



State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

TOMÁS J. ARAGÓN, M.D., Dr.PH
Director and State Public Health Officer

To: Laboratories using Electronic Laboratory Reporting (ELR)

Subject: Electronic reporting of Interferon Gamma Release Assay (IGRA) results in the California Reportable Disease Information Exchange (CalREDIE): Update on reporting of non-positive IGRA results

Dear Reporting Laboratory,

I am writing to inform you that the reporting of non-positive IGRA results by laboratories will be required by the California Department of Public Health per the California Code of Regulations, Title 17, Section 2505, Section A and is effective November 1, 2022. Non-positive IGRA results include, but are not limited to, results that are negative, indeterminate, or borderline. Positive IGRA results have been required to be reported by laboratories since October 2019. The reporting of non-positive in addition to positive IGRA results will facilitate follow-up on all patients involved in contact investigations and enables public health action on IGRA conversions from negative to positive by public health staff. It will also allow more complete understanding of IGRA testing in California.

Please submit IGRA results using the guidance below which was developed in collaboration with the Association of Public Health Laboratories and Regenstrief Institute. The guidance details how to submit results for IGRAs using ELR (QFT-Plus and T-SPOT.TB), and specific codes to be used for each test subcomponent. We are also including sample HL7 ELR messages for each test. Applying this guidance will optimize consistency across laboratories and ensure that results are actionable. Note that this guidance has not changed from prior communications on this matter.

Thank you for your assistance in improving tuberculosis-related ELR. If you have questions about laboratory reporting, please contact the CalREDIE ELR help desk at calredieelr@cdph.ca.gov. If you have further questions about tuberculosis reporting, please contact me or the Chief of the TB Registry, Varsha Hampole, by email at pennan.barry@cdph.ca.gov or varsha.hampole@cdph.ca.gov, or by phone at (510) 620-3000.

Sincerely,

Pennan Barry, MD MPH



Chief, Surveillance and Epidemiology Section

QuantiFERON-TB Gold Plus (QFT-Plus)

Panel code LOINC: 71775-1

Long name: Mycobacterium tuberculosis stimulated gamma interferon panel - Blood

For CalREDIE, to support proper and complete interpretation of QFT-Plus test results, ALL items should be reported together.

1. Nil or Negative Control Tube (grey cap)

LOINC: 71776-9

Long Name: Gamma interferon background [Units/volume] in blood by immunoassay

2. Mitogen or Positive Control Tube (purple cap)

LOINC: 71774-4

Long Name: Mitogen stimulated gamma interferon [Units/volume] corrected for background in
Mitogen minus nil

3. TB Antigen (green cap TB 1)

LOINC: 64084-7

Long Name: Mycobacterium tuberculosis stimulated gamma interferon [Units/volume] corrected for
background in blood

*TB Antigen minus nil

4. TB Antigen (yellow cap TB 2)

LOINC: 88517-8

Long Name: Mycobacterium tuberculosis stimulated gamma interferon release by helper CD4 and cytotoxic CD8 cells [Units/volume] corrected for background in Blood

5. Calculation of Positive, Negative, or Indeterminate

LOINC: 71773-6

Long Name: Mycobacterium tuberculosis stimulated gamma interferon [Presence] in blood

Interpretation Criteria for QuantiFERON-Plus (Adapted from QFT-Plus Package Insert)

Nil (IU/mL)	TB1 minus Nil (IU/mL)	TB2 minus Nil (IU/mL)	Mitogen minus Nil (IU/mL)	QFT-PLUS Result	Report/Interpretation	SNOMED CT
LOINC 71776-9	LOINC 64084-7	LOINC 88517-8	LOINC 71774-4	LOINC 71773-6		
≤8.0	≥0.35 and ≥ 25% of Nil value	Any	Any	Positive	<i>M. tuberculosis</i> infection likely	10828004
	Any	≥0.35 and ≥ 25% of Nil value				
	<0.35 or ≥0.35 and <25% of Nil value	<0.35 or ≥0.35 and <25% of Nil value	≥0.5	Negative	<i>M. tuberculosis</i> infection NOT likely	260385009
	<0.35 or ≥0.35 and <25% of Nil value	<0.35 or ≥0.35 and <25% of Nil value	<0.5	Indeterminate	Likelihood of <i>M. tuberculosis</i> infection cannot be determined	82334004
>8.0	Any					

