

External Quality Assessment Scheme

Faecal elastase Round 1, 2023

Specimens

Please find enclosed two lyophilized faecal samples S001 and S002, each 500 µL.

Caution

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

Examinations

Faecal elastase (quantitative result and interpretation)

Storage and use

Store the samples at +2...8 °C before use. Before analysing add 500 µL distilled or reagent grade water, do not mix at this stage but allow to stand for 10 min at RT. After that mix (vortex) the samples about 30 seconds. Check that the samples are homogeneous. Analyse immediately after reconstitution same way as a patient sample. Follow the standard operating procedure of your laboratory for disposal of the samples.

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.

S001



S002



2023-03-28

INSTRUCTIONS

Product no. 2754
LQ747823011-012/DE
UN3373

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

The results should be reported no later than **April 19, 2023.**

The expected results of the round are published in LabScala in the View Reports section by April 21, 2023

Inquiries

EQA Coordinator
Outi Rauta
outi.rauta@labquality.fi

Labquality Oy

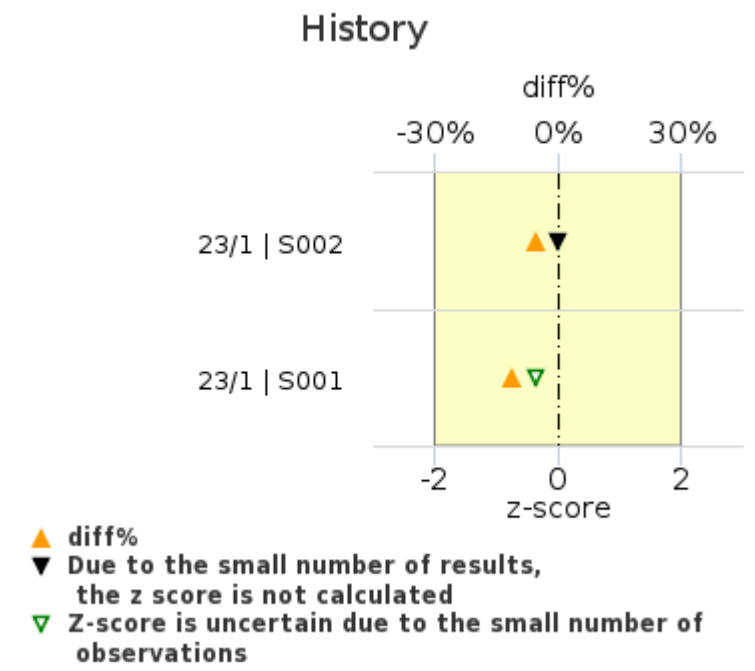
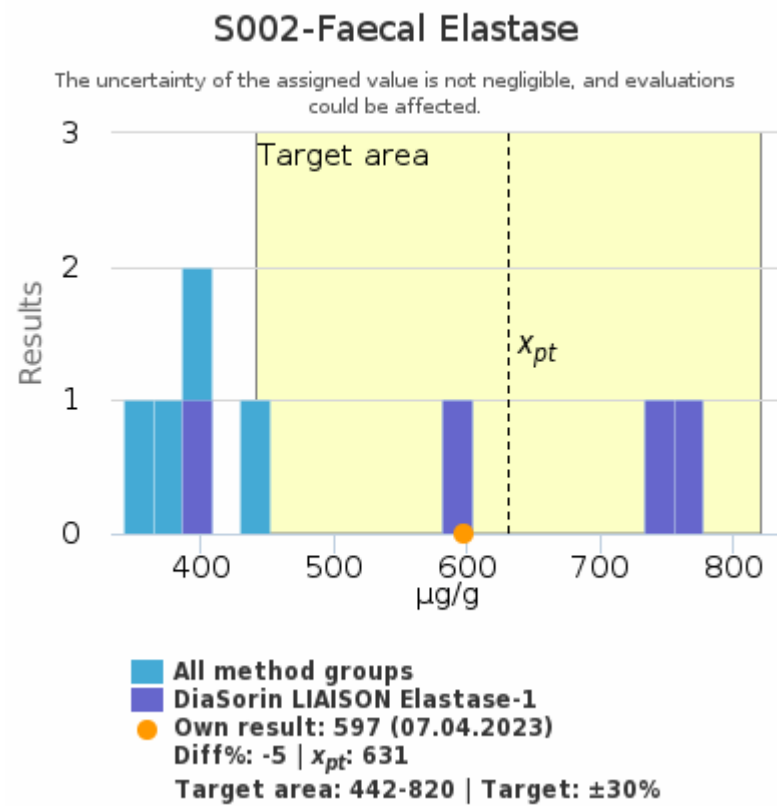
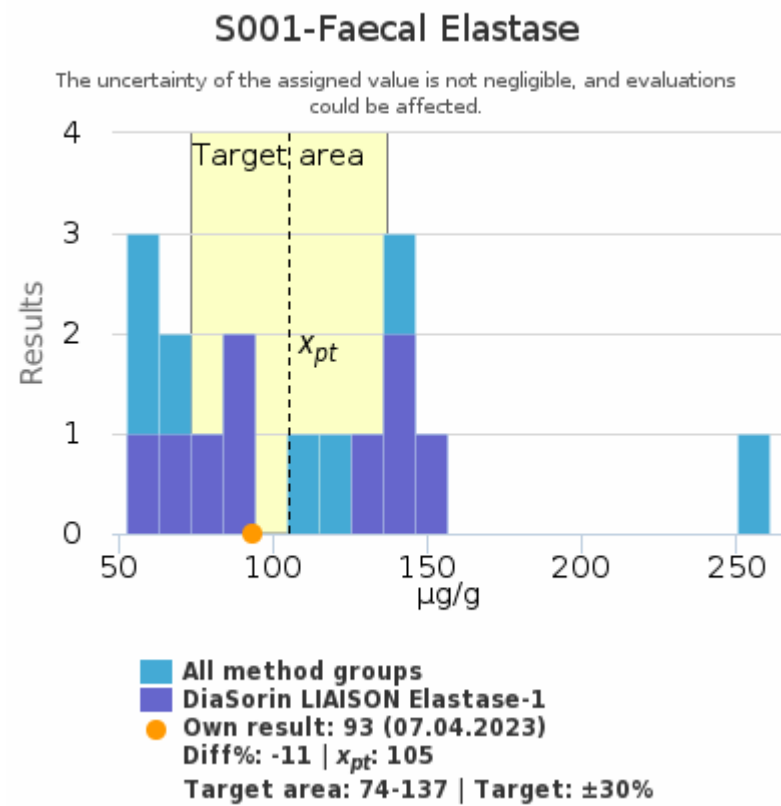
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Faecal Elastase, quantitative



