LABQUALITY

External Quality Assessment Scheme

Interferon Gamma Release Assay (IGRA) for *Mycobacterium tuberculosis* Round 1, 2023

Specimens
Please find enclosed a sample set corresponding to one patient sample, which includes 3 lyophilized samples simulating plasma: S001A, S001B and S001C, 1 blank/NIL sample (S001X) 270 µL and the water (H_2O) 1.5 mL needed to dissolve the lyophilized samples. The preanalytical steps (transportation, incubation and centrifugation) are covered in the preanalytical section and these steps are not included in the sample processing. The EQA samples in question correspond to samples of the analysis phase, i.e., they are ready for testing after dissolution.

Caution
The specimens simulate patient samples and should be handled with the same care as patient samples, i.e., as potential transmitters of serious diseases. Note! The samples contain ProClin 300 as a preservative.

Examinations
Detection of *Mycobacterium tuberculosis* infection with Interferon Gamma Release Assay (IGRA)
Pre-analytical section with questions (not related to the sample in question)

Storage and use
After arrival, the samples should be stored at +2…8 °C, and used as soon as possible, preferably within a week.

Allow the sample tubes to warm up to room temperature (+17…27°C) before dissolving.

1. Add 250 µL of room temperature water (H_2O) included in the shipment to each sample tube S001A, S001B and S001C. Beware of water contamination, replace the pipette tip with a new one after each tube.
2. Gently mix the sample tubes several times, being careful not to foam. Ensure the homogeneity of the suspension before performing the test.
3. Perform the measurements following the manufacturer's instructions for your test and using the tubes according to the table below:

Method	S001X	S001A	S001B	S001C
QuantiFeron-TB Gold (3 tubes)	NIL	Do not use	TB	Mitogen
QuantiFeron-TB Gold Plus (4 tubes)	NIL	TB1	TB2	Mitogen
Others	Aski if needed			

Result reporting
Please enter the results and methods via LabScala (www.labscala.com). The e-form has separate reporting tables for the 3 and 4 tube tests. If you cannot find your test from the registry or if you do not know which tube group your test belongs to, please contact the EQA Coordinator. For each sample, you are asked to report the raw data of the measurement result and the measurement result from which the background blank/NIL of the sample has been subtracted. A qualitative result and interpretation should be reported based on the measurement result from which the background blank/NIL has been subtracted. The mandatory pre-analytical section must be answered on its own tab on the same e-form.

2023-03-14

INSTRUCTIONS

Product no. 5250
LQ763023011-014/US, 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 6, 2023**.

Inquiries
EQA Coordinator
Kati Luiro
kati.luiro@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

Pre-analytical section
A 60-year-old man arrives at the regional hospital laboratory on Friday morning for phlebotomy. His physician has ordered a test for *M. tuberculosis* IFNg release assay for him. Phlebotomy is performed at the laboratory and the blood is drawn in the appropriate tubes according to the instructions with the proper tube order and filling. The tubes were shaken to mix antigen with the blood.

The sample tubes are transported at room temperature and arrive at the test site on the following Monday at 10 am with a note that the samples were stored at room temperature over the weekend.

Questions of the pre-analytical section
Was the sample collected correctly?
1. Yes
2. No
3. Not evident in this case

Was the sample transported correctly?
1. Yes
2. No
3. Not evident in this case

Was the sample incubated correctly?
1. Yes
2. No
3. Not evident in this case

Was the sample handled correctly after incubation?
1. Yes
2. No
3. Not evident in this case

Would you accept the sample for analysis based on the description of the process?
1. Yes
2. No, the sample was not collected correctly
3. No, the sample was not transported correctly
4. No, the sample was not incubated correctly
5. No, the sample was not handled correctly after incubation
6. I do not know, please add your explanation as a comment

LABQUALITY

Interferon Gamma Release Assay (IGRA) for Mycobacterium tuberculosis, February, 1-2023

