LABQUALITY

External Quality Assessment Scheme

Urine bacterial screening with automated analyzers
Round 1, 2023

Specimens
Please find enclosed 1 liquid Sample S001 (5 mL) and lyophilized Synthetic urine sample. After rehydration according to the instructions, the sample simulates patient urine sample.

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
Urine bacterial counting, urine leukocytes (WBC) and urine erythrocytes (RBC).

Storage and use
After arrival the sample should be stored at +2…8°C. After rehydration the sample should be analyzed within 1 hour similarly to patient samples. Let the samples warm up to room temperature at least 30 min before rehydration.

1. Pour the liquid Sample S001 to Synthetic urine sample vial. Allow the vial stand at least 5 minutes, so that the particles are dissolved. After this, re-suspend several times with pipette to homogenize the solution. Be sure that the lyophilized material is not remaining in pipette.
2. Analyse the sample with your automated analyzers. You can send results from 3 analyzers if you like.

Follow the standard operating procedure of your laboratory for disposal of the sample.

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 must be rechecked before reporting if not routinely in use.

The Bacterial screening result and Further handling parts are mandatory:

Bacterial screening result	Further handling

If you get results below (<) or above (>) of your method's detection limit, please mark these results with < or > characters so that the character and your result are typed together without space (eg. <5 or >100). Please do not report "zero" results, if some analyte is not in use in your laboratory, just leave that result field (also the date) empty.

S001

LQ744823011

2023-04-24

INSTRUCTIONS

Product no. 3170
LQ744823011/FR
UN3373

Subcontracting: Sample pretesting

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

The results should be reported no later than **May 12, 2023**.

Inquiries
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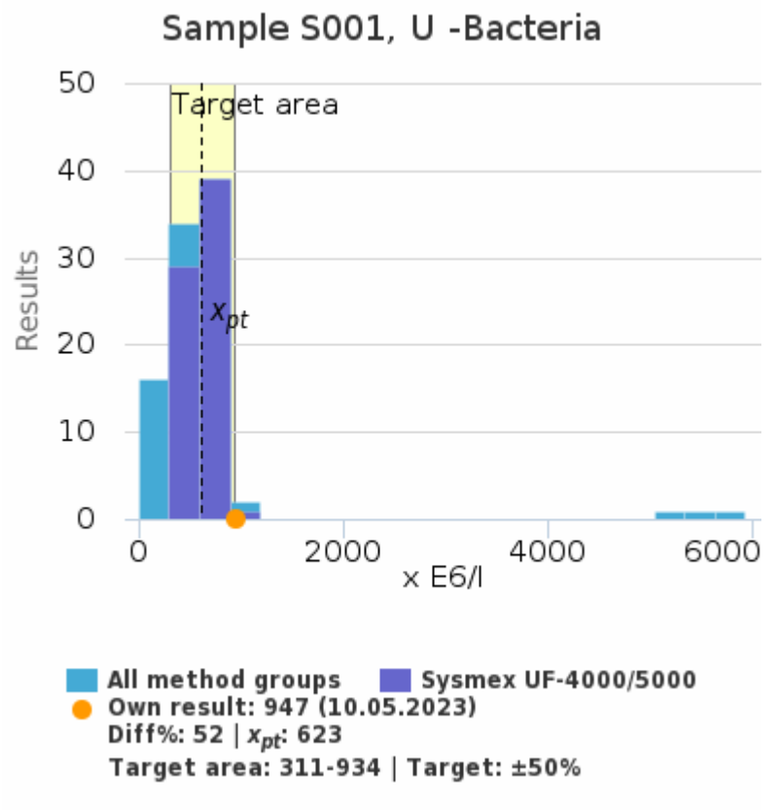
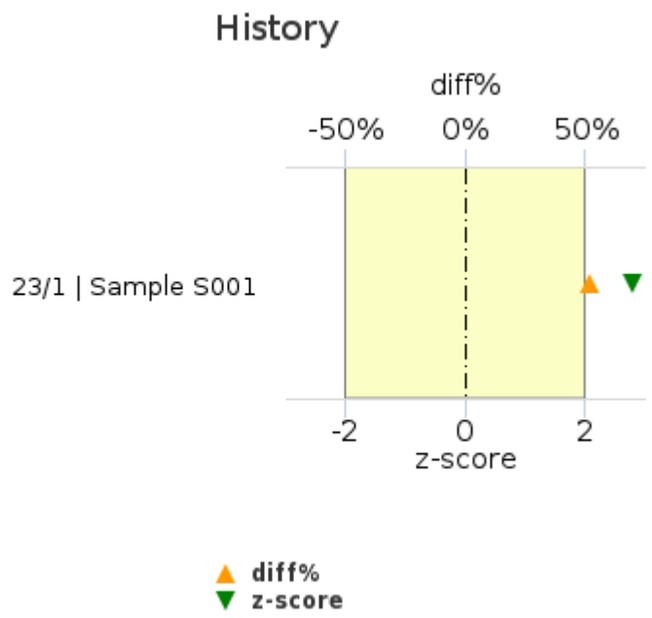
U -Bacteria





Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S001	623	947	52%	2.79

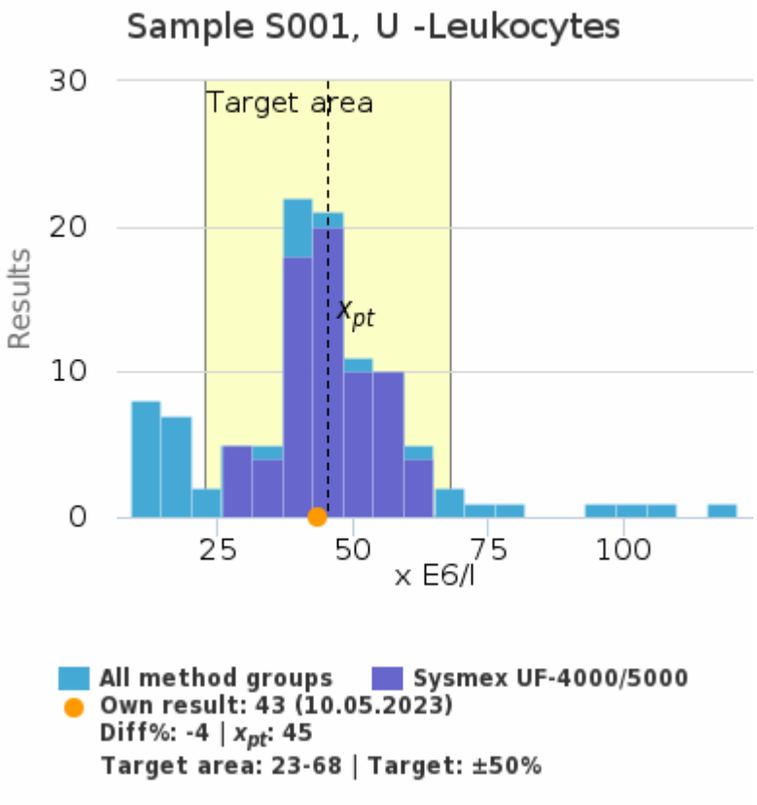
	x_{pt}	sd	SEM	CV%	n
Sysmex UF-4000/5000	623 x E6/l	116	14	18.7	69
All methods	529 x E6/l	223	23	42.1	94

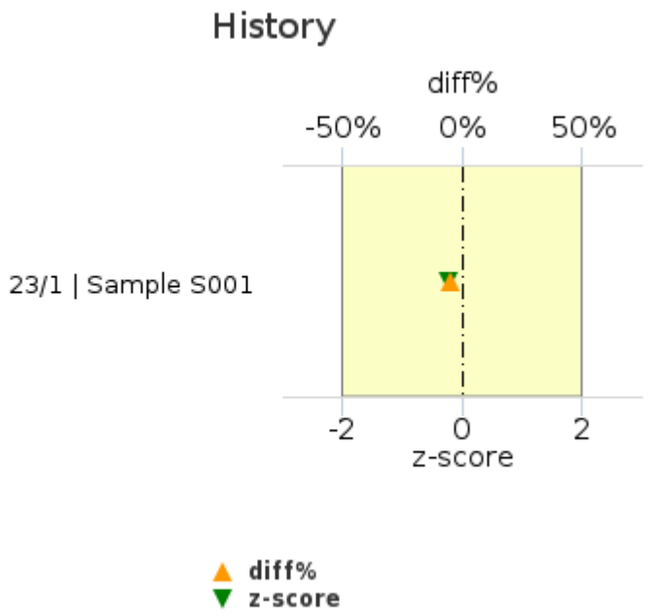
Bacterial screening result and further handling

Sample S001

Bacterial screening result	Number of results	Further handling	Number of results
Negative	37		
		Would not be referred	35
		Would be referred	2
Positive	72		
		Would not be referred	26
		Would be referred	43
		New sample would be requested	3
All	**109**		**109**