	x_{pt}	sd	SEM	CV%	n
DiaSorin LIAISON Elastase-1	105 µg/g	35	12	32.8	9
All methods	101 µg/g	35	9	34.8	16

	x_{pt}	sd	SEM	CV%	n
DiaSorin LIAISON Elastase-1	631 µg/g	170	85	26.9	4
All methods	511 µg/g	172	61	33.7	8

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	S002	631	597	-5%	-
23/1	S001	105	93	-11%	-0.35

Faecal Elastase, interpretation

S001

Methodics	Normal	Mild pancreatic insufficiency	Severe pancreatic insufficiency	Total
Bioserv Fecal Pancreatic Elastase	-	2	1	3
DiaSorin LIAISON Elastase-1	-	4	5	9
Eurospital Diagnostic Elaprest Turbo	1	-	-	1
ScheBo Pancreatic Elastase 1 ELISA Stool test	-	1	2	3
Total	1	7	8	16

S002

Methodics	Normal	Total
Bioserv Fecal Pancreatic Elastase	4	4
DiaSorin LIAISON Elastase-1	8	8
Eurospital Diagnostic Elaprest Turbo	1	1
ScheBo Pancreatic Elastase 1 ELISA Stool test	3	3
Total	16	16

Report info**Participants**

18 participants from 10 countries.

Report info

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

Assigned values (\bar{x}_p , 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.