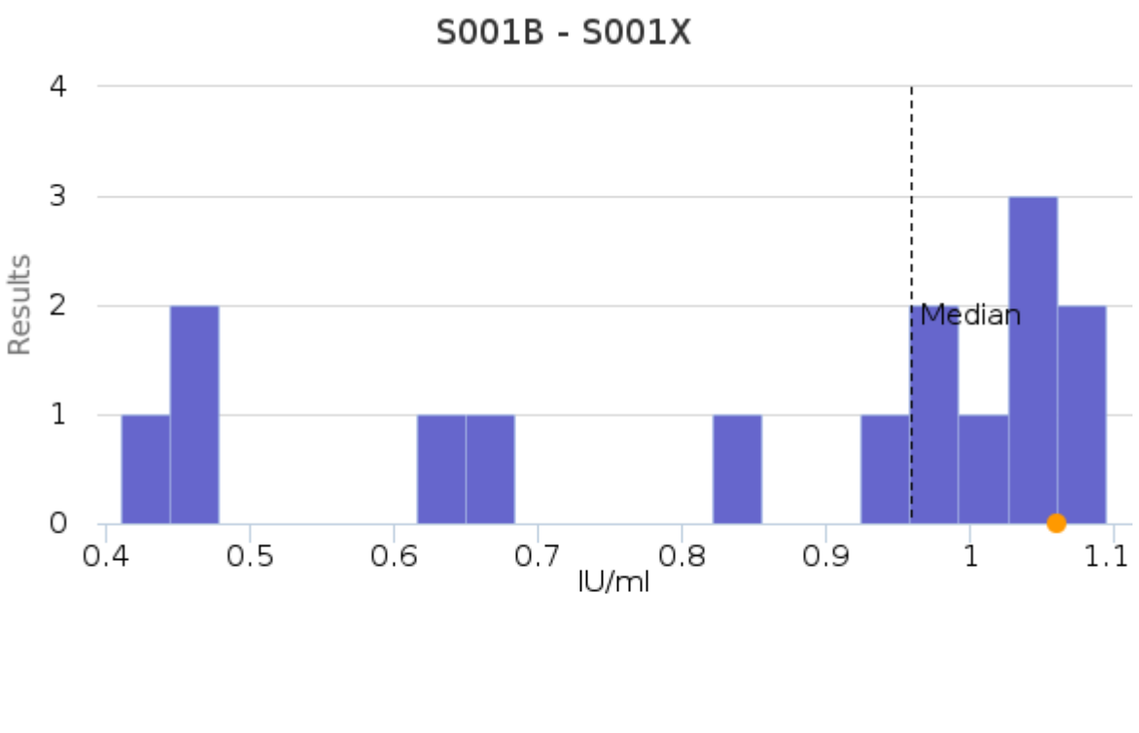
XXXX

Sample S001 | Interferon Gamma Release Assay (IGRA) for Mycobacterium tuberculosis

Methodics	Positive	Low positive	Negative	Indeterminate	No result	Total
Quantiferon-TB Gold Plus	1	-	-	-	-	1
Quantiferon-TB Gold Plus (Diasorin LIAISON)	◉ 11	1	-	-	-	12
Quantiferon-TB Gold Plus (Manual ELISA)	2	1	-	-	-	3
Total	**14**	**2**	**-**	**-**	**-**	**16**

Clinical interpretation	Interpretation	Total
	TB infection likely	◉ 9
	Likelihood of MB infection cannot be determined	2
	Laboratory does not give clinical interpretation	5
	Total:	**16**

Quantitative results (For methods using four tubes)



Measurand	Median	min	max	n
S001B - S001X	0.96	0.41	1.10	15
All methods	**0.96**	**0.41**	**1.10**	**15**

Report info

Participants

15 participants from 8 countries.