U -Leukocytes

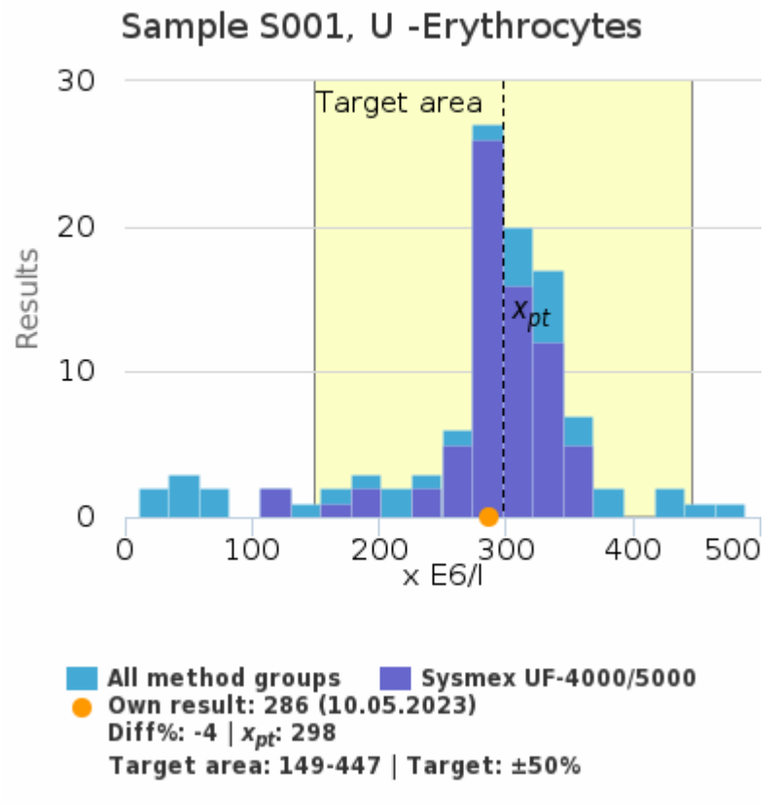


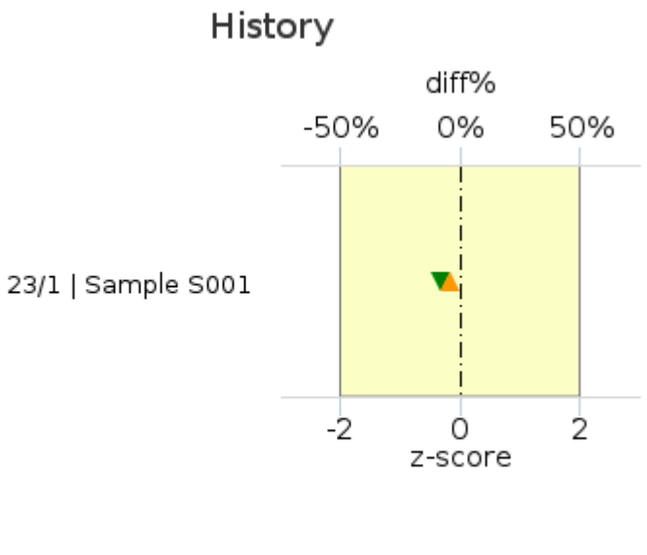


Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S001	45	43	-4%	-0.24

	x_{pt}	sd	SEM	CV%	n
Sysmex UF-4000/5000	45 x E6/l	9	1	18.8	71
All methods	42 x E6/l	17	2	40.0	104

U -Erythrocytes





Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S001	298	286	-4%	-0.34

	x_{pt}	sd	SEM	CV%	n
Sysmex UF-4000/5000	298 x E6/l	36	4	12.0	71
All methods	289 x E6/l	75	7	25.8	103

Report info

Participants

87 participants from 11 countries.

Report info

Your own result should be compared to others using the same method.
Assigned values (x_{pt}, target values) are means 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). 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 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.

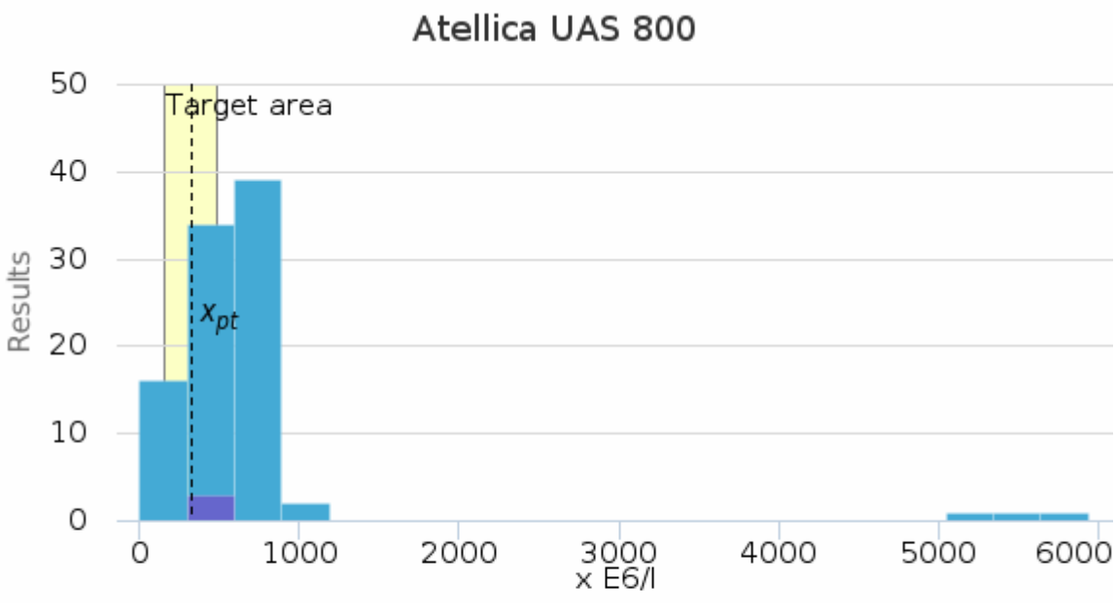
For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

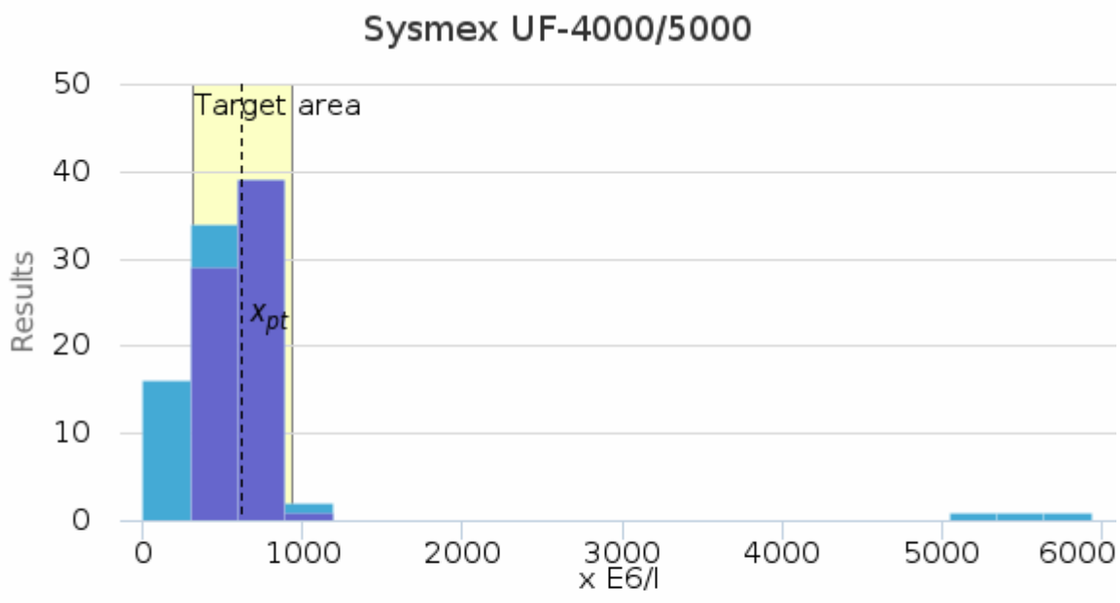
Urine bacterial screening with automated analyzers, April, 1-2023

