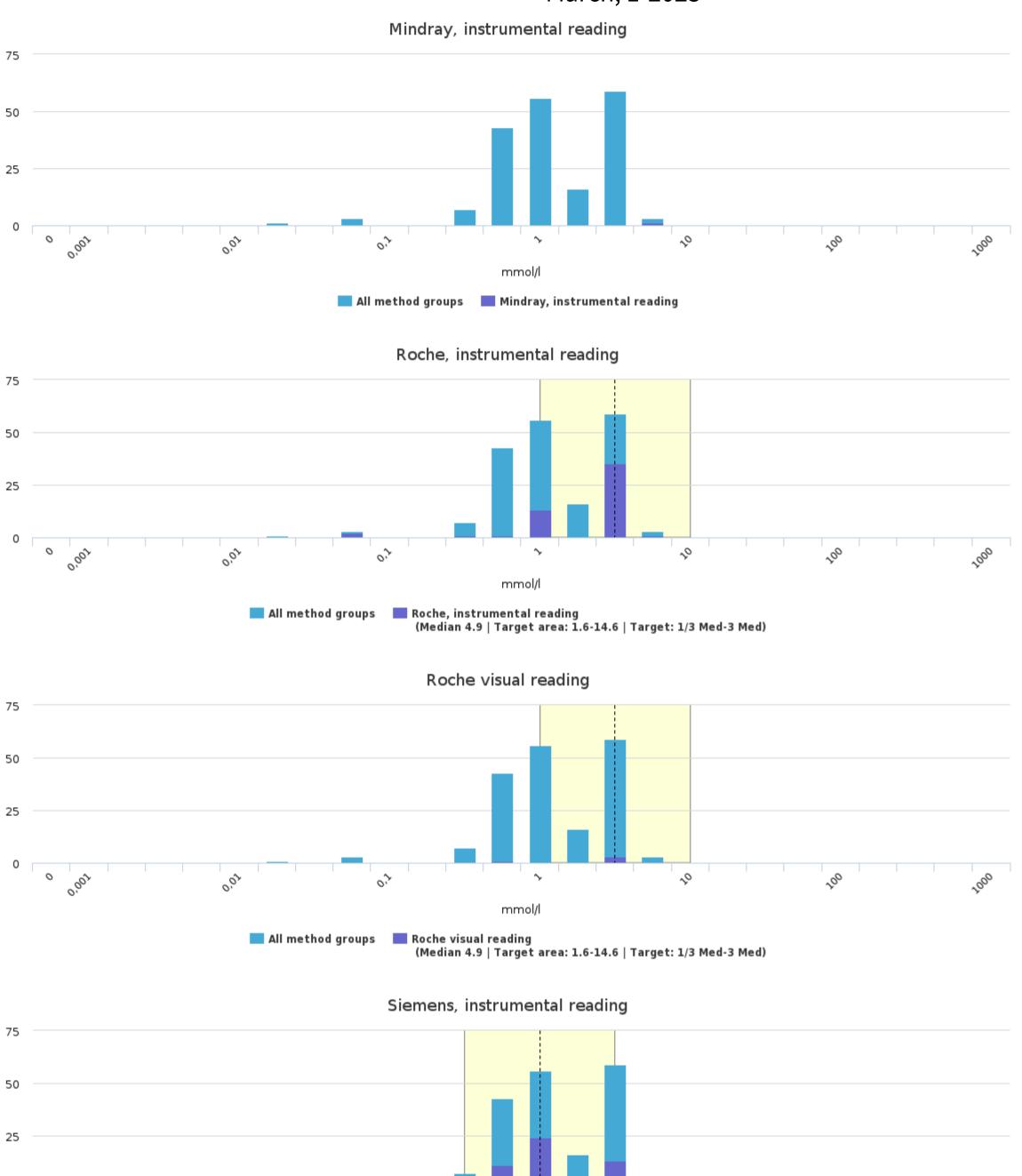




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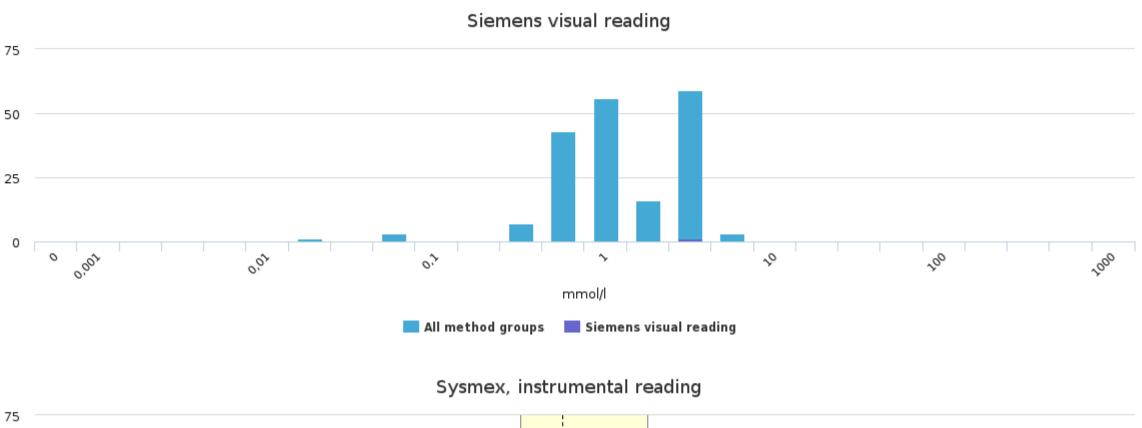
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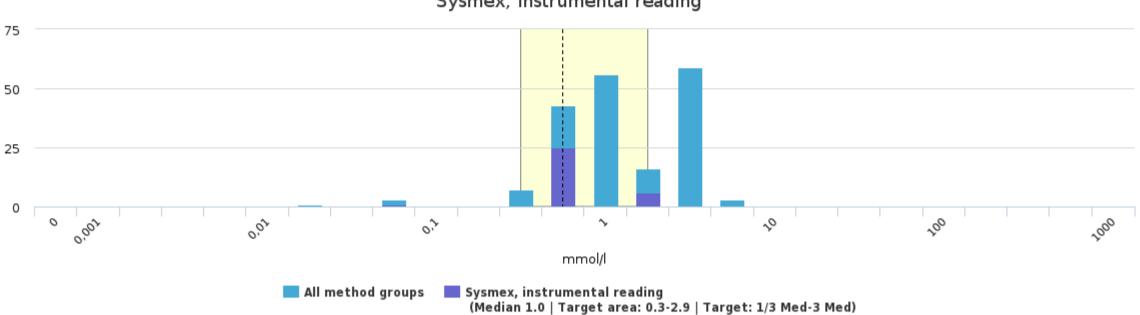
mmol/l

(Median 1.5 | Target area: 0.5-4.5 | Target: 1/3 Med-3 Med)

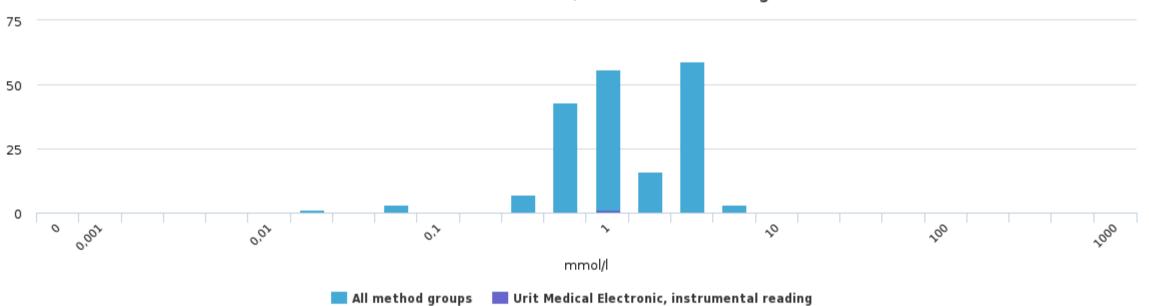
All method groups
Siemens, instrumental reading



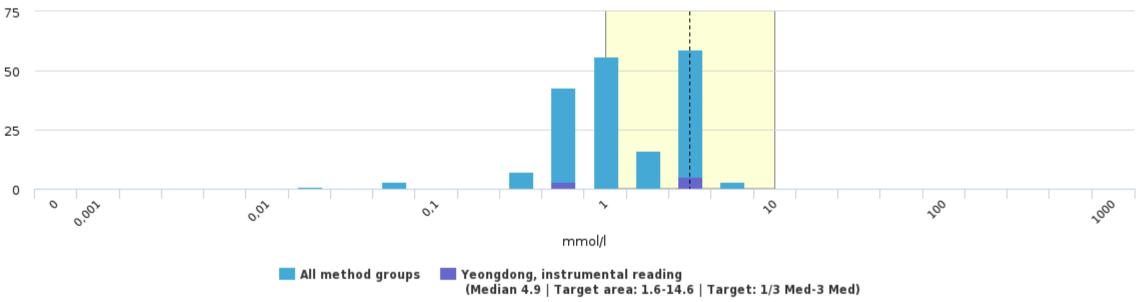








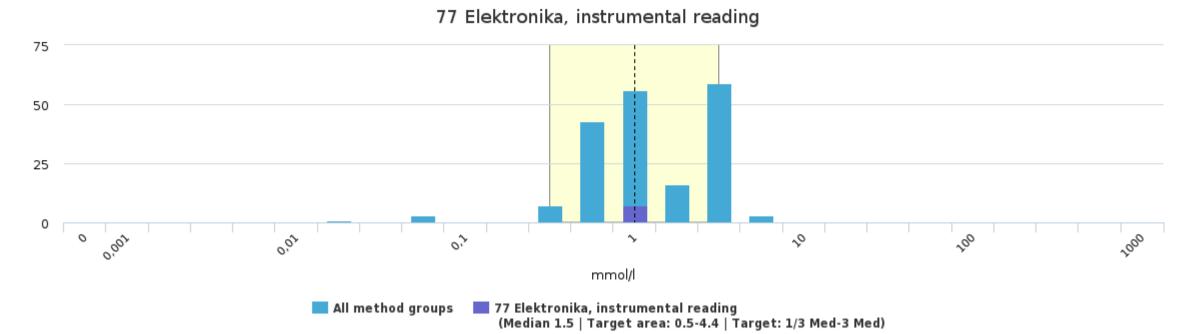




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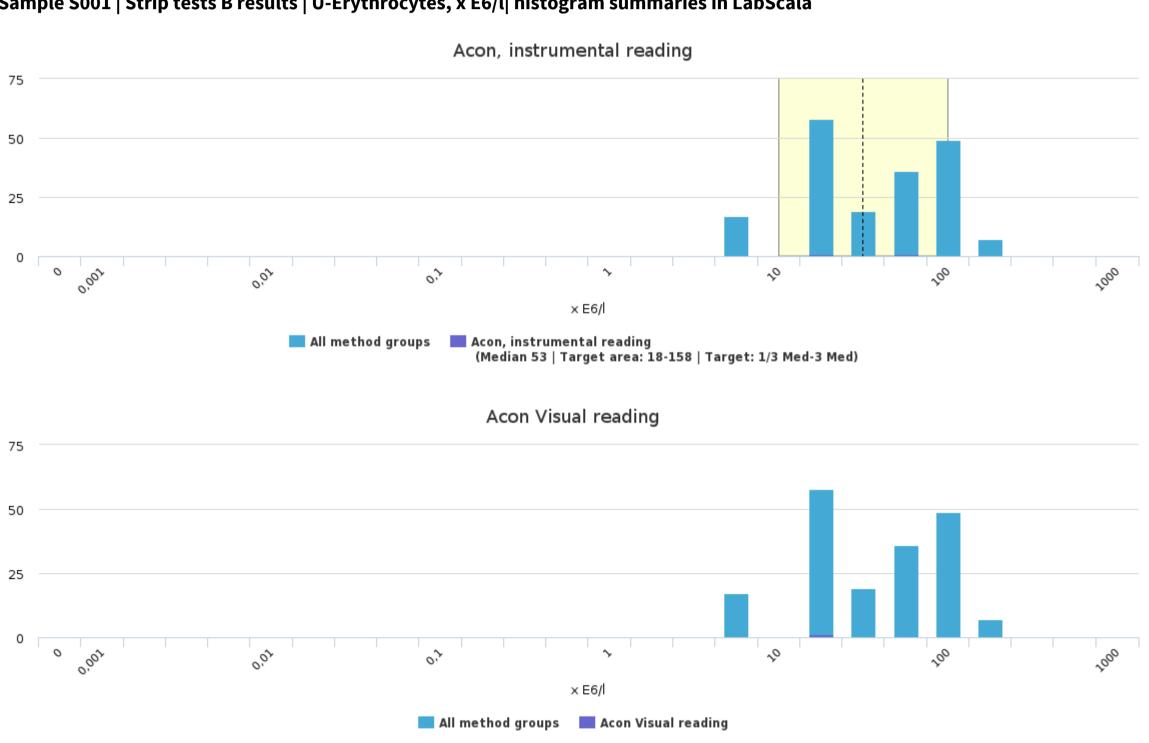
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Sample S001 | Strip tests B results | U-Erythrocytes, x E6/l

Methodics	Median	sd	CV%	SEM	min	max	Outliers	n
Acon, instrumental reading	53	39	74.1	28	25	80	-	2
Acon Visual reading	-	-	-	-	25	25	-	1
AMP diagnostics, instrumental reading	-	-	-	-	25	25	-	1
Analyticon, instrumental reading	-	-	-	-	50	50	-	1
Arkray, instrumental reading	-	-	-	-	18	18	-	1
Dirui, instrumental reading	-	-	-	-	80	80	-	1
Dirui visual reading	-	-	-	-	50	50	-	1
Erba Lachema, instrumental reading	50	23	63.0	13	10	50	-	3
Iris Diagnostics, instrumental reading	9	8	66.3	3	9	30	-	11
Macherey-Nagel, instrumental reading	10	<1	<0.1	<1	10	10	-	2
Menarini, instrumental reading	50	<1	<0.1	<1	50	50	-	3
Mindray, instrumental reading	-	-	-	-	80	80	-	1
Roche, instrumental reading	150	<1	<0.1	<1	150	150	5	52
Roche visual reading	113	95	68.8	39	50	250	-	6
Siemens, instrumental reading	80	27	47.8	4	10	80	-	54
Siemens visual reading	25	<1	<0.1	<1	25	25	-	2
Sysmex, instrumental reading	18	1	5.3	<1	18	20	1	30
Urit Medical Electronic, instrumental reading	-	-	-	-	23	23	-	1
Yeongdong, instrumental reading	100	97	79.3	37	10	250	-	7
77 Elektronika, instrumental reading	50	<1	<0.1	<1	50	50	-	6
All	50	54	75.9	4	9	150	7	18

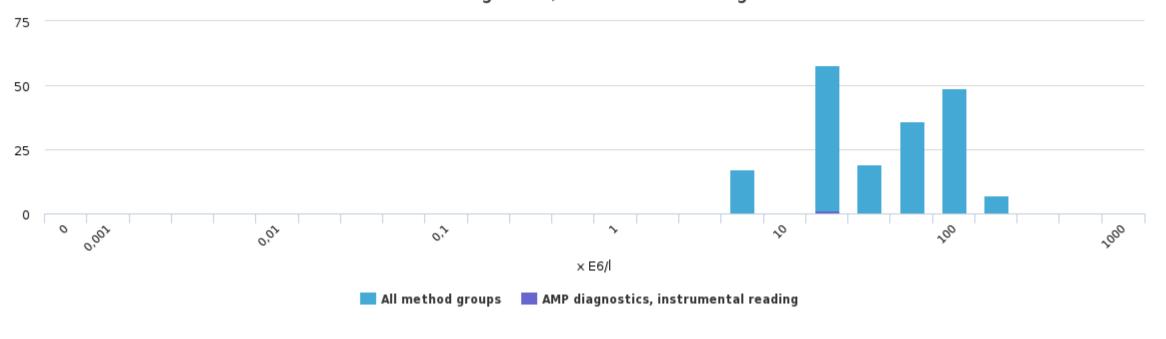
Sample S001 | Strip tests B results | U-Erythrocytes, x E6/l| histogram summaries in LabScala



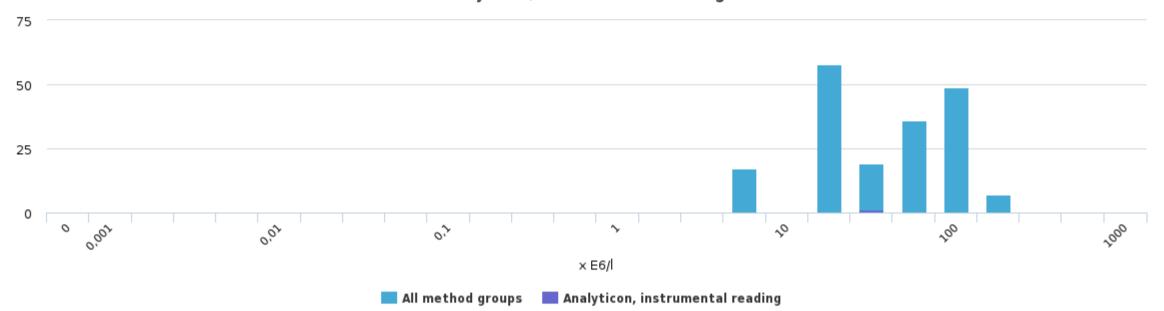
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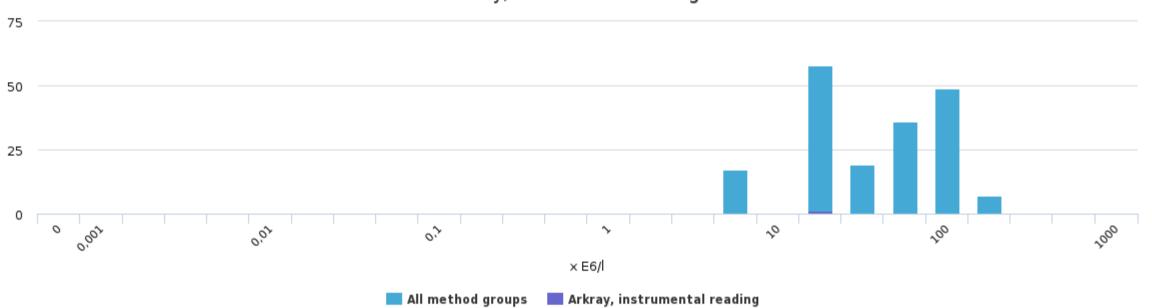




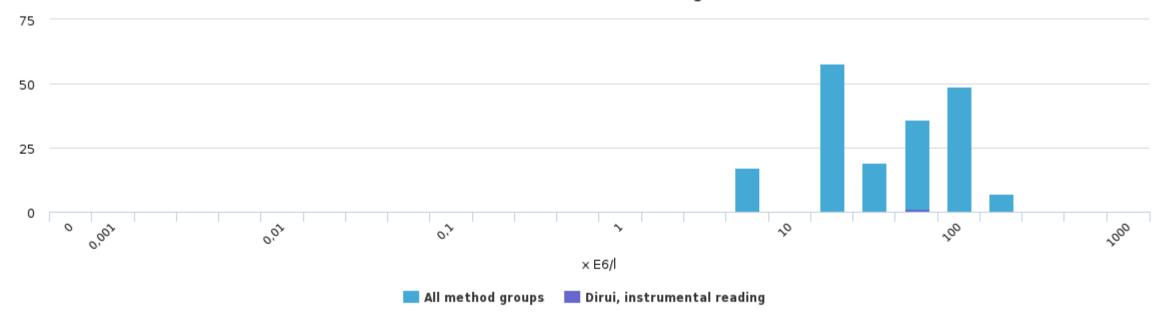
Analyticon, instrumental reading



Arkray, instrumental reading

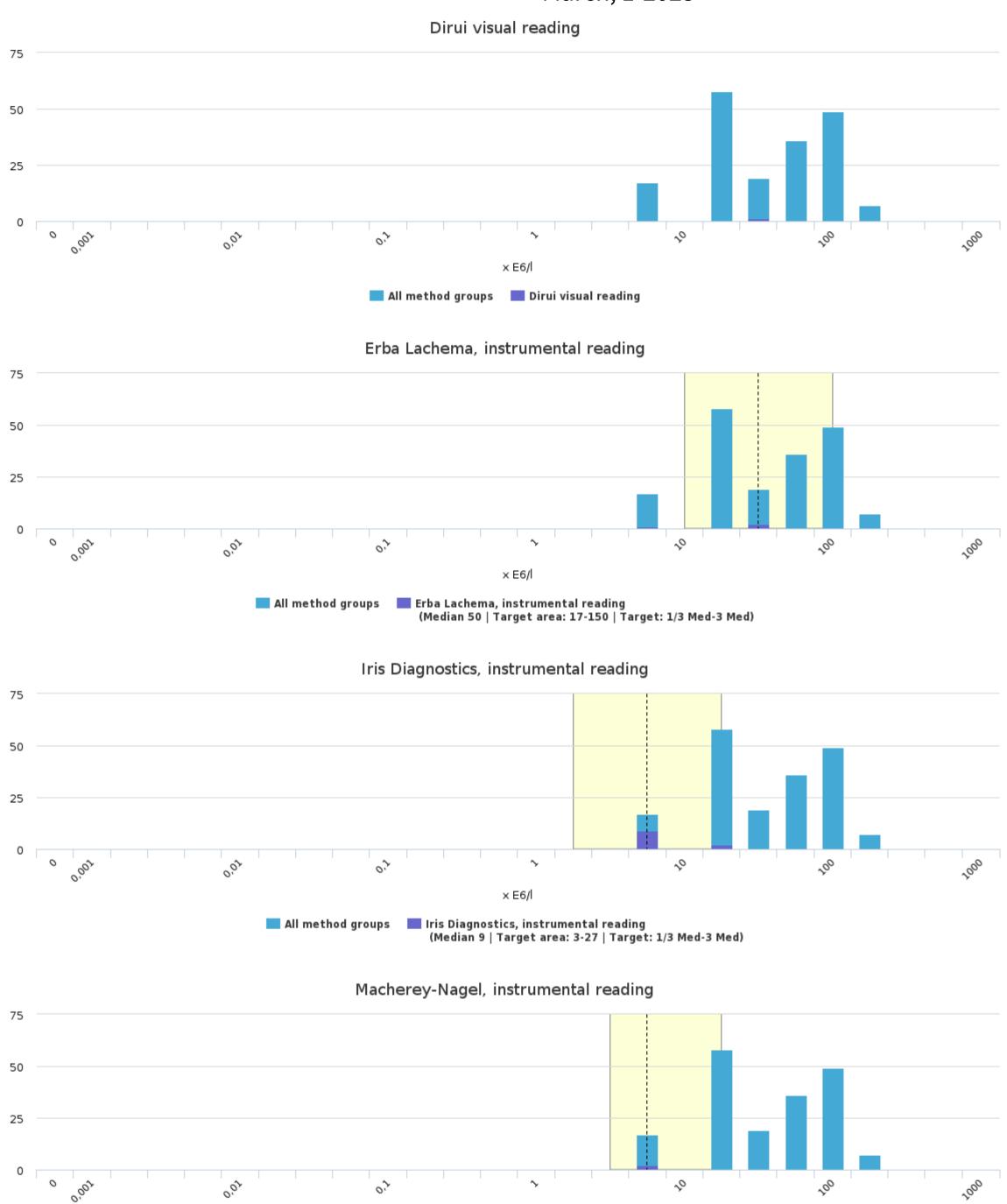


Dirui, instrumental reading



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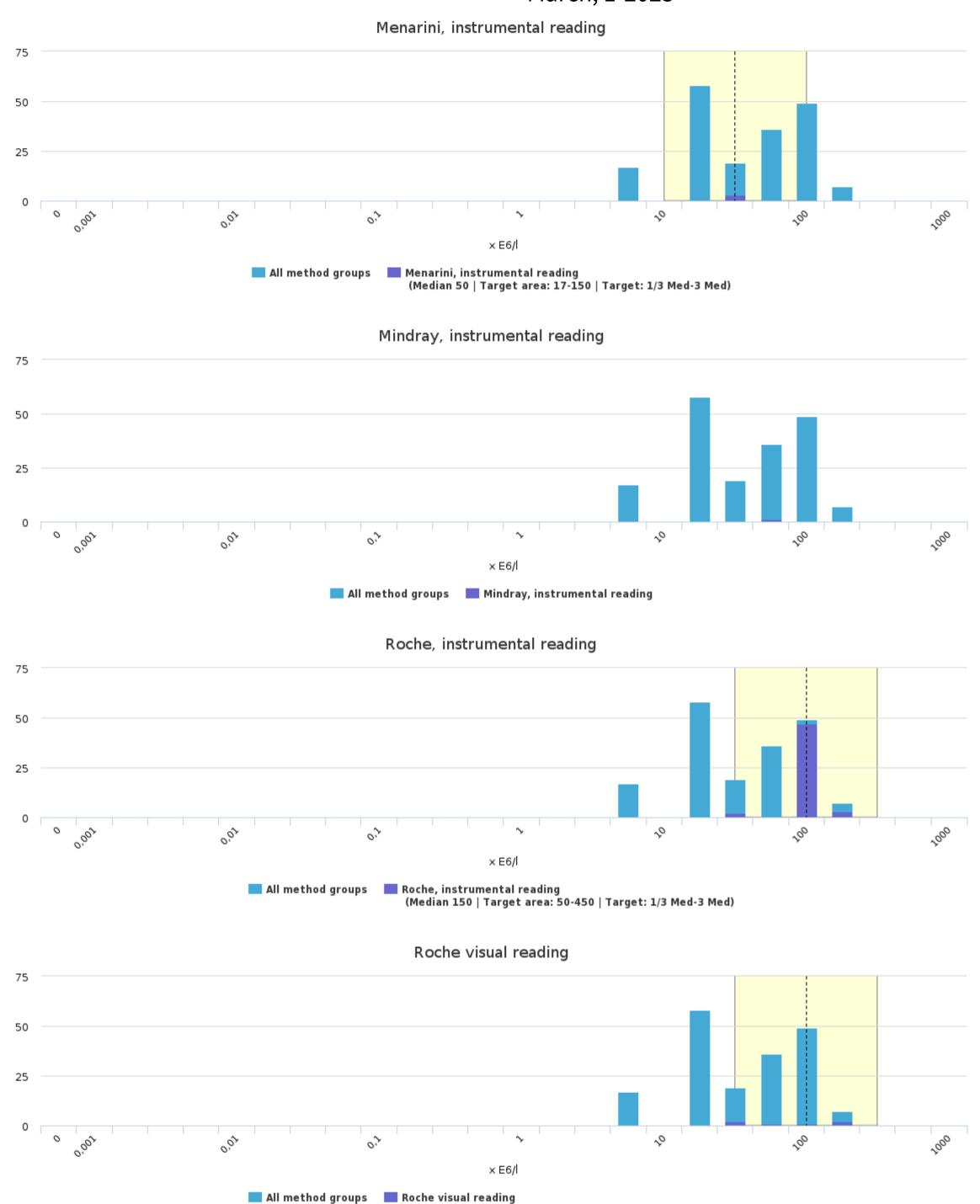
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× E6/l