Report info

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green colour and laboratory's own result with a black radio button ◉. If you have not reported any results you will get a note: "You have not responded in time, only global report is available." Always compare your results to those obtained with the same test method.

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.

Interferon Gamma Release Assay (IGRA) for Mycobacterium tuberculosis, February, 1-2023

Preanalytical questions

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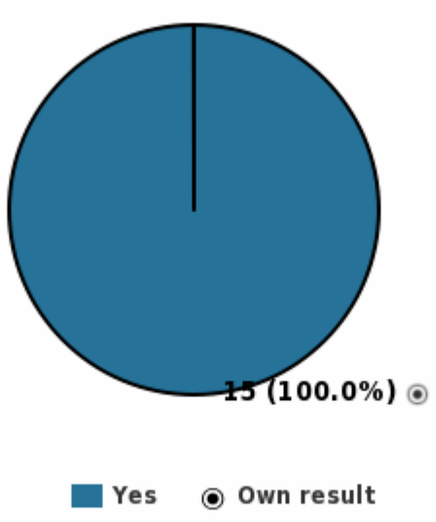
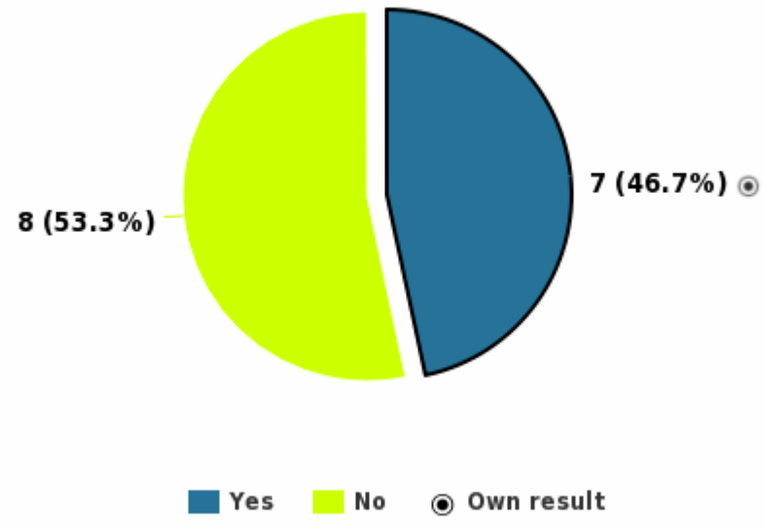
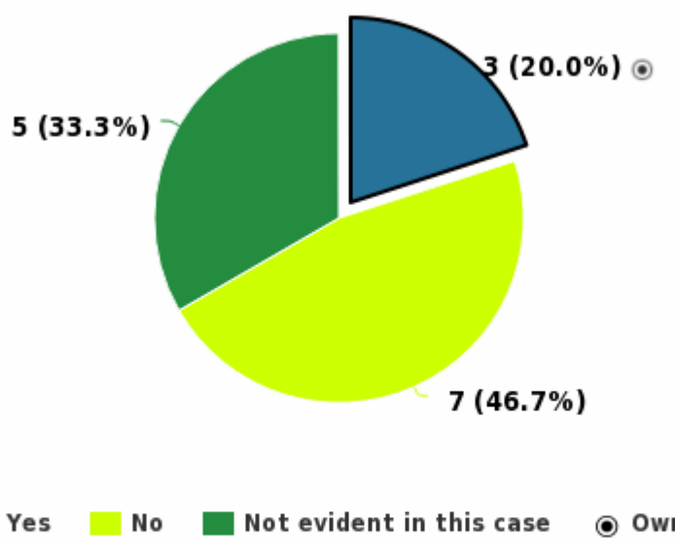
Was the sample collected correctly?



