

External Quality Assessment Scheme

Faecal Occult Blood, quantitative Round 1, 2023

Specimens

Please find enclosed 2 liquid ready-to-use preparations, samples S001 and S002, each 0.5 mL.

Caution

Samples contain material of human origin that has been tested and found negative for HIV1&2 antibodies, HCV antibodies and HbsAg but should be handled as if it is capable of transmitting infectious agents. Disposal of material should be in accordance with national and local law.

Examinations

F -hHb (quantitative)

Storage and use

Specimens are artificial liquids that may contain human hemoglobin (hHb) in buffer containing <0.1% sodium azide. Analysis is requested to be done immediately after arrival of the samples. If this is not possible, please store the samples at +2 ... +8 °C before use. Please mark the date of analysis to LabScala eForm.

NOTE: [Please read the separate sample handling instructions carefully before proceeding with the analysis \(page 2/2\).](#)

Result reporting

Please enter the results and methods via LabScala. If you can't find your method from the dropdown registry, please contact the EQA Coordinator.

S001:



S002:



Results are to be reported in unit µg/g. Note: If possible, please choose the unit ug/g on your analyzer. If your analyzer reports the result in ng/mL the results must be converted to ug/g using the method specific conversion factor. If you don't know the conversion factor of your method, please contact the manufacturer or Labquality.

To calculate your result from ng/mL to µg/g:

Result in ng/mL x Method specific conversion factor = Result in µg/g

2023-03-06

INSTRUCTIONS

Product no. 2749
LQ747723011-012/FI

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 11, 2023.**

Inquiries

EQA Coordinator
Satu Eklund
satu.eklund@labquality.fi

Labquality Oy

Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com



Instructions for sample handling (2749 1, 2023)

Sample handling for all POCT methods except immunochromatographic methods:

- Using the pipette included, pipet 100 µL of EQA sample directly in your test cuvette, test tube or test strip.
- Proceed according to your test instructions.
- **Note:** If your analyzer reports the result in ng/mL please calculate the final result to be reported in ug/g using your method specific conversion factor.

Sample handling for immunochromatographic POCT methods:

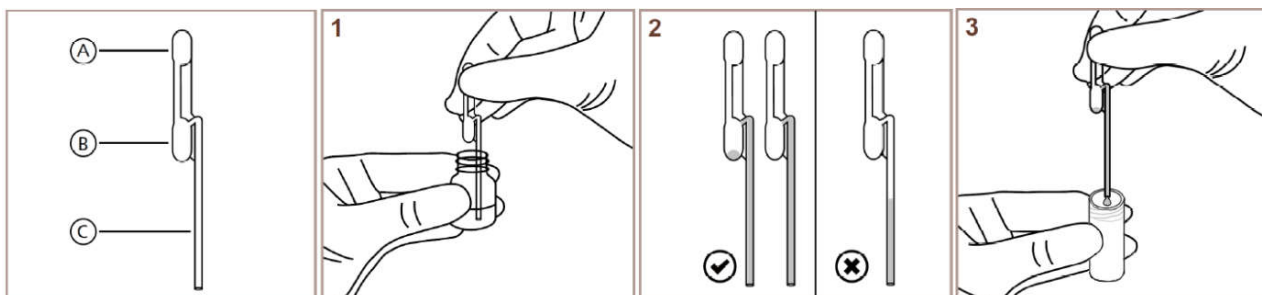
Perform a 1:2 dilution of the provided liquid EQA sample and the buffer of you test collection tube according to the instructions:

- Pipet 100 µL of the EQA sample with the included pipette into a clean, empty microtube.
- Pipet 100 µL of the buffer from a new collection tube of your test and transfer it to the same microtube as the EQA sample material.
- Mix the EQA sample material and the buffer by inverting the microtube several times.
- Pipet 100 µL of the mixed dilution from the inverted microtube to the sample well of your test cassette.
- Proceed according to your test instructions.
- **Note:** The test result obtained should be multiplied by the dilution coefficient 2 to obtain the correct result.
- **Note:** If your analyzer reports the result in ng/mL please calculate the final result to be reported in ug/g using your method specific conversion factor.

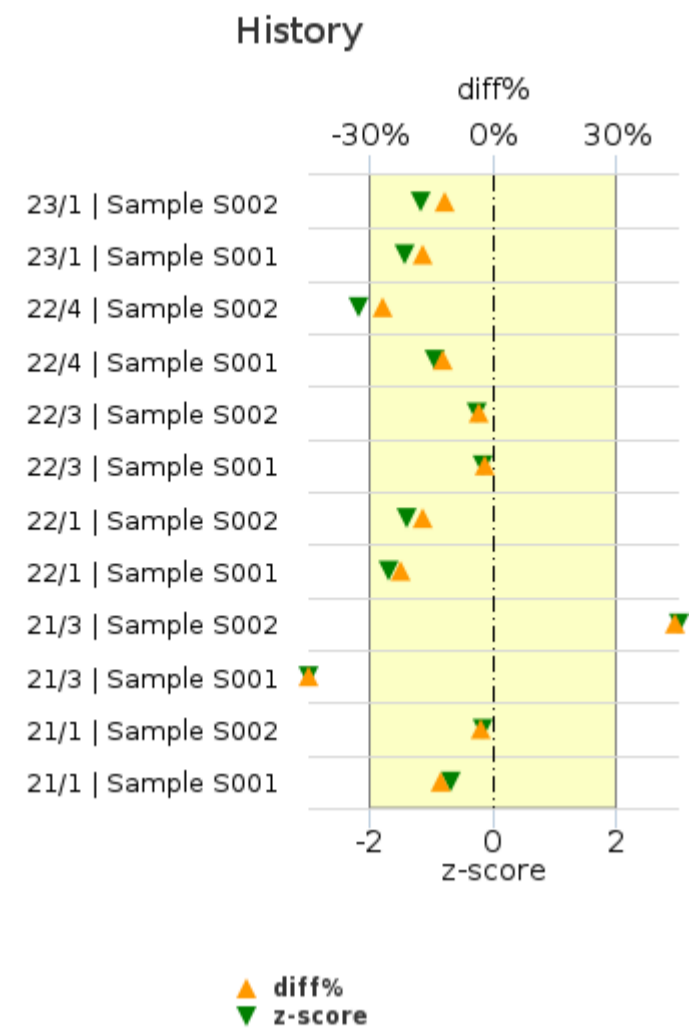
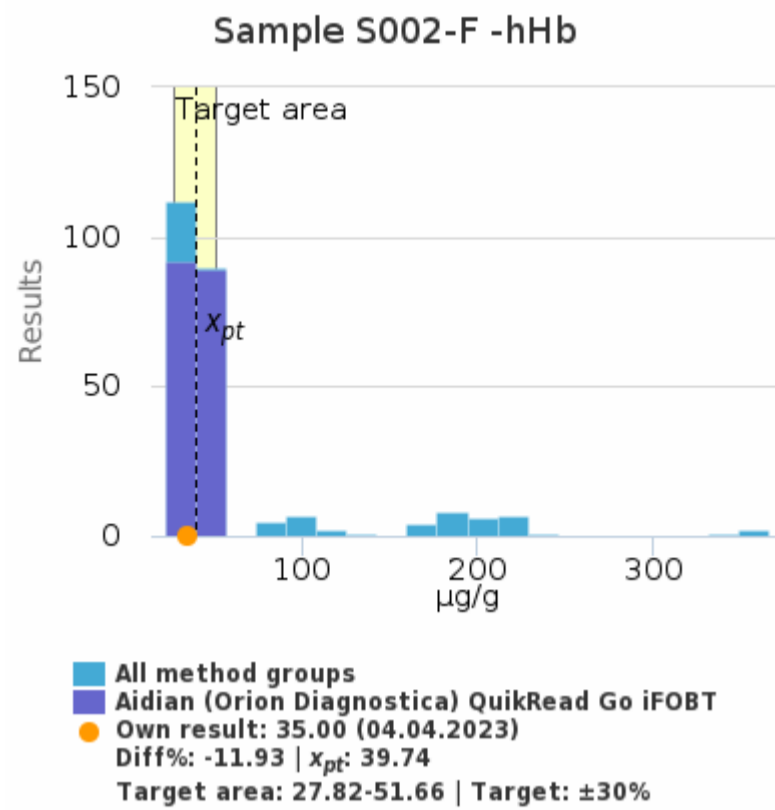
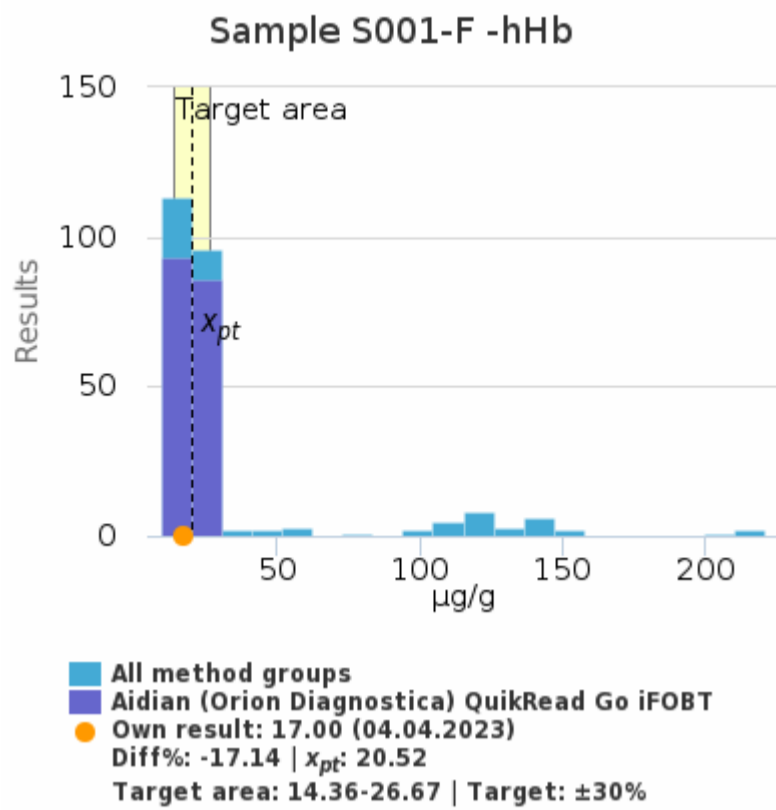
Sample handling for automatic laboratory analyzers:

- Transfer the EQA sample to a clean cup to be placed on your analyzer, do not dilute the sample
- Present the EQA sample to your analyzer in the same way as your internal control samples
- **Note:** If your analyzer reports the result in ng/mL please calculate the final result to be reported in ug/g using your method specific conversion factor.

How to use the pipette (see fig): Squeeze the upper bulb of the pipette (A), then insert the tip into the control liquid and release the bulb so that the liquid fills the entire tip (C), lift the pipette from the control liquid and transfer it to your test cuvette/test tube/test strip by squeezing the upper bulb (A) firmly. All of the liquid from the tip should be released. **Do not squeeze the lower bulb (B) at any time.** If some liquid is in the lower bulb it should remain there.