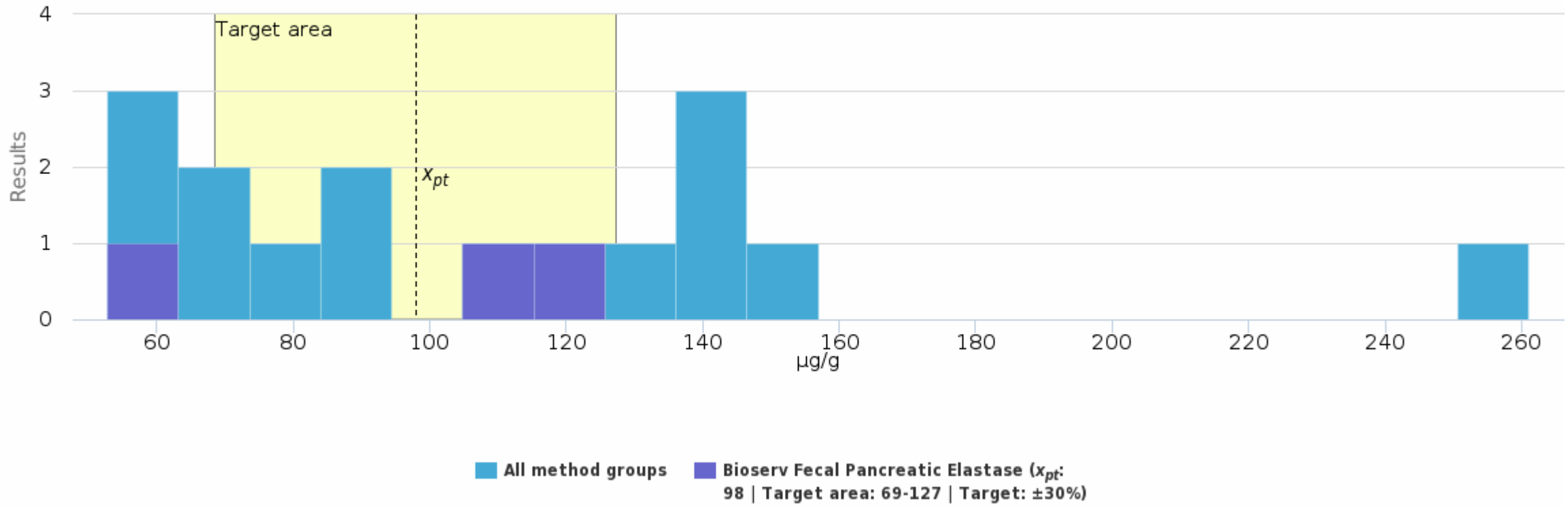
Results reported with $<$ or $>$ -signs cannot be included in the statistics.

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

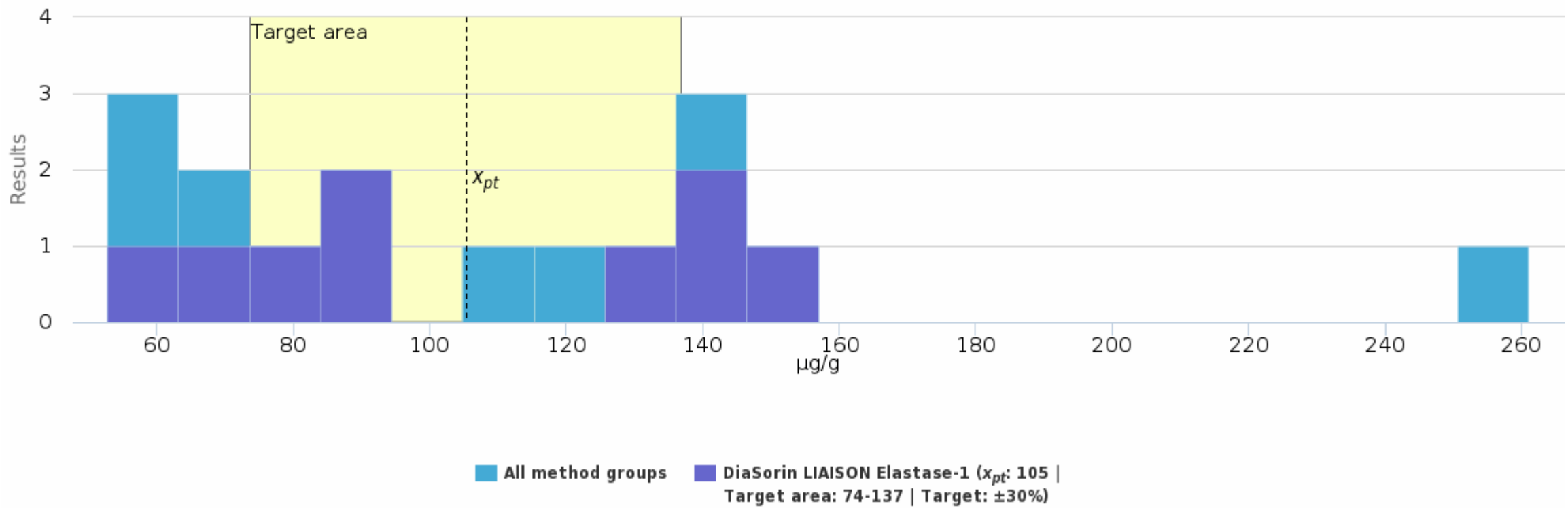
S001 | Faecal Elastase, quantitative, µg/g