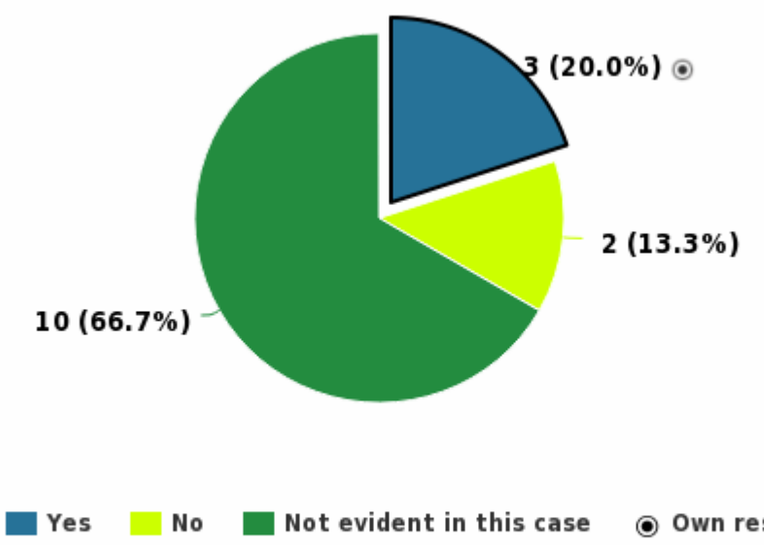
Was the sample transported correctly?



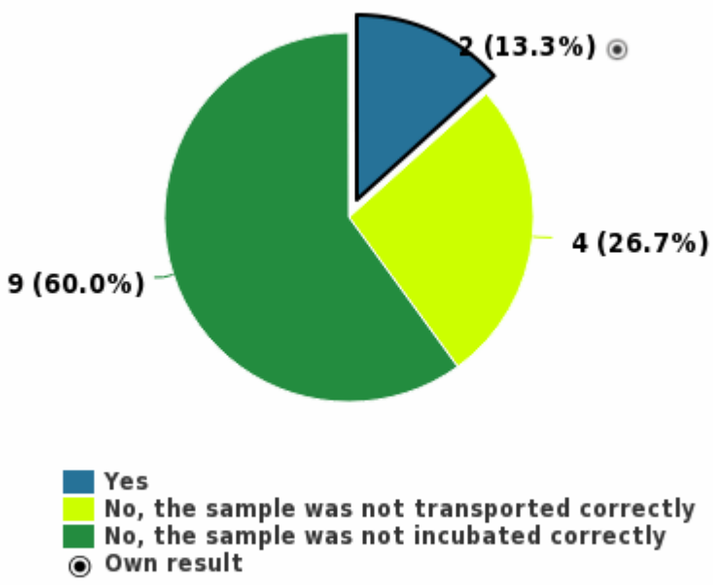
Was the sample incubated correctly?



Was the sample handled correctly after incubation?



Would you accept the sample for analysis based on the description of the process?



Interferon Gamma Release Assay (IGRA) for Mycobacterium tuberculosis, February, 1-2023

Sample S001 | Interferon Gamma Release Assay (IGRA) for Mycobacterium tuberculosis