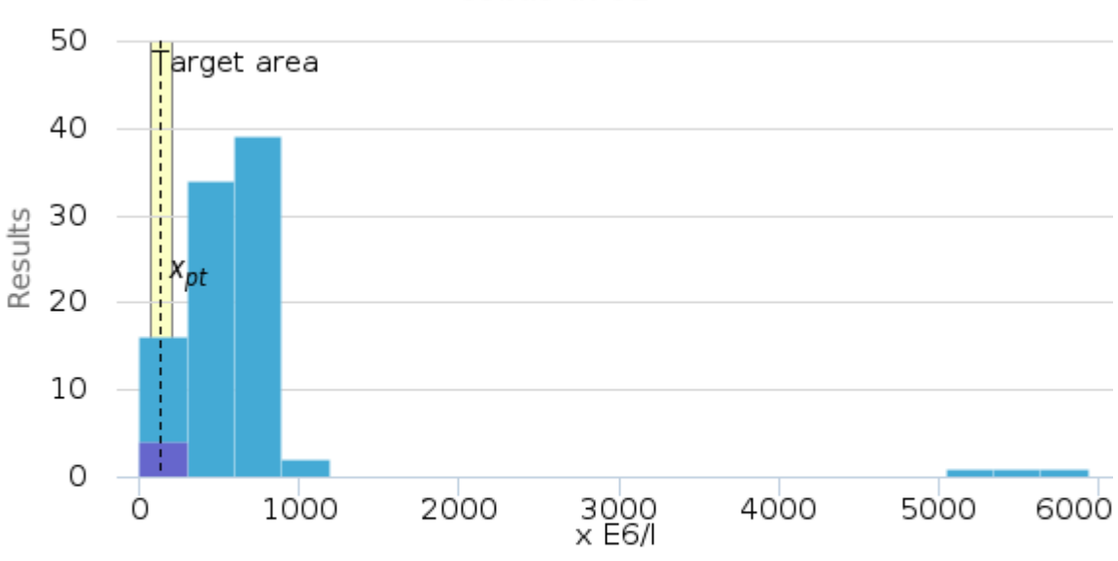
Sample S001 | U -Bacteria, x E6/l

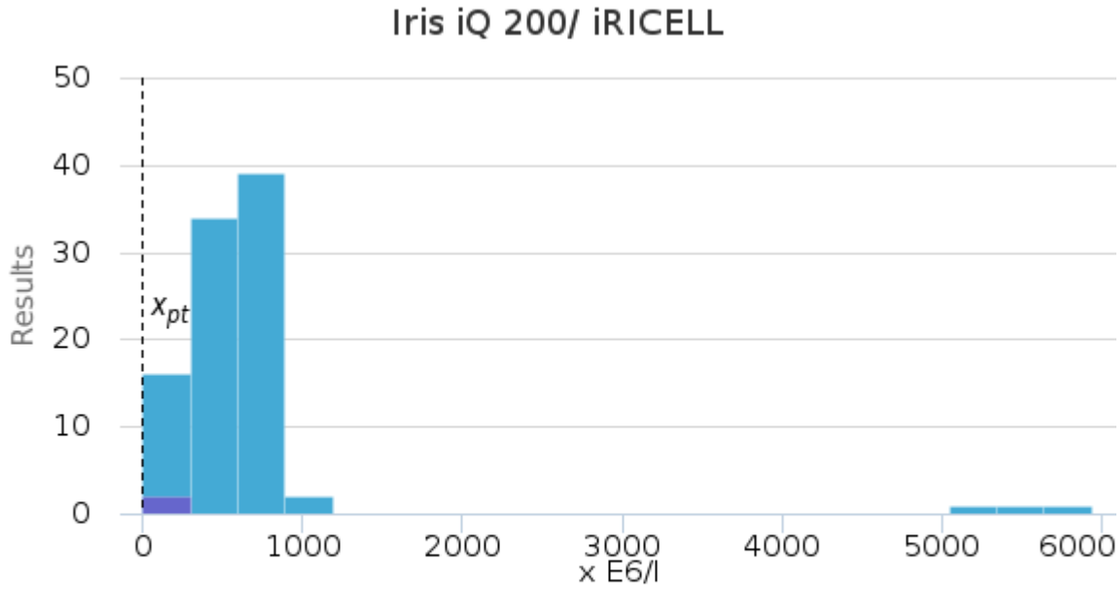
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Atellica UAS 800	326	323	14	4.2	8	315	341	-	3
Sysmex UF-4000/5000	623	613	116	18.7	14	369	947	-	69
cobas u701	137	140	16	11.5	8	118	150	-	4
Iris iQ 200/ iRICELL	3	3	<1	28.3	<1	2	3	-	2
sediMAX	200	215	70	34.8	26	122	308	-	7
sediMAX ConTRUST/ConTRUST Pro	219	213	49	22.3	22	174	300	-	5
Dirui MUS 3600	4436	5334	2220	50.0	1110	1142	5935	-	4
All	**529**	**571**	**223**	**42.1**	**23**	**2**	**1142**	**3**	**94**

