# **UK NEQAS**

Immunology, Immunochemistry & Allergy

Sheffield Teaching Hospitals NHS

Distribution: 243

Date: 04-Jun-2024

Laboratory: 14489 Page 1 of 11

Interferon Gamma - Specimen: 243-1

UK NEQAS INTERFERON GAMMA RELEASE ASSAYS

389 / 448 (87%) laboratories returned results for this distribution.

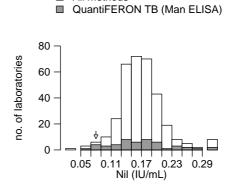
Sample 243-1 was from a 16 year old male with a persistent cough whose friend has recently been diagnosed with MTB. This sample was linked to iEQA case 286. Participants must register for the iEQA scheme to gain access to further clinical details. Please contact us if you require further information about iEQA registration.

Your MRVIS is 101 Your MRBIS is -48 Your SDBIS is 110

0

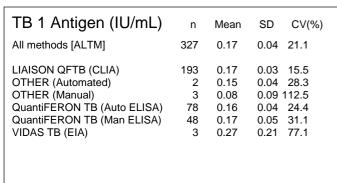
The statistics for the VIDAS TB (EIA) method group are calculated against MLTM. However, as the minimum number of returned results required to make scoring statistically meaningful was not met for this method group, it will not be subject to variance index scoring.

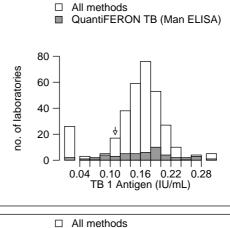
Nil (IU/mL) SD CV(%) n Mean All methods [ALTM] 337 0.17 0.03 18.7 LIAISON QFTB (CLIA) 194 0.17 0.03 14.6 OTHER (Automated) 4 0.14 0.06 43.8 OTHER (Manual) 3 0.11 0.05 44.4 QuantiFERON TB (Auto ELISA) 82 0.17 0.04 24.1 QuantiFERON TB (Man ELISA) 49 0.17 0.05 31.2 SD Biosensor TB (Auto FIA) 2 0.13 54.8 0.24 VIDAS TB (EIA) 0.38 0.02 5.4



All methods

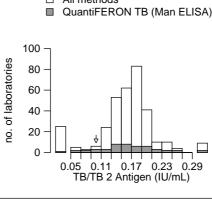
Your result 0.09 0.17 Target value (ALTM) Your BIS Standard Uncertainty 0.00 CCV 20





Your result 0.11 Target value 0.17 (ALTM) Your BIS 0.00Standard Uncertainty CCV 20

TB/TB 2 Antigen (IU/m	Mean	SD	CV(%)	
All methods [ALTM]	335	0.17	0.04	20.6
LIAISON QFTB (CLIA)	194	0.18	0.03	14.8
OTHER (Automated)	4	0.18	0.05	28.8
OTHER (Manual)	3	0.08	0.09	112.5
QuantiFERON TB (Auto ELISA)	80	0.16	0.04	23.9
QuantiFERON TB (Man ELISA)	48	0.17	0.05	30.3
SD Biosensor TB (Auto FIA)	3	0.24	0.10	39.1
VIDAS TB (EIA)	3	0.27	0.21	76.9

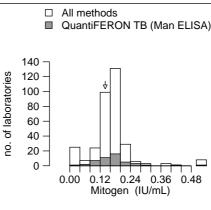


Target value 0.17 (ALTM) Your BIS Standard Uncertainty 0.00 CCV 20

0.11

Your result

Mitogen (IU/mL)	n	Mean	SD CV(%)
All methods [ALTM]	336	0.16	0.07 41.6
LIAISON QFTB (CLIA) OTHER (Automated) OTHER (Manual) QuantiFERON TB (Auto ELISA) QuantiFERON TB (Man ELISA) SD Biosensor TB (Auto FIA) VIDAS TB (EIA)	194 4 3 81 48 3 3	0.16 0.41 0.07 0.16 0.17 0.37 0.26	0.05 33.8 0.49 121.3 0.08 102.3 0.04 26.4 0.06 35.8 0.19 51.1 0.21 80.0