Methodics	Positive	Low positive	Negative	Indeterminate	No result	Total
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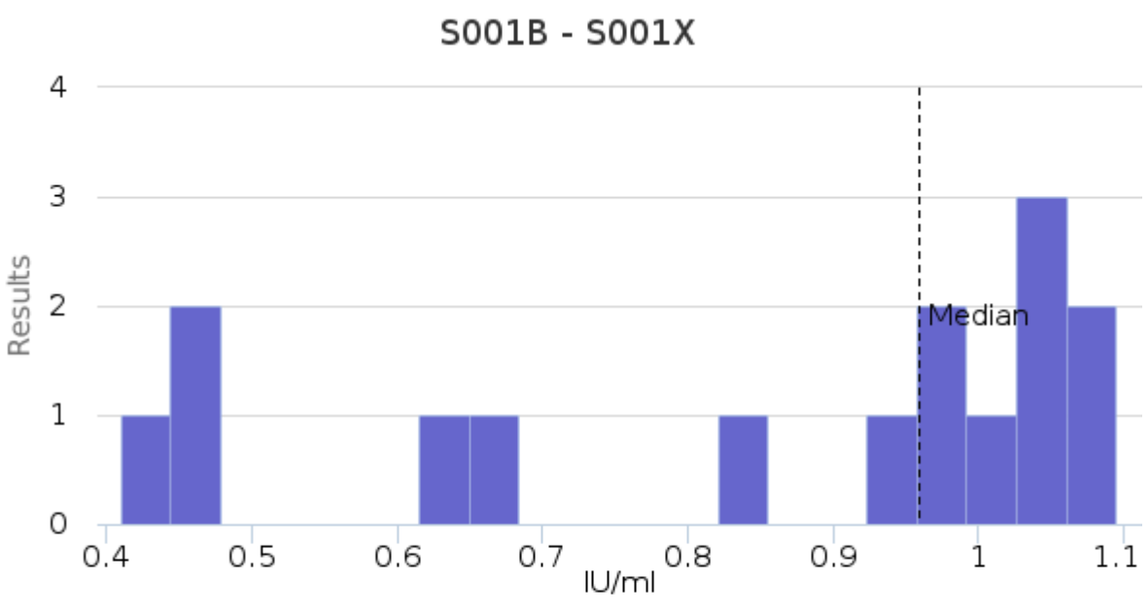

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Interferon Gamma Release Assay (IGRA) for Mycobacterium tuberculosis, February, 1-2023

Preanalytical questions

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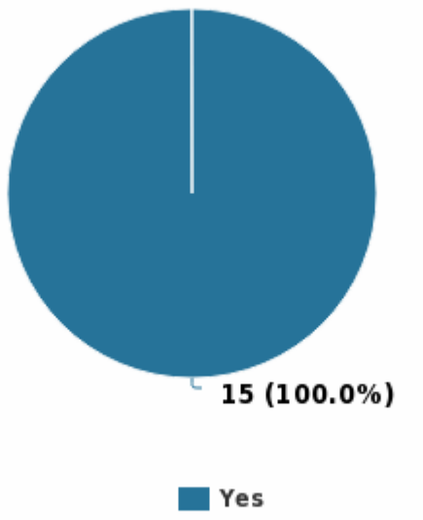
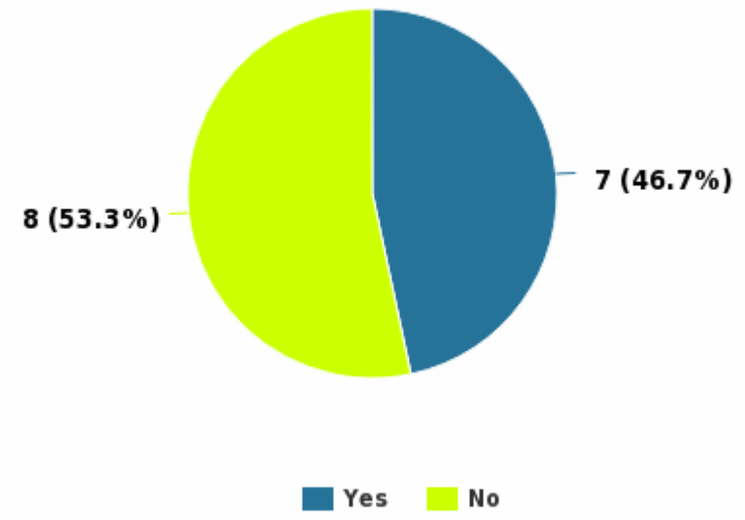
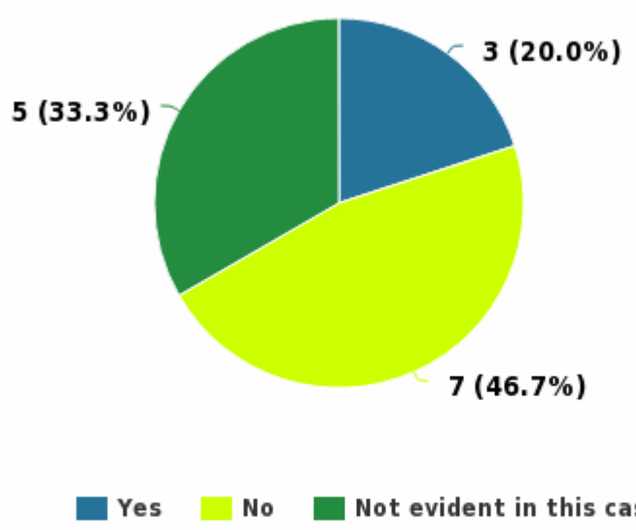