Sample S001 | U -Bacteria, x E6/l| histogram summaries in LabScala

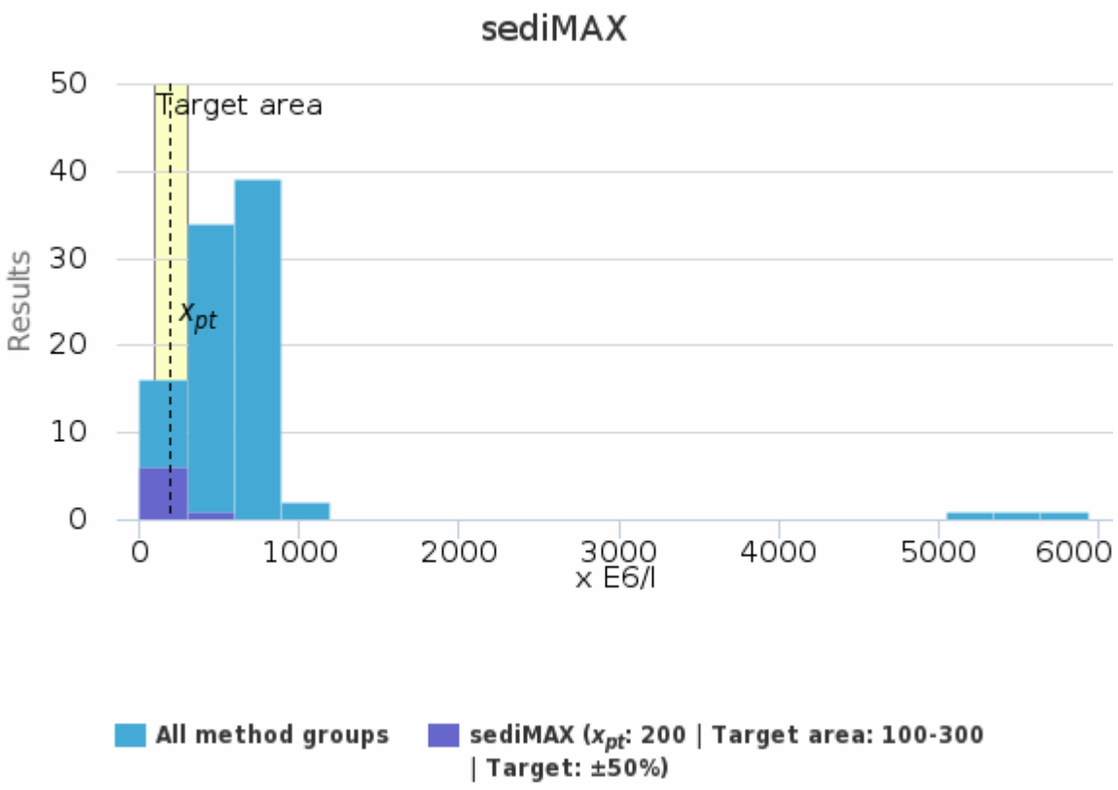


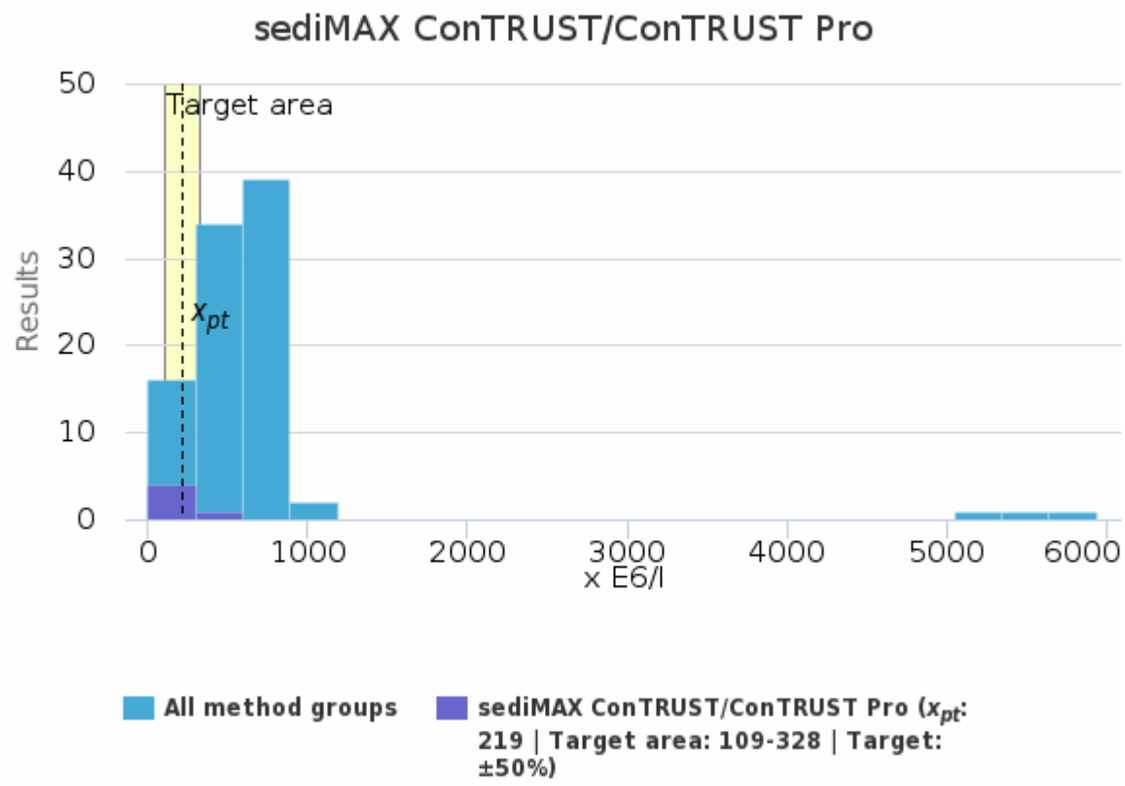


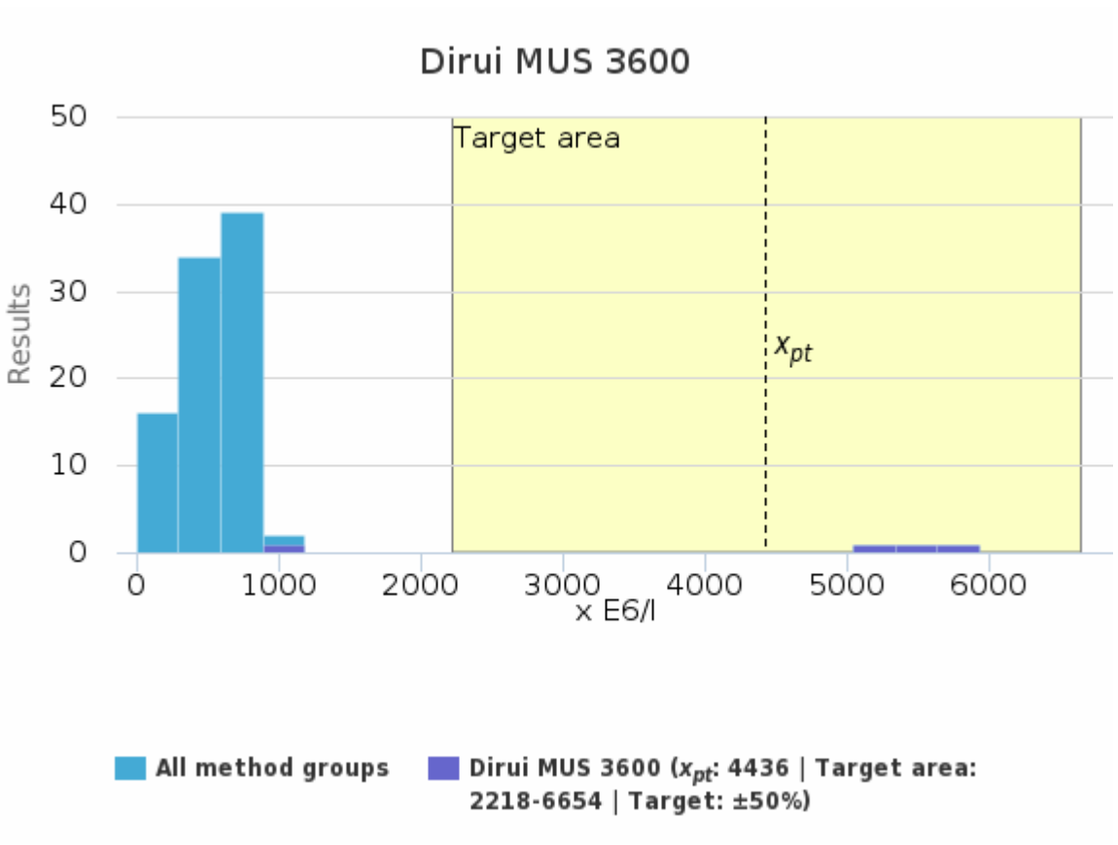




Urine bacterial screening with automated analyzers, April, 1-2023







Sample S001 | Bacterial screening result and further handling

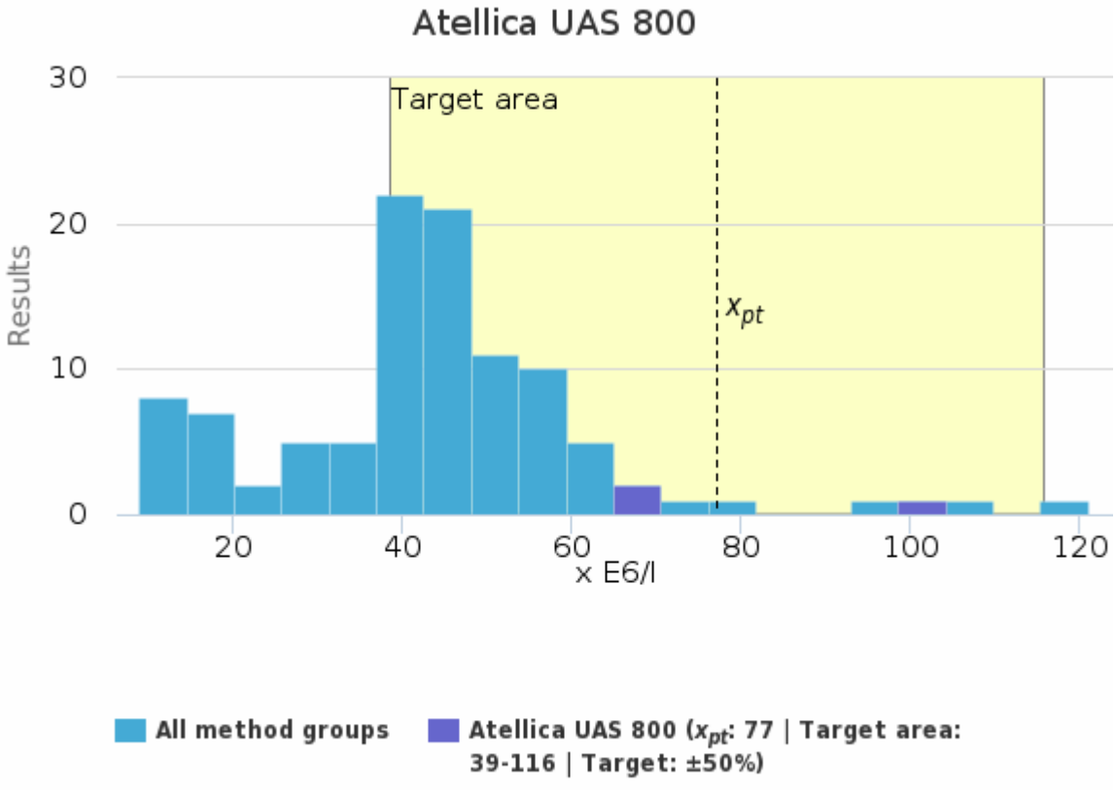
Bacterial screening result	Number of results	Further handling	Number of results
Negative	37		
		Would not be referred	35
		Would be referred	2
Positive	72		
		Would not be referred	26
		Would be referred	43
		New sample would be requested	3
All	**109**		**109**

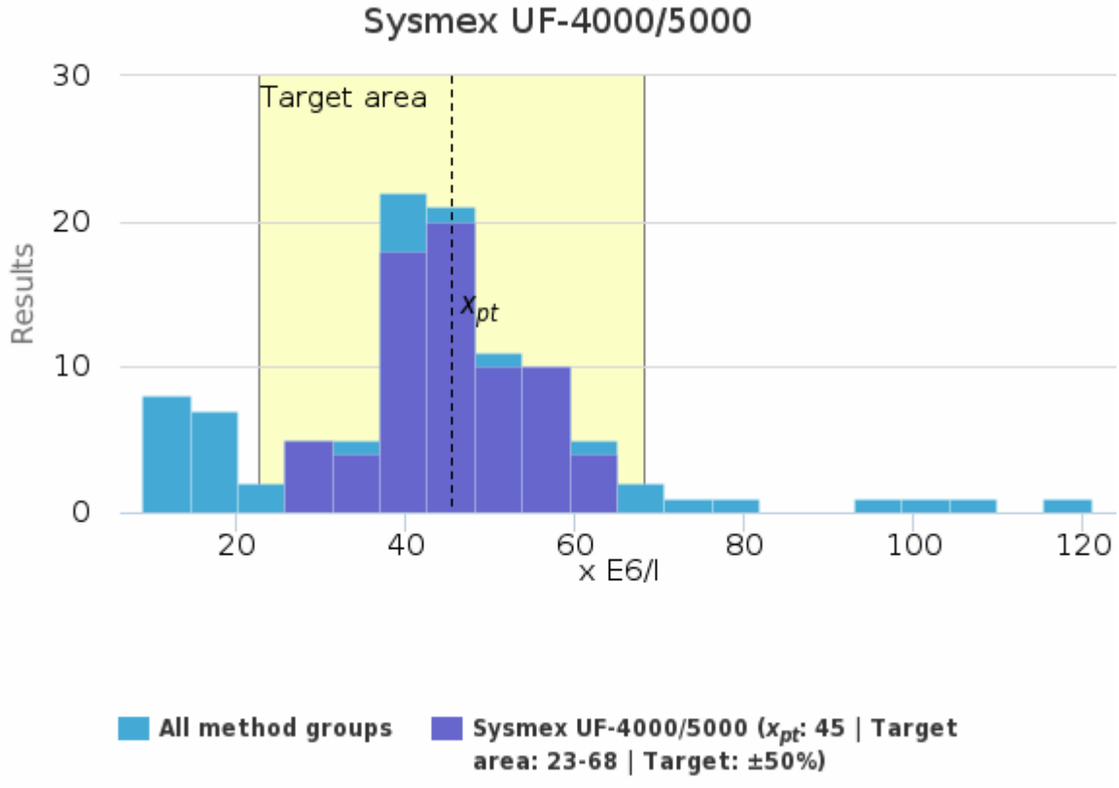
Urine bacterial screening with automated analyzers, April, 1-2023