(Median 10 | Target area: 3-30 | Target: 1/3 Med-3 Med)

All method groups Macherey-Nagel, instrumental reading



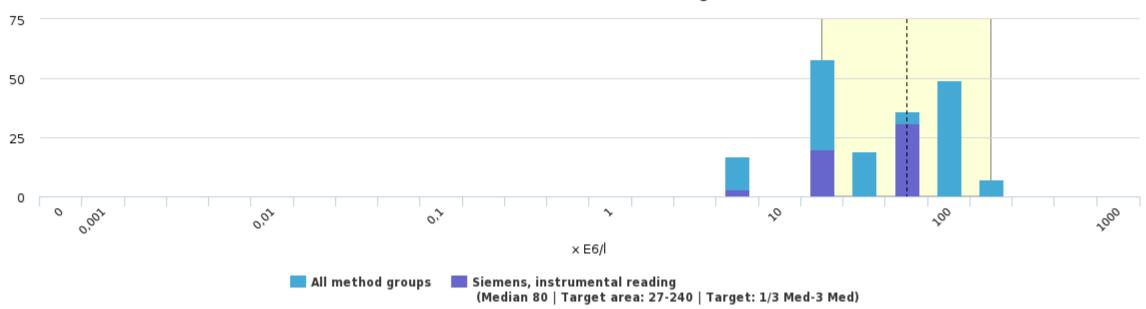


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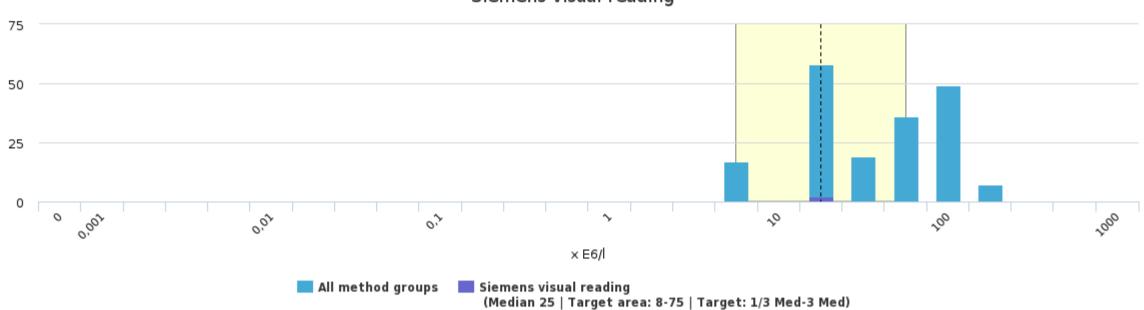
(Median 113 | Target area: 38-338 | Target: 1/3 Med-3 Med)



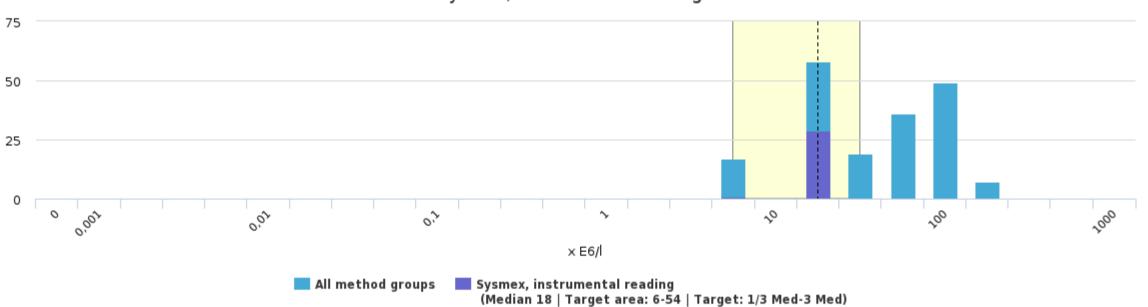




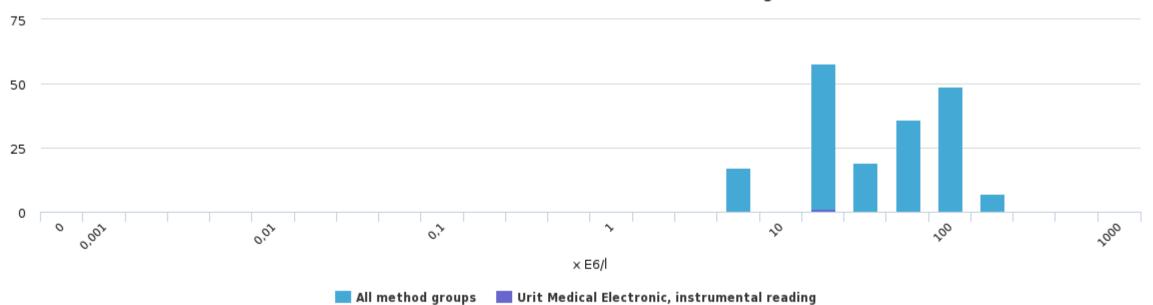
Siemens visual reading



Sysmex, instrumental reading



Urit Medical Electronic, instrumental reading

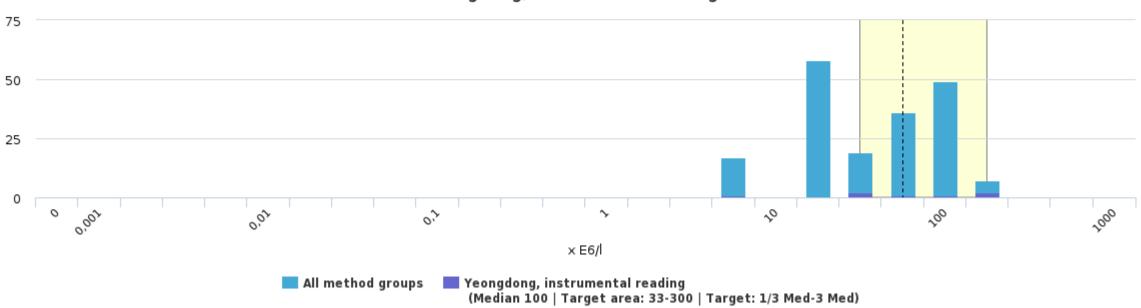


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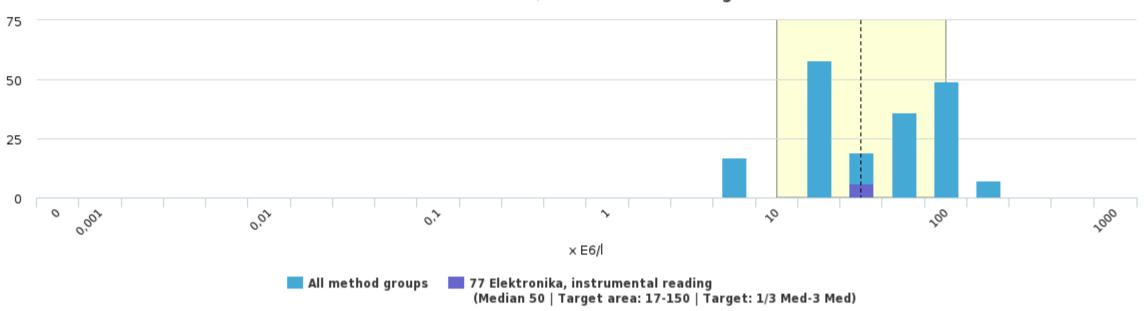
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77 Elektronika, instrumental reading



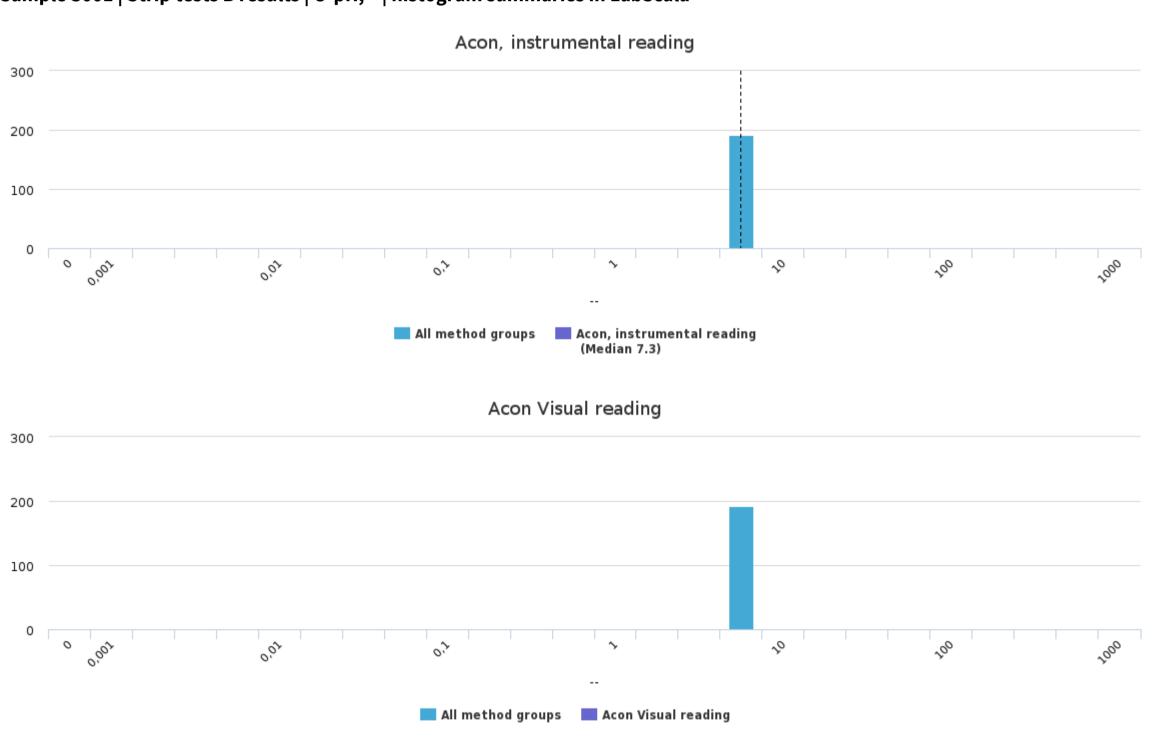
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Sample S001 | Strip tests B results | U-pH, --

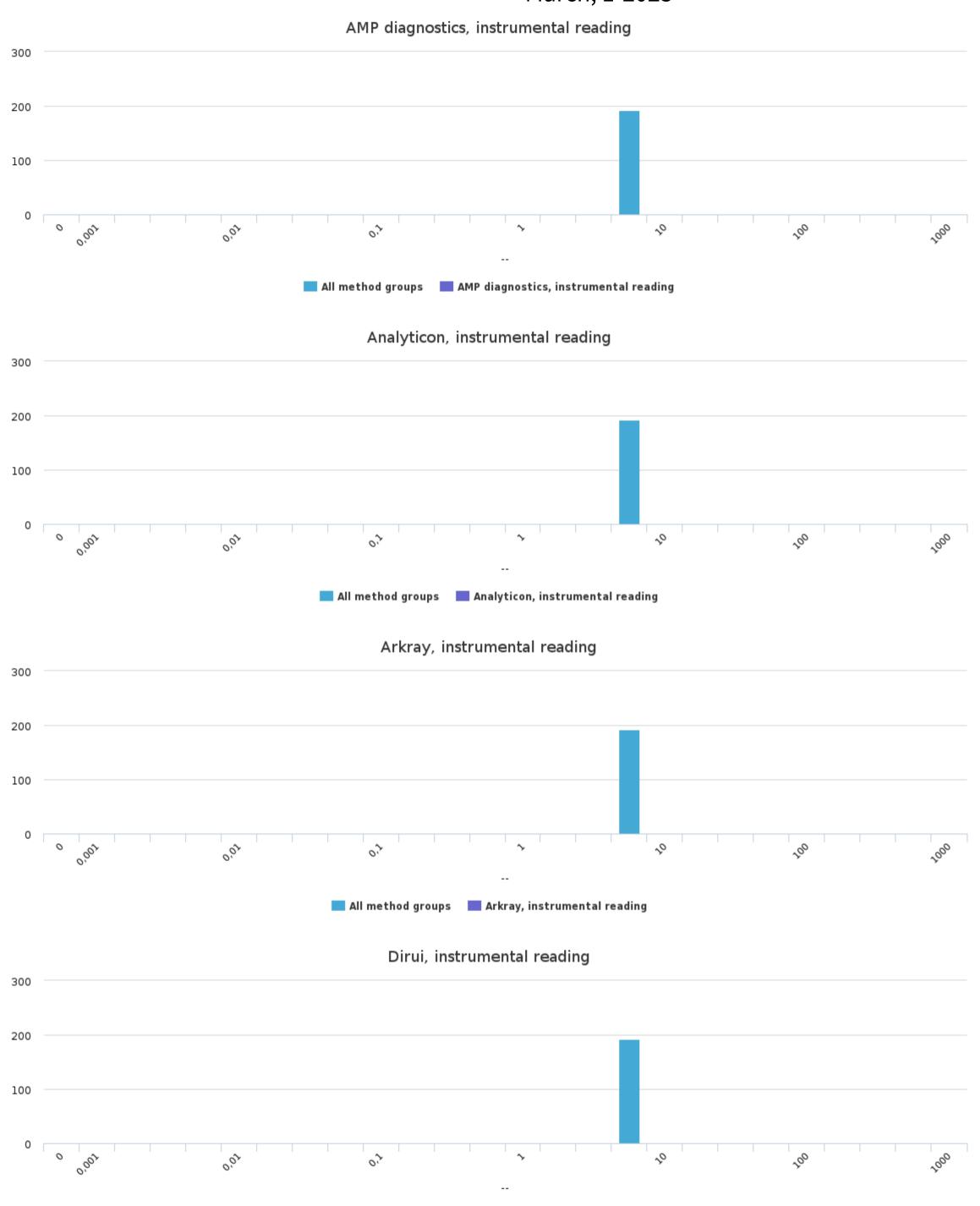
Methodics	Median	sd	CV%	SEM	min	max	Outliers	n
Acon, instrumental reading	7.3	0.4	4.9	0.3	7.0	7.5	-	2
Acon Visual reading	-	-	-	-	7.5	7.5	-	1
AMP diagnostics, instrumental reading	-	-	-	-	7.5	7.5	-	1
Analyticon, instrumental reading	-	-	-	-	7.5	7.5	-	1
Arkray, instrumental reading	-	-	-	-	7.5	7.5	-	1
Dirui, instrumental reading	-	-	-	-	7.0	7.0	-	1
Dirui visual reading	-	-	-	-	7.0	7.0	-	1
Erba Lachema, instrumental reading	8.0	<0.1	<0.1	<0.1	8.0	8.0	-	3
Iris Diagnostics, instrumental reading	8.0	0.3	3.2	<0.1	7.5	8.0	-	11
Macherey-Nagel, instrumental reading	7.0	<0.1	<0.1	<0.1	7.0	7.0	-	3
Menarini, instrumental reading	7.5	0.3	3.9	0.2	7.0	7.5	-	3
Mindray, instrumental reading	-	-	-	-	7.0	7.0	-	1
Roche, instrumental reading	8.0	<0.1	0.9	<0.1	7.5	8.0	6	53
Roche visual reading	7.0	0.3	3.5	0.1	7.0	7.5	-	4
Siemens, instrumental reading	7.5	0.2	3.2	<0.1	7.5	8.0	-	56
Siemens visual reading	7.5	<0.1	<0.1	<0.1	7.5	7.5	-	2
Sysmex, instrumental reading	7.5	<0.1	<0.1	<0.1	7.5	7.5	-	32
Urit Medical Electronic, instrumental reading	-	-	-	-	7.5	7.5	-	1
Yeongdong, instrumental reading	7.0	0.3	3.8	<0.1	6.5	7.5	-	8
77 Elektronika, instrumental reading	7.0	0.2	2.7	<0.1	7.0	7.5	-	7
All	7.5	0.4	4.7	<0.1	6.5	8.0	-	192

Sample S001 | Strip tests B results | U-pH, --| histogram summaries in LabScala



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All method groups Dirui, instrumental reading

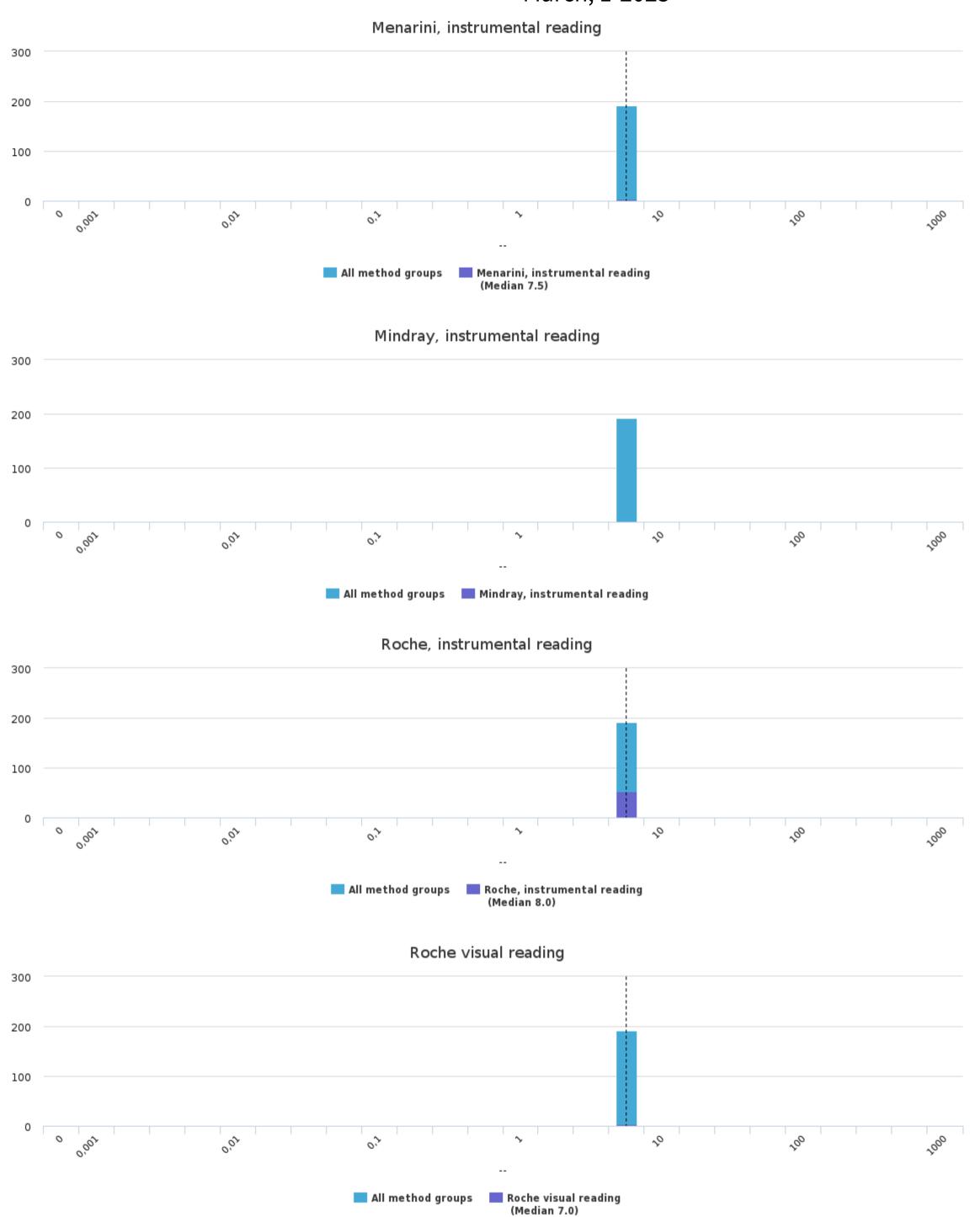




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(Median 7.0)





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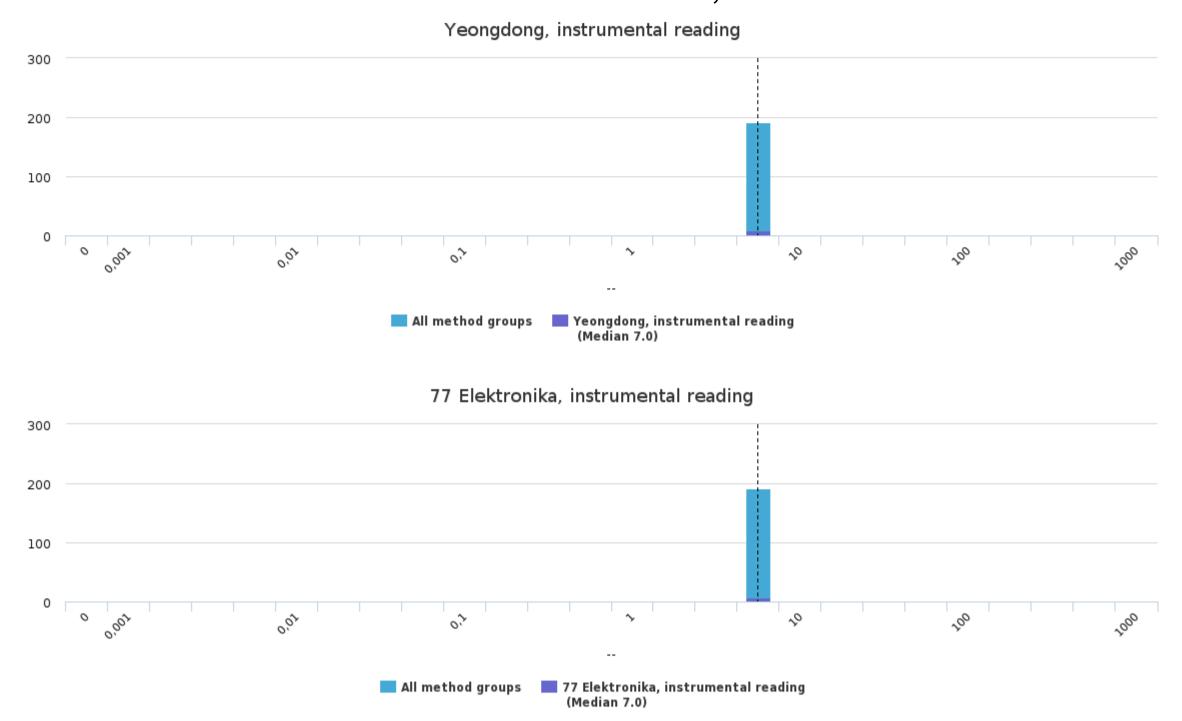