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Bioserv Fecal Pancreatic Elastase	98	110	33	33.3	19	61	123	-	3
DiaSorin LIAISON Elastase-1	105	93	35	32.8	12	60	150	-	9
Eurospital Diagnostic Elaprest Turbo	-	-	-	-	-	261	261	-	1
ScheBo Pancreatic Elastase 1 ELISA Stool test	89	69	49	55.5	29	53	145	-	3
All	101	93	35	34.8	9	53	150	1	16

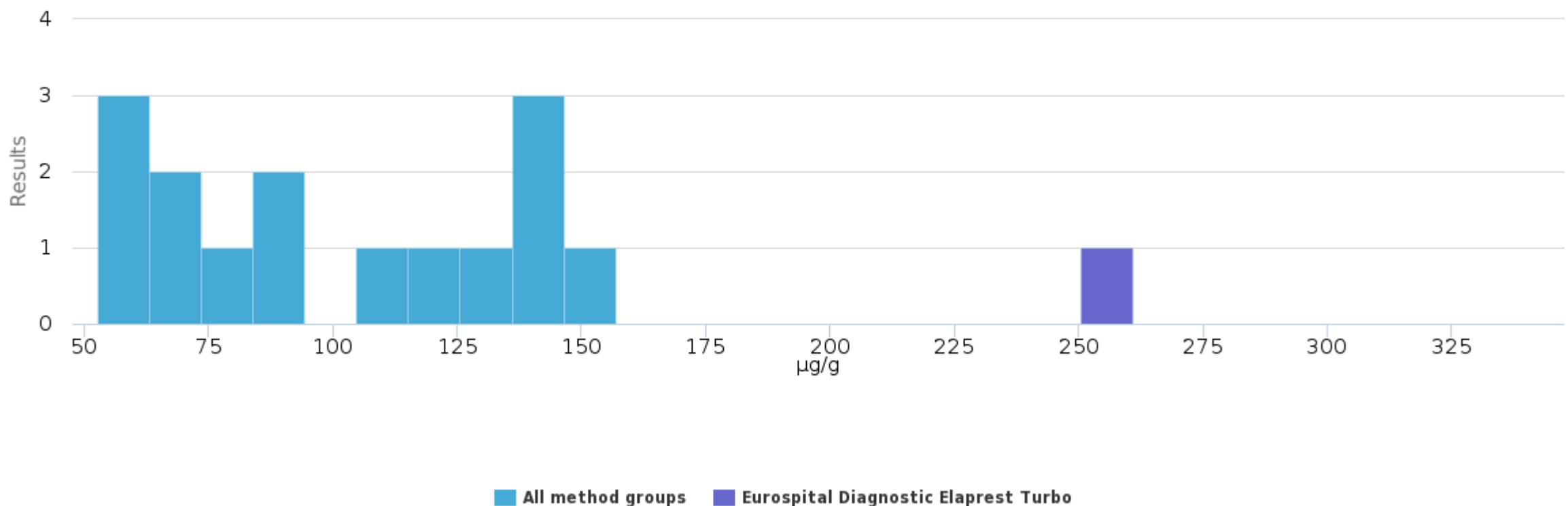
Bioserv Fecal Pancreatic Elastase