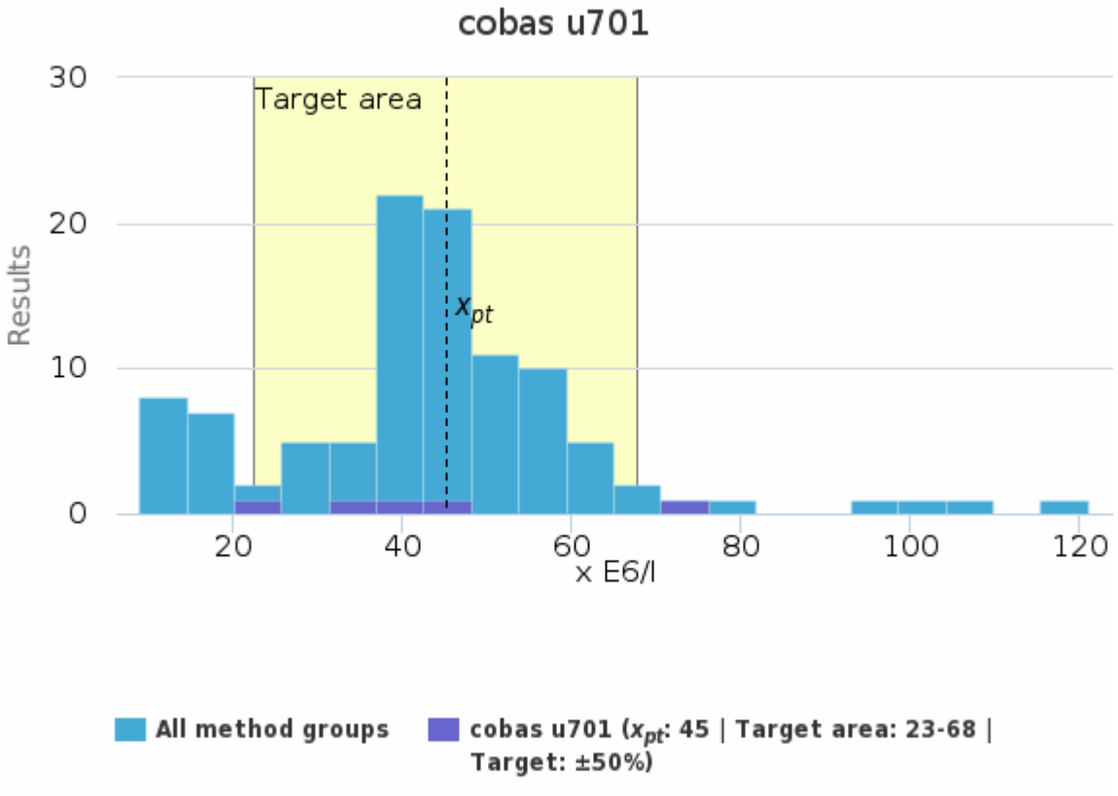
Sample S001 | U -Leukocytes, x E6/l

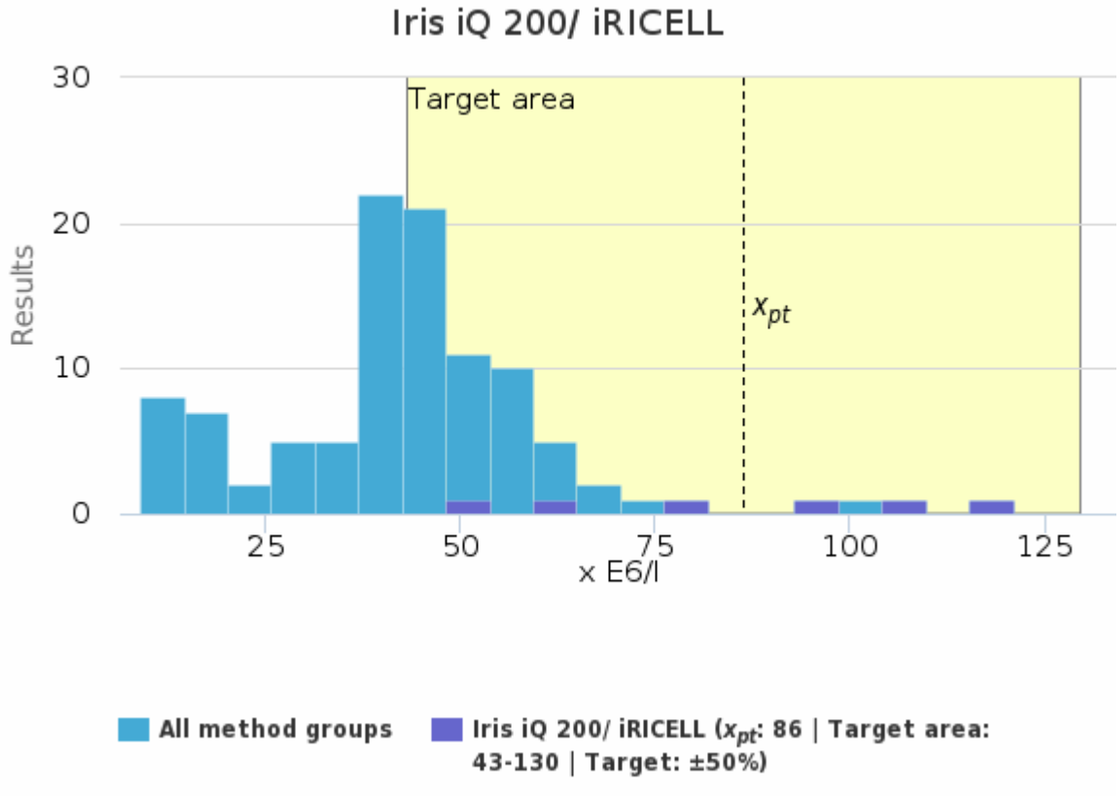
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Atellica UAS 800	77	66	20	25.7	11	65	100	-	3
Sysmex UF-4000/5000	45	45	9	18.8	1	27	64	-	71
cobas u701	45	42	19	41.1	8	25	75	-	5
Iris iQ 200/ iRICELL	86	88	26	30.4	11	52	121	-	6
sediMAX	19	14	11	59.5	4	9	39	-	9
sediMAX ConTRUST/ConTRUST Pro	15	16	5	35.4	2	9	22	-	7
Dirui MUS 3600	25	17	14	55.4	8	17	41	-	3
All	**42**	**43**	**17**	**40.0**	**2**	**9**	**100**	**2**	**104**