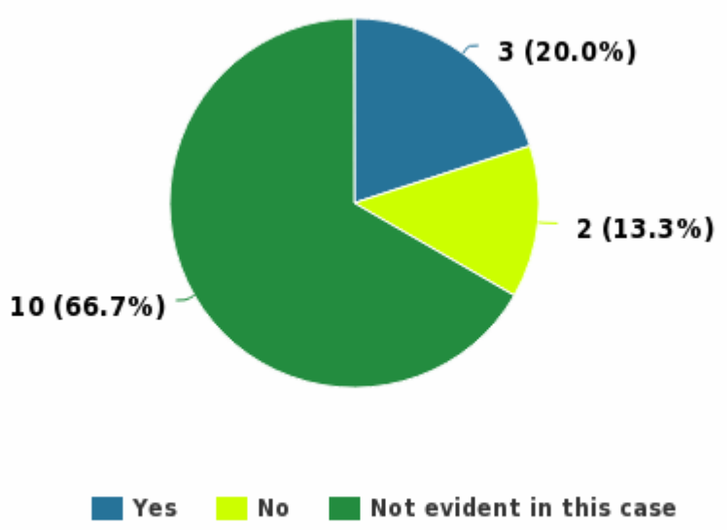
Was the sample transported correctly?



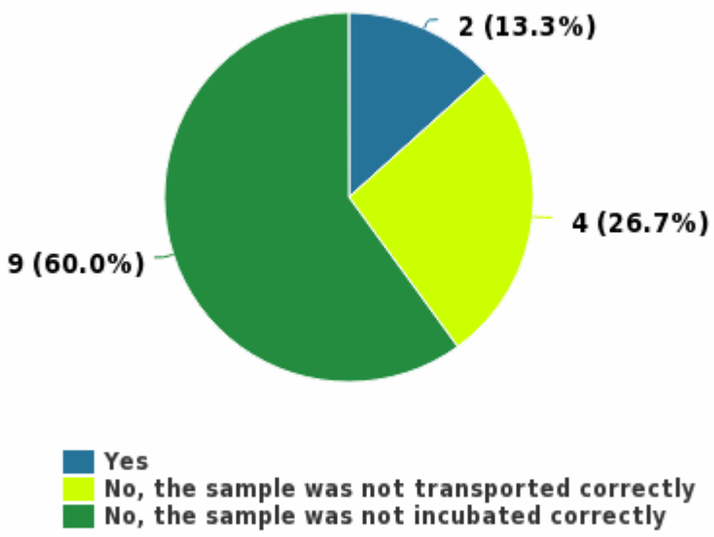
Was the sample incubated correctly?



Was the sample handled correctly after incubation?



Would you accept the sample for analysis based on the description of the process?