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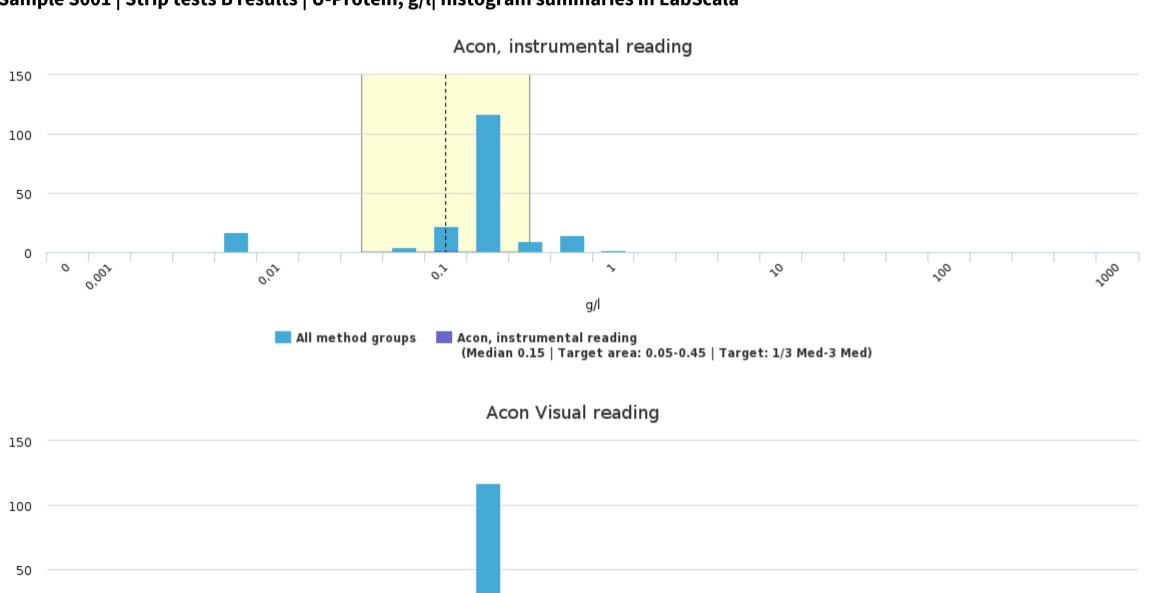
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Sample S001 | Strip tests B results | U-Protein, g/l

Methodics	Median	sd	CV%	SEM	min	max	Outliers	n
Acon, instrumental reading	0.15	<0.01	<0.1	<0.01	0.15	0.15	-	2
Acon Visual reading	-	-	-	-	1.00	1.00	-	1
AMP diagnostics, instrumental reading	-	-	-	-	0.10	0.10	-	1
Arkray, instrumental reading	-	-	-	-	1.50	1.50	-	1
Dirui, instrumental reading	-	-	-	-	0.01	0.01	-	1
Dirui visual reading	-	-	-	-	0.30	0.30	-	1
Erba Lachema, instrumental reading	0.01	0.57	168.1	0.33	0.01	1.00	-	3
Iris Diagnostics, instrumental reading	0.50	0.06	13.2	0.02	0.30	0.50	1	11
Macherey-Nagel, instrumental reading	0.01	0.17	157.0	0.10	0.01	0.30	-	3
Menarini, instrumental reading	0.15	0.78	129.9	0.45	0.15	1.50	-	3
Mindray, instrumental reading	-	-	-	-	0.15	0.15	-	1
Roche, instrumental reading	0.25	0.22	61.7	0.03	0.01	0.75	-	52
Roche visual reading	-	-	-	-	0.30	0.30	-	1
Siemens, instrumental reading	0.30	0.05	20.0	<0.01	0.15	0.30	3	55
Siemens visual reading	0.01	0.17	157.0	0.10	0.01	0.30	-	3
Sysmex, instrumental reading	0.30	0.07	25.5	0.01	0.15	0.30	-	31
Urit Medical Electronic, instrumental reading	-	-	-	-	0.15	0.15	-	1
Yeongdong, instrumental reading	0.01	0.10	144.1	0.03	0.01	0.28	-	8
77 Elektronika, instrumental reading	0.15	0.09	60.5	0.04	0.01	0.30	-	6
All	0.25	0.17	61.6	0.01	0.01	0.75	4	185

Sample S001 | Strip tests B results | U-Protein, g/l| histogram summaries in LabScala

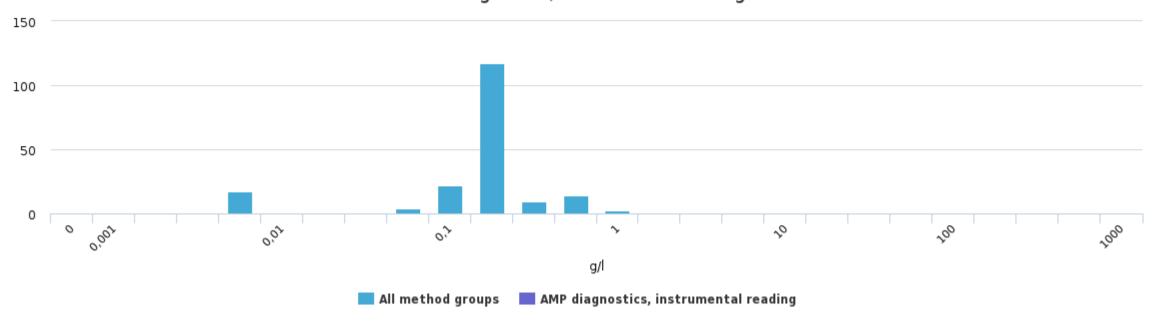


All method groups Acon Visual reading

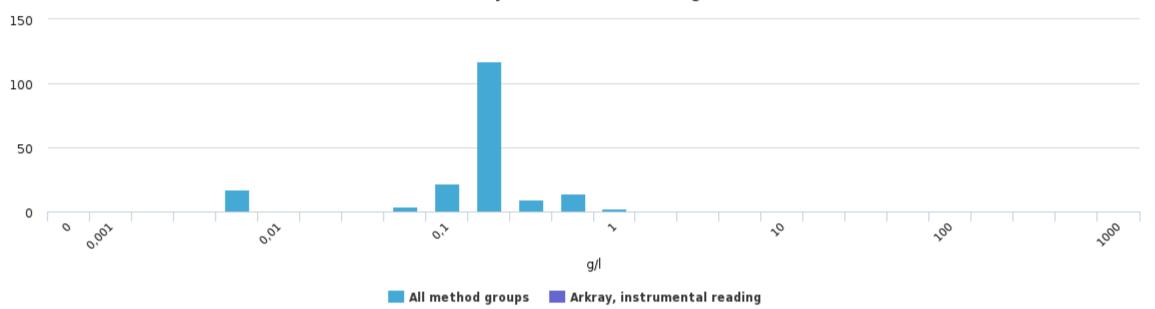
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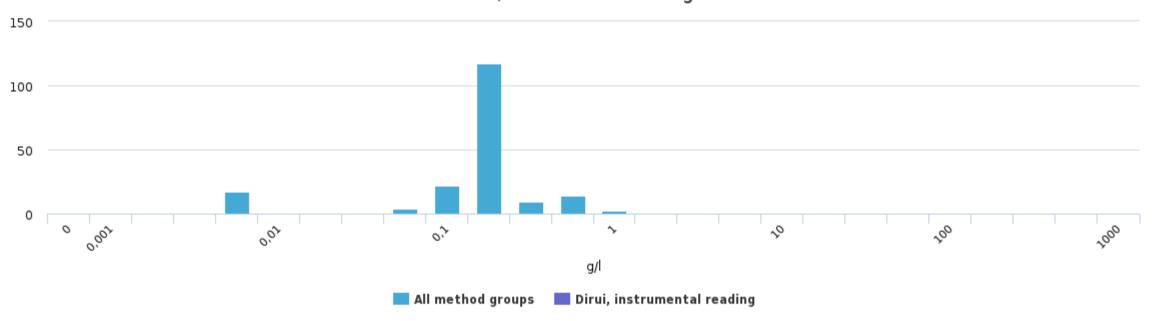




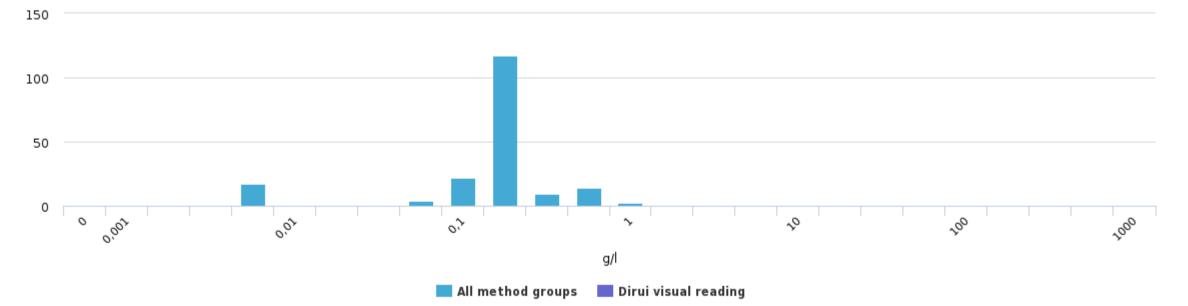
Arkray, instrumental reading



Dirui, instrumental reading



Dirui visual reading

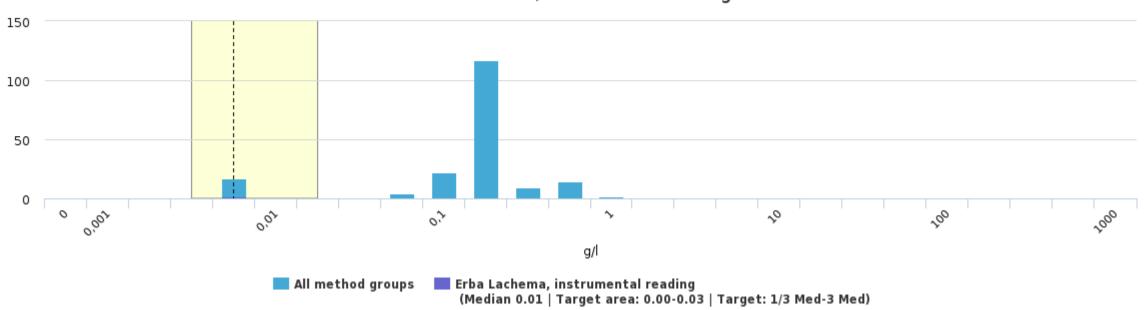


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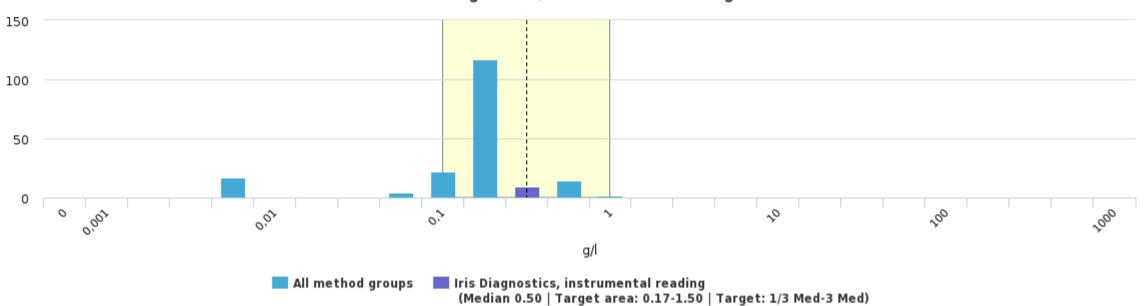
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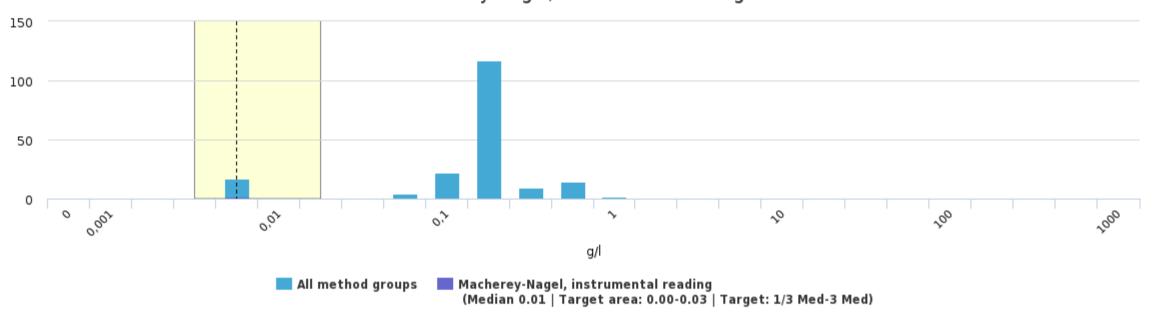




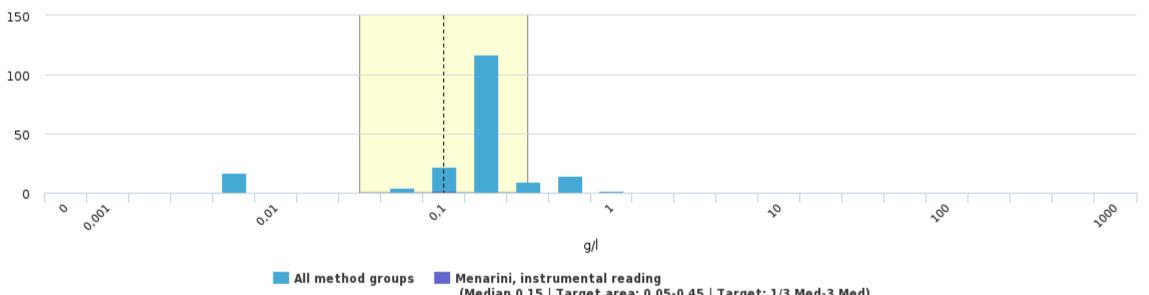
Iris Diagnostics, instrumental reading



Macherey-Nagel, instrumental reading



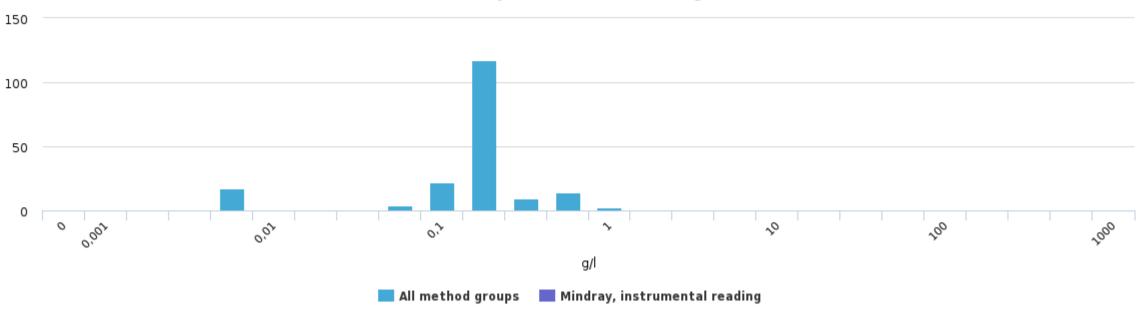
Menarini, instrumental reading

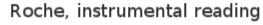


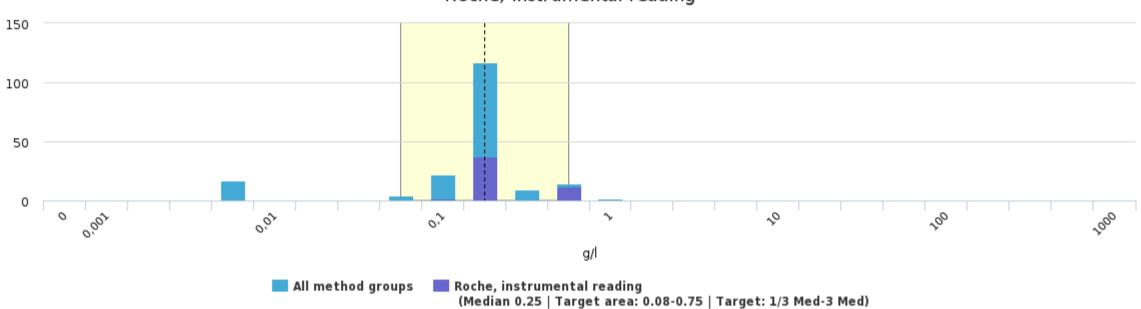
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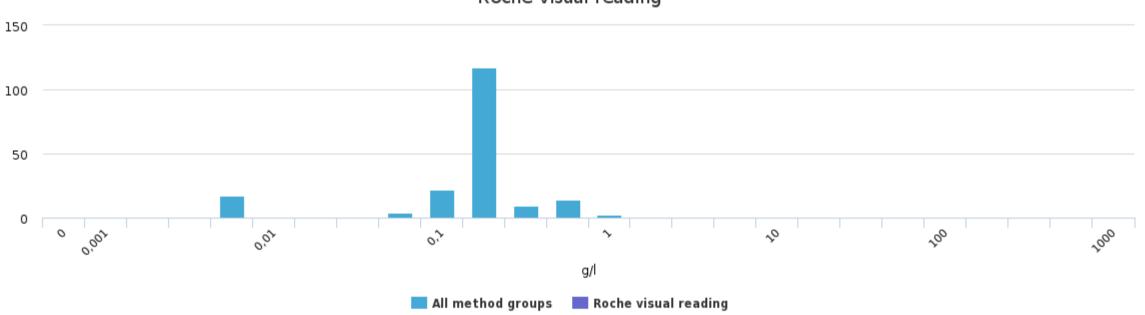




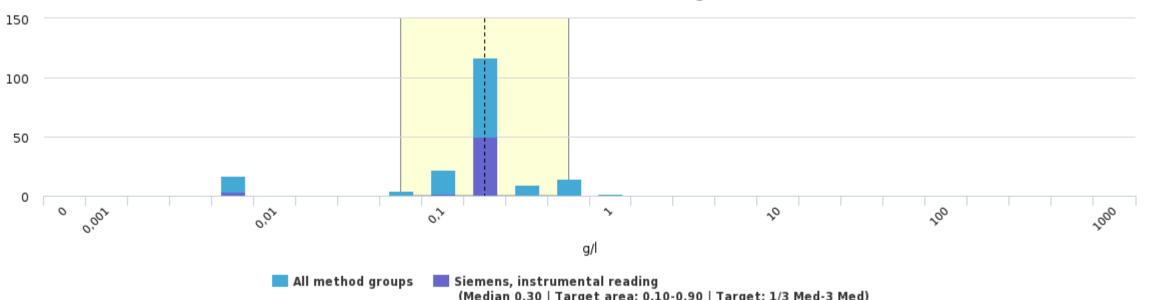




Roche visual reading



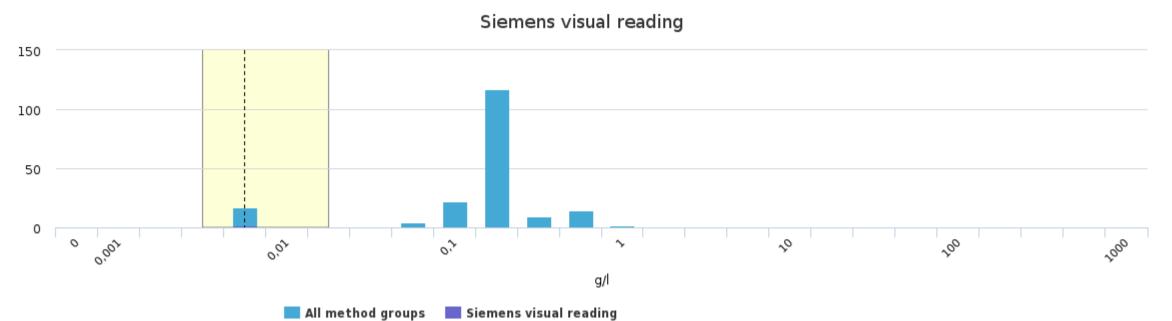
Siemens, instrumental reading

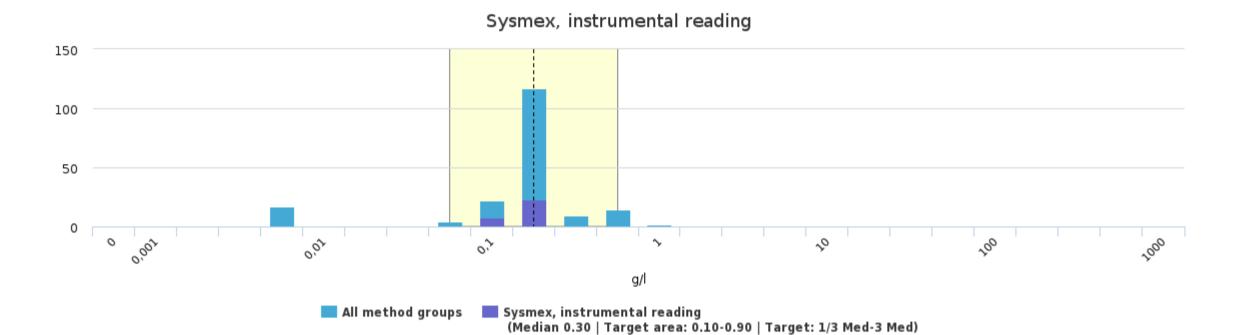


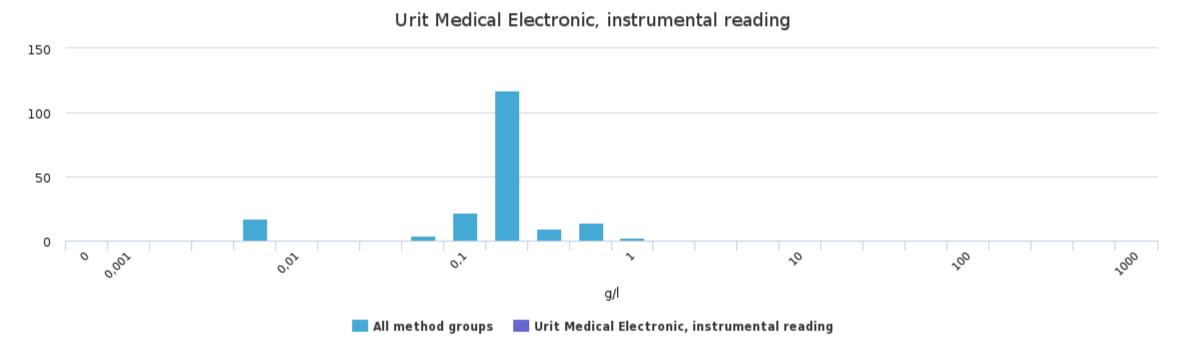
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(Median 0.01 | Target area: 0.00-0.03 | Target: 1/3 Med-3 Med)