Sample S001 | U -Leukocytes, x E6/l| histogram summaries in LabScala

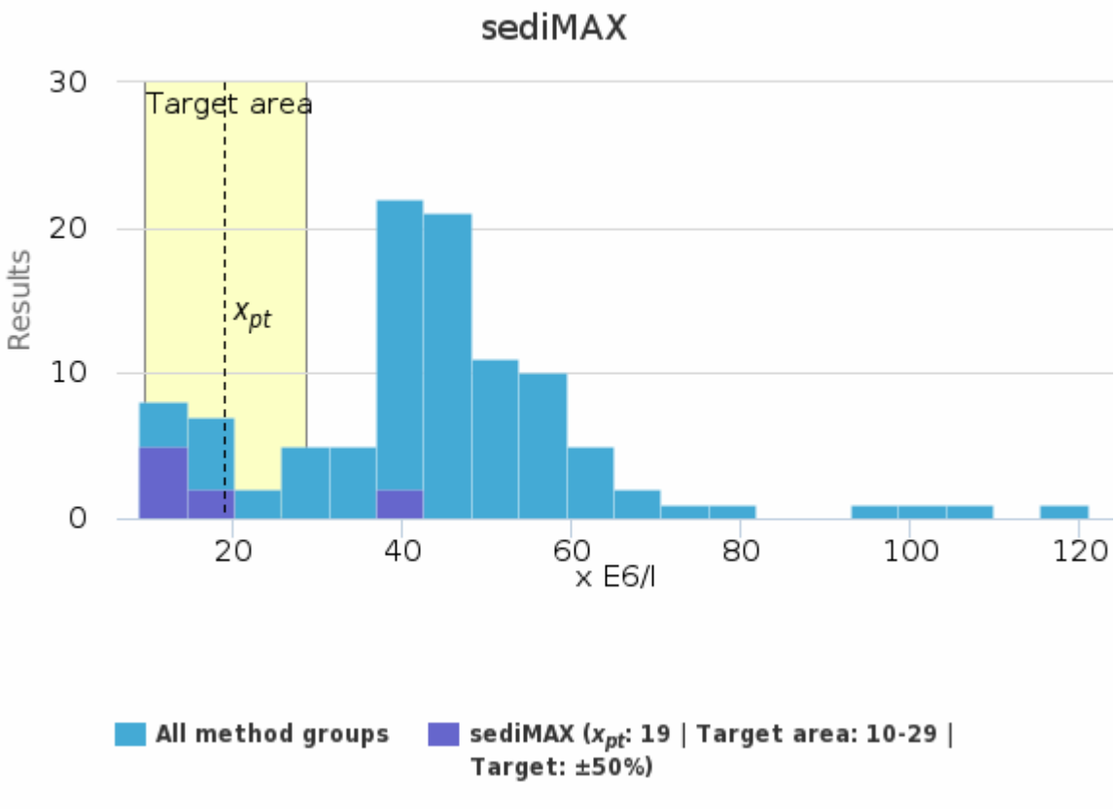


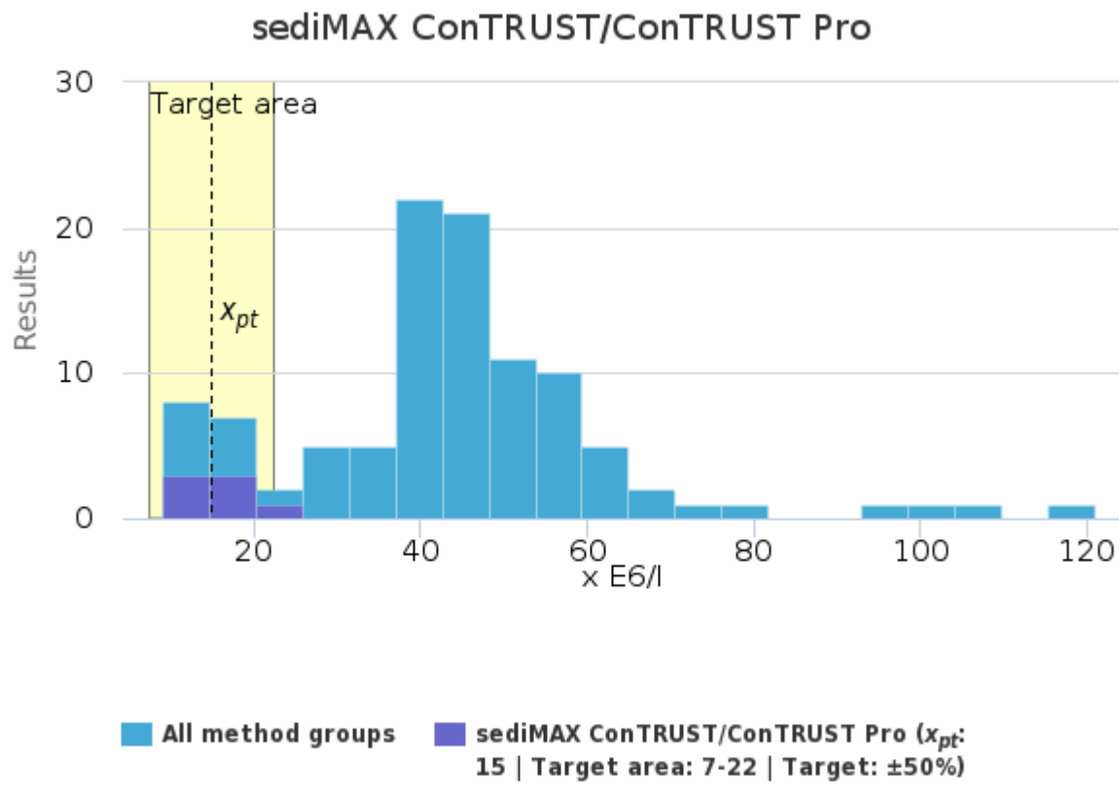


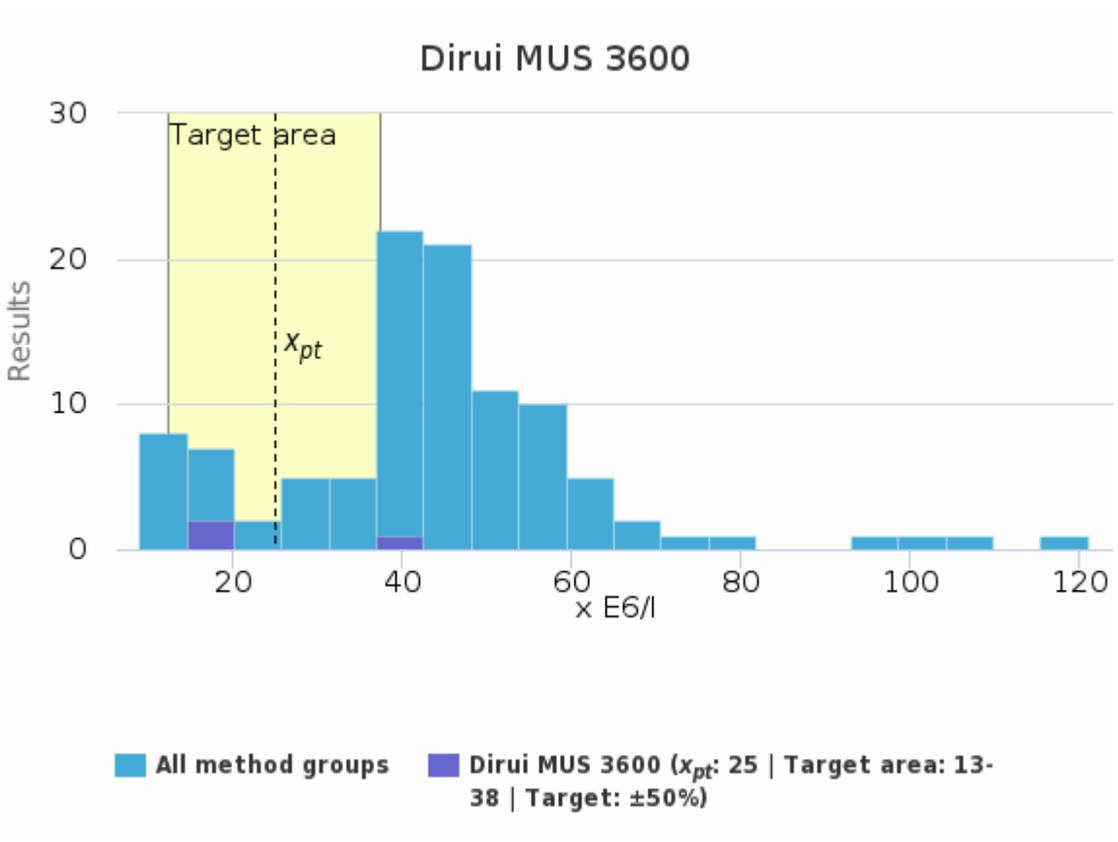




Urine bacterial screening with automated analyzers, April, 1-2023



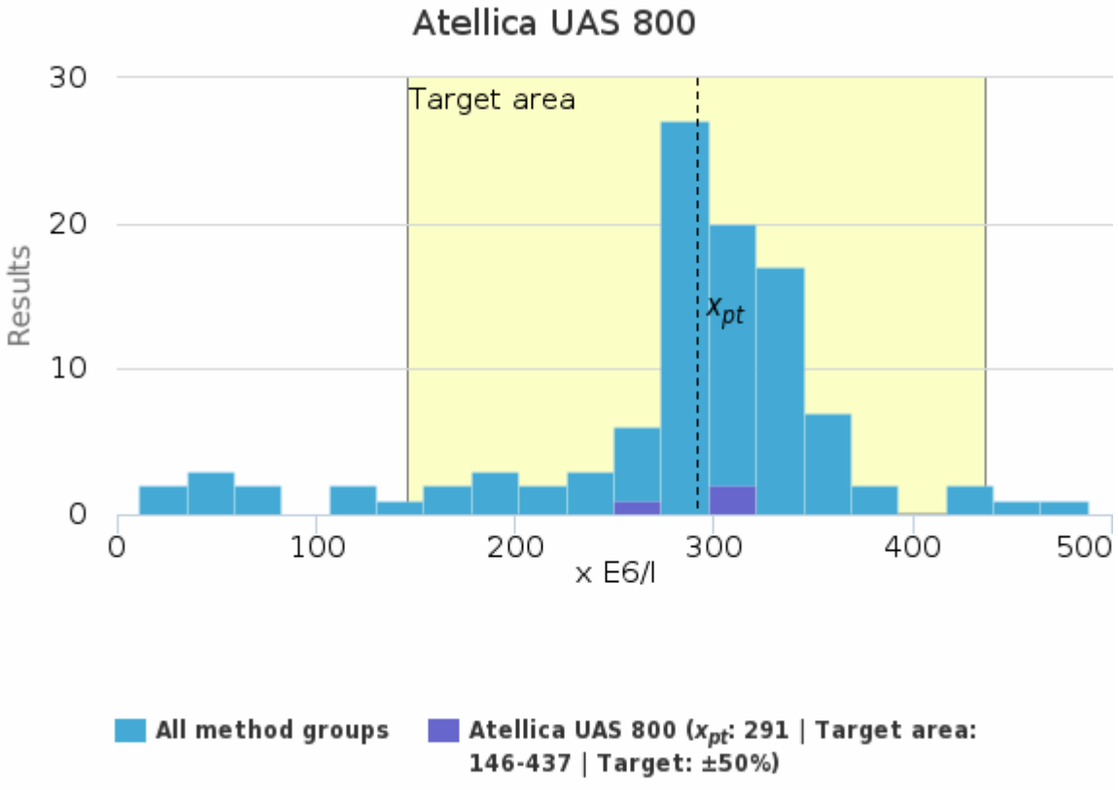


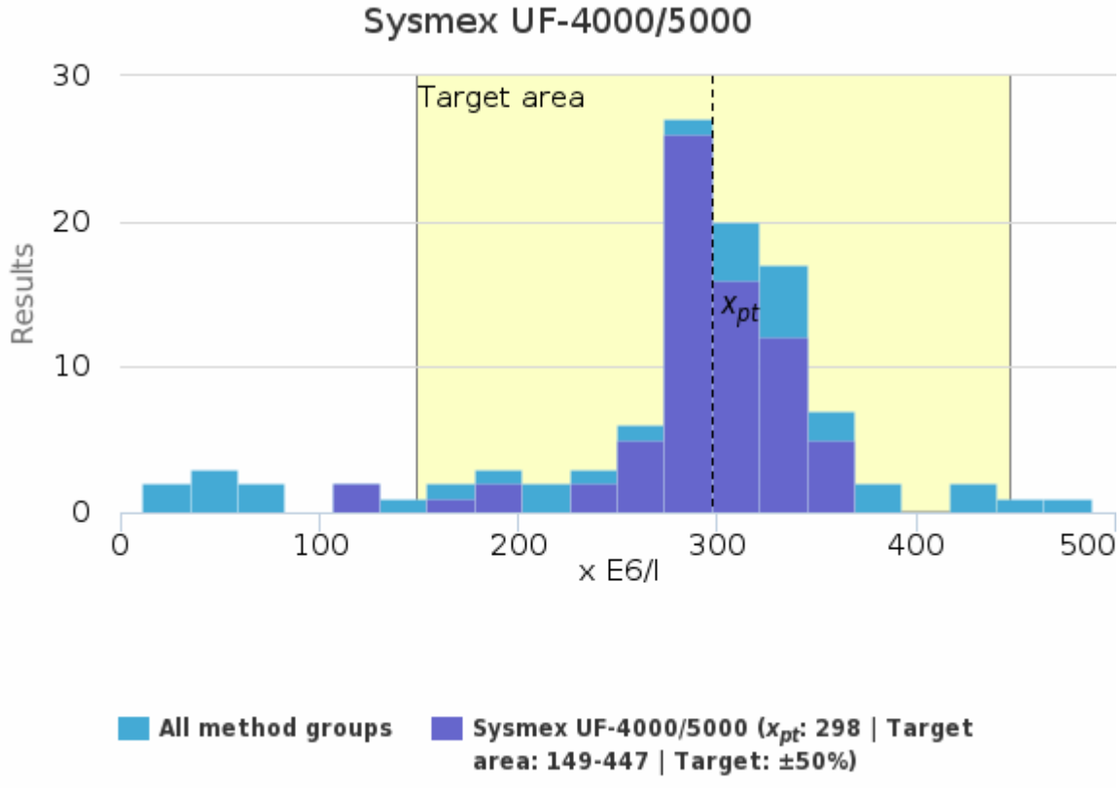


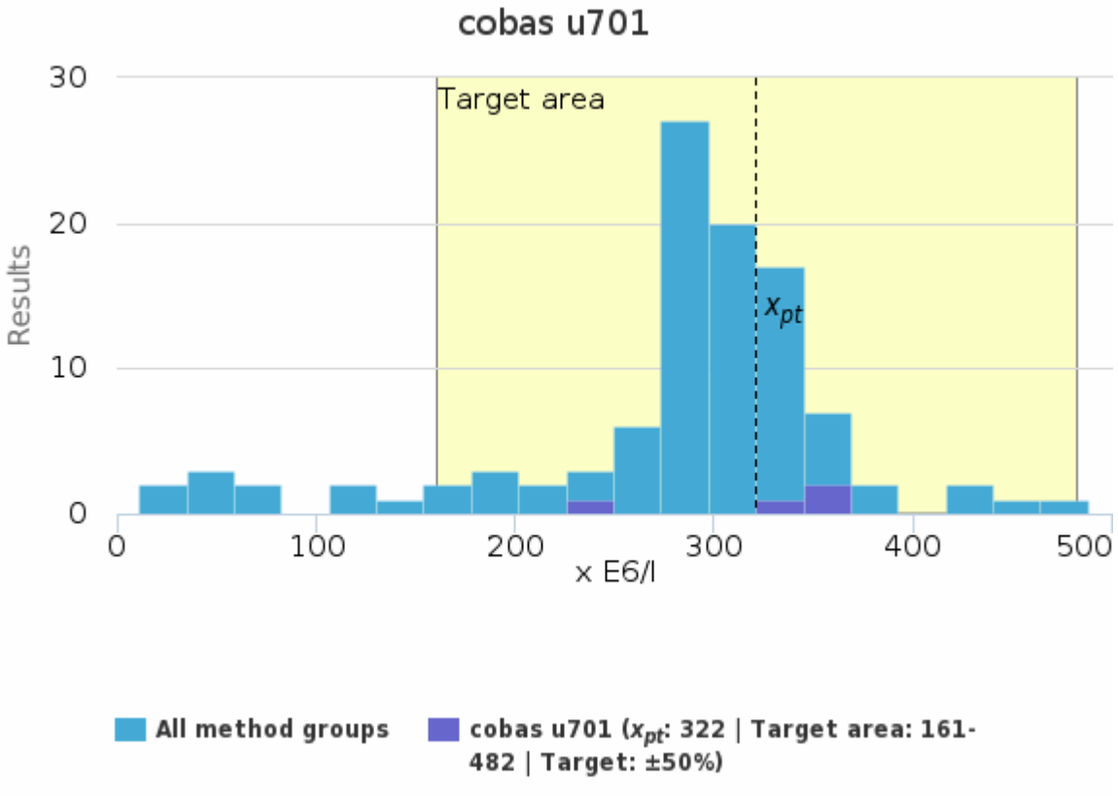
Sample S001 | U -Erythrocytes, x E6/l

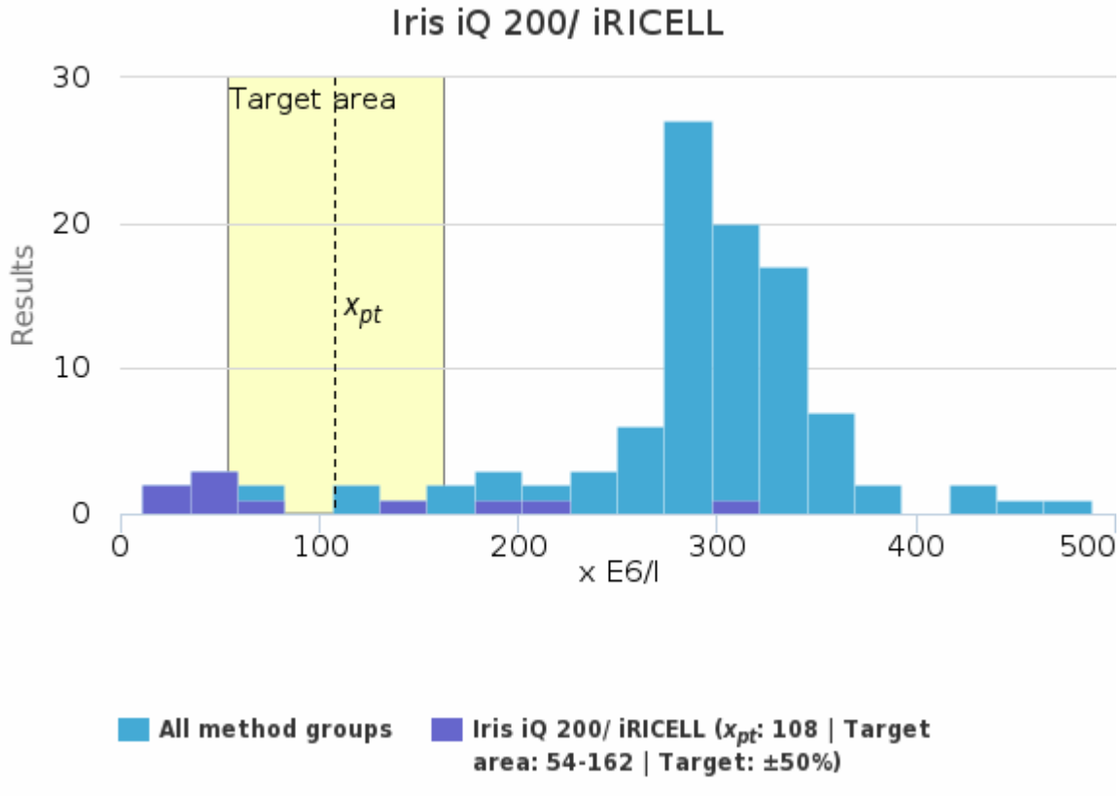
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Atellica UAS 800	291	305	27	9.3	16	260	309	-	3
Sysmex UF-4000/5000	298	295	36	12.0	4	173	353	2	71
cobas u701	322	341	52	16.2	26	246	359	-	4
Iris iQ 200/ iRICELL	108	64	100	92.2	32	11	312	-	10
sediMAX	276	322	135	48.8	51	76	488	-	7
sediMAX ConTRUST/ConTRUST Pro	389	378	46	11.9	21	326	442	-	5
Dirui MUS 3600	340	311	67	19.8	39	292	417	-	3
All	**289**	**297**	**75**	**25.8**	**7**	**37**	**488**	**3**	**103**