F -hHb



	x_{pt}	sd	SEM	CV%	n
Aidian (Orion Diagnostica) QuikRead Go iFOBT	20.52 $\mu\text{g/g}$	2.45	0.18	11.9	179
All methods	28.83 $\mu\text{g/g}$	26.45	1.73	91.8	246

	x_{pt}	sd	SEM	CV%	n
Aidian (Orion Diagnostica) QuikRead Go iFOBT	39.74 $\mu\text{g/g}$	4.08	0.30	10.3	181
All methods	58.41 $\mu\text{g/g}$	49.01	3.16	83.9	246

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	39.74	35.00	-11.93%	-1.16
23/1	Sample S001	20.52	17.00	-17.14%	-1.44
22/4	Sample S002	19.12	14.00	-26.78%	-2.17
22/4	Sample S001	41.04	36.00	-12.28%	-0.94
22/3	Sample S002	19.62	19.00	-3.18%	-0.26
22/3	Sample S001	41.84	41.00	-2.00%	-0.16
22/1	Sample S002	34.91	29.00	-16.92%	-1.39
22/1	Sample S001	34.84	27.00	-22.50%	-1.69
21/3	Sample S002	19.47	35.00	79.76%	5.01
21/3	Sample S001	38.40	20.00	-47.92%	-3.20
21/1	Sample S002	47.41	46.00	-2.97%	-0.16
21/1	Sample S001	29.79	26.00	-12.74%	-0.69

Sample S002

Methodics	Negative	Positive	No interpretation	Total
Nal von Minden Colibri	-	3	-	3
Sentinel FOB Gold/SentiFIT 270	-	6	-	6
Eiken Chemical OC-Sensor 10/iO	-	3	-	3
Aidian (Orion Diagnostica) QuikRead Go iFOBT	2	177	2	181
Boditech iChroma iFOB Neo/iChroma II	1	9	-	10
SD Biosensor Standard F100, F200	2	26	1	29
Veda-Lab iFOB Veda-Lab Easy Reader / Easy Reader+	-	4	-	4
CERtest FOB Turbilatex	-	2	-	2
Eiken Chemical OC-Sensor Pledia	2	3	-	5
Sentinel FOB Gold/Abbott Architect	-	3	-	3
EXDIA iFOB	-	3	-	3
Sentinel FOB Gold/Siemens Atellica	-	1	-	1
Eurospital SpA FOB-Test Turbo	1	-	-	1
Sentinel FOB Gold/Roche cobas	-	4	-	4
Total	8	244	3	255

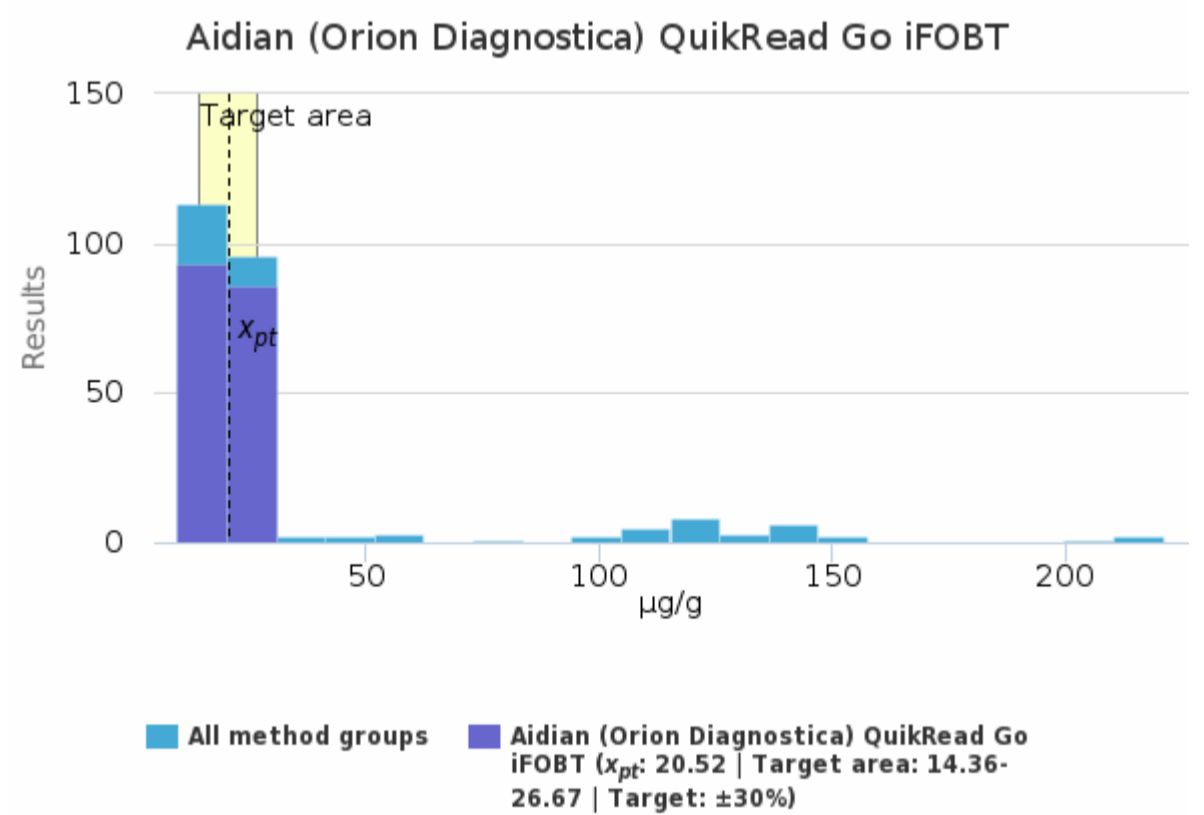
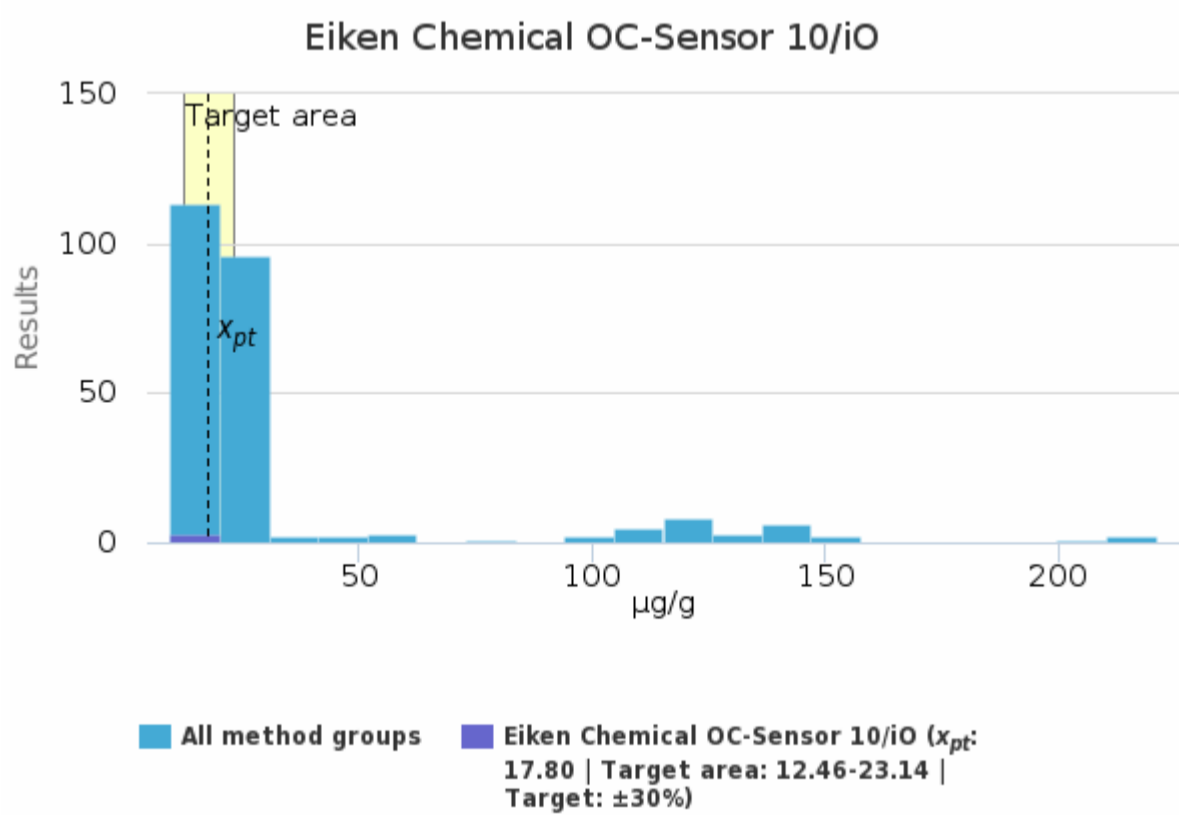
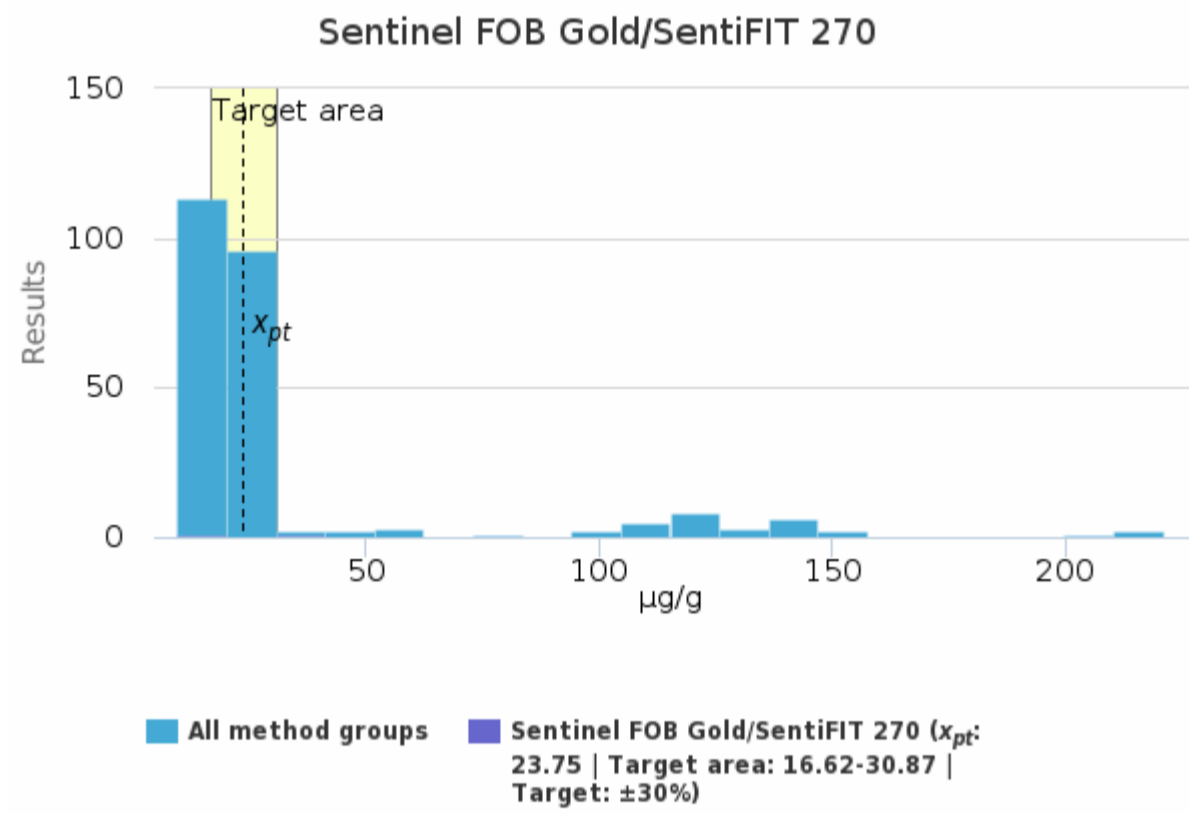
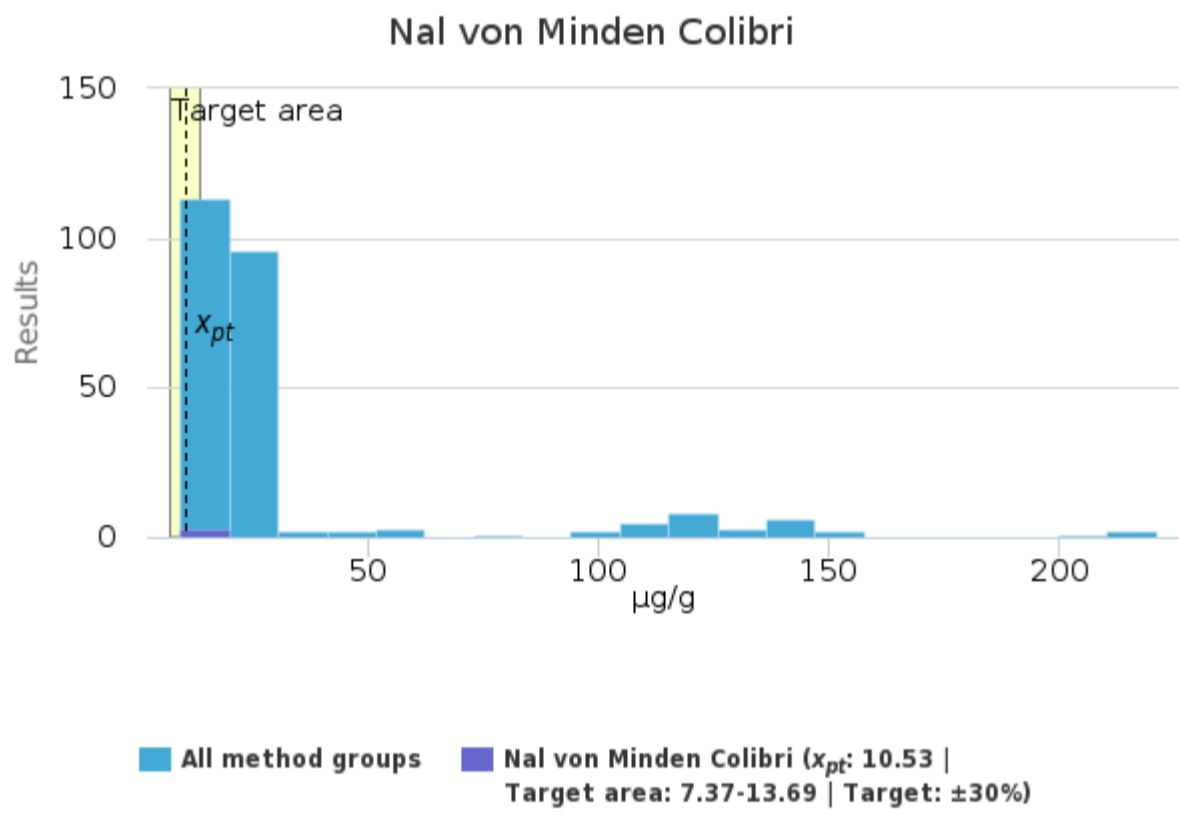
Sample S001