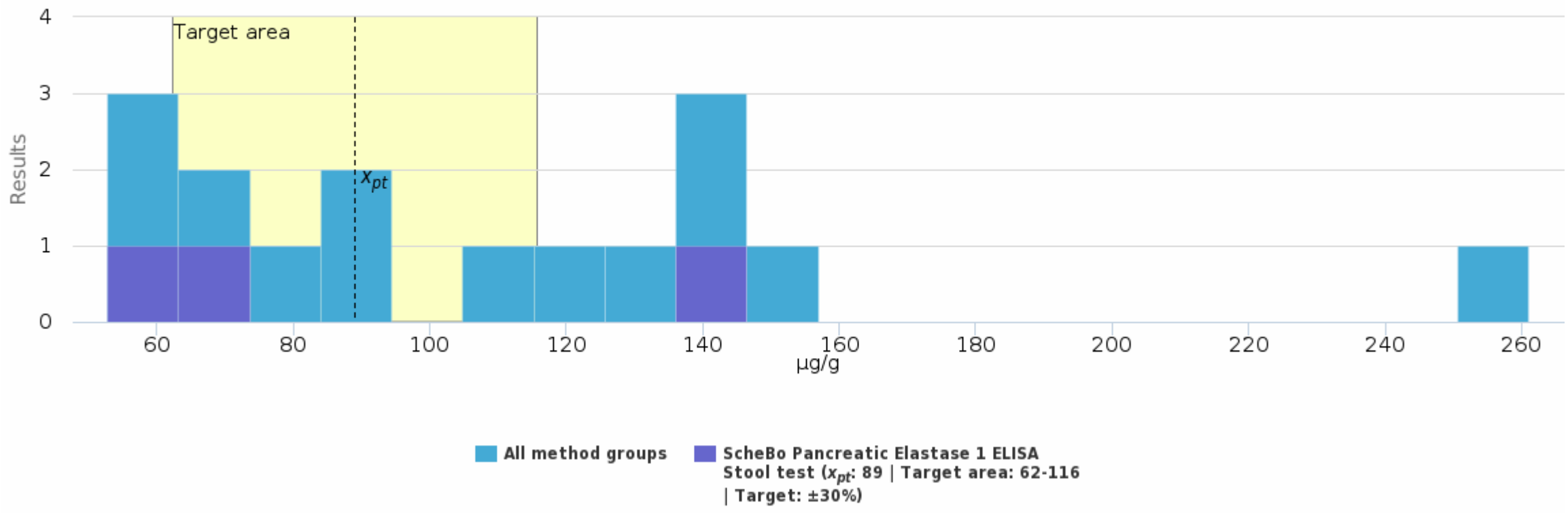
DiaSorin LIAISON Elastase-1



Eurospital Diagnostic Elaprest Turbo



ScheBo Pancreatic Elastase 1 ELISA Stool test



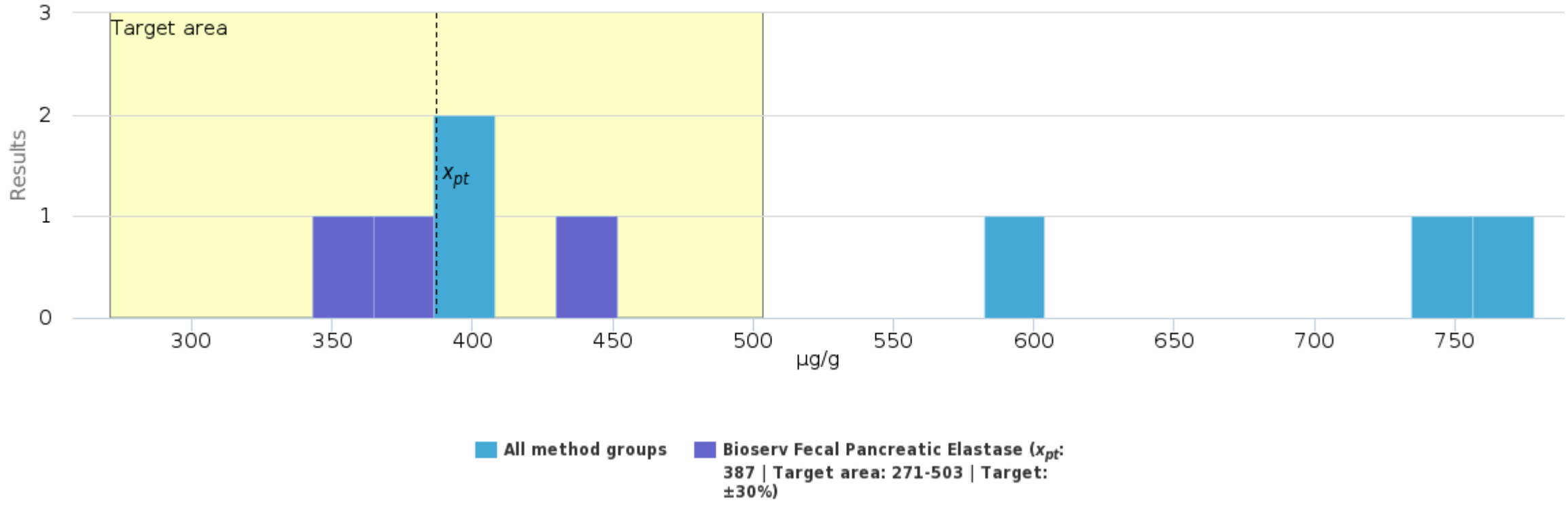
S001 | Faecal Elastase, interpretation

Methodics	Normal	Mild pancreatic insufficiency	Severe pancreatic insufficiency	Total
Bioserv Fecal Pancreatic Elastase	-	2	1	3
DiaSorin LIAISON Elastase-1	-	4	5	9
Eurospital Diagnostic Elaprest Turbo	1	-	-	1