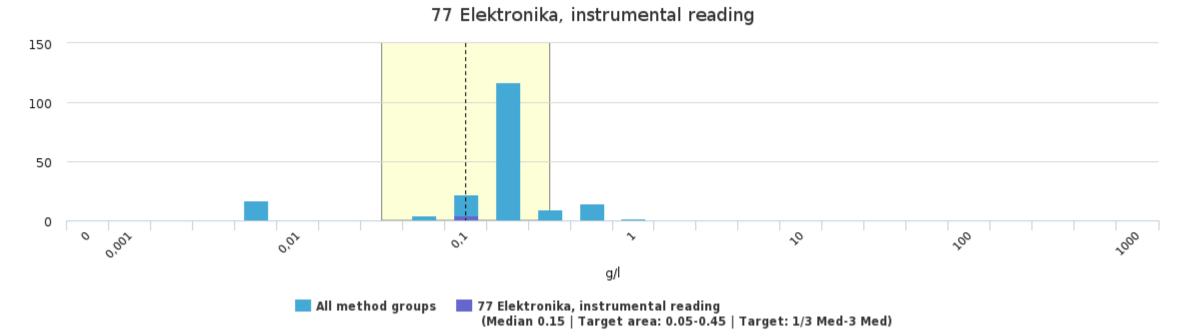






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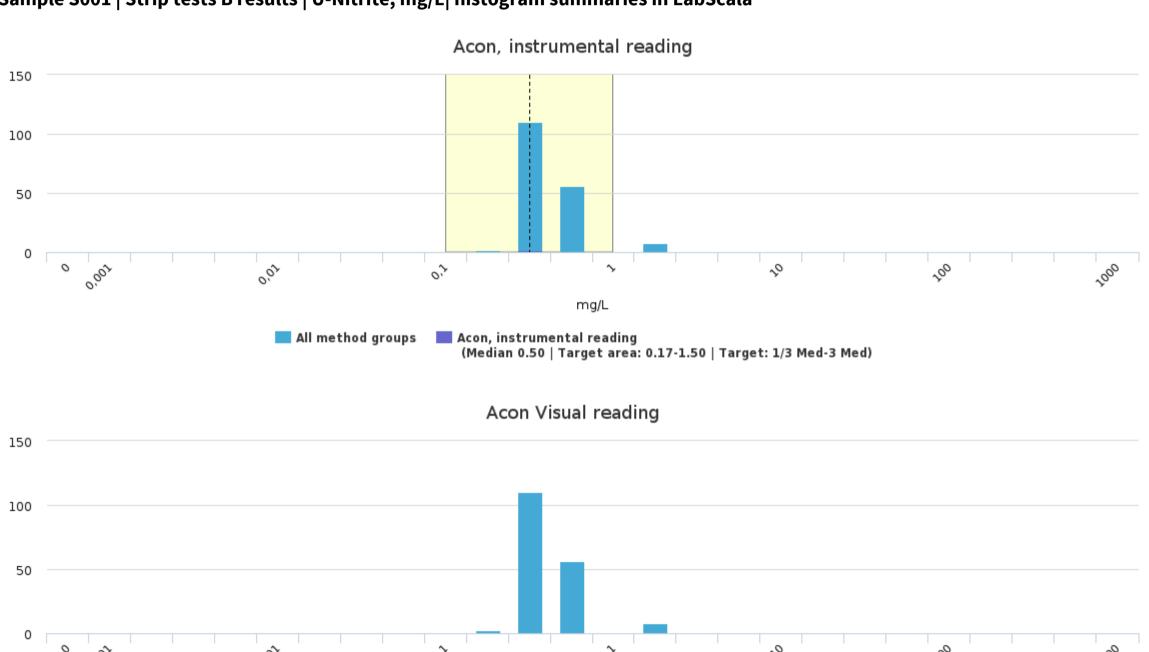




Sample S001 | Strip tests B results | U-Nitrite, mg/L

Methodics	Median	sd	CV%	SEM	min	max	Outliers	n
Acon, instrumental reading	0.50	<0.01	<0.1	<0.01	0.50	0.50	-	2
Acon Visual reading	-	-	-	-	0.76	0.76	-	1
AMP diagnostics, instrumental reading	-	-	-	-	0.60	0.60	-	1
Arkray, instrumental reading	-	-	-	-	0.80	0.80	-	1
Dirui, instrumental reading	-	-	-	-	2.50	2.50	-	1
Dirui visual reading	-	-	-	-	0.56	0.56	-	1
Erba Lachema, instrumental reading	0.80	<0.01	<0.1	<0.01	0.80	0.80	-	3
Iris Diagnostics, instrumental reading	2.00	0.76	52.6	0.23	0.20	2.00	-	11
Macherey-Nagel, instrumental reading	0.50	<0.01	<0.1	<0.01	0.50	0.50	-	3
Menarini, instrumental reading	0.90	0.14	15.7	0.10	0.80	1.00	-	2
Mindray, instrumental reading	-	-	-	-	1.00	1.00	-	1
Roche, instrumental reading	0.50	<0.01	<0.1	<0.01	0.50	0.50	-	46
Roche visual reading	0.50	0.12	26.6	0.07	0.30	0.50	-	3
Siemens, instrumental reading	0.75	0.11	16.6	0.02	0.50	0.80	2	55
Siemens visual reading	-	-	-	-	0.76	0.76	-	1
Sysmex, instrumental reading	0.50	0.17	29.9	0.03	0.50	1.00	-	32
Urit Medical Electronic, instrumental reading	-	-	-	-	0.00	0.00	-	1
Yeongdong, instrumental reading	0.50	0.16	35.0	0.06	0.06	0.50	-	8
77 Elektronika, instrumental reading	0.50	<0.01	<0.1	<0.01	0.50	0.50	-	7
All	0.50	0.16	28.6	0.01	0.00	1.00	8	180

Sample S001 | Strip tests B results | U-Nitrite, mg/L| histogram summaries in LabScala



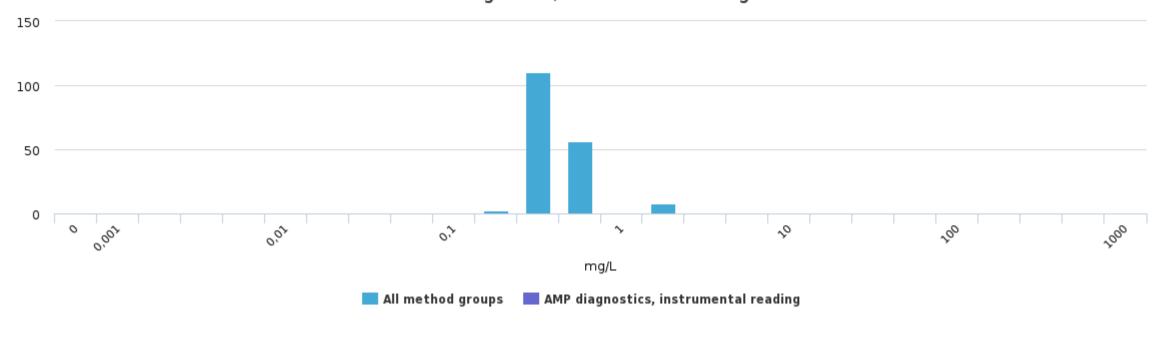
mg/L

All method groups Acon Visual reading

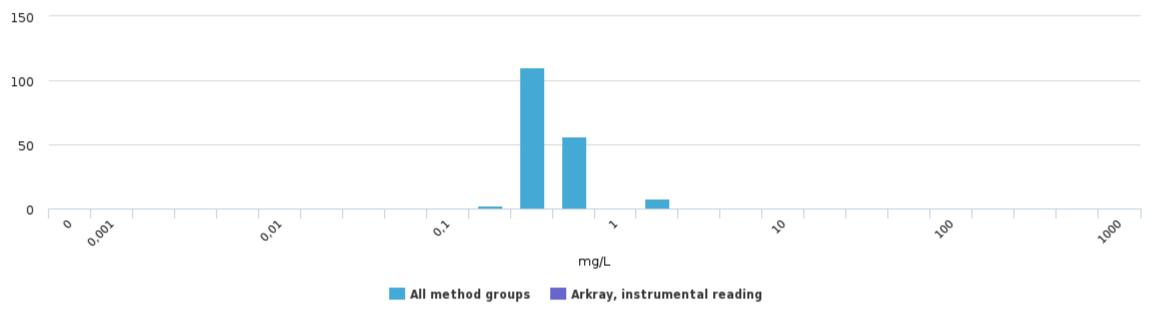
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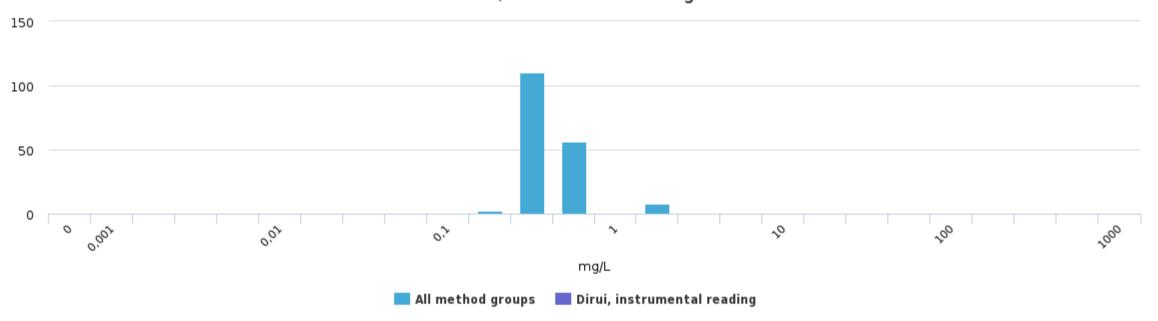




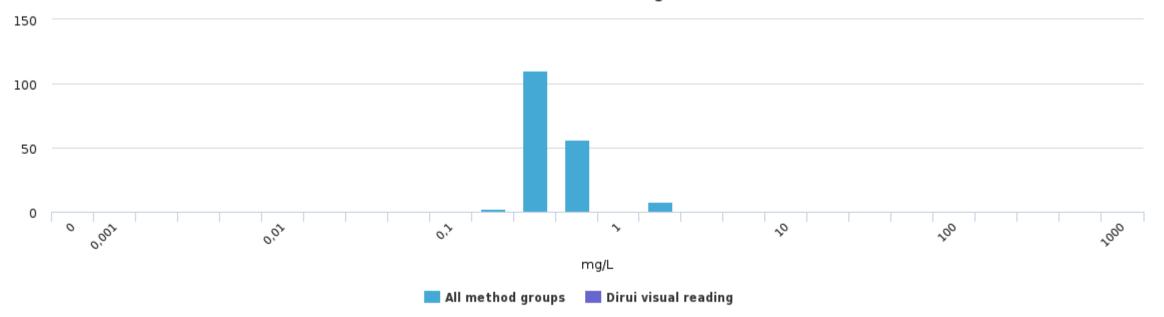
Arkray, instrumental reading



Dirui, instrumental reading



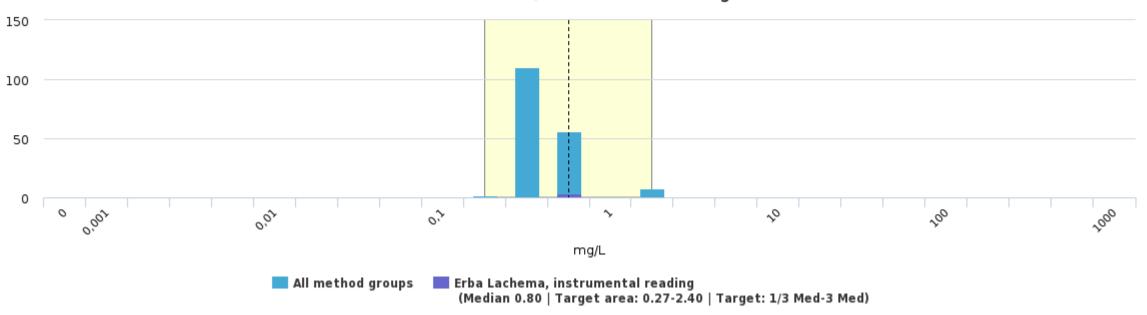
Dirui visual reading



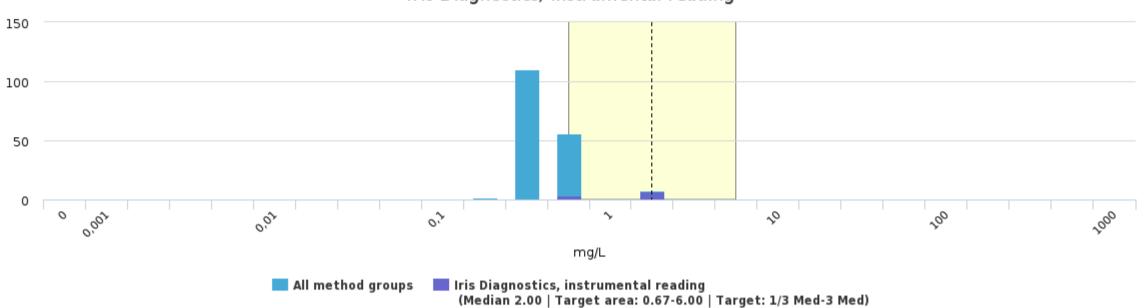
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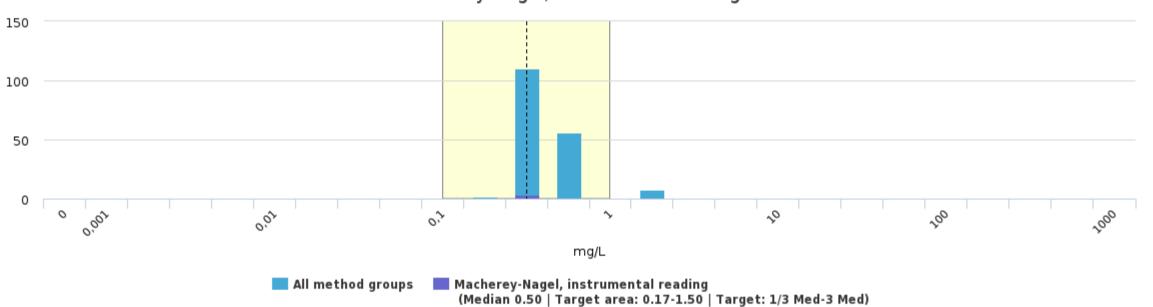




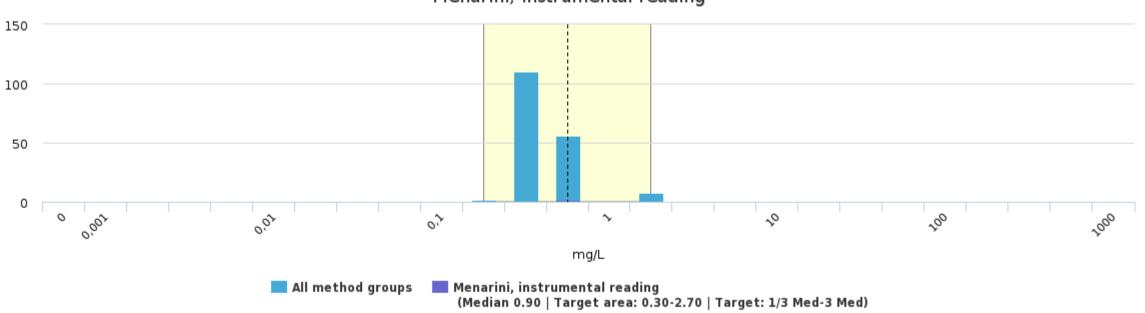
Iris Diagnostics, instrumental reading



Macherey-Nagel, instrumental reading



Menarini, instrumental reading

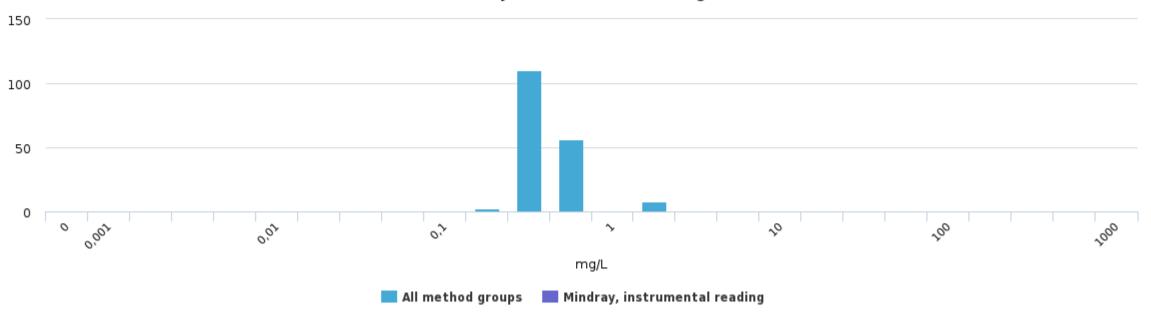


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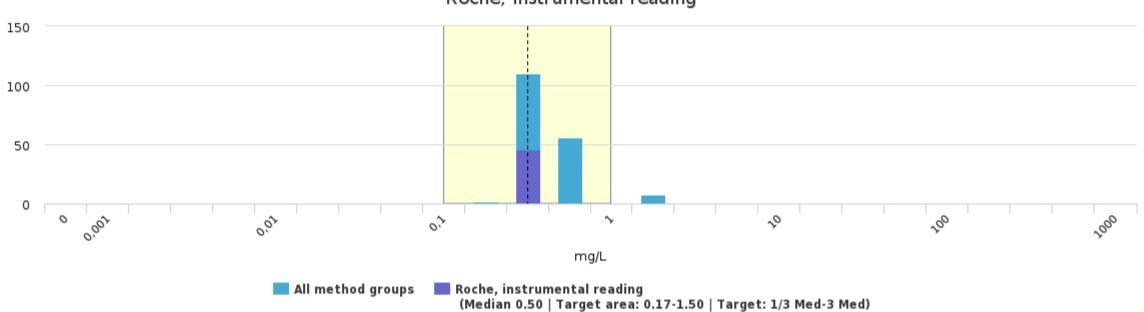
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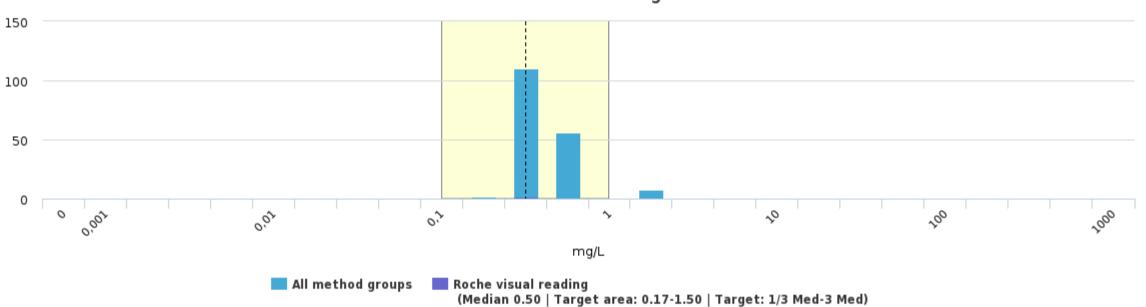




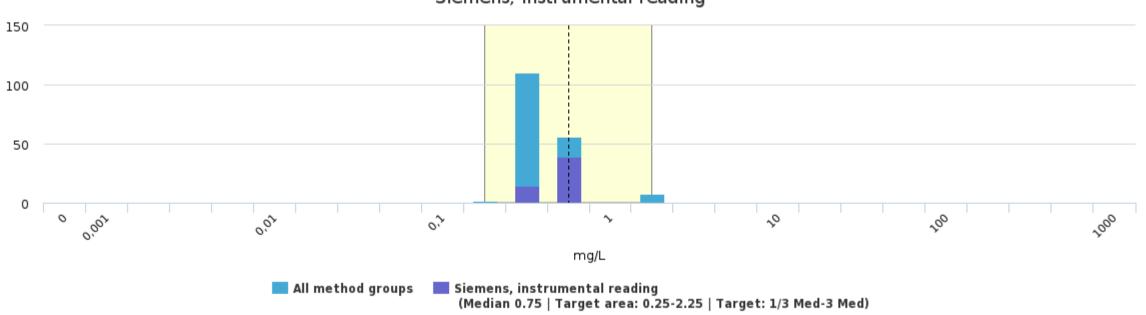
Roche, instrumental reading



Roche visual reading



Siemens, instrumental reading

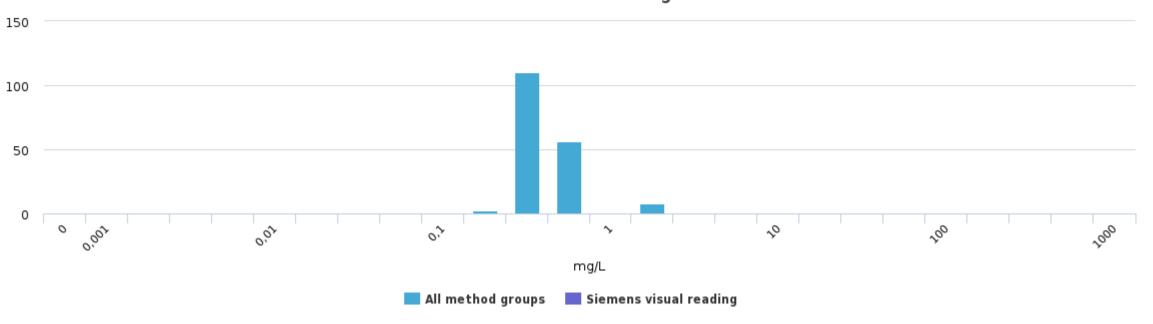


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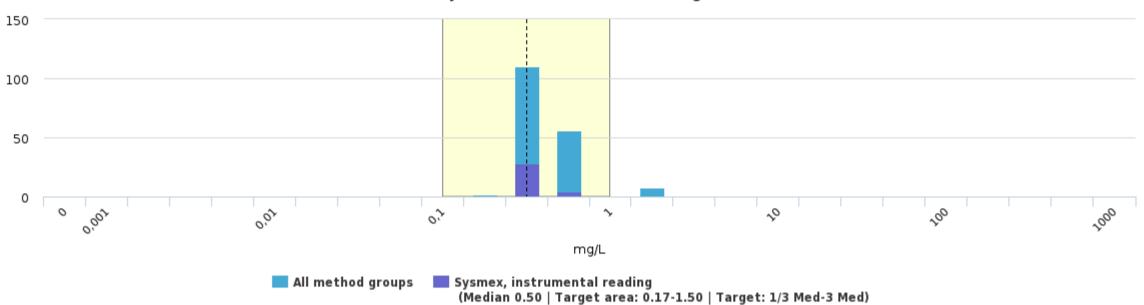
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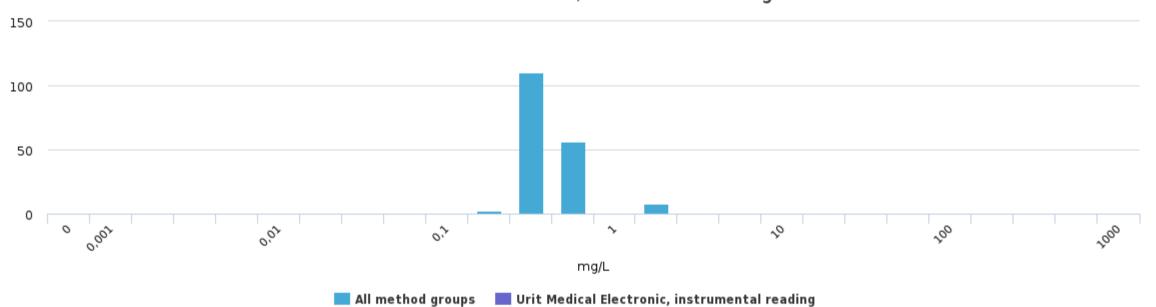