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

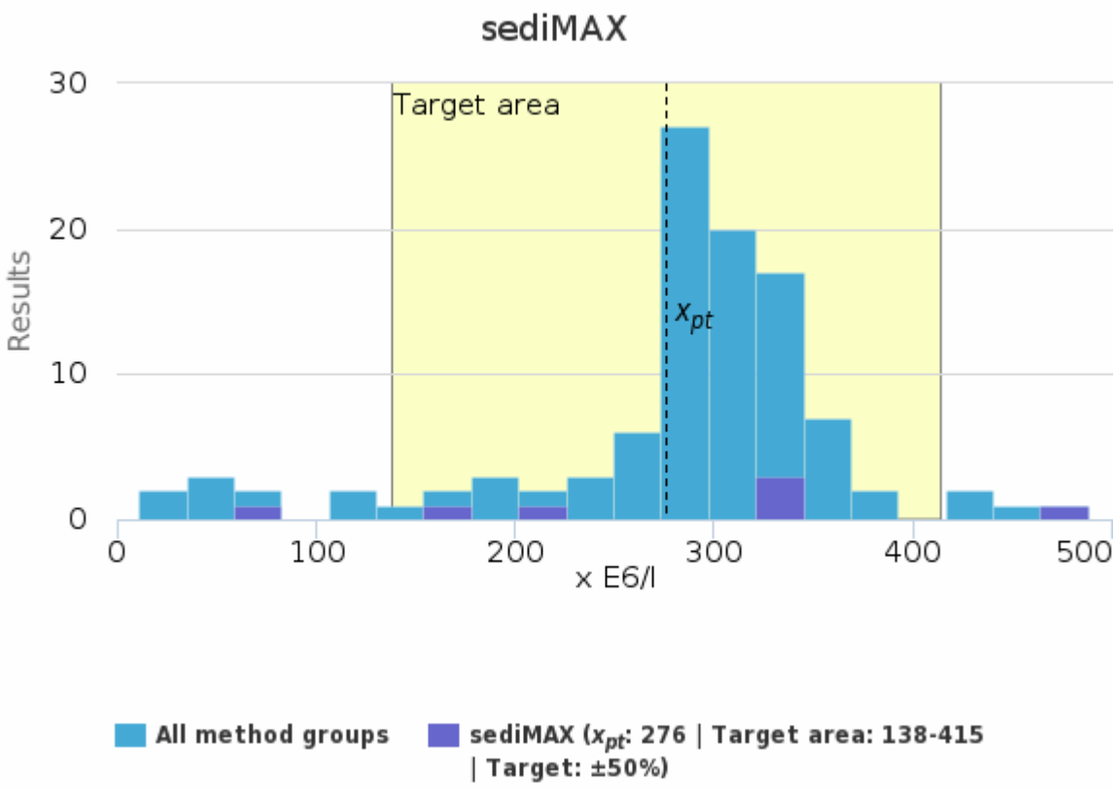


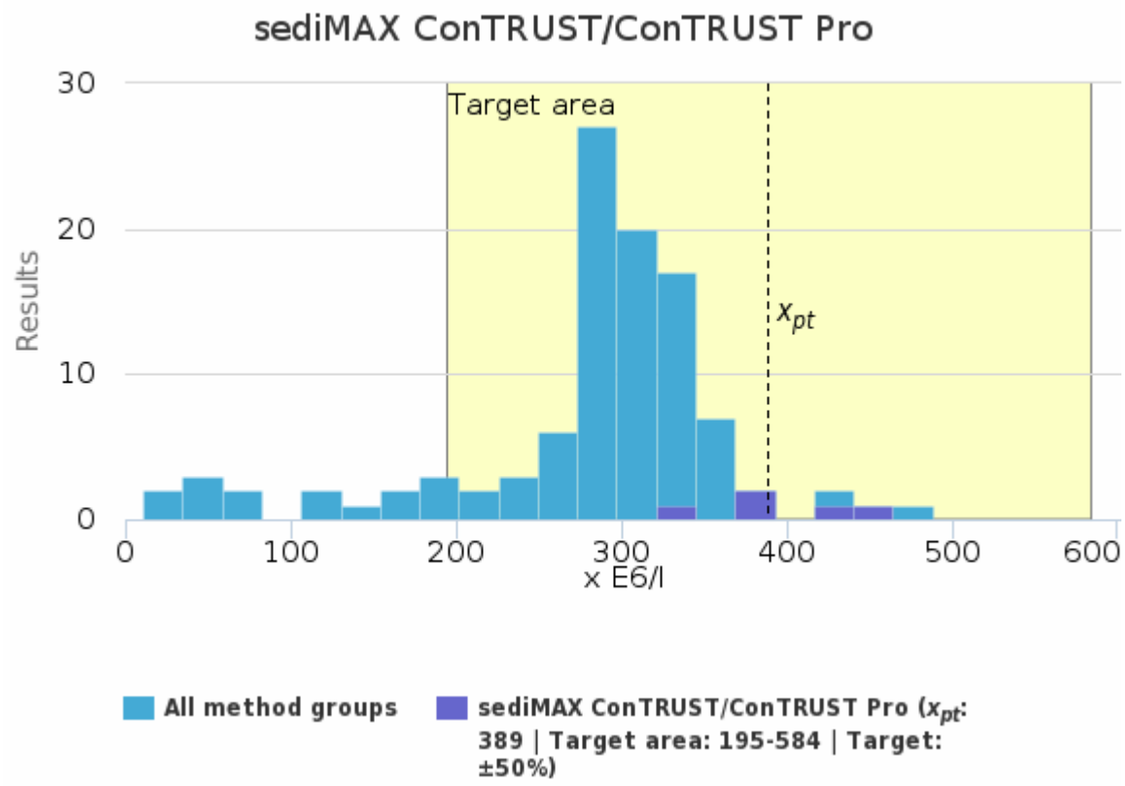


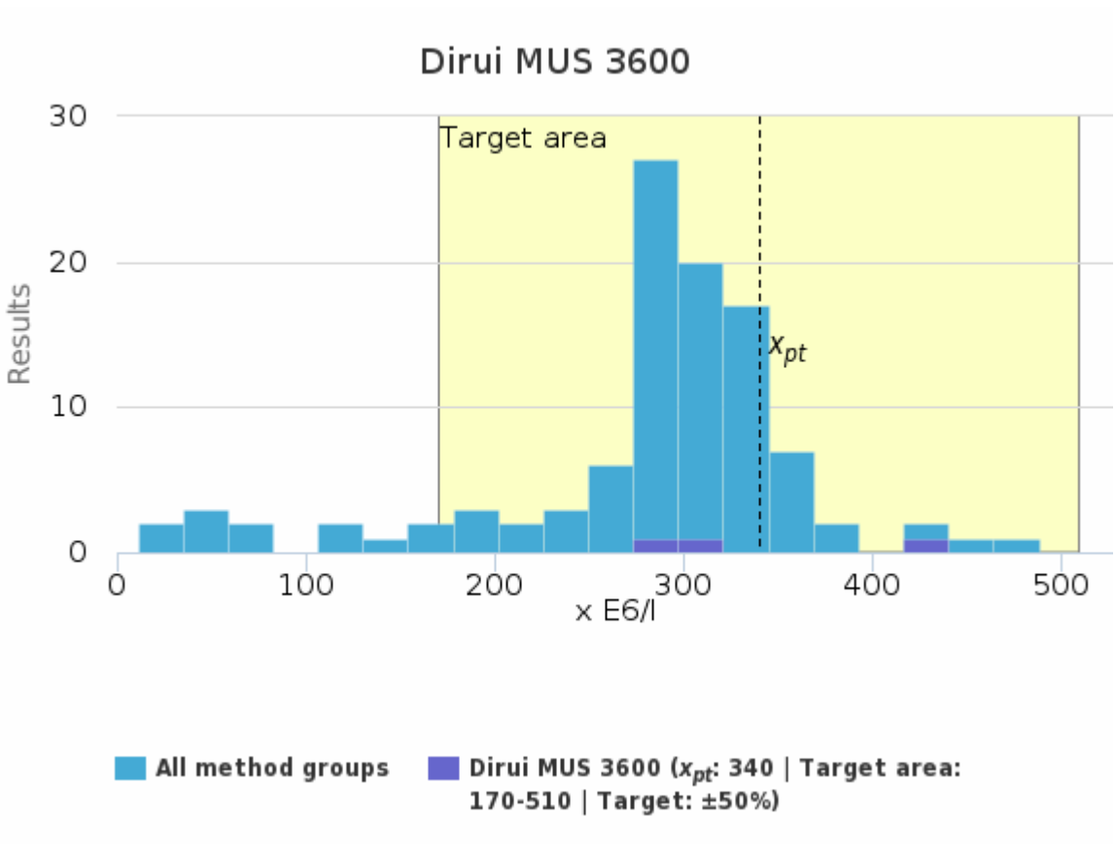




Urine bacterial screening with automated analyzers, April, 1-2023







Report info

Participants

87 participants from 11 countries.

Report info

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LABQUALITY

External Quality Assessment Scheme

Urine bacterial screening with automated analyzers
Round 1, 2023

Specimen
Sample S001 (LQ744823011) was liquid sample containing erythrocytes and leukocytes and the lyophilized Synthetic urine sample contained bacteria. After rehydration according to the instructions, the sample simulated patient urine sample. Based on the pre-testing and the results obtained in the round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

Pre-test methods: Two different Sysmex UF-5000 analyzers.

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.

Comments – Expert
Urinary tract infections are among the most common reasons, after the respiratory tract infections, to seek medical care. Urine bacterial screening is used to help the treatment plan. The term bacterial screening is used to describe methods with shorter turnaround times than bacterial culture.

Urine bacterial screening can be performed using several parameters. In this round the parameters used are bacteria, leukocytes, and erythrocytes. Each laboratory defines the cut-offs for parameters used for the screening. As a result, some of the screened samples are answered negative, while others need further tests. The screening is based on quantitative results, thus, this round Urine bacterial screening with automated analyzers, round 1, 2023 was quantitative. Sample S001 had elevated concentrations of bacteria, leukocytes, and erythrocytes.

Bacteria
The manufacturer´s concentration for sample S001 was 0.1–1 x10^6 CFU/mL. In this round, the unit for particle count is x10^6/L. It was seen that a part of the results has been reported in a different unit. All < and > results have been excluded from the data analysis. The reason for outliers can also be, for example, poor dilution of the lyophilized sample.

The mean for all the methods was 529 x10^6/L, and the median 571 x10^6/L. As was the case in previous round, majority of the participants (73%) reported results from Sysmex UF-4000/5000 analyzers. A surprisingly significant difference in the results is seen between the results in different method groups. It is likely that different units have been used (Iris iQ200 / iRICELL the mean of the results 3 x10^6/L, Dirui MUS 3600 4436 x10^6/L). The results for Dirui MUS 3600 method group represent the high-end of the results. **It is essential to define the cut-offs for the screening for every method separately.**

2023-05-22

FINAL REPORT

Product no. 3170

Subcontracting: Sample pretesting

Samples sent	2023-04-24
Round closed	2023-05-12
Final report	2023-05-22

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
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The processes after the screening for bacteria differ from one laboratory to another. It is worth mentioning that a sample with a negative screening result for bacteria can be directed to further tests, for example due to elevated number of leukocytes. Furthermore, different patient demographics may need separate cut-offs. Typically, women, men and children have their own cut-offs.

Leukocytes
For the Sample S001, the mean of leukocyte concentration for all the methods was again 42 $x10^6$/L, representing an elevated level of leukocytes. However, some normal results were also reported. In total, the range for the results was 9–100 $x10^6$/L. Furthermore, the range for means for results in different method groups was 15–86 $x10^6$/L.

Erythrocytes
The mean of erythrocyte concentration for all the methods for sample S001 was 289 $x10^6$/L, representing elevated erythrocyte concentration. Lower erythrocyte concentrations were again reported using method iRIS iQ200/ iRISELL method (mean 108 $x10^6$/L vs. mean of all the methods 289 $x10^6$/L). As was the case in leukocyte count, some results were also reported as normal.

The results of this round included 7 different methods. The number of results in a method group differ significantly. Some of the methods had only few results. The small number of results per method has to be taken into consideration when interpreting the results.

Several results below or above the methods' quantitation limits were reported in this round (Annex 1, Table 1).

End of report

Annex 1.

Table 1: Results reported below or above the methods' quantitation limits from the round 1, 2023

Analyte	Analyzer	Results, xE6/L
Bacteria		
	Iris iQ 200/iRICELL	<1 six results and <5 and <10 results
	sediMAX	<200 and <500 results
	SediMAX ConTRUST/ConTRUST Pro	<130 result
Leukocytes		
	Iris iQ 200/iRICELL	<1 two results
Erythrocytes		
	sediMAX	>10 and >100 results
	SediMAX ConTRUST/ConTRUST Pro	>100 result