Your result	0.13
Target value (ALTM)	0.16
Your BIS	
Standard Uncertainty	0.00
CCV	20

Sheffield Teaching Hospitals NHS NHS Foundation Trust

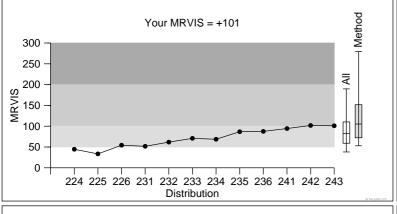
UK NEQAS INTERFERON GAMMA RELEASE ASSAYS

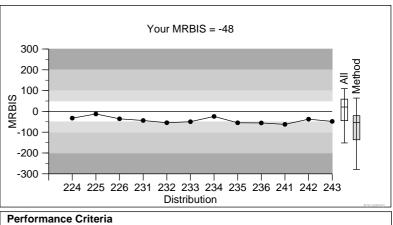
Distribution: 243 Date: 04-Jun-2024

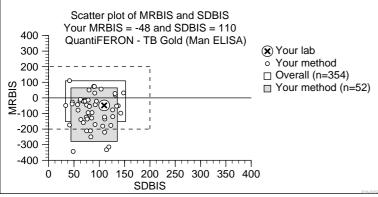
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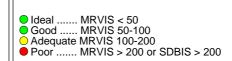
Laboratory: 14489

Interferon Gamma - Specimen: 243-1









For further performance criteria information please see our website at www.immgas.org.uk. If laboratories require further assistance please contact the centre.

Distribution: 243 Date: 04-Jun-2024 Page 3 of 11 Sheffield Teaching Hospitals **NHS** Elispot - Specimen: 243-1 Nil control Your result : Target response: <5 Method <5 5-7 Oxford Immunotec TSPOT.TB 8-20 >20 12 48 60 Ó 24 36 Number of responses Panel A Your result : Target response : <5 Method n <5 5-7 Oxford Immunotec TSPOT.TB 49 8-20 >20 12 24 48 60 0 36 Number of responses Panel B Your result: Target response : <5 Method n <5 5-7 Oxford Immunotec TSPOT.TB 8-20 >20 12 60 0 24 36 48 Number of responses Pos control Your result : Target response : <5 Method n <5 5-7 Oxford Immunotec TSPOT. TB 49 8-20 >20 Ó 12 48 60 24 36 Number of responses

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Distribution: 243 Date: 04-Jun-2024 Page 4 of 11 Sheffield Teaching Hospitals NHS Specimen: 243-1 **Qualitative Results** Your result : Indeterminate Designated response : Indeterminate Your MIS : 0 Positive Negative Your OMIS: 0 (0=Good, 1=Adequate, >1=Poor) Indeterminate □ Interferon Gamma ■ Elispot 240 400 0 80 320 160 Number of responses Correct Incorrect See comments **Technical Interpretation** Your response: T3,T5,T12,T14 Designated response: T3,T5,T7,T12,T14 T2 T3 T4 T5 ☐ Interferon Gamma T6 Elispot T7 T8 Correct T10 Incorrect T11 See comments T12 T13 T14 T15 0 80 160 240 320 400 Number of responses **Technical Interpretation code** T1 - Reactive to MTB T2 - Non-Reactive to MTB T3 - Indeterminate Response to MTB T4 - QC satisfactory T5 - QC unsatisfactory T6 - Sample transposition
T7 - QC fail - PHA response poor
T8 - Wrong Specimen type T9 - Sample mislabelling T10 - QC fail - High negative background T11 - Sample too old T12 - Sample over/under filled T13 - Repeat on same sample T14 - Repeat with new sample T15 - No Action

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Immunology, Immunochemistry & Allergy