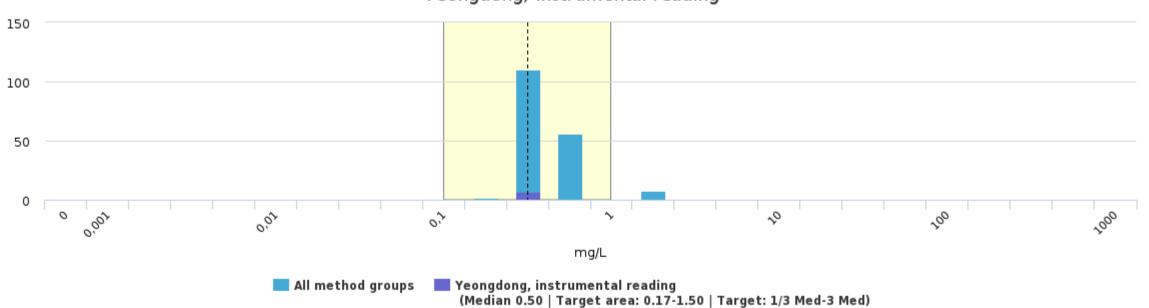
Sysmex, instrumental reading



Urit Medical Electronic, instrumental reading



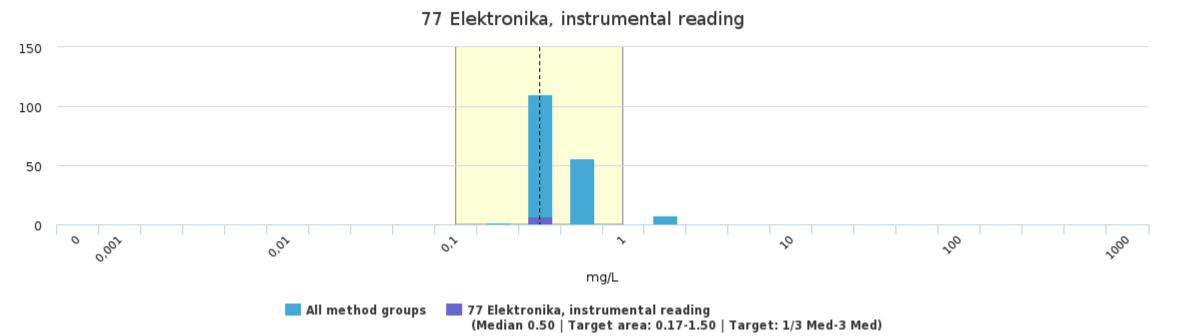
Yeongdong, instrumental reading



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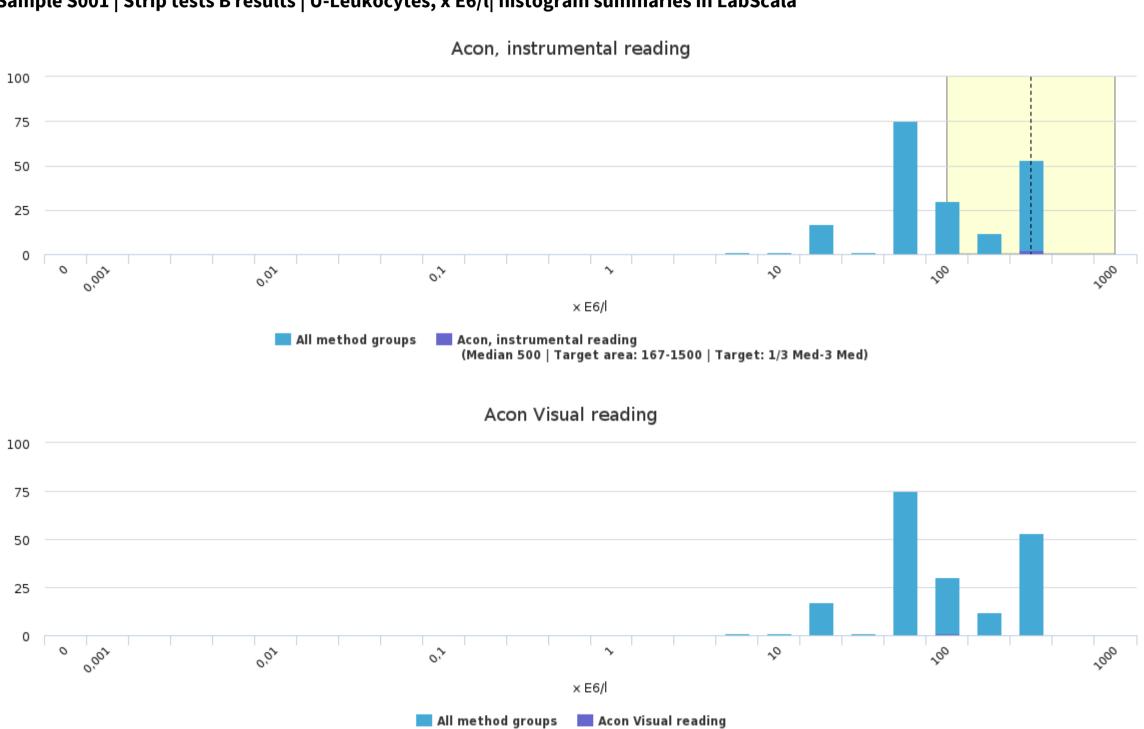
36/59



Sample S001 | Strip tests B results | U-Leukocytes, x E6/l

Methodics	Median	sd	CV%	SEM	min	max	Outliers	n
Acon, instrumental reading	500	<1	<0.1	<1	500	500	-	2
Acon Visual reading	-	-	-	-	110	110	-	1
AMP diagnostics, instrumental reading	-	-	-	-	125	125	-	1
Analyticon, instrumental reading	-	-	-	-	500	500	-	1
Arkray, instrumental reading	-	-	-	-	500	500	-	1
Dirui, instrumental reading	-	-	-	-	125	125	-	1
Dirui visual reading	-	-	-	-	60	60	-	1
Erba Lachema, instrumental reading	75	<1	<0.1	<1	75	75	-	3
Iris Diagnostics, instrumental reading	250	62	27.7	19	75	250	-	11
Macherey-Nagel, instrumental reading	75	<1	<0.1	<1	75	75	-	3
Menarini, instrumental reading	500	245	68.5	142	75	500	-	3
Mindray, instrumental reading	-	-	-	-	125	125	-	1
Roche, instrumental reading	500	199	57.3	27	25	500	-	53
Roche visual reading	63	38	65.3	19	10	100	-	4
Siemens, instrumental reading	125	139	92.1	19	20	500	-	56
Siemens visual reading	-	-	-	-	125	125	-	1
Sysmex, instrumental reading	75	23	38.1	4	25	75	-	31
Urit Medical Electronic, instrumental reading	-	-	-	-	125	125	-	1
Yeongdong, instrumental reading	25	28	65.0	10	15	80	-	8
77 Elektronika, instrumental reading	500	<1	<0.1	<1	500	500	-	7
All	105	188	90.2	14	10	500	-	190

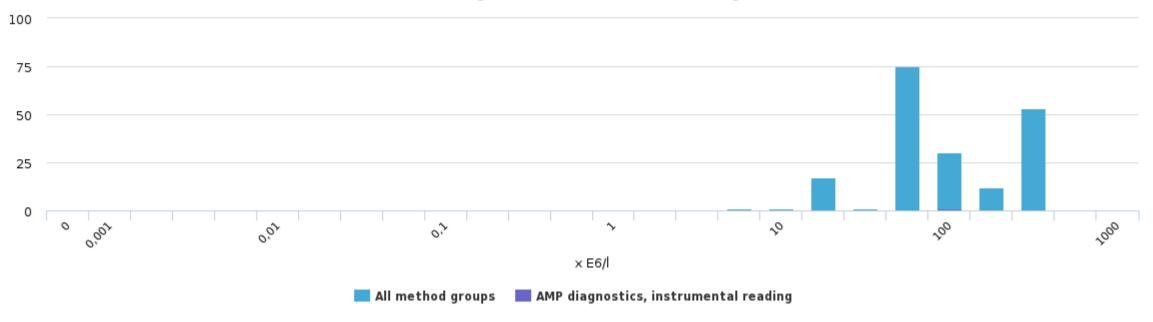
Sample S001 | Strip tests B results | U-Leukocytes, x E6/l| histogram summaries in LabScala



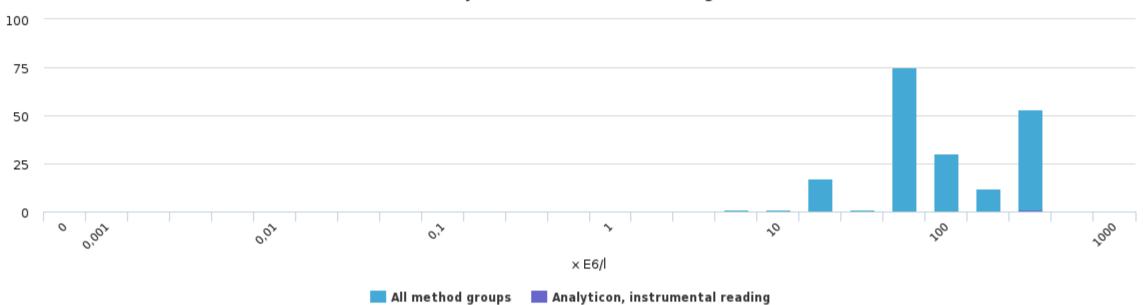
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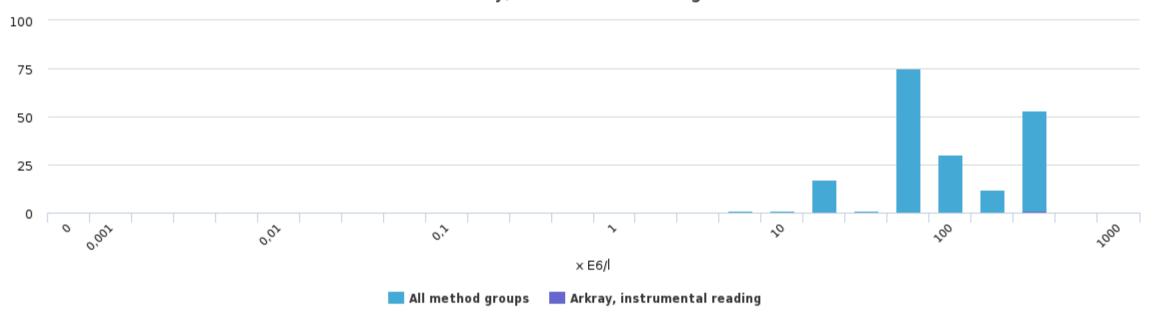




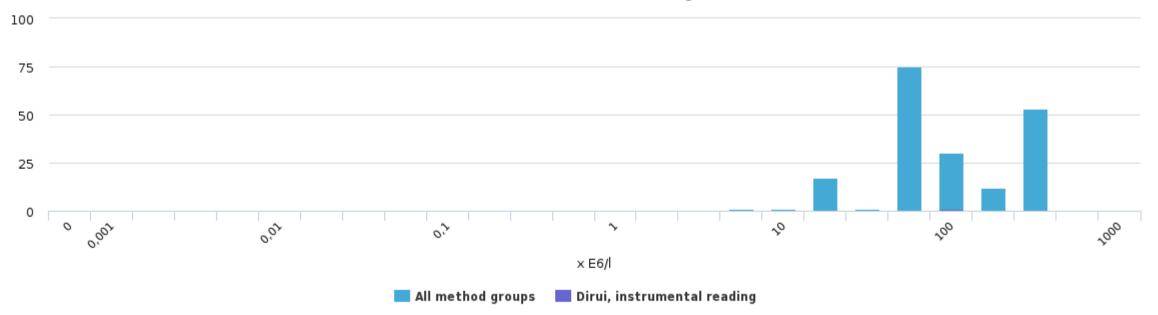
Analyticon, instrumental reading



Arkray, instrumental reading



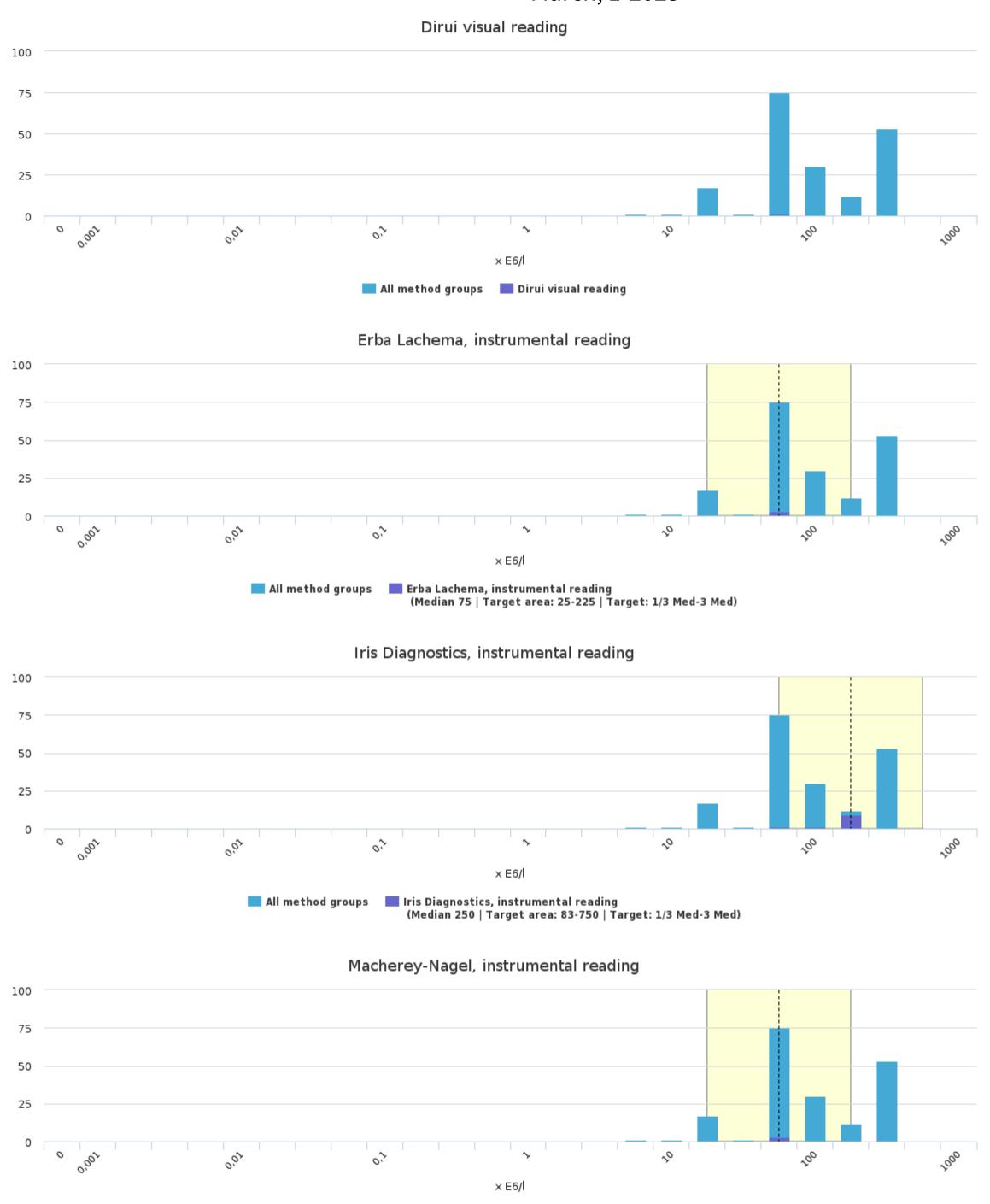
Dirui, instrumental reading



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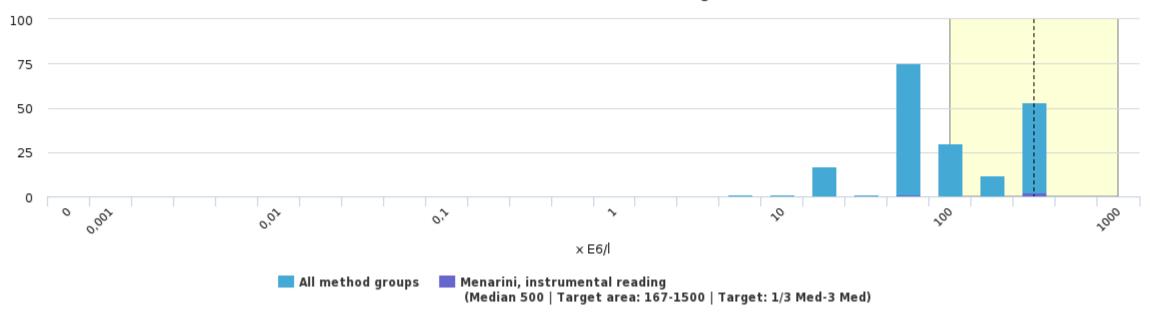
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(Median 75 | Target area: 25-225 | Target: 1/3 Med-3 Med)

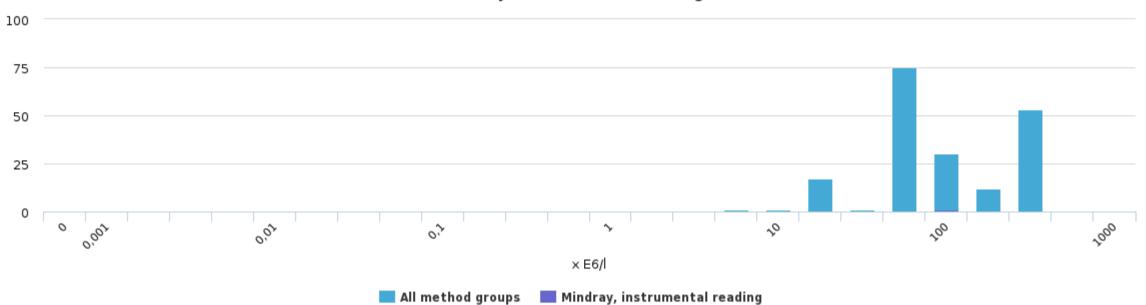
All method groups Macherey-Nagel, instrumental reading



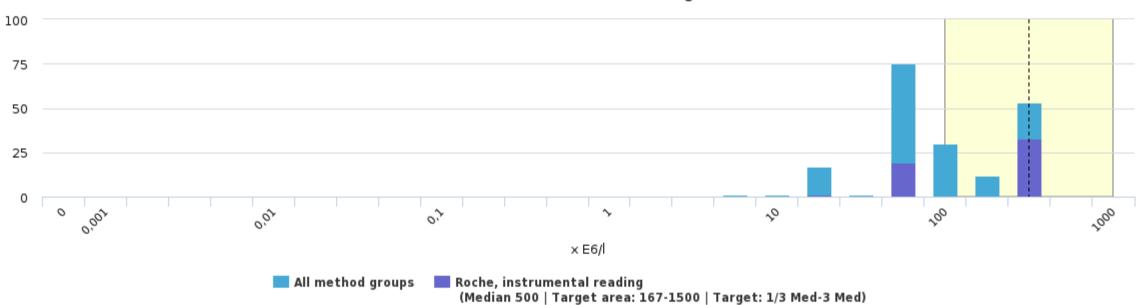




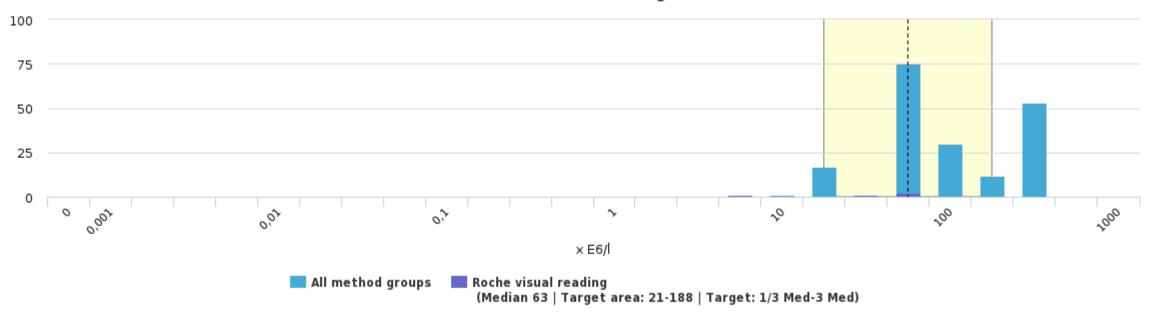
Mindray, instrumental reading



Roche, instrumental reading



Roche visual reading

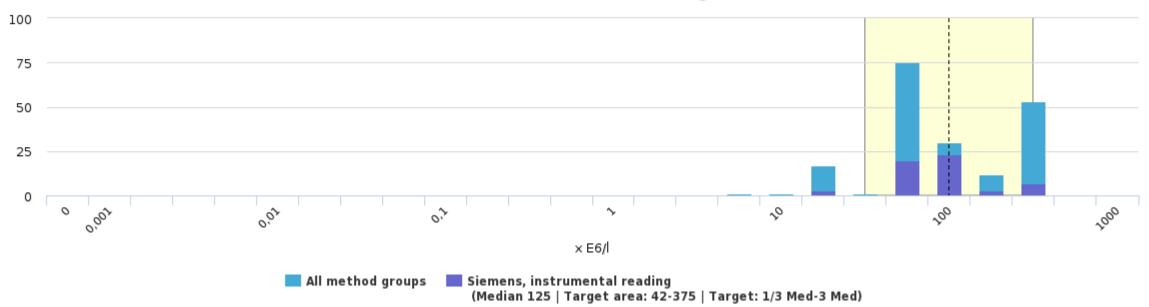


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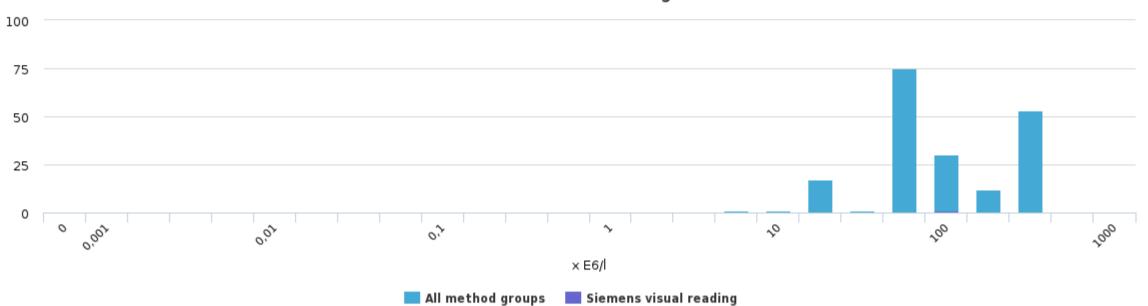
18.04.2023 40/59



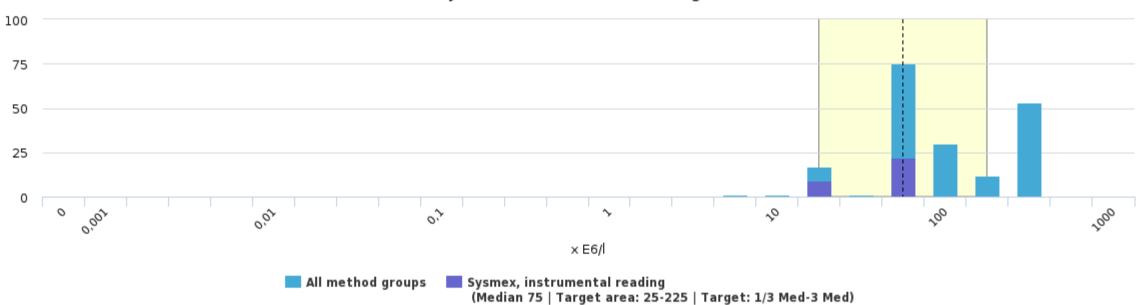




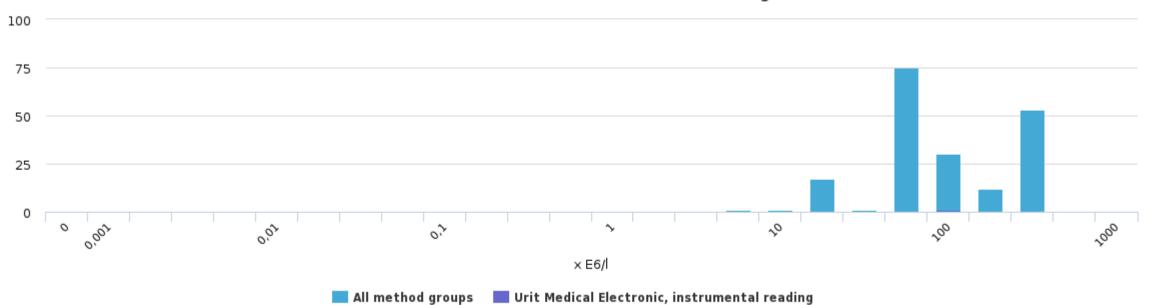
Siemens visual reading



Sysmex, instrumental reading



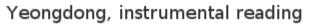
Urit Medical Electronic, instrumental reading