ScheBo Pancreatic Elastase 1 ELISA Stool test	-	1	2	3
Total	1	7	8	16

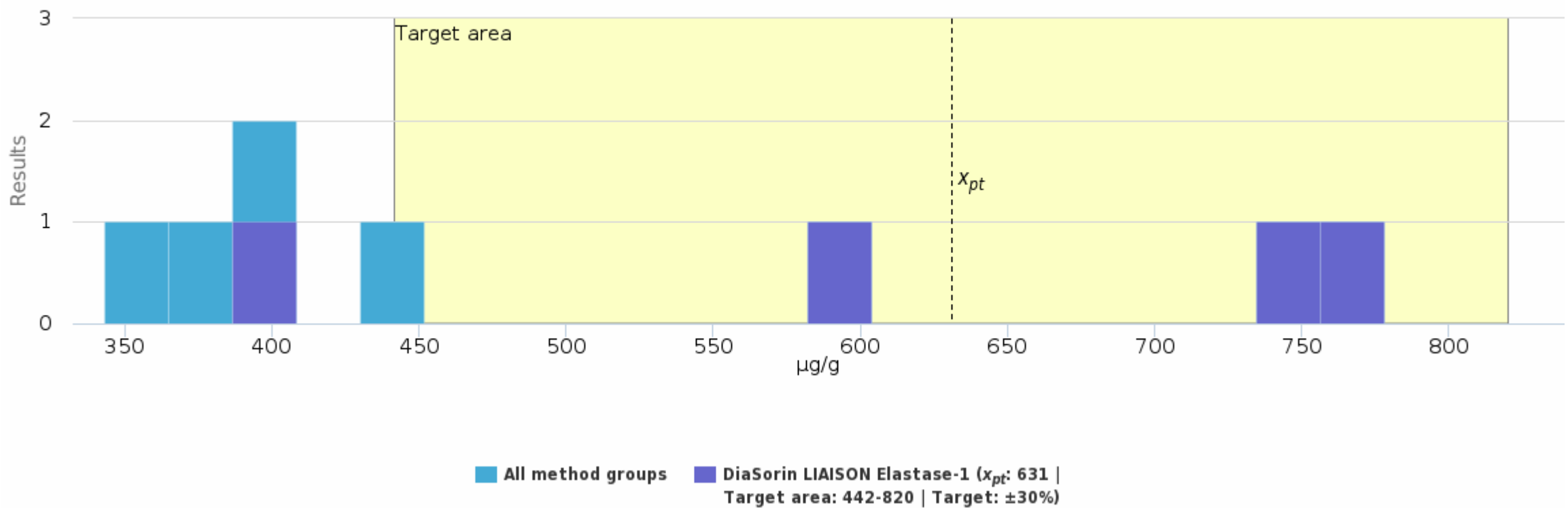
S002 | Faecal Elastase, quantitative, µg/g

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Bioserv Fecal Pancreatic Elastase	387	383	47	12.0	27	343	436	-	3
DiaSorin LIAISON Elastase-1	631	671	170	26.9	85	405	778	-	4
Eurospital Diagnostic Elaprest Turbo	-	-	-	-	-	400	400	-	1
All	511	420	172	33.7	61	343	778	-	8