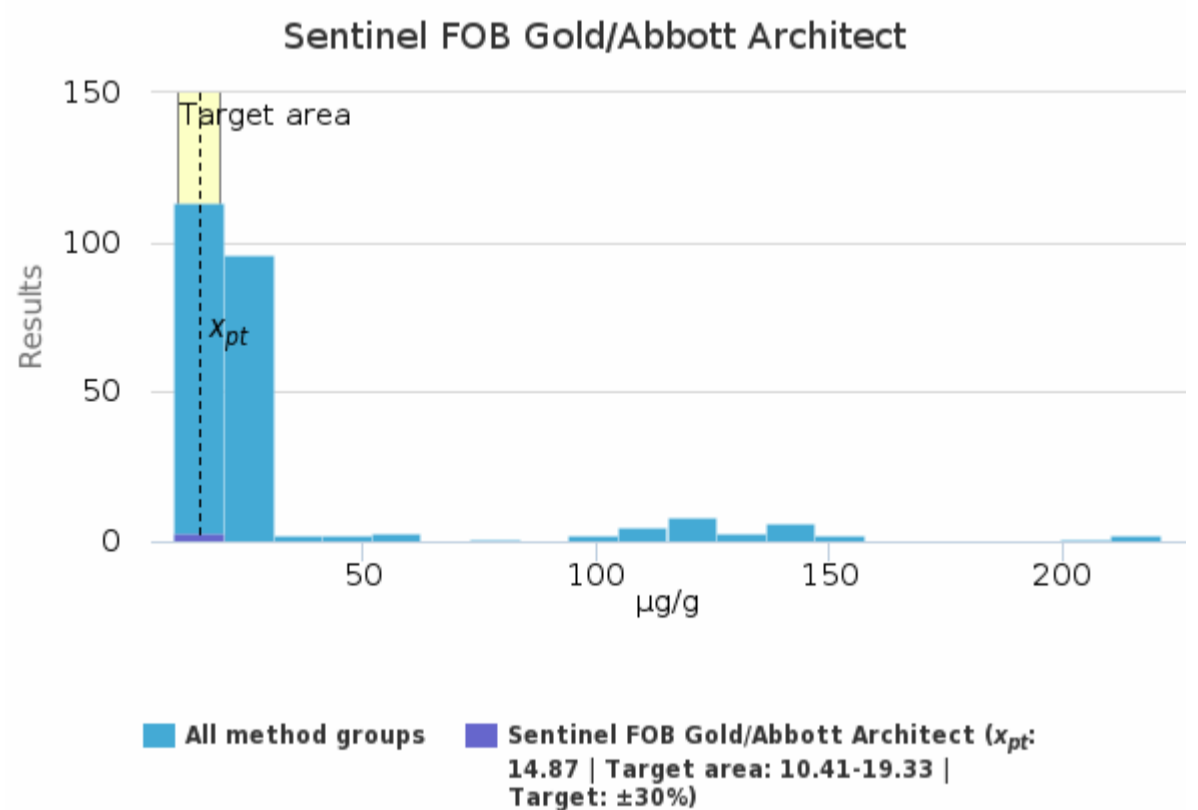
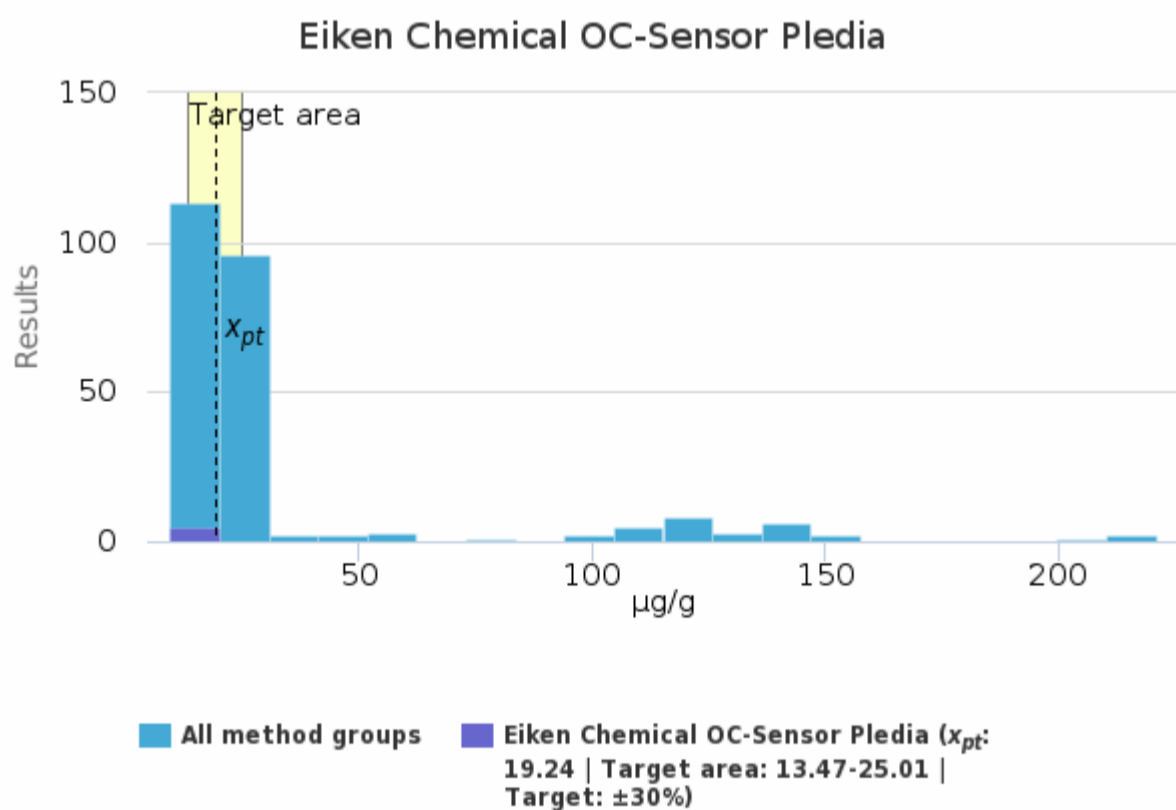
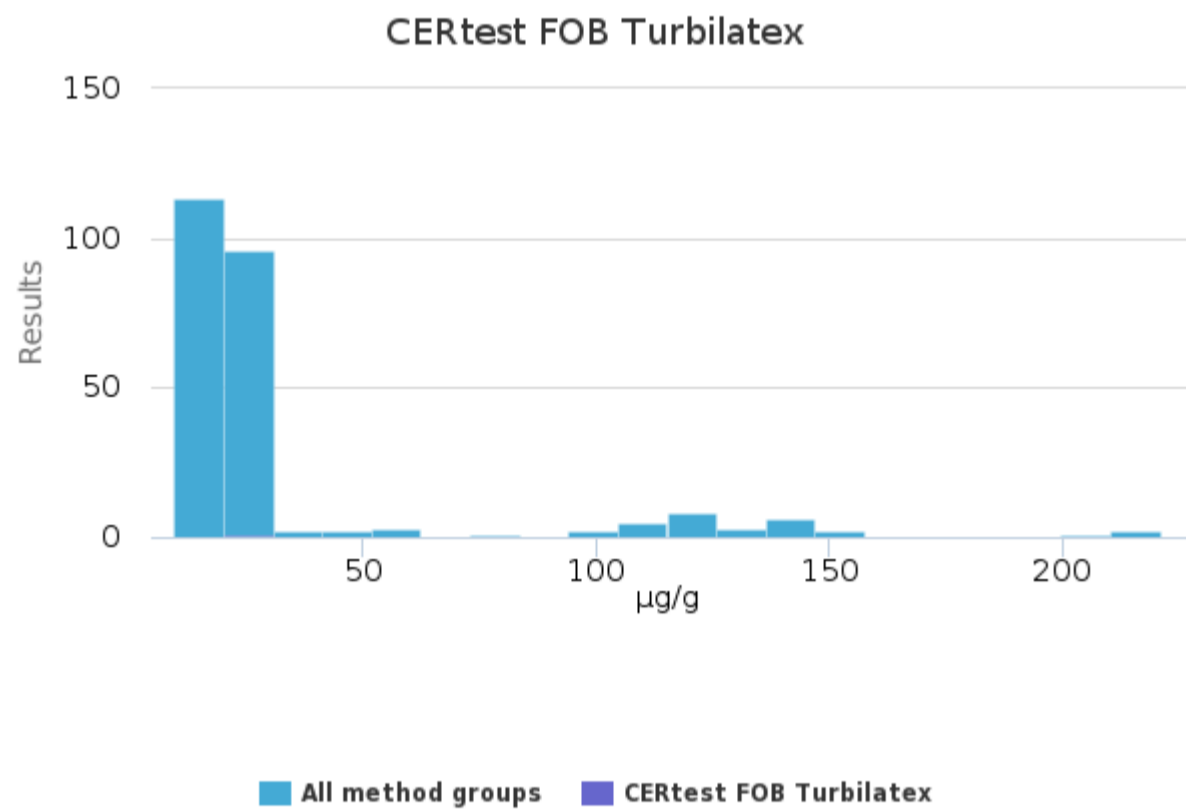
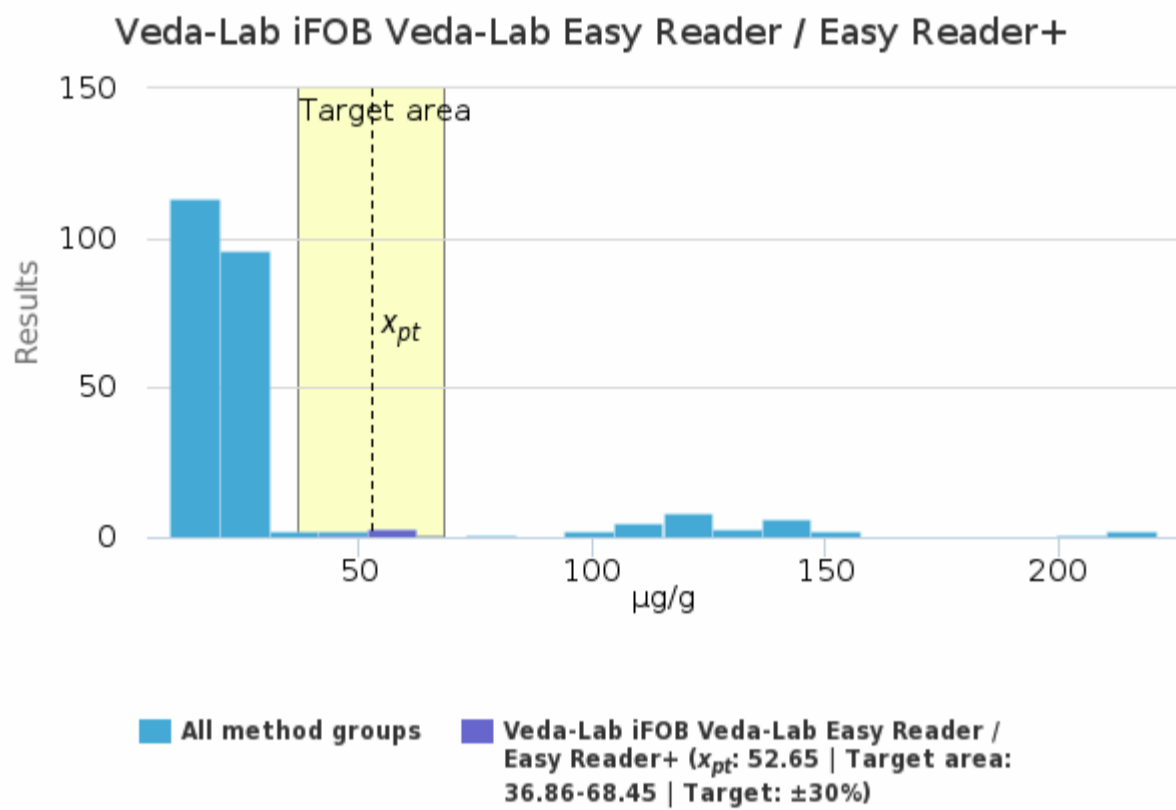
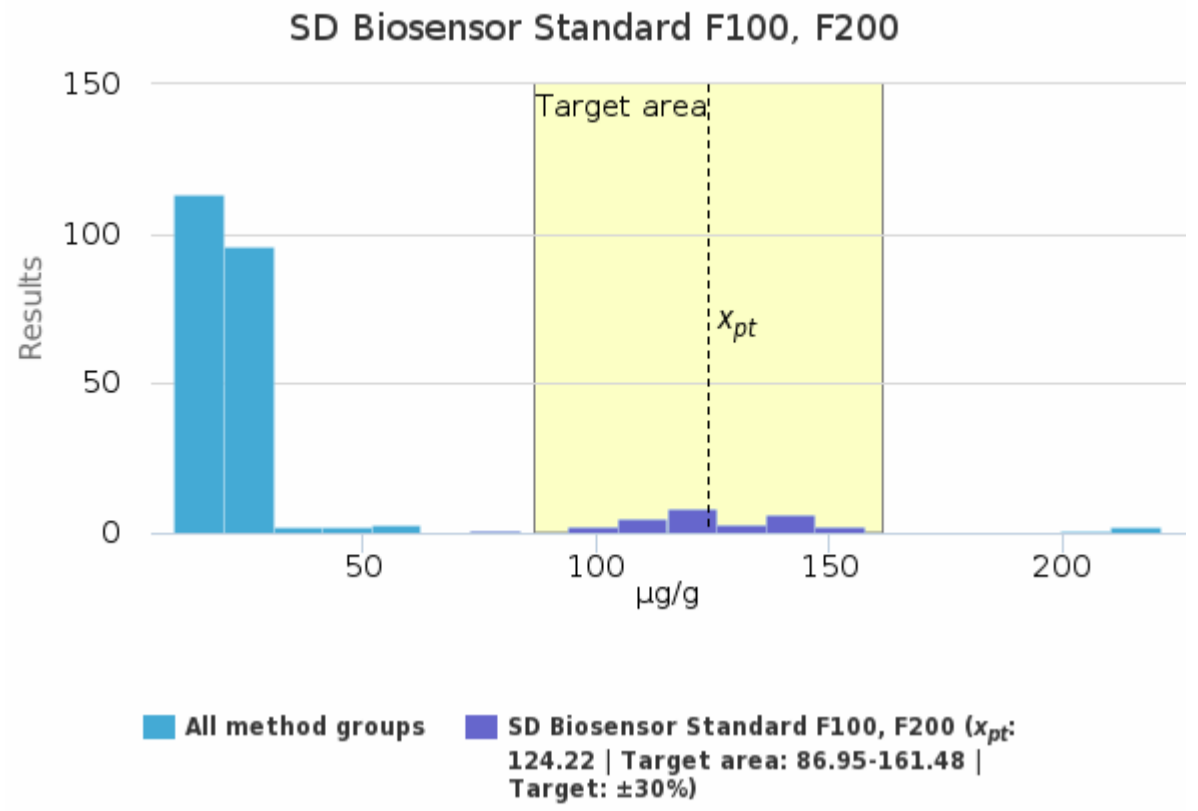
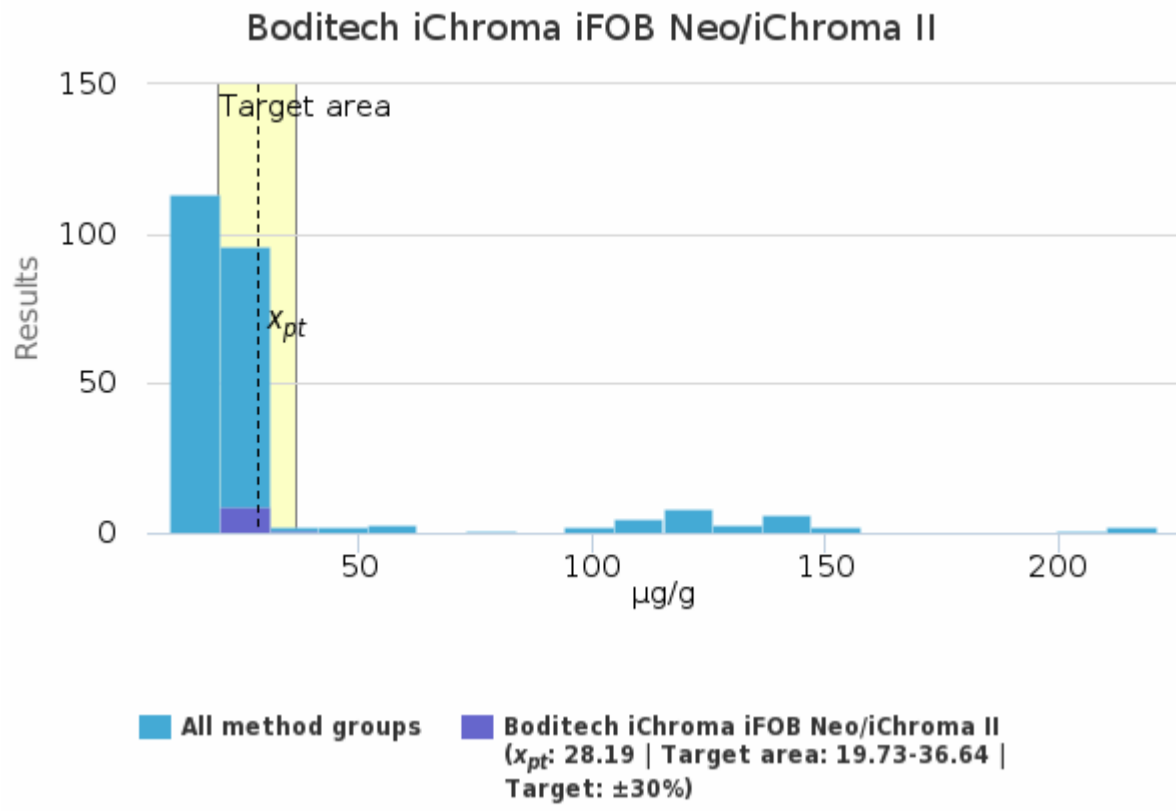
Methodics	Negative	Positive	No interpretation	Total
Nal von Minden Colibri	2	1	-	3
Sentinel FOB Gold/SentiFIT 270	1	5	-	6
Eiken Chemical OC-Sensor 10/iO	2	1	-	3
Aidian (Orion Diagnostica) QuikRead Go iFOBT	4	175	2	181