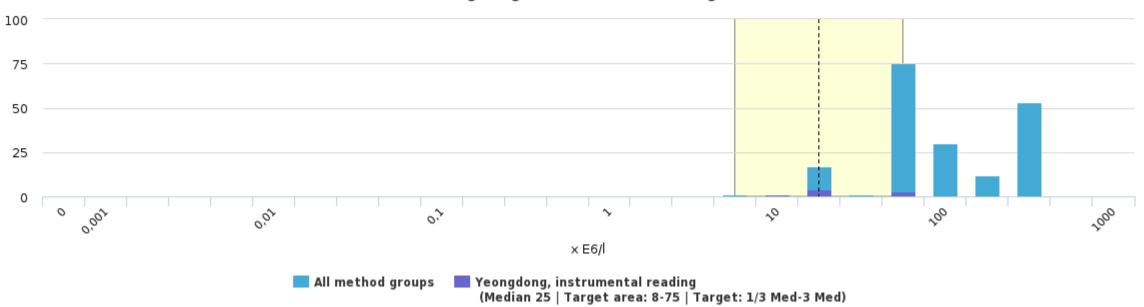


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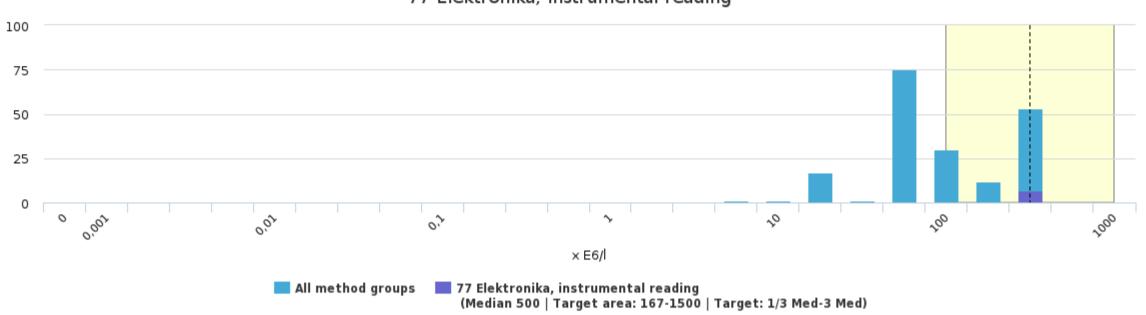
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77 Elektronika, instrumental reading

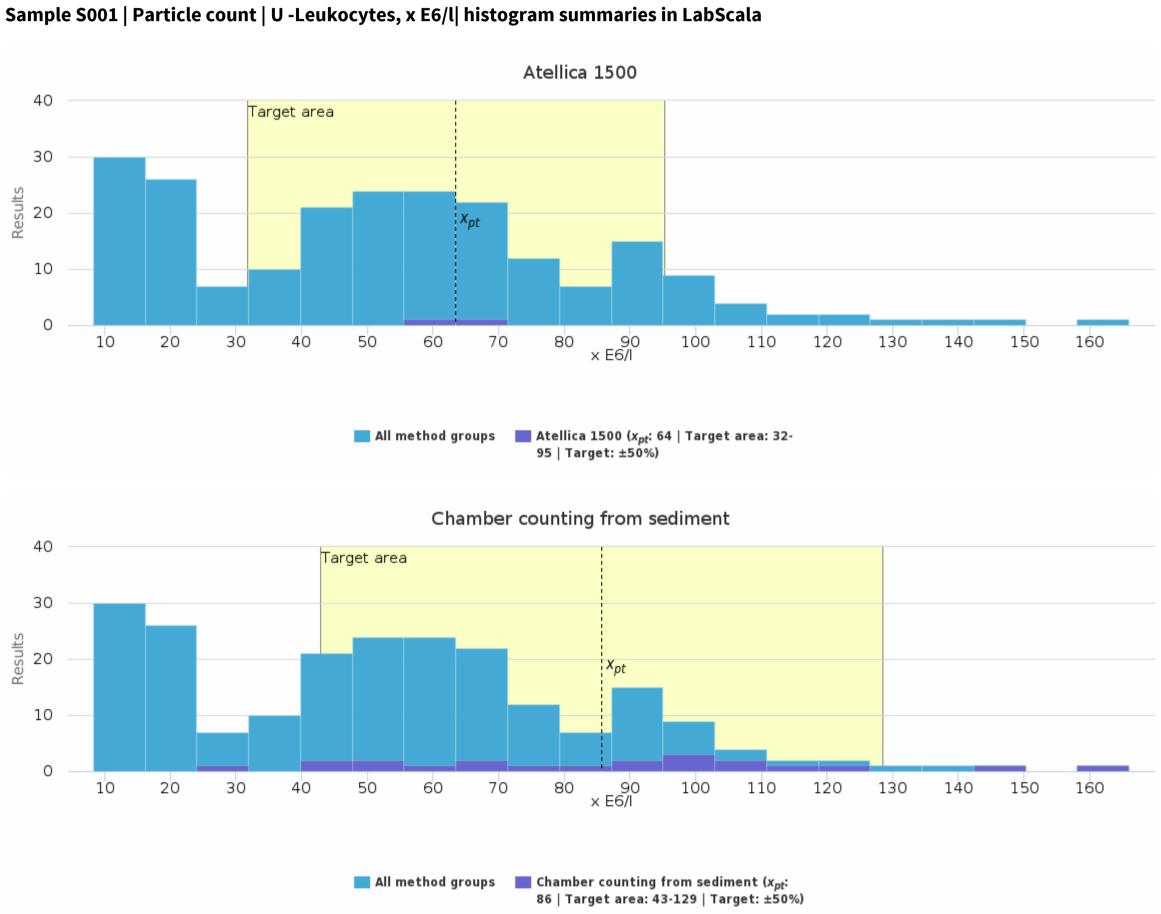


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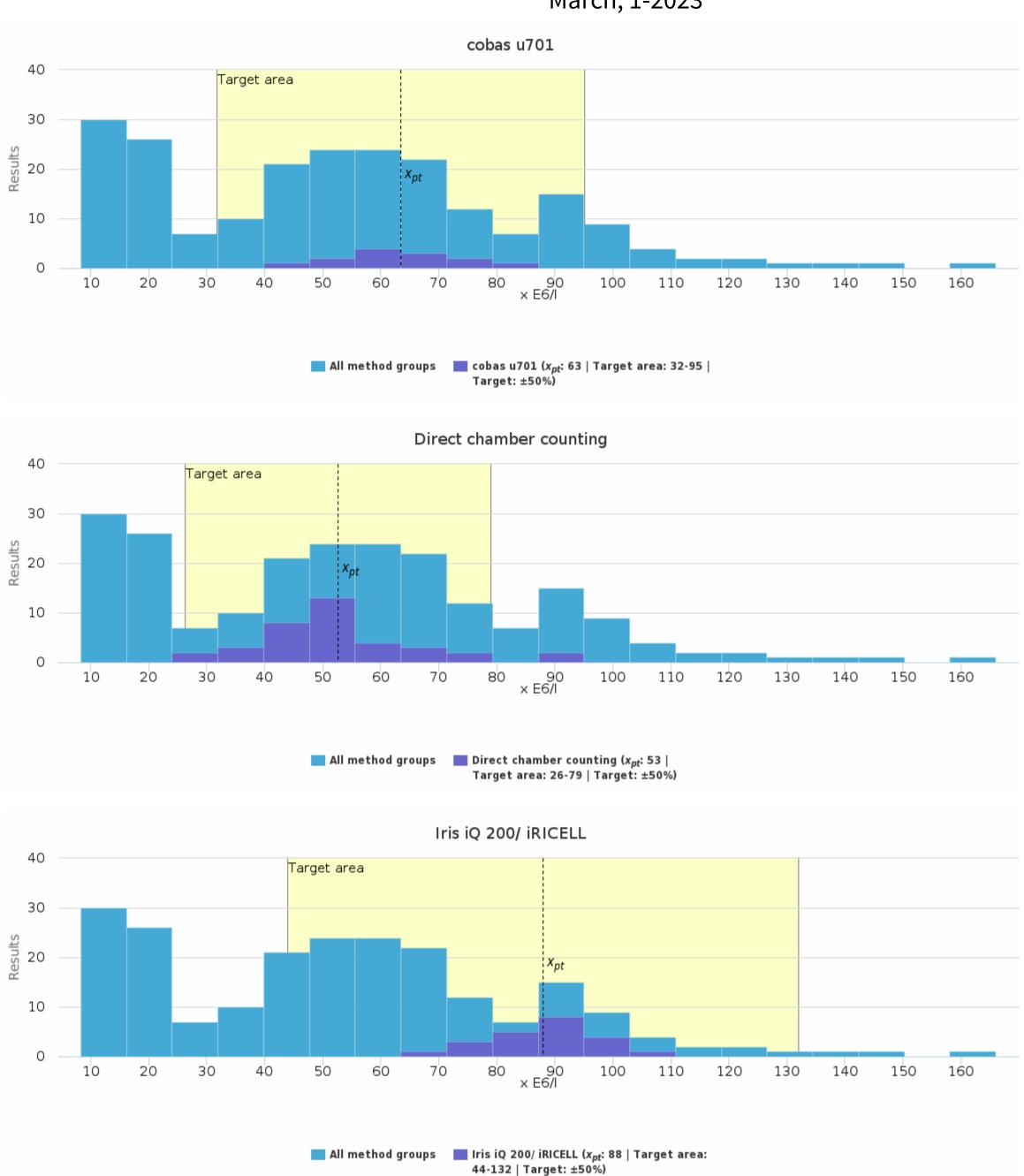


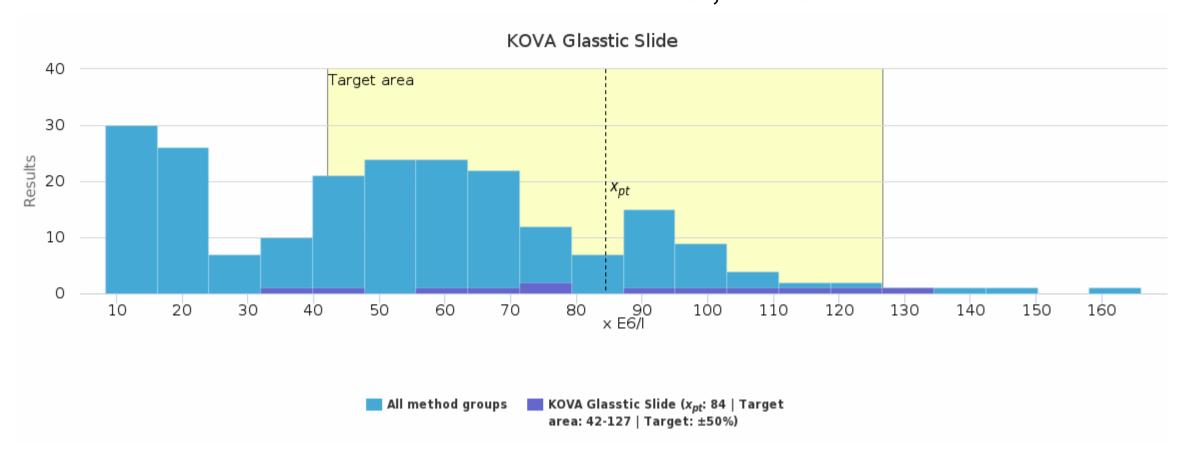
Sample S001 | Particle count | U -Leukocytes, x E6/l

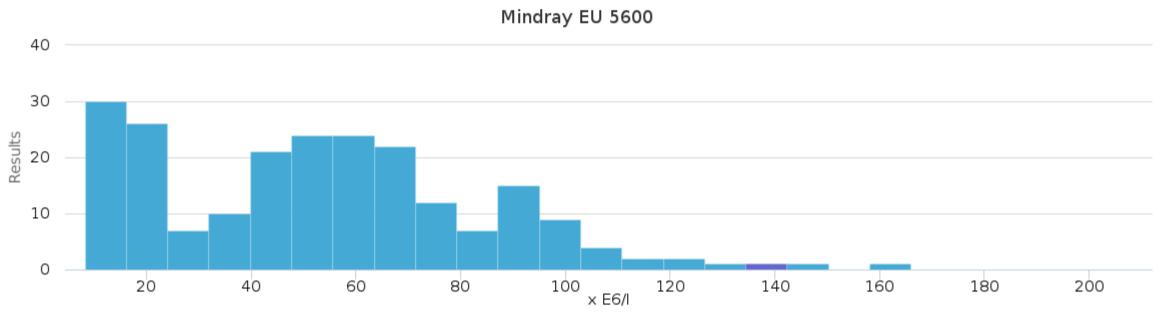
Methodics	x _{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Atellica 1500	64	64	4	5.6	3	61	66	-	2
Chamber counting from sediment	86	88	36	41.4	8	25	166	-	21
cobas u701	63	63	11	17.7	3	45	87	-	13
Direct chamber counting	53	52	14	26.2	2	29	91	-	37
Iris iQ 200/ iRICELL	88	90	10	11.2	2	66	107	-	22
KOVA Glasstic Slide	84	83	32	37.9	9	34	128	-	12
Mindray EU 5600	-	-	-	-	-	138	138	-	1
Other method	34	36	15	44.4	5	18	56	-	8
sediMAX	37	21	26	70.2	12	17	70	-	5
sediMAX ConTRUST/ConTRUST Pro	62	63	3	5.5	1	57	67	-	6
Standardized sediment examination	54	51	17	31.8	4	30	97	-	23
Sysmex UF-4000/5000	16	15	4	26.2	<1	8	27	-	48
Sysmex UF-500i/1000i	-	-	-	-	-	31	31	-	1
Uriscan PluScope	25	20	12	46.8	5	15	41	-	5
UriSed 3/UriSed 3 Pro/UriSed mini	62	62	13	21.0	3	38	88	-	14
UriSed/UriSed 2	-	-	-	-	-	33	33	-	1
All	52	52	29	56.2	2	8	138	2	219