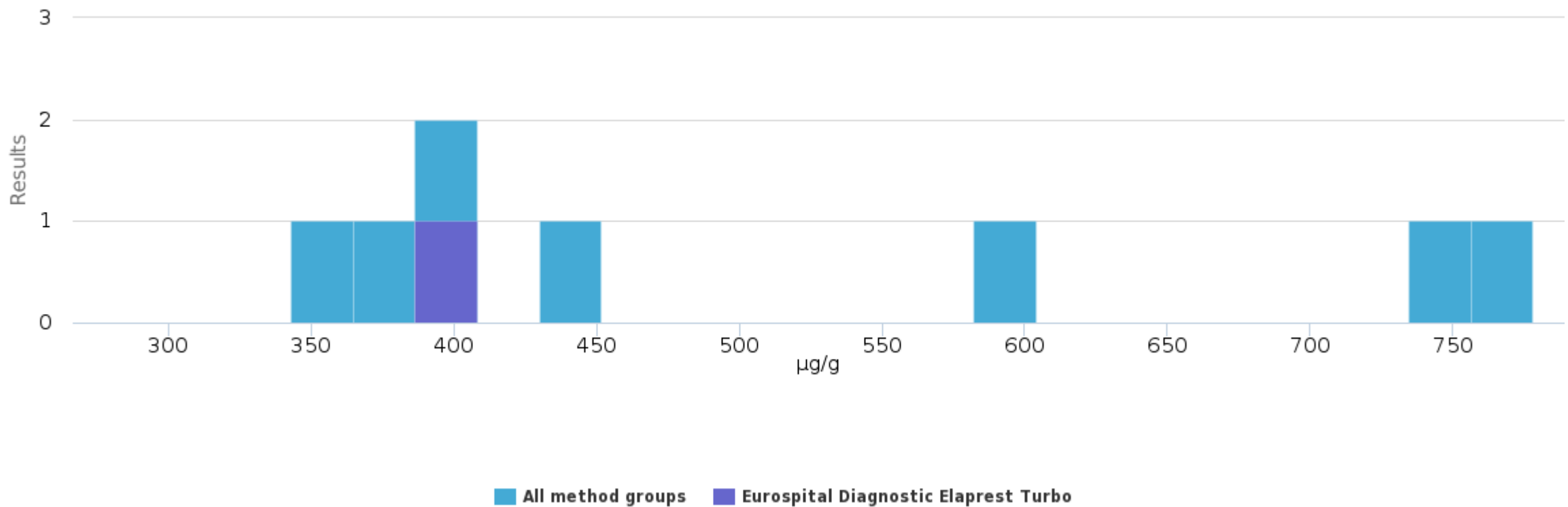
Bioserv Fecal Pancreatic Elastase



DiaSorin LIAISON Elastase-1



Eurospital Diagnostic Elaprest Turbo



S002 | Faecal Elastase, interpretation

Methodics	Normal	Total
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Bioserv Fecal Pancreatic Elastase	4	4
DiaSorin LIAISON Elastase-1	8	8
Eurospital Diagnostic Elaprest Turbo	1	1
ScheBo Pancreatic Elastase 1 ELISA Stool test	3	3
Total	16	16

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External Quality Assessment Scheme

Faecal elastase Round 1, 2023

Specimens

Samples S001 and S002 (LQ747823011 and LQ747823012) were lyophilized faecal samples.

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.

Comments – Expert

This was the first official faecal elastase round from Labquality. Seventeen laboratories (17/18) reported their results in this round and results from four different methods were reported. The distribution of the results was quite large despite of the method used. Nevertheless, there was a good consensus between the result levels concerning both samples.

The first sample of the round (S001) represented sample with low elastase level. The average of all results was 101 µg/g (a target range 71-131 µg/g) when taking account all the method used. Method specific target range can be found along the graphs. With one exception, the laboratories interpreted this sample as an indication of pancreatic insufficiency (one laboratory interpreted their quantitative result correctly as normal).

The second sample of the round (S002) represented the result of the normal elastase level, and the target value settled on the normal area. The average value of all results was high, 511 µg/g (a target range 358-664 µg/g). It is good to notice that the upper limit of the measurement varies between methods/laboratories and indeed many laboratories have reported the result of this sample as a result above the upper limit. Which is the most important, all interpreted the result as indication of normal pancreatic function.

End of report

2023-05-09

FINAL REPORT

Product no. 2754

Samples sent	2023-03-28
Round closed	2023-04-19
Final report	2023-05-09

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

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