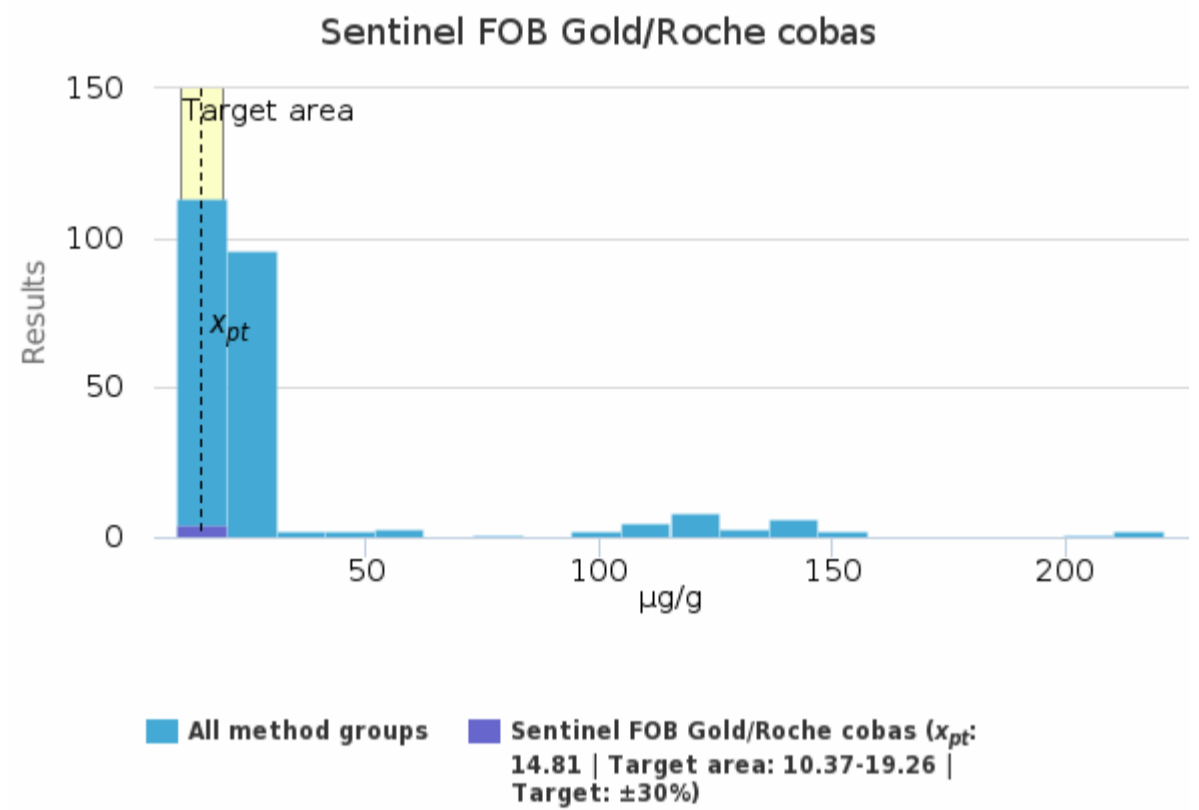
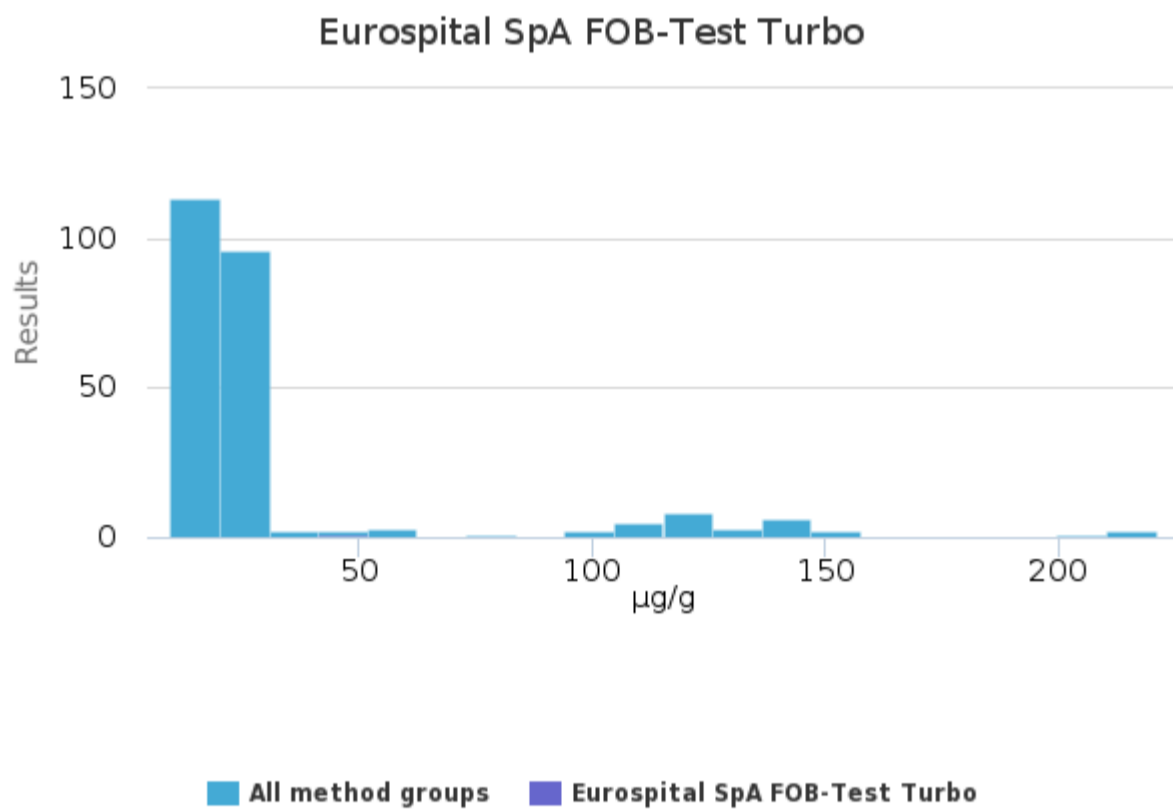
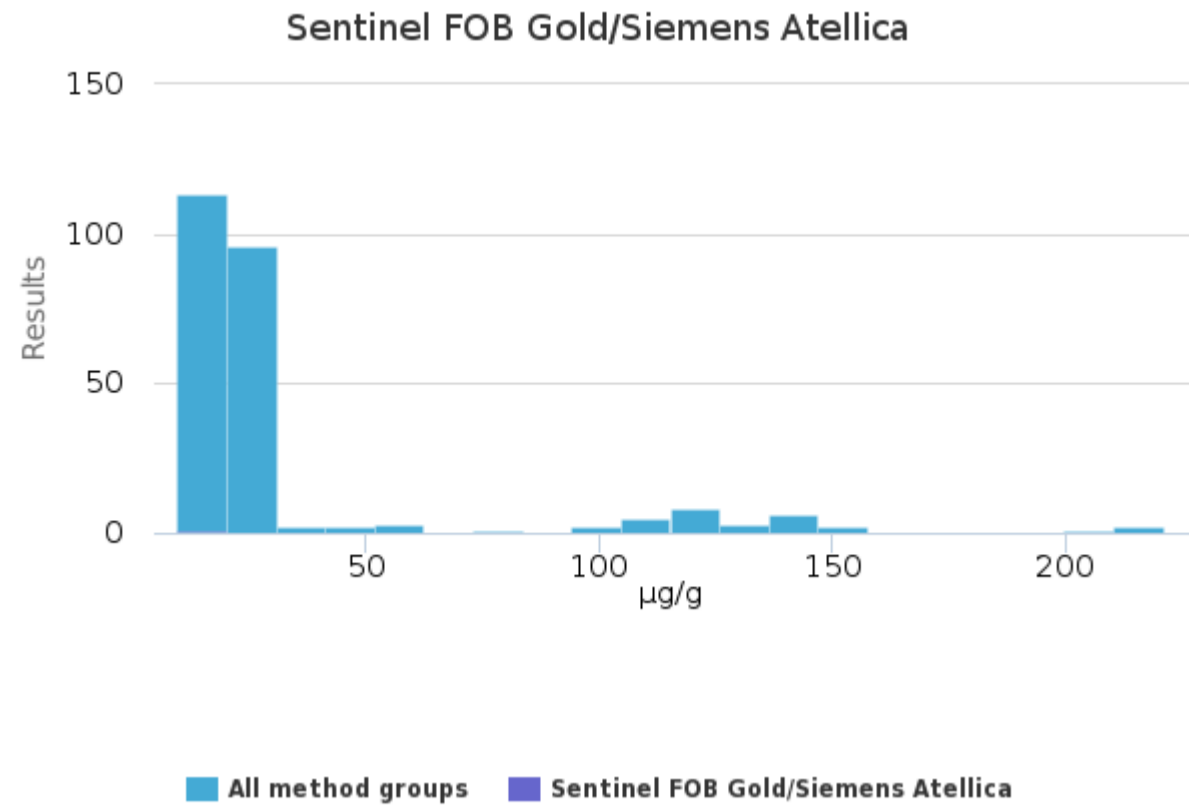
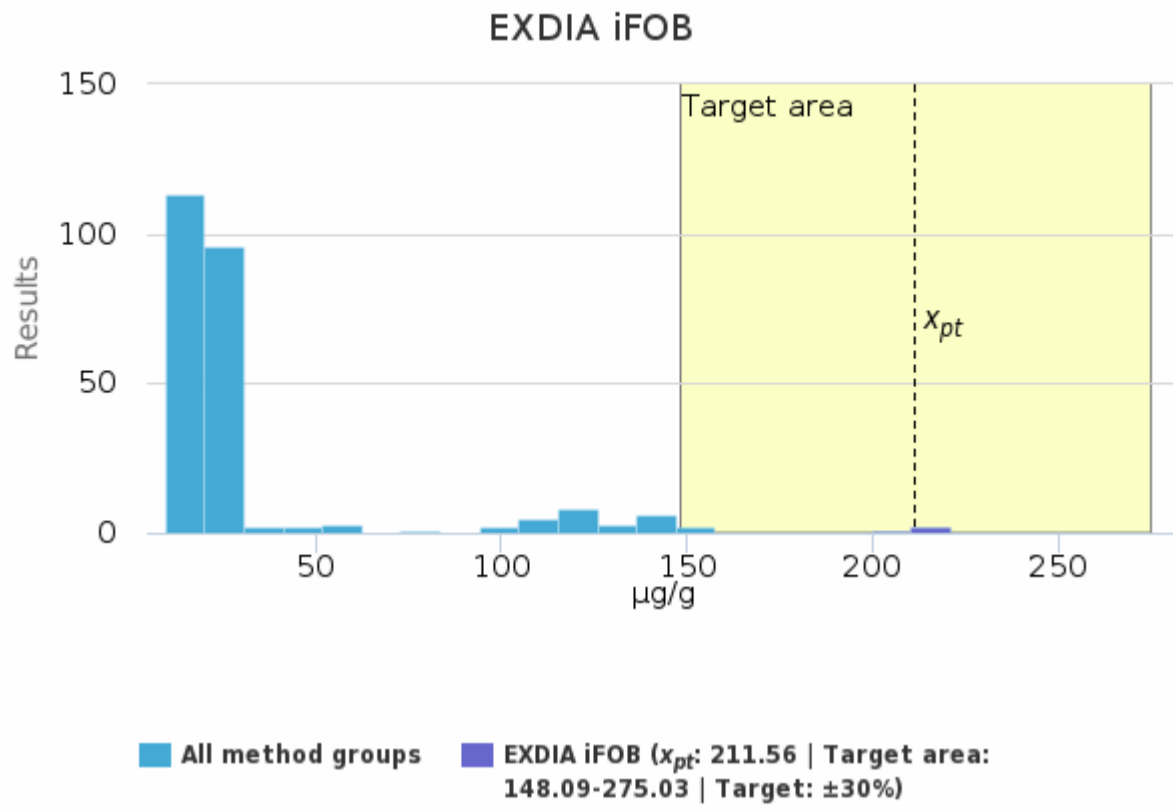
Boditech iChroma iFOB Neo/iChroma II	2	8	-	10
SD Biosensor Standard F100, F200	2	27	-	29
Veda-Lab iFOB Veda-Lab Easy Reader / Easy Reader+	-	4	-	4
CERtest FOB Turbilatex	-	2	-	2
Eiken Chemical OC-Sensor Pledia	5	-	-	5
Sentinel FOB Gold/Abbott Architect	-	3	-	3
EXDIA iFOB	-	3	-	3
Sentinel FOB Gold/Siemens Atellica	-	1	-	1
Eurospital SpA FOB-Test Turbo	-	-	-	1
Sentinel FOB Gold/Roche cobas	-	4	-	4
Total	18	234	2	254