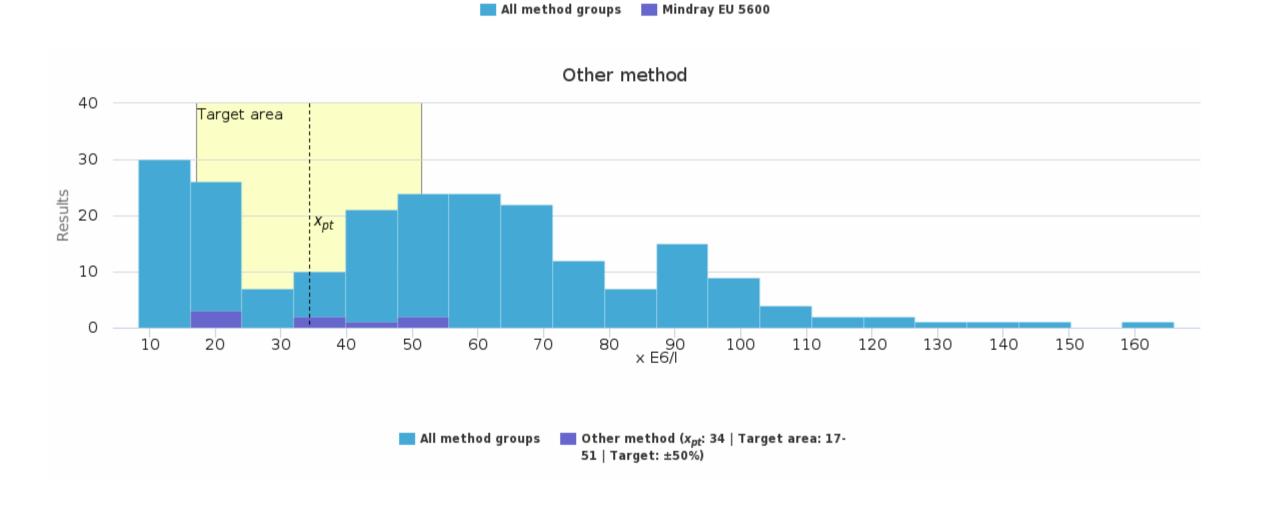


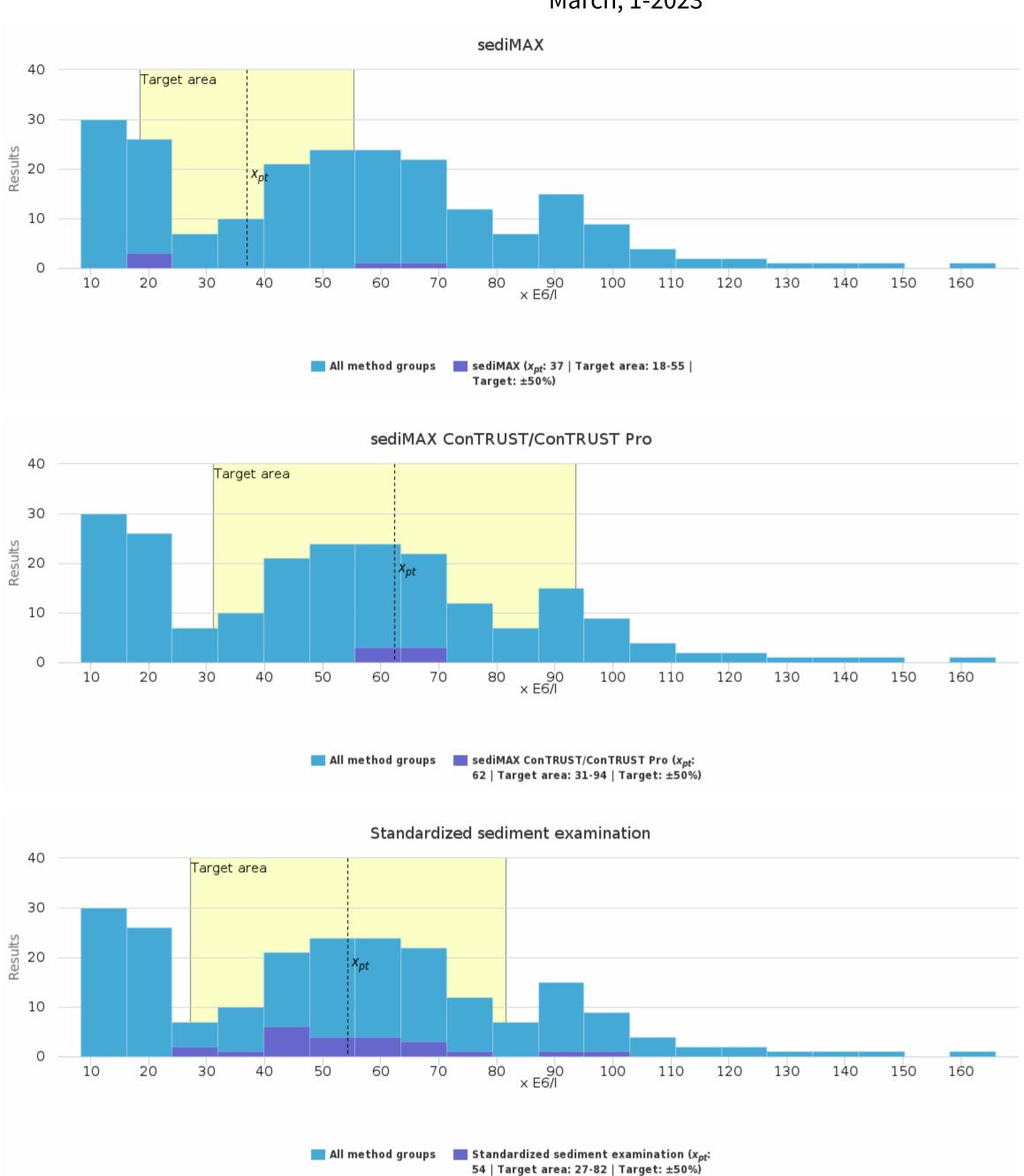
18.04.2023 43/59



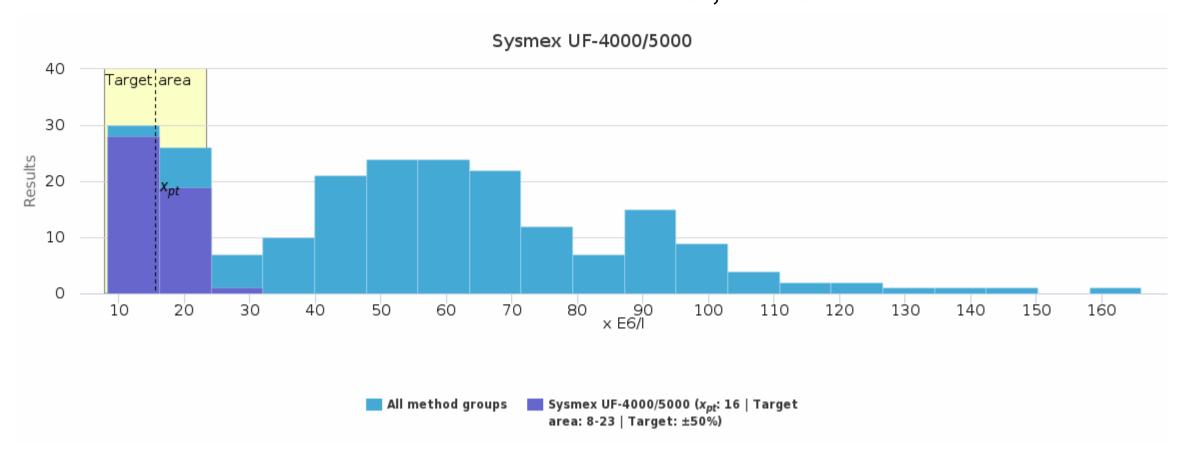


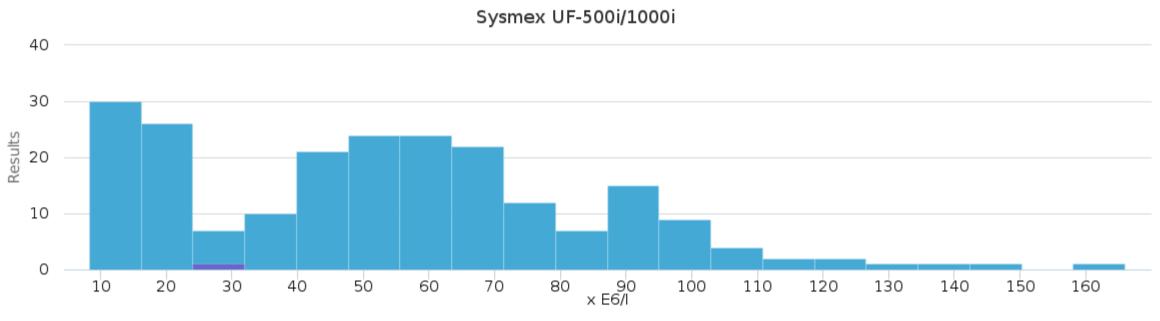


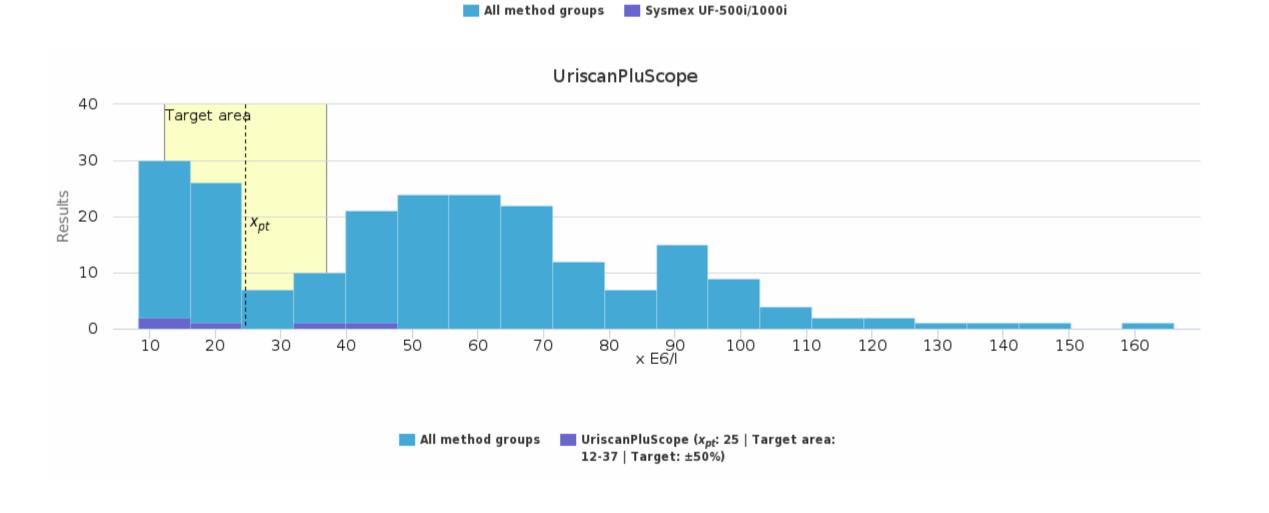


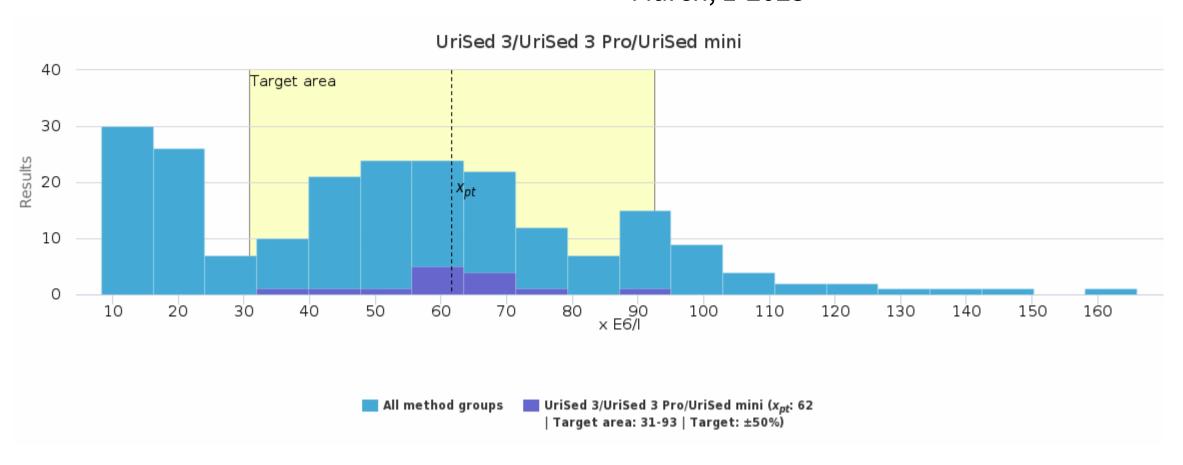


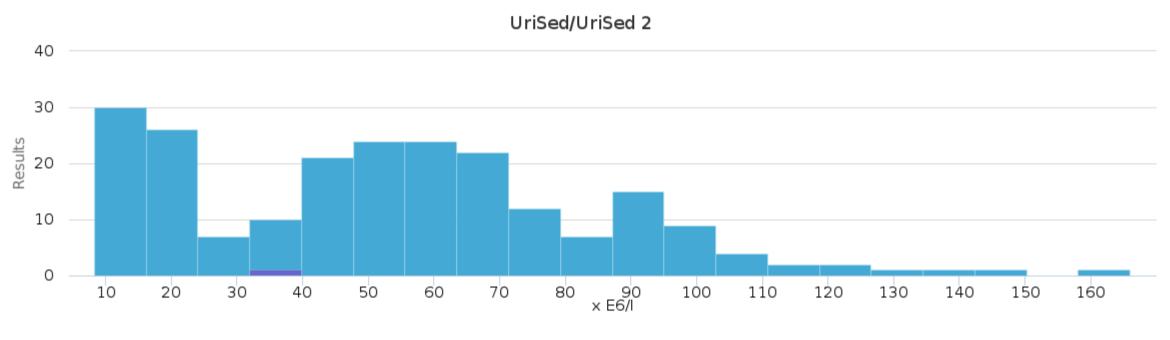
18.04.2023 46/59











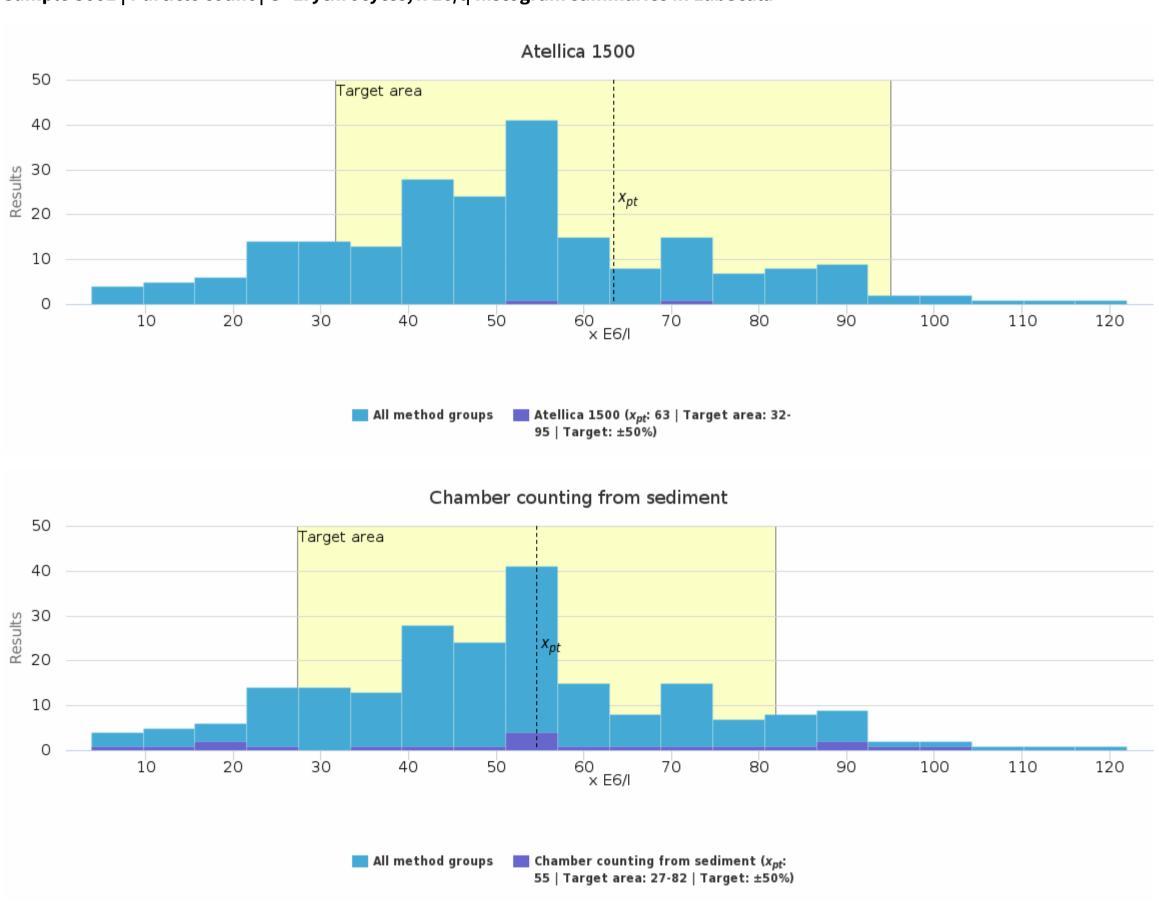
All method groups UriSed/UriSed 2



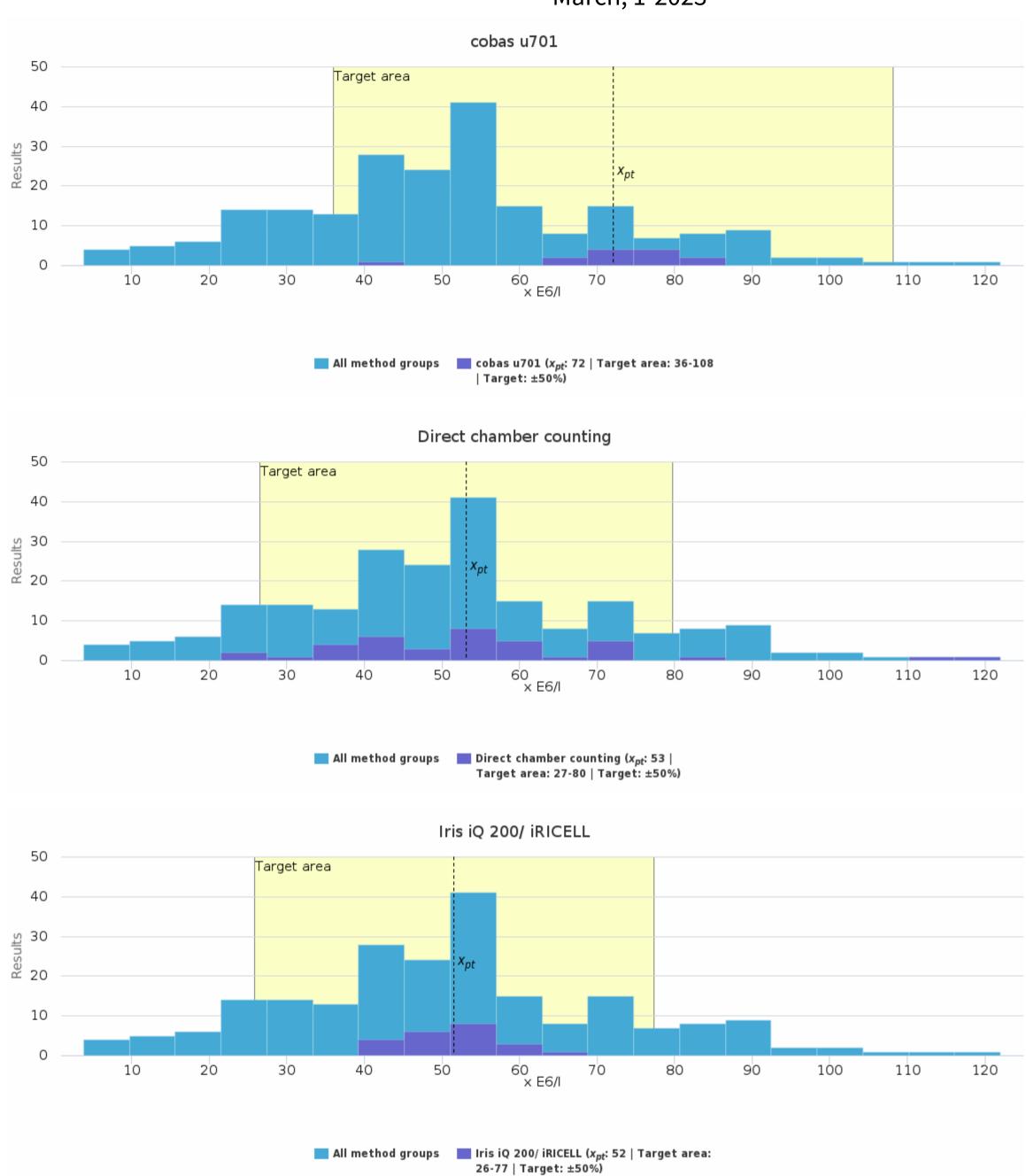
Sample S001 | Particle count | U -Erythrocytes, x E6/l

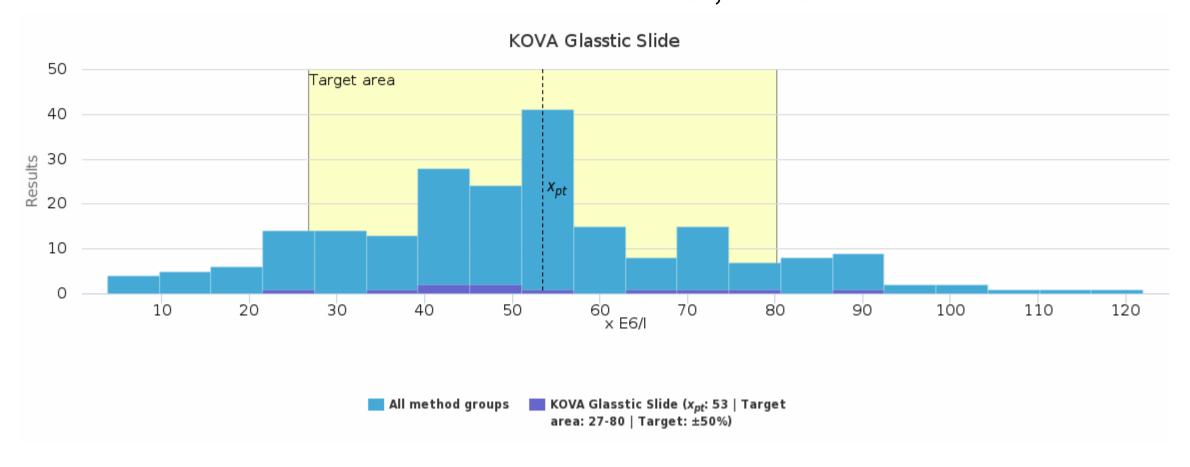
Methodics	* _{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Atellica 1500	63	63	9	14.8	7	57	70	-	2
Chamber counting from sediment	55	54	28	51.2	6	9	99	-	21
cobas u701	72	72	10	14.2	3	45	86	-	13
Direct chamber counting	53	53	17	31.0	3	26	112	1	38
Iris iQ 200/ iRICELL	52	52	6	11.9	1	41	63	-	22
KOVA Glasstic Slide	53	48	19	35.5	6	24	87	-	11
Mindray EU 5600	-	-	-	-	-	110	110	-	1
Other method	48	45	18	36.7	7	23	71	-	7
sediMAX	32	28	17	50.9	7	17	60	-	5
sediMAX ConTRUST/ConTRUST Pro	69	72	22	31.1	9	39	90	-	6
Standardized sediment examination	35	31	13	38.0	3	12	67	-	23
Sysmex UF-4000/5000	41	47	15	35.6	2	4	57	-	50
Sysmex UF-500i/1000i	-	-	-	-	-	9	9	-	1
Uriscan PluScope	38	38	4	10.5	2	34	42	-	3
UriSed 3/UriSed 3 Pro/UriSed mini	82	84	13	15.4	3	58	103	-	14
UriSed/UriSed 2	-	-	-	-	-	33	33	-	1
All	51	52	21	40.7	1	4	112	1	218

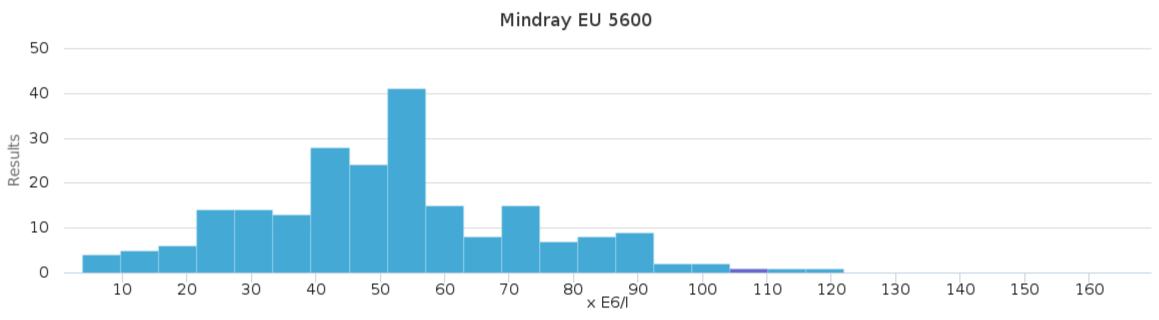
Sample S001 | Particle count | U -Erythrocytes, x E6/l| histogram summaries in LabScala

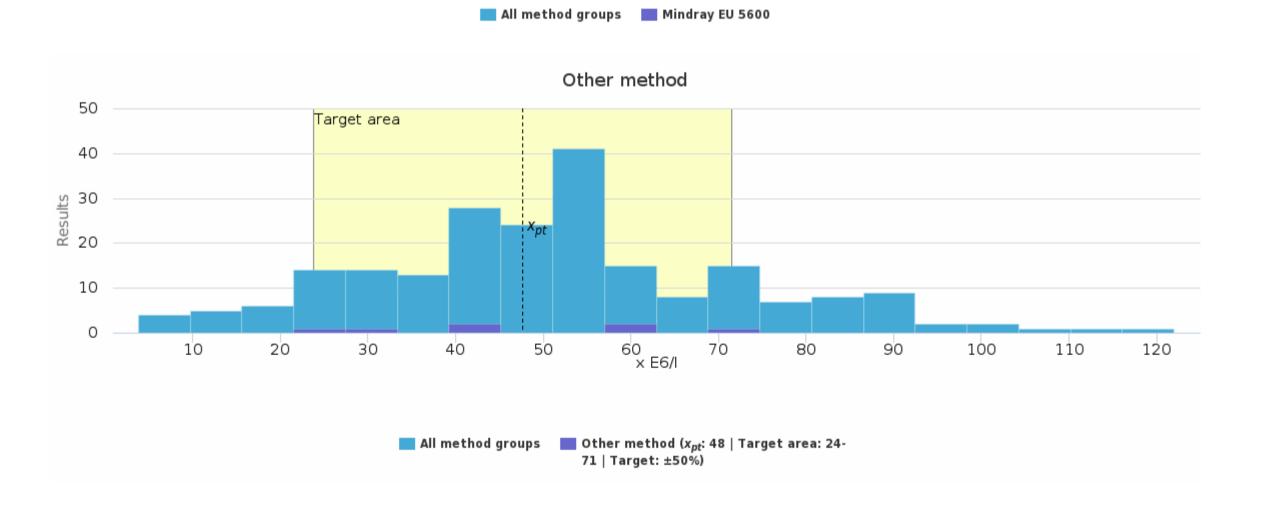


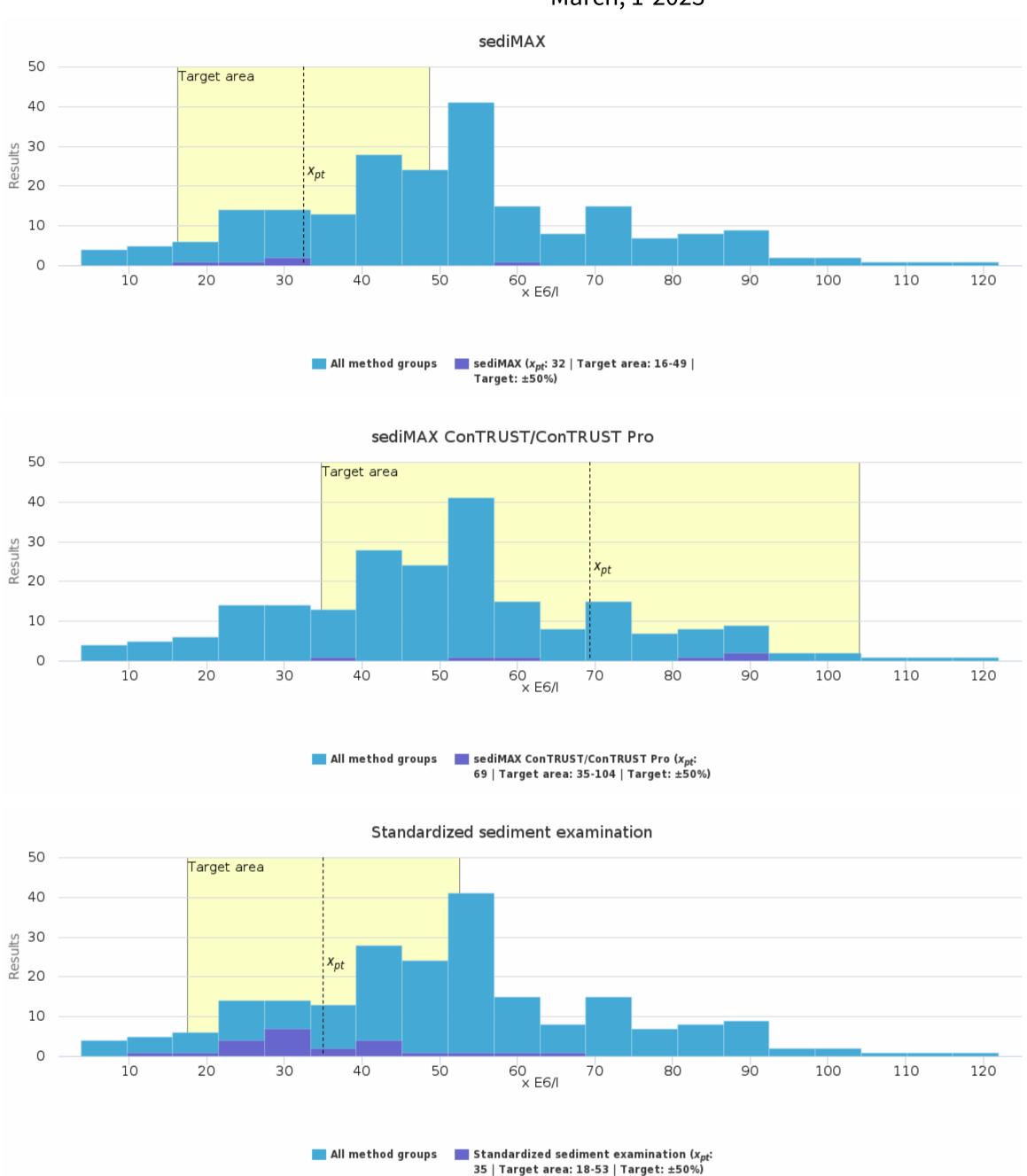
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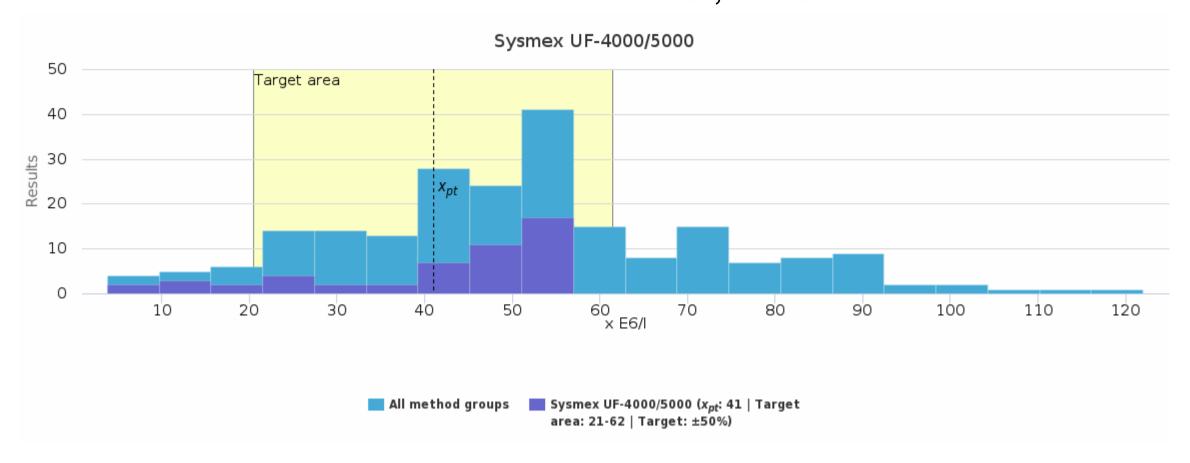