LABQUALITY

External Quality Assessment Scheme

Interferon Gamma Release Assay (IGRA) for *Mycobacterium tuberculosis* Round 1, 2023

Specimens
The sample of the round was a lyophilized, simulated interferon gamma (IFN-γ) plasma sample set corresponding to one patient sample. Based on the results obtained in the pilot round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The accepted results were as follows:

Sample S001	
Qualitative result	Positive
Clinical interpretation	TB infection likely

Report info
Please see the description of the data analysis on the last page of the laboratory-specific reports and global 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
Fifteen laboratories participated in this round, one of which reported two results. All of the participants were using the Quantiferon-TB Gold Plus method. The Liaison Analyzer was used by 73% (11/15) of the participants.

The sample S001A-S001X (TB1-NIL) was negative for interferon gamma (IFN-γ) and the sample S001C-S001X (Mitogen-NIL) was IFN-γ positive. For these samples, all reported quantitative results were as expected.

The sample S001B-S001X (TB2-NIL) contained a moderate level of IFN-γ. The variation between quantitative results was 0.41–1.1 IU/ml. Two laboratories interpreted the IFN-γ result of the sample S001 as low positive, the others as positive.

The round went well. There was a consensus on the qualitative result and on the clinical interpretation.

Exceptions
Qualitative results that were interpreted as “low positive” were also accepted.

Pre-analytical section
A 60-year-old man arrives at the regional hospital laboratory on Friday morning for phlebotomy. His physician has ordered a test for *M. tuberculosis* IFNg release assay for him. Phlebotomy is performed at the laboratory and the blood is drawn in the appropriate tubes according to the instructions with the proper tube order and filling. The tubes were shaken to mix antigen with the blood.

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2023-04-25

FINAL REPORT

Product no. 5250

Samples sent	2023-03-14
Round closed	2023-04-06
Final report	2023-04-25

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
Kati Luiro
kati.luiro@labquality.fi

Expert
Microbiologist, Kaisa Rantasärkkä
Tyks Clinical Microbiology,
Turku, Finland

Labquality Oy
Kumpulantie 15
FI-00520 HELSINKI
Finland

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

info@labquality.fi
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Comments – Expert
All the participating laboratories of this round also gave answer to the preanalytical part.

The preanalytical part described a case in which samples were not handled properly. Samples were taken according to the instructions. Depending on the interpretation, the samples were either incubated incorrectly (at room temperature >24 hours) and sent correctly or sent incorrectly (on the way >16 hours) in which case the description of incubation was not evident. The samples were not acceptable for analysis. However, 2/15 of the respondents would have approved the samples for analysis. In IGRAs, the correct preanalytical handling of the blood sample is essential for successful analysis and the reliability of the result.

Questions based on the preanalytical case, and expected answers:

Was the sample collected correctly?
Yes

Was the sample transported correctly?
Yes / No

Was the sample incubated correctly?
No / Not evident in this case

Was the sample handled correctly after incubation?
Not evident in this case

Would you accept the sample for analysis based on the description of the process?
No, the sample was not transported/incubated correctly

Annex
Quantitative results by methods (Annex 1).

End of report

Annex 1. Quantitative results by methods

Method	S001A-S001X	S001B-S001X	S001C-S001X	
	Quantitative result	Quantitative result	Quantitative result	Unit
Quantiferon-TB Gold Plus (Diasorin LIAISON)	-0.02	0.64	2.86	IU/ml
	-0.01	0.84	3.10	IU/ml
	-0.01	0.94	3.98	IU/ml
	-0.01	0.96	4.01	IU/ml
	0.00	0.97	4.44	IU/ml
	0.00	1.00	4.54	IU/ml
	0.00	1.04	4.58	IU/ml
	0.00	1.06	4.58	IU/ml
	0.00	1.06	4.66	IU/ml
	0.01	1.09	5.00	IU/ml
	0.02	1.10	5.05	IU/ml
Quantiferon-TB Gold Plus (Manual ELISA)	-0.02	0.41	2.03	IU/ml
	0.00	0.47	2.51	IU/ml
	0.00	0.65	3.22	IU/ml
Quantiferon-TB Gold Plus	-0.01	0.47	2.43	IU/ml