Sample S001 | F-hHb

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Nal von Minden Colibri	10.53	10.00	1.29	12.2	0.74	9.60	12.00	-	3
Sentinel FOB Gold/SentiFIT 270	23.75	23.75	10.95	46.1	7.75	16.00	31.49	-	2
Eiken Chemical OC-Sensor 10/iO	17.80	17.60	0.53	3.0	0.31	17.40	18.40	-	3
Aidian (Orion Diagnostica) QuikRead Go iFOBT	20.52	20.00	2.45	11.9	0.18	14.00	27.00	-	179
Boditech iChroma iFOB Neo/iChroma II	28.19	28.06	1.46	5.2	0.46	26.20	31.25	-	10
SD Biosensor Standard F100, F200	124.22	121.80	17.29	13.9	3.33	81.00	152.10	-	27
Veda-Lab iFOB Veda-Lab Easy Reader / Easy Reader+	52.65	52.90	2.02	3.8	1.01	50.00	54.80	-	4
CERtest FOB Turbilatex	-	-	-	-	-	26.10	26.10	-	1
Eiken Chemical OC-Sensor Pledia	19.24	19.40	0.79	4.1	0.35	18.00	20.00	-	5
Sentinel FOB Gold/Abbott Architect	14.87	14.60	0.74	5.0	0.43	14.30	15.70	-	3
EXDIA iFOB	211.56	213.56	10.70	5.1	6.18	200.00	221.12	-	3
Sentinel FOB Gold/Siemens Atellica	-	-	-	-	-	16.16	16.16	-	1
Eurospital SpA FOB-Test Turbo	-	-	-	-	-	45.00	45.00	-	1
Sentinel FOB Gold/Roche cobas	14.81	14.74	0.99	6.7	0.49	13.77	16.00	-	4
All	28.83	20.50	26.45	91.8	1.73	9.60	130.90	11	246