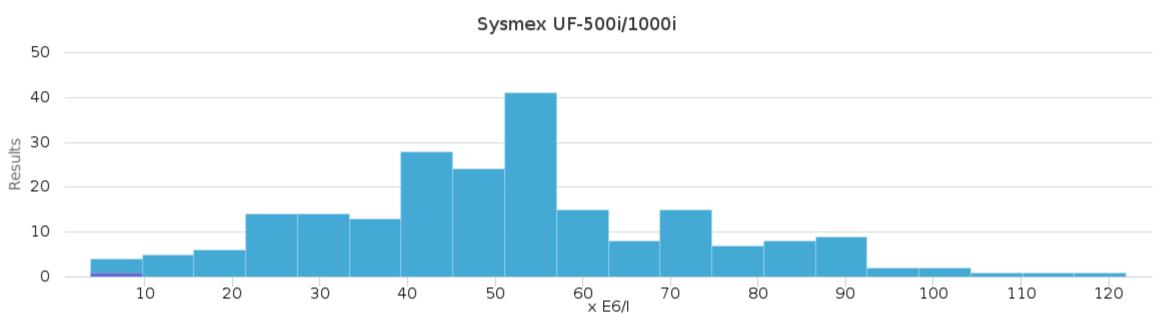


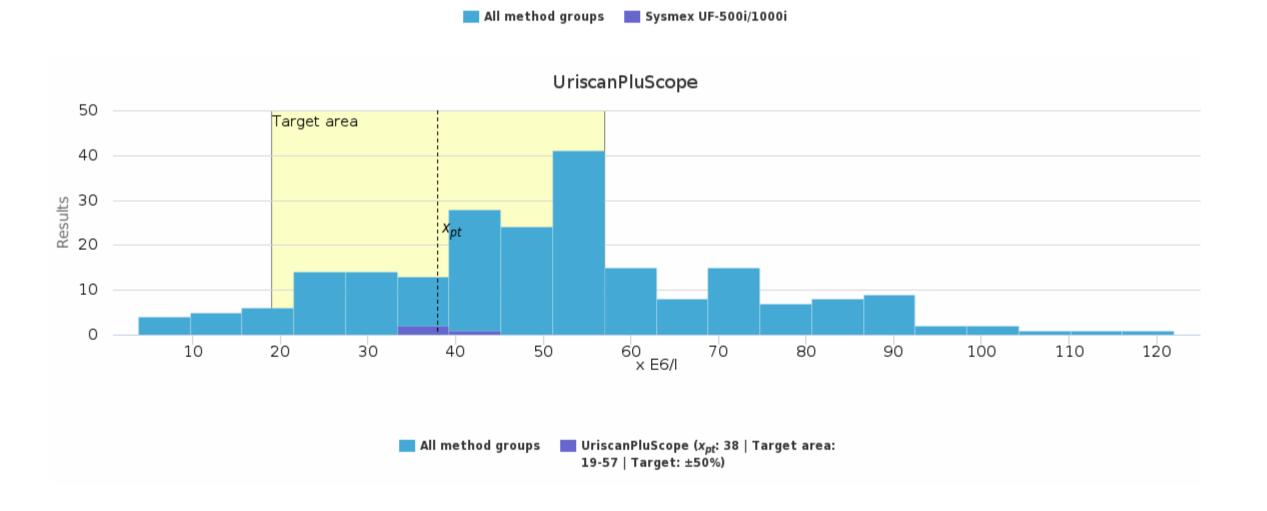


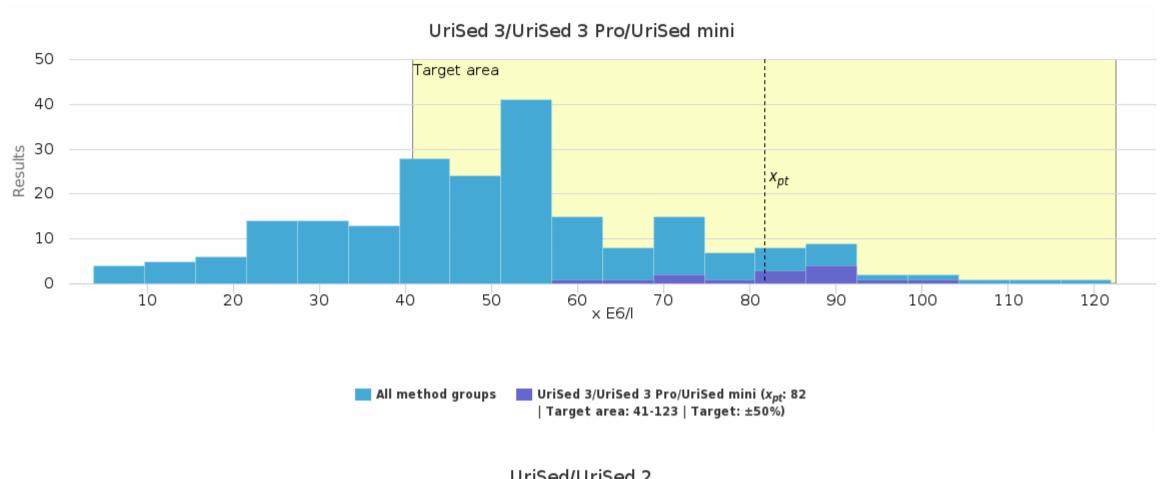


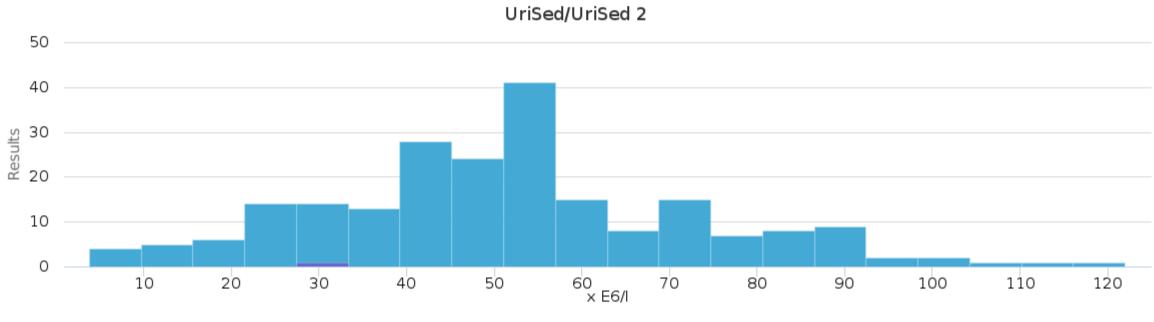












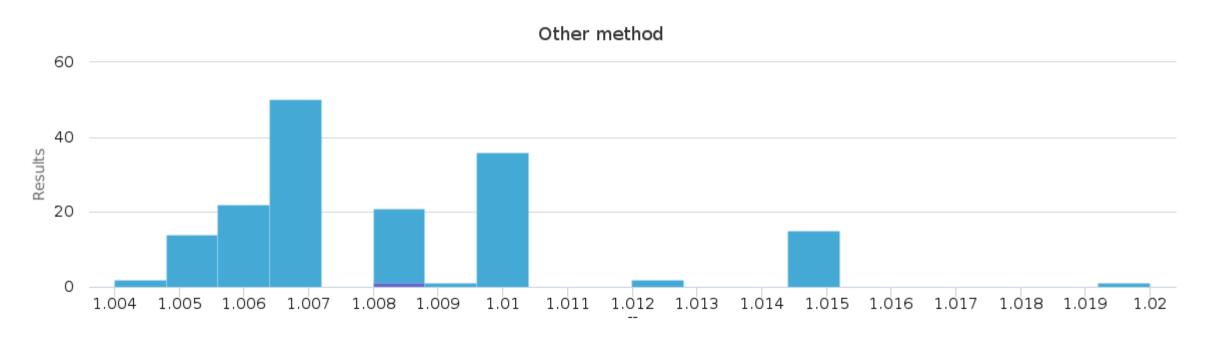
All method groups UriSed/UriSed 2

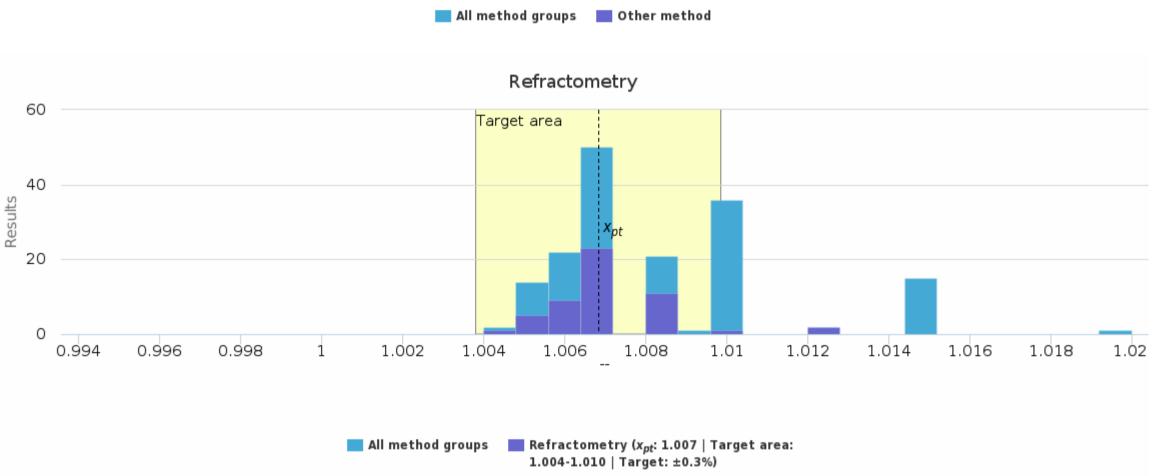


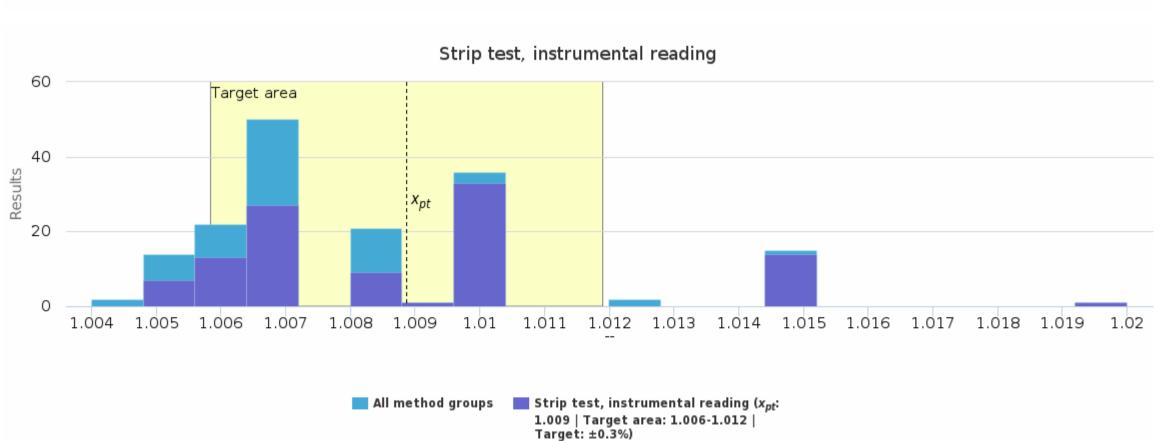
Sample S001 | Estimation of density | U-Relative density, --

Methodics	x _{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Other method	-	-	-	-	-	1.008	1.008	-	1
Refractometry	1.007	1.007	0.001	0.1	<0.001	1.004	1.010	2	52
Strip test, instrumental reading	1.009	1.008	0.003	0.3	<0.001	1.005	1.015	1	105
Strip test, visual reading	1.008	1.008	0.004	0.4	0.002	1.004	1.015	_	6
All	1.008	1.007	0.003	0.3	<0.001	1.004	1.015	1	164

Sample S001 | Estimation of density | U-Relative density, -- | histogram summaries in LabScala

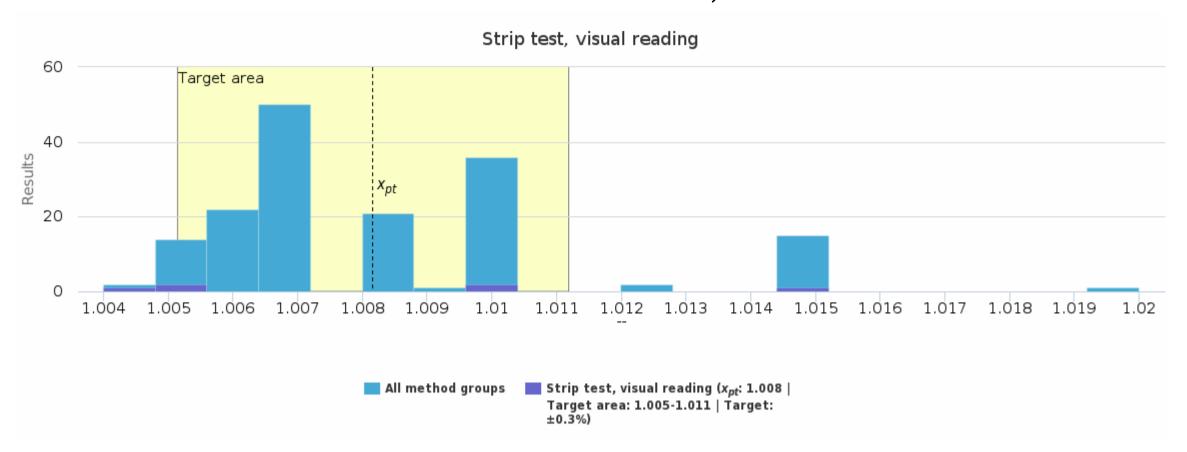






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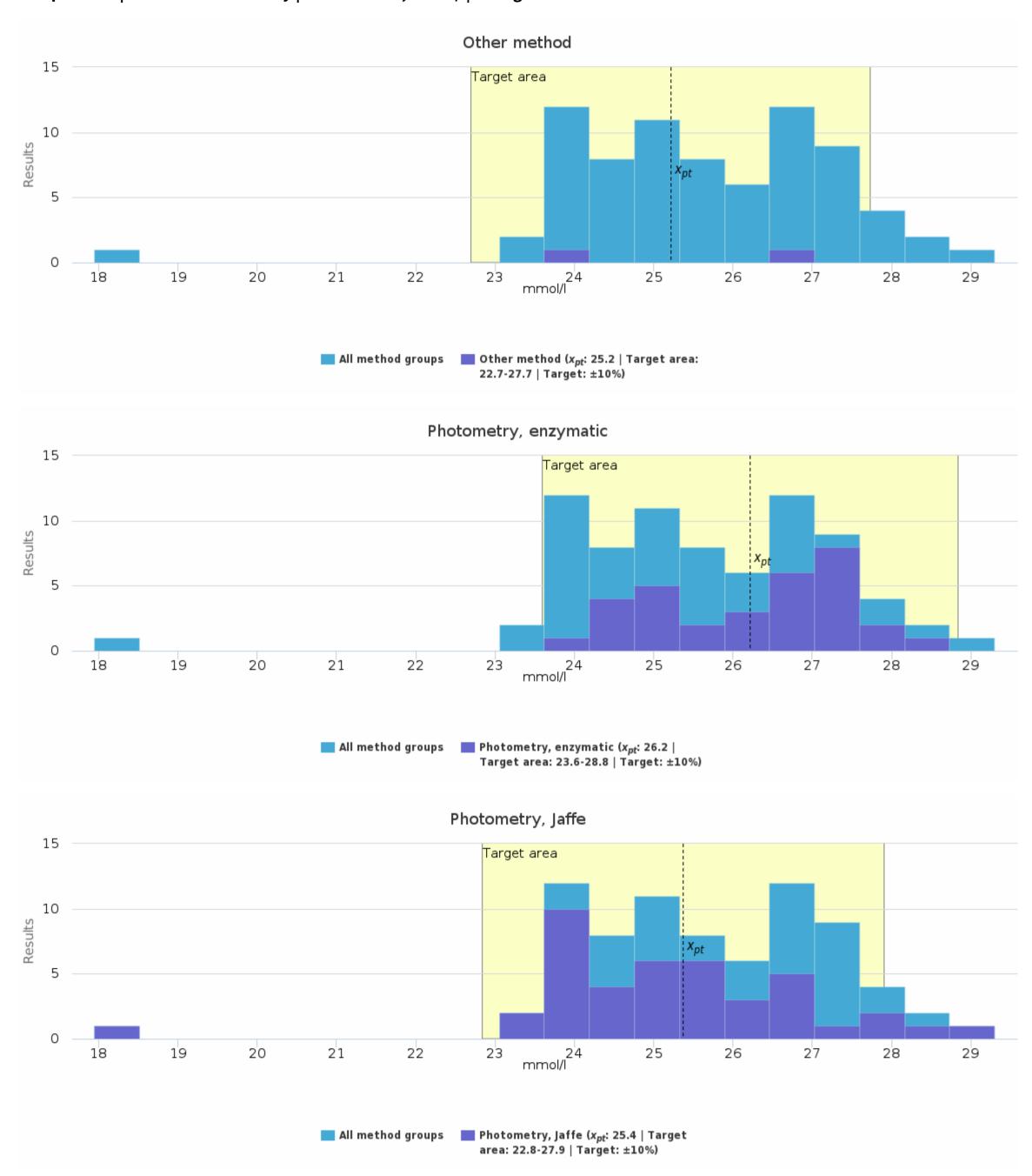




Sample S001 | Estimation of density | U-Creatinine, mmol/l

Methodics	x _{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Other method	25.2	25.2	1.8	7.3	1.3	23.9	26.5	-	2
Photometry, enzymatic	26.2	26.6	1.2	4.6	0.2	23.9	28.3	-	32
Photometry, Jaffe	25.4	25.0	1.4	5.7	0.2	23.2	29.3	1	42
All	25.7	25.8	1.4	5.4	0.2	23.2	29.3	1	76

Sample S001 | Estimation of density | U-Creatinine, mmol/l| histogram summaries in LabScala



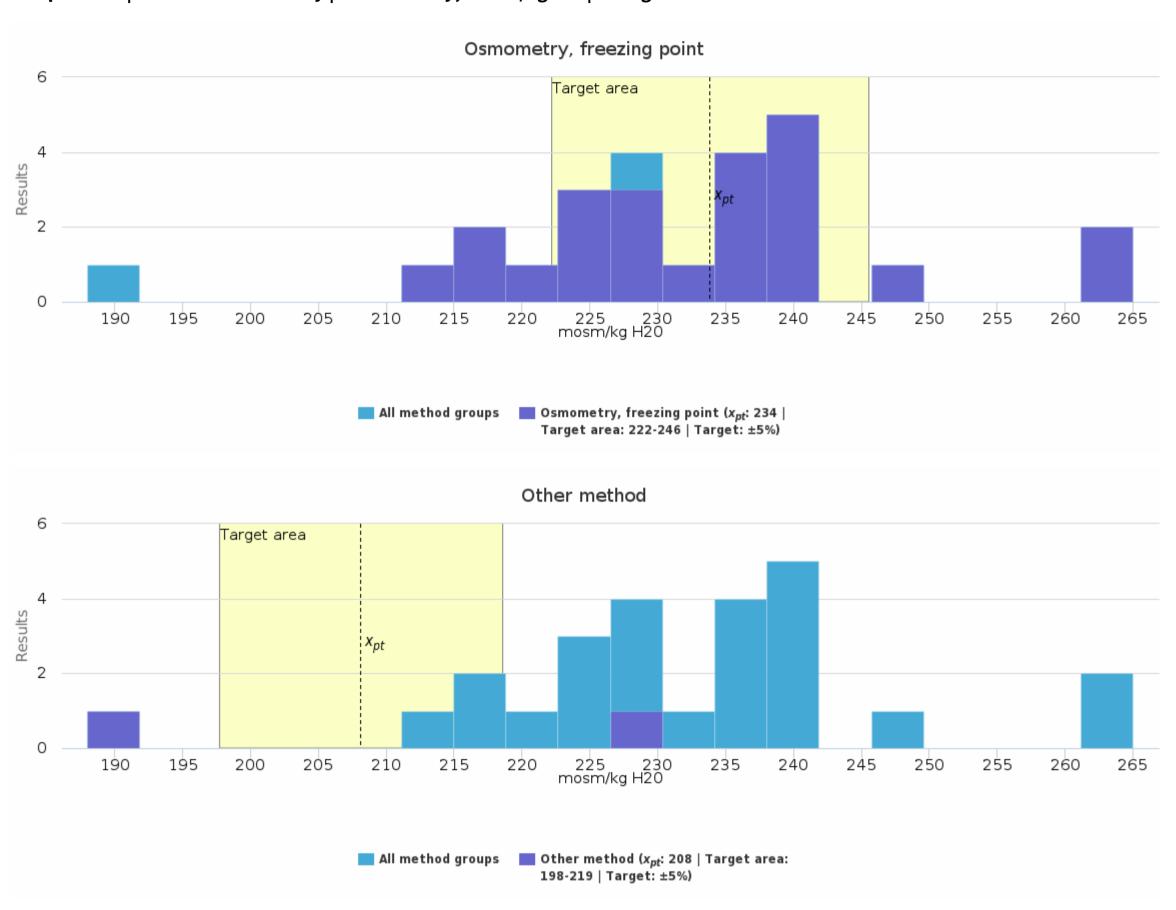
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Sample S001 | Estimation of density | U-Osmolality, mosm/kg H20

Methodics	x _{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Osmometry, freezing point	234	235	13	5.5	3	212	265	-	23
Other method	208	208	28	13.7	20	188	228	-	2
All	232	231	15	6.6	3	188	265	-	25

Sample S001 | Estimation of density | U-Osmolality, mosm/kg H20| histogram summaries in LabScala



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Report info

Participants

212 participants from 16 countries.

Report info

Your own result should be compared to others using the same method.

Particle count and Estimation of density parts assigned values (x_{pt}, target values) are means of the results where results deviating more than +/- 3*standard deviation from the

median are removed. Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

In strip tests B part the assigned values (Med, target values) are median of the results where results deviating more than +/- 3*standard deviation from the median are removed.

The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM).

In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method. Results reported with < or > -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" LabScala User instructions (top right corner? Help link).

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LABQUALITY

External Quality Assessment Scheme

Urine strip test B, particle count and estimation of density Round 1, 2023

Specimens

Sample S001 (LQ744623011) was lyophilized human urine. Based on the previous tests and the results of this round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific histograms and Numerical Summary reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

The method-specific and also all methods target ranges ($1/3 \times Med - 3 \times Med$) of the strip test results are shown below each histogram except the pH target range, which is median of the pH results \pm 0.5. The history graphs are not seen for strip tests.

Due to the logarithmic scale used in test strip summaries, negative results (below the cut-off value) are in client-specific reports as follows:

- at the value 0.01: protein and nitrite
- at the value 0.1: glucose and ketone bodies
- at the value 1: erythrocytes and leukocytes.

"Trace" category was combined into the negative category.

Comments – Expert

In the EQA scheme Urine strips test B, particle count and estimation of density, the results are reported quantitatively. Several results can be reported from different methods. However, one result is to be reported to one method only, i.e., same result is not to be reported to both urine strip and particle counting.

Strip Test

The sample S001 represented neutral urine. Expected results for the strip test were positive. The results for the strip test (protein, nitrite, glucose, ketone bodies, erythrocytes, leukocytes, pH, specific gravity) are reported in arbitrary concentrations using SI units. The values can be found from the instructions given by the strip manufacturer. Results deviating more than ±3 x standard deviation from the median in this specific method group are considered as outliers. Outliers are discarded from the numerical reports. Typically, an error in reported units makes the result an outlier. Extra attention is needed with used units. Once again, in this round, some of the results were clearly reported with incorrect units or to incorrect analytes. Thus, they are excluded from the results handling.

The strips in different method groups may vary. Different cut-offs can be seen in this round, for example, in erythrocyte strip test. The strip test results in Iris Diagnostics group are lower than in larger groups (Siemens, Roche and Sysmex), as was in round 4, 2022.

2023-04-18

FINAL REPORT

Product no. 3130-3131

 Samples sent
 2023-03-13

 Round closed
 2023-03-31

 Final report
 2023-04-18

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

EQA Coordinator Anna-Riitta Vanhanen anna-riitta.vanhanen@labquality.fi

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Particle count

The sample S001 included elevated number of particles mimicking leukocytes and erythrocytes. Direct particle count performed in chamber is considered as a reference method for urine particle count. Means for leukocytes and erythrocytes using direct count in chamber were both $53 \times E6/L$. The reported results for leukocytes show a two-peak behavior. Sysmex and Uriscan PluScope results represent the low-end (8 - 41 x E6/L) compared to the other results (15 - 166 x E6/L). In erythrocyte counting the distribution of the results was more even, but the results were deviated in wide range (4 - 122 x E6/L).

Visual counting has been successful if the CV% < 30% between the laboratories is seen, and reasonable if the CV% < 40%. In this round, the CV% for direct counting in chamber was 26.2% for leukocyte counting and 31.0% for erythrocyte counting. Thus, the counting can be considered near successful. Automated instruments should perform more precisely than human beings, with a CV% < 20% if successful.

Estimation of density

Refractometric results provide the basis for assessment for specific gravity. The sample S001 represented urine with 1.007 specific gravity measured with refractometer. The used accuracy of the results is seen in the results reported from the analyzers. Although using the same strips the used accuracy can vary from 0.001 to 0.005 between laboratories and even between analyzers in the same laboratory.

For creatinine, the mean for all the methods was 25.7 mmol/L. For osmolality, the mean was 232 mosm/kg H₂O. Furthermore, for osmolality, only two results were reported in other group than to the change in freezing point.

End of report

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