Sheffield Teaching Hospitals NHS

Distribution: 243

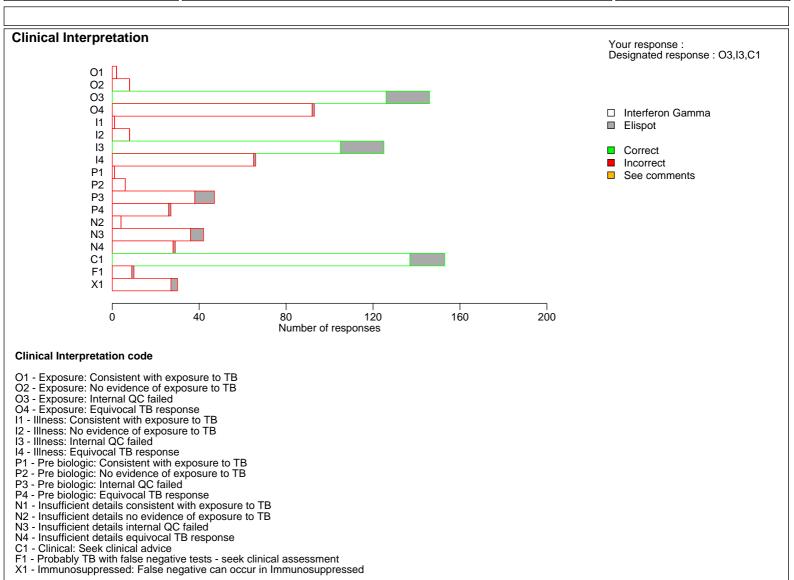
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Specimen: 243-1

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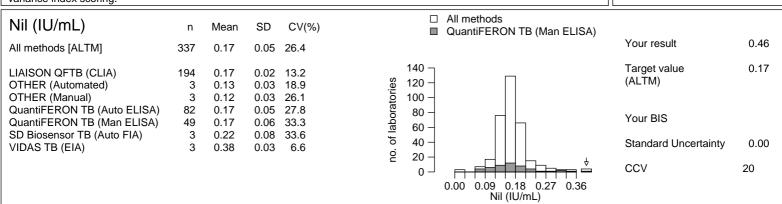
Laboratory: 14489

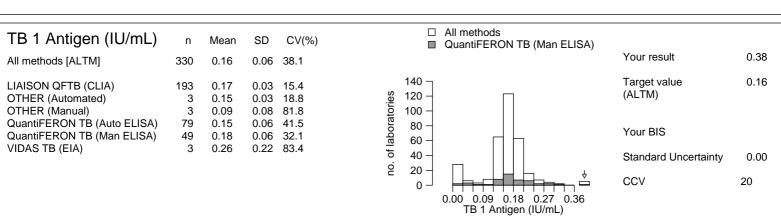
Interferon Gamma - Specimen: 243-2

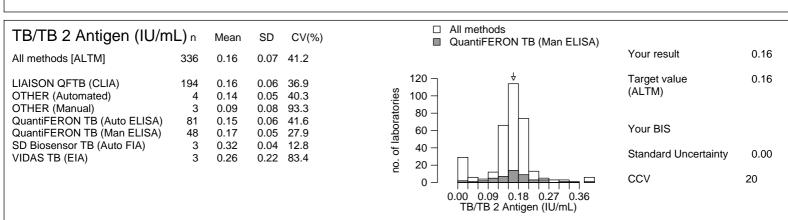
389 / 448 (87%) laboratories returned results for this distribution.

Sample 243-2 was from a 54 year old female who was being tested as part of occupational health screening. She had a positive TST which required further investigation. This sample was linked to iEQA case 287. Participants must register for the iEQA scheme to gain access to further clinical details. Please contact us if you require further information about iEQA registration.

The statistics for the VIDAS TB (EIA) method group are calculated against MLTM. However, as the minimum number of returned results required to make scoring statistically meaningful was not met for this method group, it will not be subject to Your MRVIS is 101 Your MRBIS is -48 0 Your SDBIS is 110







Mitogen (IU/mL)	n	Mean	SD	CV(%)	☐ All methods ■ QuantiFERON TB (Man ELISA)	
All methods [ALTM]	337	2.24	0.37	16.5	Your result	1.82
LIAISON QFTB (CLIA) OTHER (Automated) OTHER (Manual) QuantiFERON TB (Auto ELISA) QuantiFERON TB (Man ELISA) SD Biosensor TB (Auto FIA) VIDAS TB (EIA)	194 4 2 82 49 3 3	2.33 1.65 2.02 2.13 2.03 3.62 4.69		25.8 34.6 17.1 20.5 15.6	si	0.03