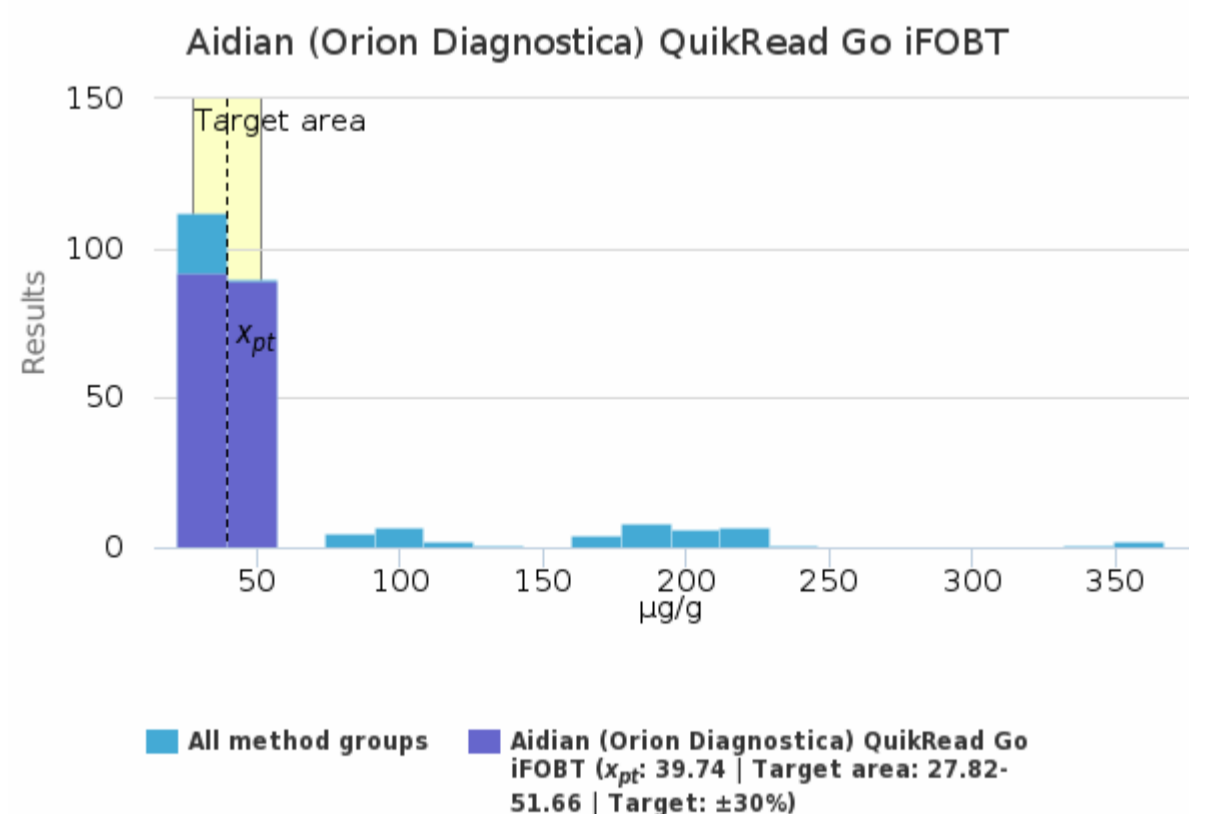
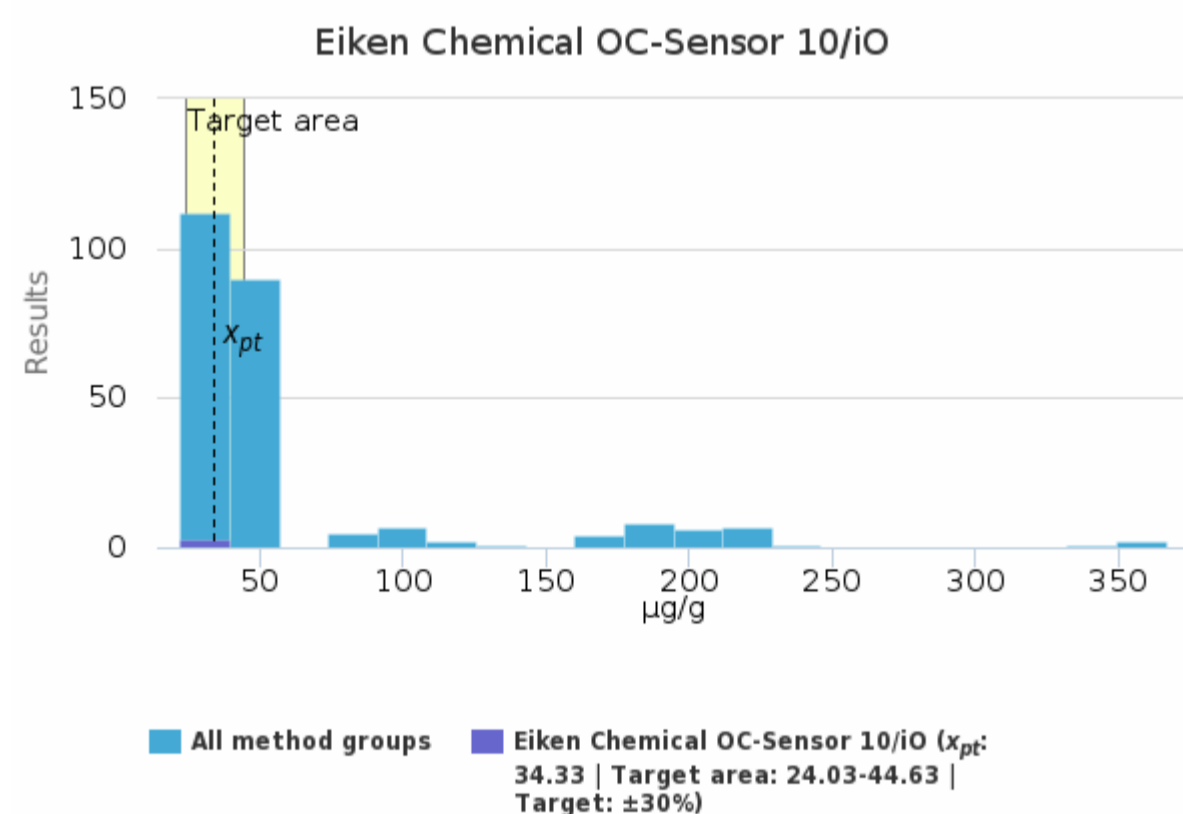
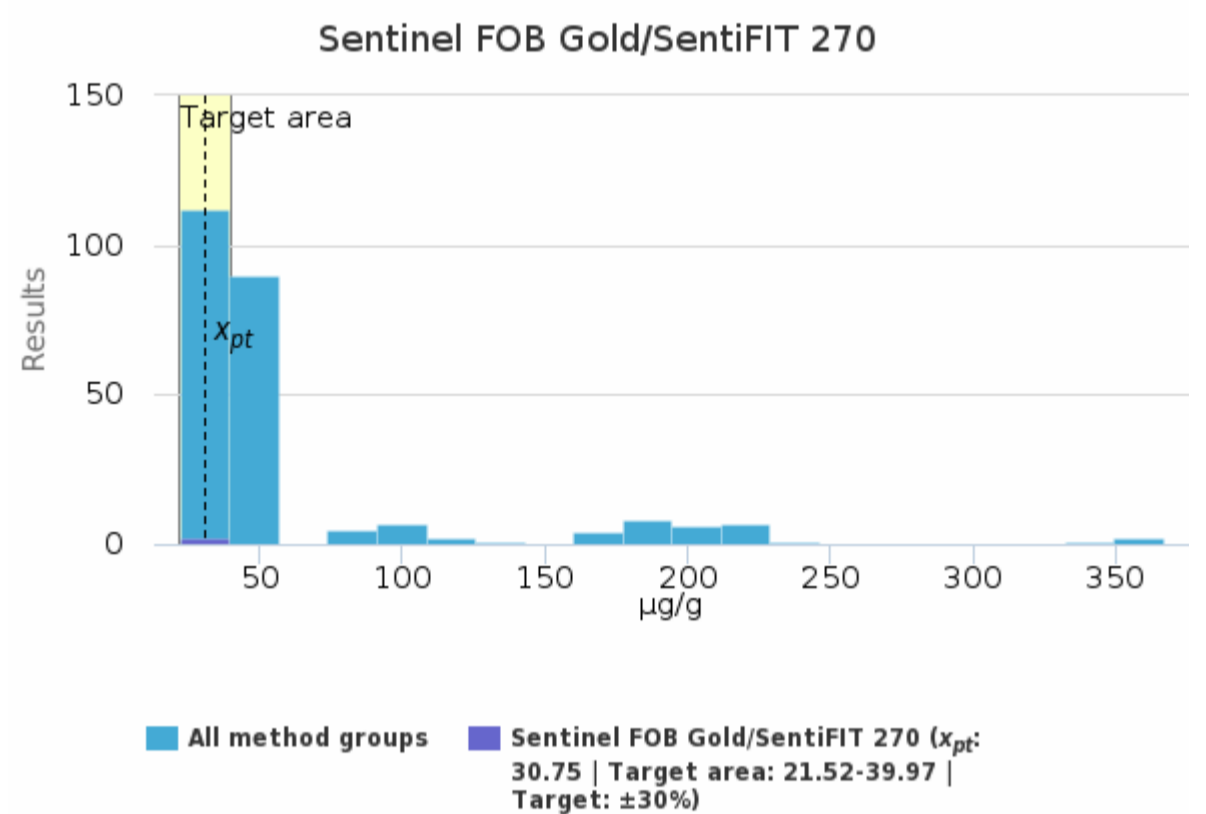
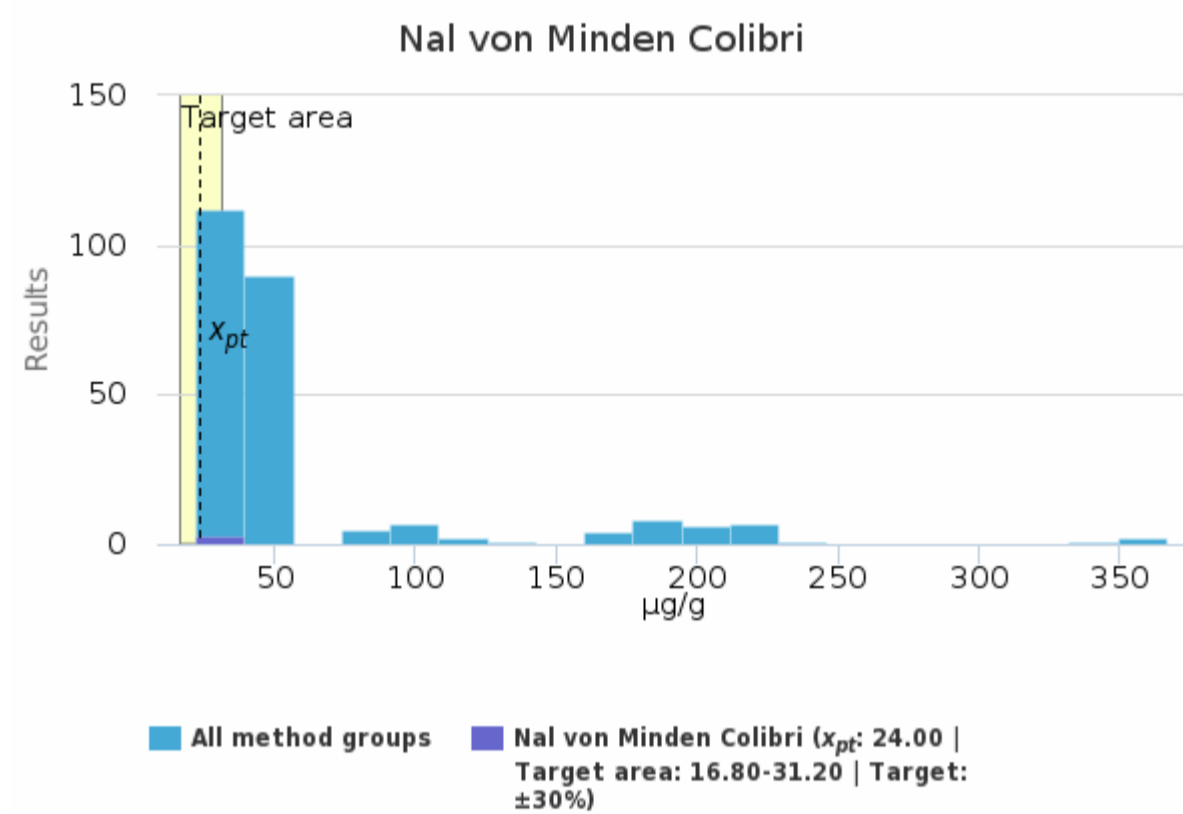


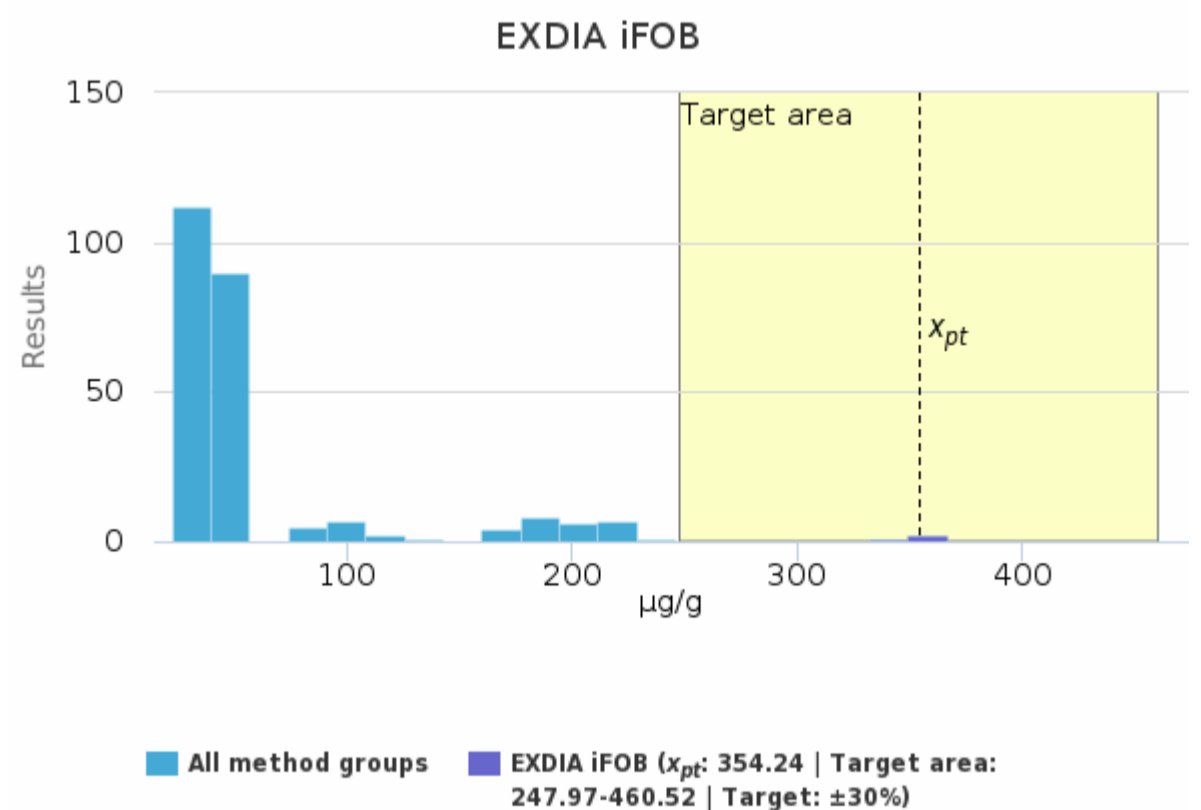
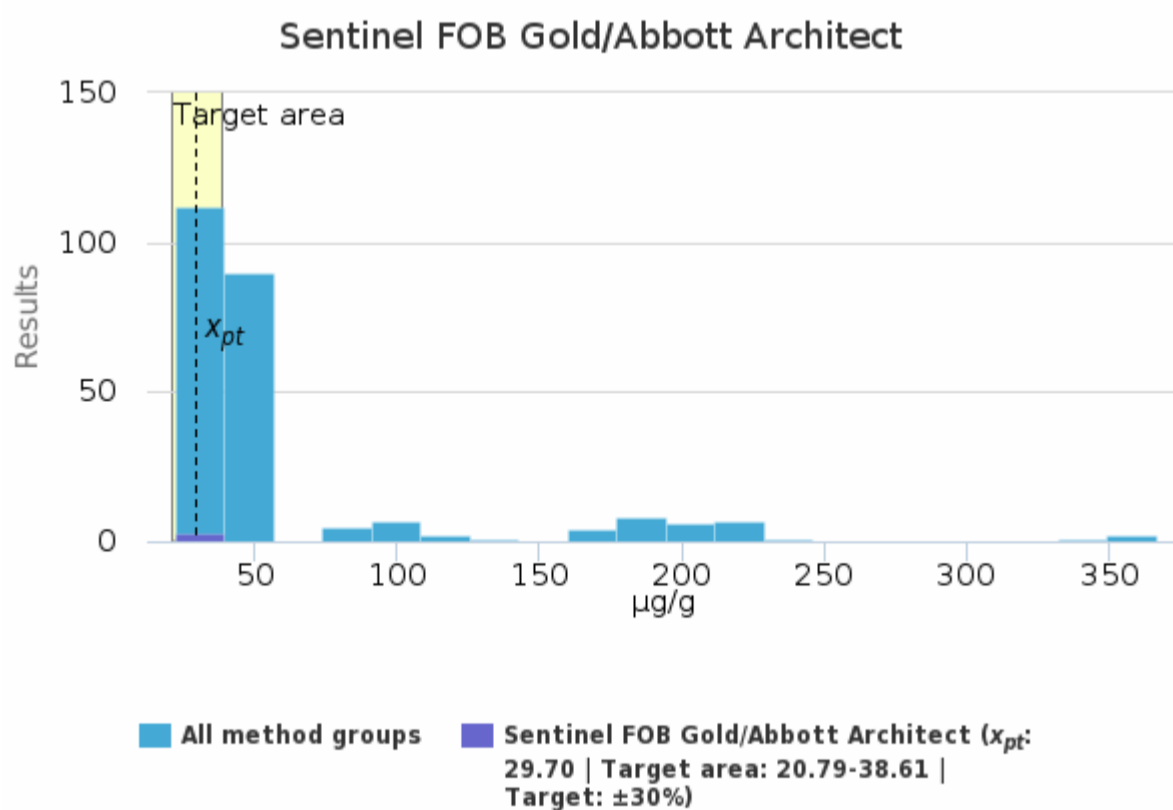
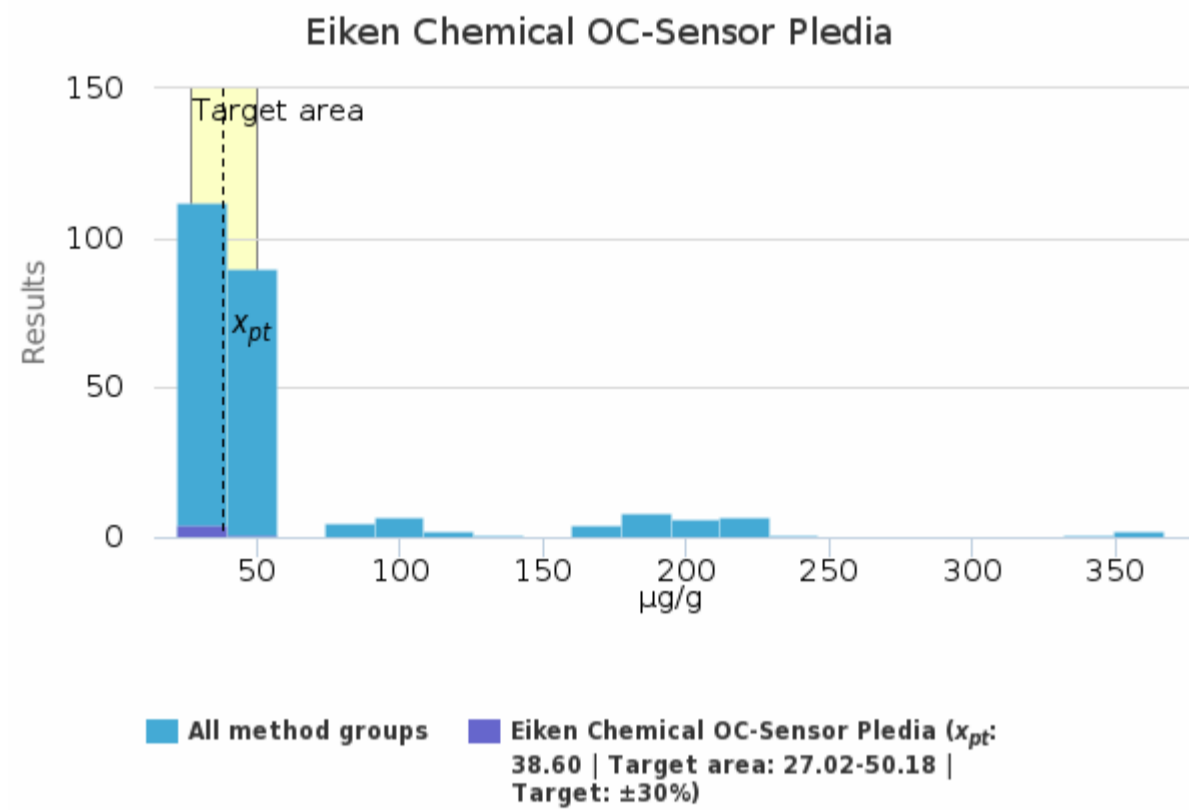
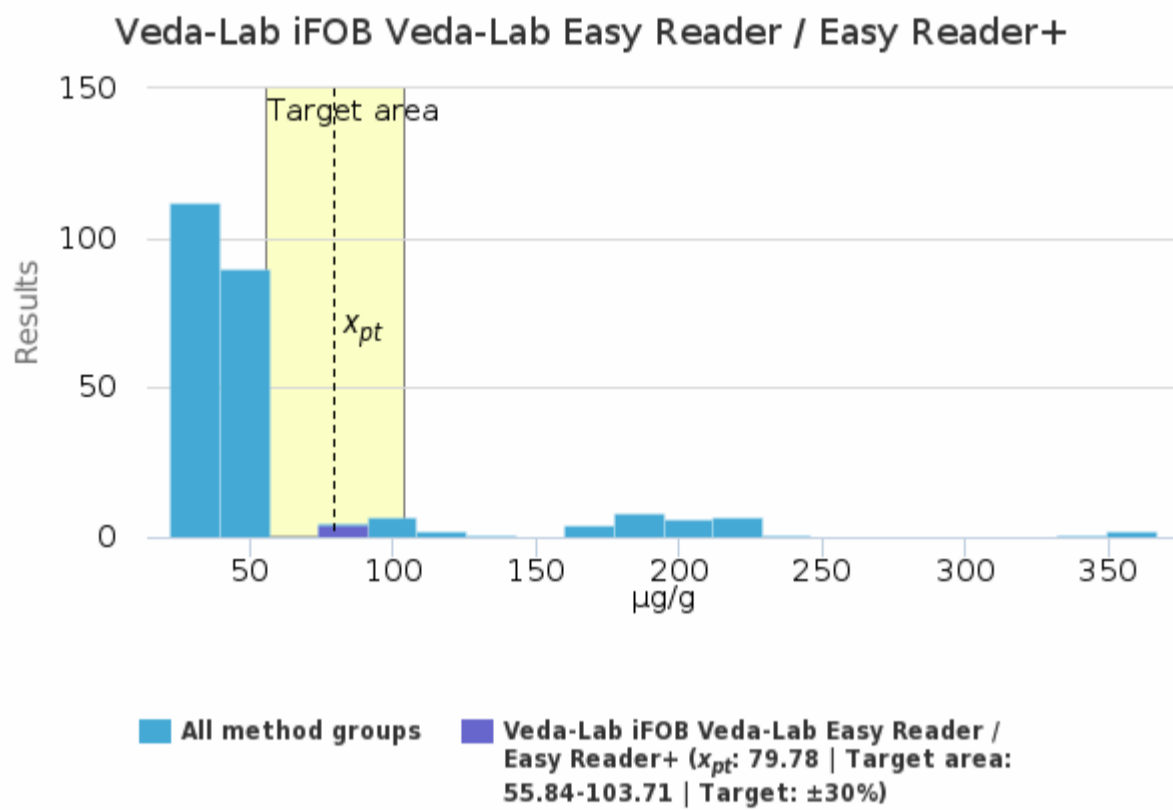
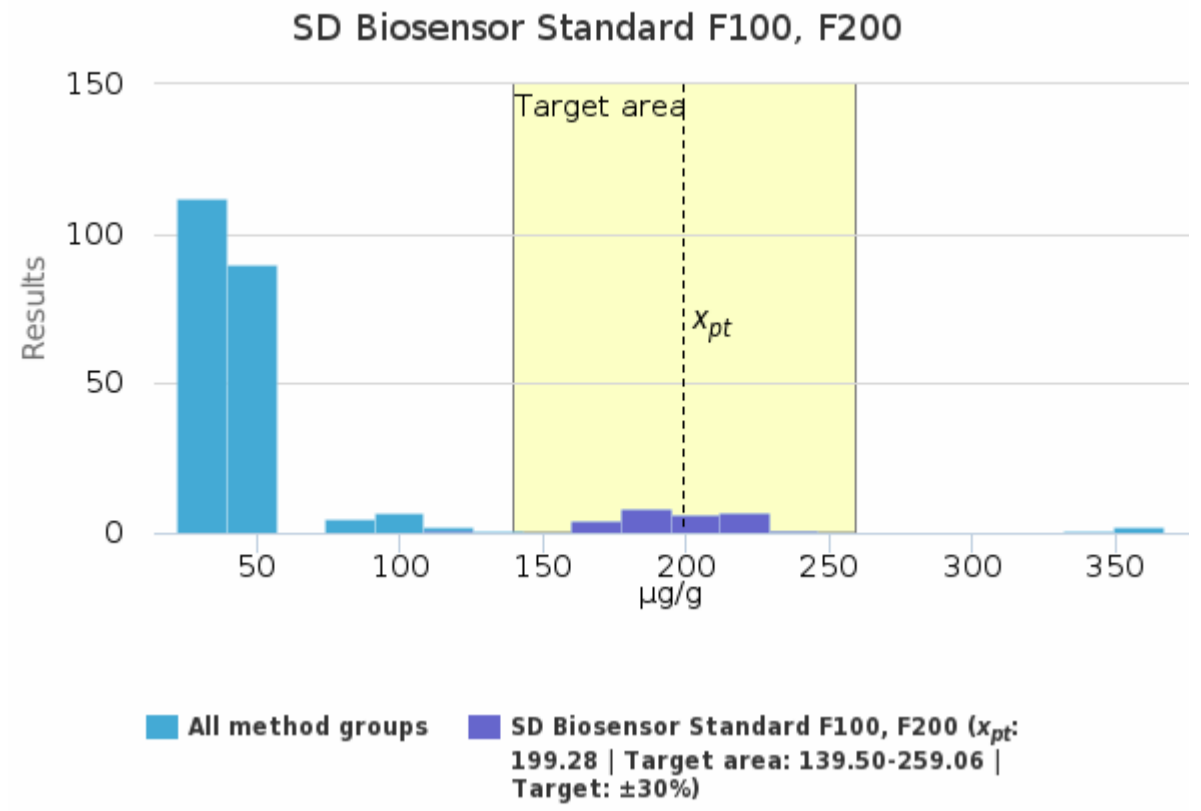
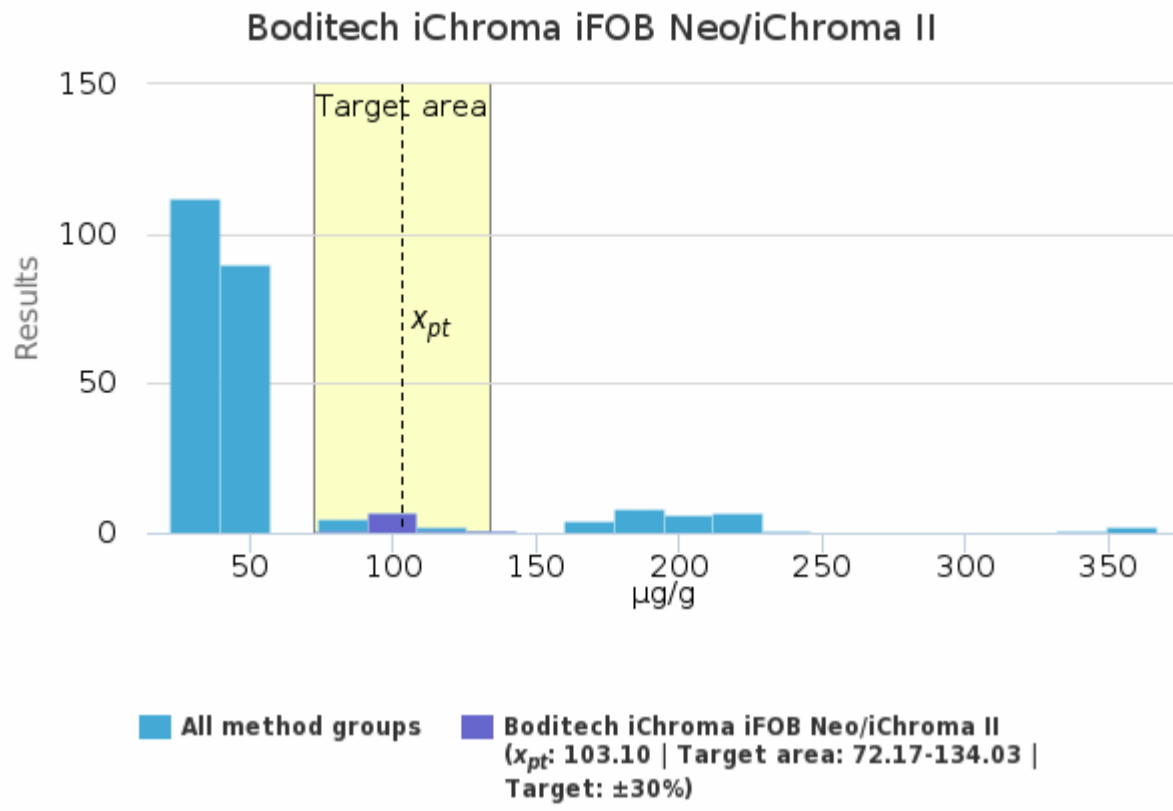