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UK NEQAS INTERFERON GAMMA RELEASE ASSAYS

Date: 04-Jun-2024

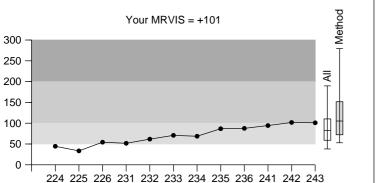
Performance Criteria

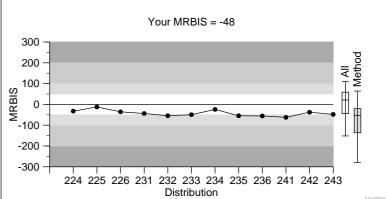
Laboratory: 14489

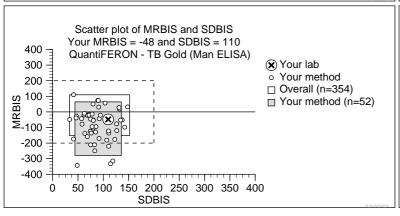
Interferon Gamma - Specimen: 243-2

Distribution: 243

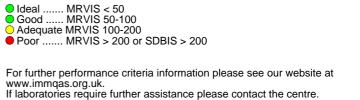
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Distribution



Distribution: 243 Date: 04-Jun-2024 Page 8 of 11 Sheffield Teaching Hospitals **NHS** Elispot - Specimen: 243-2 Nil control Your result : Target response: <5 Method n <5 5-7 Oxford Immunotec TSPOT.TB 50 8-20 >20 12 48 Ó 24 36 60 Number of responses Panel A Your result : Target response : <5 Method n <5 5-7 50 Oxford Immunotec TSPOT.TB 8-20 >20 12 60 24 0 36 48 Number of responses Panel B Your result: Target response : <5 Method n <5 5-7 Oxford Immunotec TSPOT.TB 8-20 >20 12 60 0 24 36 48 Number of responses Pos control Your result : Target response : >20 Method n <5 5-7 Oxford Immunotec TSPOT. TB 50 8-20 >20 0 12 60 24 36 48 Number of responses

UK NEQAS INTERFERON GAMMA RELEASE ASSAYS

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Immunology, Immunochemistry & Allergy

Distribution: 243 Date: 04-Jun-2024 Page 9 of 11 Sheffield Teaching Hospitals **NHS** Specimen: 243-2 **Qualitative Results** Your result : Negative Designated response : Negative Your MIS : 0 Positive Your OMIS: 0 (0=Good, 1=Adequate, >1=Poor) Negative Indeterminate □ Interferon Gamma Elispot 240 400 0 80 320 160 Number of responses Correct Incorrect See comments **Technical Interpretation** Your response : T2,T4,T15 Designated response: T2,T4,T15 T1 T2 Т3 T4 Interferon Gamma T5 Elispot T6 T7 Correct T14 Incorrect T15 See comments Ó 80 160 240 320 400 Number of responses **Technical Interpretation code** T1 - Reactive to MTB T2 - Non-Reactive to MTB
T3 - Indeterminate Response to MTB T4 - QC satisfactory
T5 - QC unsatisfactory T6 - Sample transposition
T7 - QC fail - PHA response poor T8 - Wrong Specimen type
T9 - Sample mislabelling
T10 - QC fail - High negative background
T11 - Sample too old T12 - Sample over/under filled T13 - Repeat on same sample T14 - Repeat with new sample T15 - No Action

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C1 - Clinical: Seek clinical advice

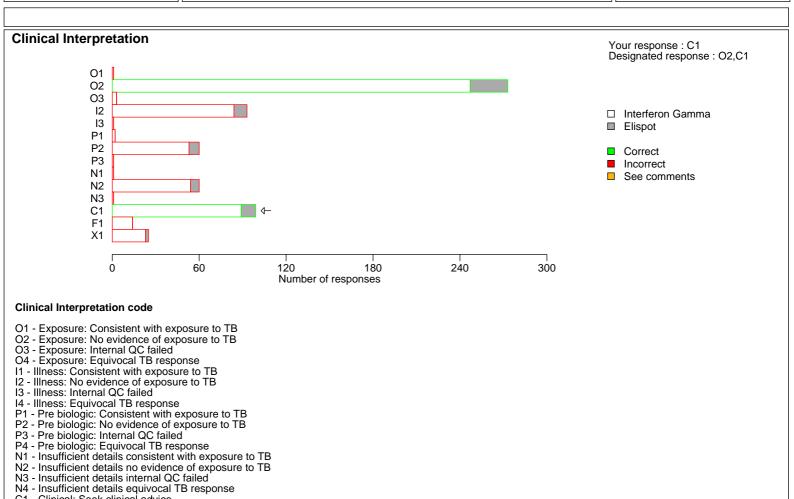
F1 - Probably TB with false negative tests - seek clinical assessment X1 - Immunosuppressed: False negative can occur in Immunosuppressed