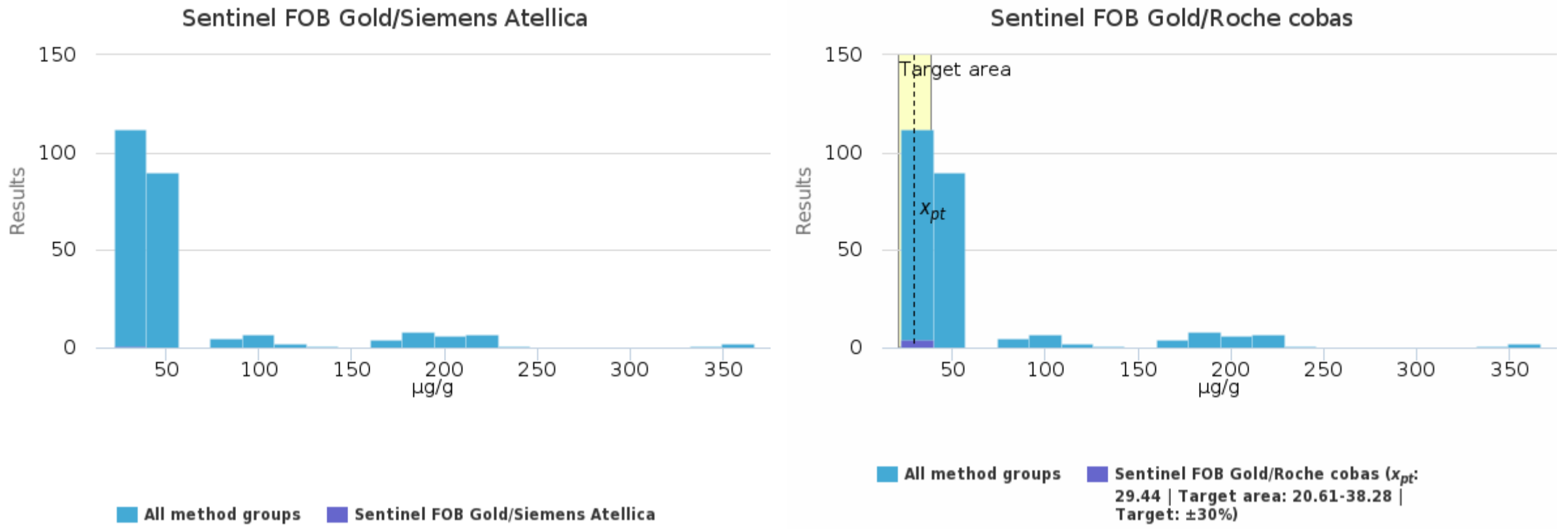
Methodics	Negative	Positive	No interpretation	Total
Aidian (Orion Diagnostica) QuikRead Go iFOBT	4	175	2	181
Boditech iChroma iFOB Neo/iChroma II	2	8	-	10
CERtest FOB Turbilatex	-	2	-	2
Eiken Chemical OC-Sensor Pledia	5	-	-	5
Eiken Chemical OC-Sensor 10/iO	2	1	-	3
Eurospital SpA FOB-Test Turbo	1	-	-	1
EXDIA iFOB	-	3	-	3
Nal von Minden Colibri	2	1	-	3
SD Biosensor Standard F100, F200	2	27	-	29
Sentinel FOB Gold/Abbott Architect	-	3	-	3
Sentinel FOB Gold/Roche cobas	-	4	-	4
Sentinel FOB Gold/SentiFIT 270	1	5	-	6
Sentinel FOB Gold/Siemens Atellica	-	1	-	1
Veda-Lab iFOB Veda-Lab Easy Reader / Easy Reader+	-	4	-	4
Total	19	234	2	255

Sample S002 | F-hHb

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Nal von Minden Colibri	24.00	24.10	1.55	6.5	0.90	22.40	25.50	-	3
Sentinel FOB Gold/SentiFIT 270	30.75	30.75	1.05	3.4	0.75	30.00	31.49	-	2
Eiken Chemical OC-Sensor 10/iO	34.33	34.40	0.90	2.6	0.52	33.40	35.20	-	3
Aidian (Orion Diagnostica) QuikRead Go iFOBT	39.74	39.25	4.08	10.3	0.30	29.00	50.00	1	181
Boditech iChroma iFOB Neo/iChroma II	103.10	104.15	12.85	12.5	4.06	85.63	132.70	-	10
SD Biosensor Standard F100, F200	199.28	197.70	18.69	9.4	3.67	165.30	232.10	1	27
Veda-Lab iFOB Veda-Lab Easy Reader / Easy Reader+	79.78	78.75	2.80	3.5	1.40	77.70	83.90	-	4
Eiken Chemical OC-Sensor Pledia	38.60	38.80	1.02	2.6	0.46	37.60	40.00	-	5
Sentinel FOB Gold/Abbott Architect	29.70	29.90	0.53	1.8	0.31	29.10	30.10	-	3
EXDIA iFOB	354.24	350.09	10.93	3.1	6.31	346.00	366.64	-	3
Sentinel FOB Gold/Siemens Atellica	-	-	-	-	-	29.64	29.64	-	1
Sentinel FOB Gold/Roche cobas	29.44	29.62	1.60	5.4	0.80	27.54	31.00	-	4
All	58.41	40.50	49.01	83.9	3.16	22.40	220.60	5	246







Methodics	Negative	Positive	No interpretation	Total
Aidian (Orion Diagnostica) QuikRead Go iFOBT	2	177	2	181
Boditech iChroma iFOB Neo/iChroma II	1	9	-	10
CERtest FOB Turbilatex	-	2	-	2
Eiken Chemical OC-Sensor Pledia	2	3	-	5
Eiken Chemical OC-Sensor 10/iO	-	3	-	3
Eurospital SpA FOB-Test Turbo	1	-	-	1
EXDIA iFOB	-	3	-	3
Nal von Minden Colibri	-	3	-	3
SD Biosensor Standard F100, F200	2	26	1	29
Sentinel FOB Gold/Abbott Architect	-	3	-	3
Sentinel FOB Gold/Roche cobas	-	4	-	4
Sentinel FOB Gold/SentiFIT 270	-	6	-	6
Sentinel FOB Gold/Siemens Atellica	-	1	-	1
Veda-Lab iFOB Veda-Lab Easy Reader / Easy Reader+	-	4	-	4
Total	8	244	3	255

External Quality Assessment Scheme

Faecal occult blood, quantitative Round 1, 2023

Specimens

Sample S001 (LQ747723011) and Sample S002 (LQ747723012) were liquid ready-for-use preparations. Based on the previous tests (pretesting) and the results of this round, the samples are homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

F -hHb (quantitative):

Sample S001: 25 µg/g

Sample S002: 45 µg/g

The Hb concentrations were quantitated (pretested) by Aidian QuikRead go method.

The results were grouped according to the method information.

Report info

Please see page 2.

It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments - Expert

On this round, there were 249 participants. The major methods used by the participants were Aidian QuikRead go (179 laboratories), SD Biosensor Standard F100 or F200 (27), Veda-Lab iFOB (24) and iChroma iFOB Neo or iChroma II (10). Only a few participants used other methods.

For sample S001 In the QuikRead go group, the mean hemoglobin of 21 ug/g and CV of 12% were within the expected, acceptable range. About 98% reported results within the target limits of +/- 30% of the method mean. While the quantitative mean values of the other major methods differed from Aidian, as expected due to differences in methods, all methods with at least ten users reported acceptable CV of between 5-14%. 92% of the participants interpreted the sample as positive, with 7% reporting as negative and 1% giving no interpretation. The lower concentration of hemoglobin in the sample likely contributes to poorer consensus in the interpretation

For sample S002 In the QuikRead go group, the mean hemoglobin of 40 ug/g and CV of 10% were within the expected, acceptable range. About 99% reported results within the target limits of +/- 30% of the method mean. While the quantitative mean values of the other major methods differed from Aidian, as expected due to differences in methods, all methods with at least ten users reported good CV of between 9-13%. 96% of the participants interpreted the sample as positive, 3% as negative and 1% giving no interpretation.

Laboratories reporting results outside the consensus are asked to check their methods and procedures of the test they are using.

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2023-05-19

FINAL REPORT

Product no. 2749

Samples sent	2023-03-06
Round closed	2023-04-11
Final report	2023-05-19

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

Satu Eklund

T. +358 45 773 107 87

satu.eklund@labquality.fi

Expert

MD, PhD, Tuukka Helin

HUSLAB, Helsinki, Finland

Labquality Oy

Kumpulantie 15

FI-00520 HELSINKI

Finland

Tel. + 358 9 8566 8200

Fax + 358 9 8566 8280

info@labquality.fi

www.labquality.com



Participants

249 participants from 12 countries.

Report info

Qualitative and quantitative results are presented in the same report. Always compare your results to those obtained with the same test kit.

The qualitative results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Laboratory's own result with a black radio button . The quantitative results are presented as histograms. Quantitative results reported with < or > -signs are not processed. Assigned values (target values) are mean 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 participant specific report your own result is shown with an orange dot. The target area is presented as a yellow area in the picture.

If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

End of report

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