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Laboratory: 14489

Specimen: 243-2



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Dietribution	2/12

UK	NEQAS	INTERF	ERON C	SAMMA	RELEAS	E ASSA	YS

Distribution: 243

Date: 04-Jun-2024

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# Comments :

The response rate was good for distribution 243 with 87% (389/448) of participants submitting a result.

#### **Qualitative and Quantitative results:**

#### Sample 243-1:

An indeterminate qualitative response was reported by 375/389 of the laboratories that submitted a result for sample 243-1. Three laboratories reported a positive result, and eleven laboratories reported a negative result for this sample. Five laboratories appear to have transposed their results with sample 243-2. Laboratories that are out of consensus should check their results.

#### Sample 243-2:

A negative qualitative response was reported by 378/389 of the laboratories that submitted a result for sample 243-2. Six laboratories reported a positive result, and five laboratories reported an indeterminate result for this sample. Five laboratories appear to have transposed their results with sample 243-1. Laboratories that are out of consensus should check their results.

# **Technical Interpretation:**

## Sample 243-1:

There were 376 responses for sample 243-1 with 361 laboratories reporting comment (T3) Indeterminate Response to MTB, 201 of these laboratories reported (T5) QC unsatisfactory, 161 reported (T7) QC fail –PHA response poor, and of these; 146 laboratories reported comment (T14) Repeat with a new sample. 19 laboratories reported (T12) sample under/overfilled which was indicated within the iEQA case. There was also information in the case about issues with the time of sample collection.

Thirteen laboratories did not submit a technical response.

#### **Sample 243-2**

There were 377 responses for sample 243-2 with 368 laboratories reporting comment (T2) Non-Reactive to MTB, 345 of these laboratories also reported (T4) QC satisfactory, and of these; 175 laboratories reported comment (T15) No action.

Twelve laboratories did not submit a technical response.

# Clinical Interpretation:

### Sample 243-1

For sample 243-1, there were 280 responses of which 146 laboratories submitted comment (O3) Exposure: Internal QC failed. 106 of these laboratories reported comment (I3) Illness: Internal QC failed, and of these, 67 laboratories reported comment (C1) Clinical: Seek clinical advice.

Various other clinical comments were reported by laboratories and participants should review the iEQA case to assess if these are appropriate.

109/389 laboratories did not report a clinical interpretation for sample 243-1.

#### Sample 243-2

For sample 243-2, there were 285 responses of which 273 laboratories submitted (O2) Exposure: No evidence of exposure to TB, 91 of these laboratories also reported comment (C1) Clinical: Seek clinical advice.

Various other clinical comments were reported by laboratories and participants should review the iEQA case to assess if these are appropriate.

104/389 laboratories did not report a clinical interpretation for sample 243-2.

## The answers to iEQA cases 286 and 287 are now available. Please refer to these cases for more details about interpretation

#### Reminder:

Please remember you must register for the iEQA scheme to gain access to further clinical details.

Participants registered for the UK NEQAS for Interferon Gamma Release Assays (Mycobacterium tuberculosis) are provided with free of charge access to iEQA for 1 user.

The next distribution (244) will be linked to the necessary clinical details on the UK NEQAS Immunology interpretative scheme (iEQA) www.immqas.org.uk.

We would encourage any laboratory that is not currently registered for UK NEQAS Immunology interpretative scheme (iEQA) to contact us for further information. There is much useful educational material in the cases for both scientists and clinicians that highlight the importance of the correct use and interpretation of the assav.