Sample HL-7 message for QFT-Plus

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MSH|^~\&|...
SFT|...
PID|1|...
ORC|RE|MM0036-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069564^Filler Order
Number^2.16.840.1.113883.3.2.12.1.1^ISO|...
OBR|1|MM0036-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069564^Filler Order
Number^2.16.840.1.113883.3.2.12.1.1^ISO|71775-1^M TB IGNF pnl
Bld^LN^QFT4^QuantiFERON-Tb Gold Plus, B^L^U|...
OBX|1|CE|71773-6^M TB IGNF Bld QI^LN^QFTQ2^QuantiFERON-Tb Gold Plus
Result^L^2.63^U||10828004^Positive^SCT||Negative|A^Abnormal^HL70078^A^Abnormal^L^2.7
^V1|||F ...
OBX|2|SN|64084-7^M TB IGNF bckgrd cor Bld-aCnc^LN^DEXQE^TB1 Ag minus Nil
Result^L^2.63^U|^0.62|[IU]/mL^international unit per milliliter^UCUM
|||F ...
OBX|3|SN|88517-8^M TBIFN-g CD4 CD8 bckgrd cor Bld-aCnc^LN^DEXQF^TB2 Ag minus Nil
Result^L^2.63^U|^1.64|[IU]/mL^international unit per milliliter^UCUM
|||F ...
OBX|4|SN|71774-4^Mitogen IGNF bckgrd cor Bld-aCnc^LN^DEXQG^Mitogen minus Nil
Result^L^2.63^U|^3.84|[IU]/mL^international unit per milliliter^UCUM
|||F ...
OBX|5|SN|71776-9^Gamma interferon background Bld EIA-aCnc^LN^DEXQH^Nil
Result^L^2.63^U|^5.86|[IU]/mL^international unit per milliliter^UCUM
|||F ...
SPM|1|...

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T-SPOT.TB

Panel code LOINC: 74281-7

Long name: Mycobacterium tuberculosis stimulated gamma interferon and spot count panel- Blood

For CalREDIE, to support proper and complete interpretation of T-SPOT.TB test results, ALL items should be reported together.

1. Positive Control

LOINC: 74280-9

Long Name: Mitogen stimulated gamma interferon positive control spot count [#] in blood

2. Nil Control Well Count

LOINC: 74279-1

Long Name: Gamma interferon negative control spot count [#] in blood

3. Panel A Spot Count

LOINC: 74278-3

Long Name: Mycobacterium tuberculosis stimulated gamma interferon ESAT-6 Ag spot count [#] in blood

4. Panel B Spot Count

LOINC: 74277-5

Long Name: Mycobacterium tuberculosis stimulated gamma interferon CFP10 Ag spot count [#] in blood

5. Result Interpretation

LOINC: 71773-6

Long Name: Mycobacterium tuberculosis stimulated gamma interferon [Presence] in blood

Interpretation Criteria T-SPOT.TB Test

Nil Control Well Count (LOINC: 74279-1)	Either Panel A (LOINC: 74278-3) or Panel B (LOINC: 74277-5) has following # of spots	Result Interpretation (LOINC: 71773-6)
0	≥8	Positive

1	≥9	Positive
2	≥10	Positive
3	≥11	Positive
4	≥12	Positive
5	≥13	Positive
6	≥14	Positive
7	≥15	Positive
8	≥16	Positive
9	≥17	Positive
10	≥18	Positive
>10	n/a	Indeterminate

Note: The highest Panel-Nil spot count is to be used to determine the test outcome.

Source: Courtesy of Eric Haas (APHL Consultant)

Interpretation	SNOMED CT	Nil* LOINC: 74279-1	TB Response**	Mitogen*** LOINC: 74280-9
Positive ¹	10828004	≤10 spots	≥8 spots	Any
Borderline ²	42425007	≤10 spots	5, 6, or 7 spots	Any
Negative ³	260385009	≤10 spots	≤4 spots	
Indeterminate ⁴	82334004	>10 spots	Any	Any
		≤10 spots	<5 spots	<20 spots

Source: MMWR (2010) Based on Oxford Immunotec Limited T-Spot.TB

*Number of spots resulting from incubation of PBMCs in culture media without antigens

** The greater number of spots resulting from stimulation of PBMCs with two separate cocktails of peptides representing ESAT-6 or CFT-10 minus Nil. Electronic reporting however should be of the actual spot count of Panel A (LOINC: 74278-3) and Panel B (LOINC: 74277-5) WITHOUT subtracting the nil well spots.

***Number of spots resulting from stimulation of PBMCs with mitogen without adjustment for the number of spots resulting from incubation of PBMCs without antigens

¹ M. tuberculosis infection likely

² Uncertain likelihood of M. tuberculosis infection

³ M. tuberculosis infection NOT likely

⁴ Results are indeterminate

Sample HL-7 message for T-SPOT.TB

MSH|^~\&|...
SFT|...
PID|1|...
ORC|RE|MM0037-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069565^Filler
Order Number^2.16.840.1.113883.3.2.12.1.1^ISO|...
OBR|1|MM0037-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069565^Filler Order
Number^2.16.840.1.113883.3.2.12.1.1^ISO|74281-7^M TB IGNF+spot Pnl Bld^LN^TSPT^TSpot
test^L^U|...
OBX|1|SN|74280-9^Mitogen IGNF.spot count Bld^LN^MitPC^Mitogen IGNF Positive
Control^L^2.63^U||^7|{#}^number^UCUM||||F ...
OBX|2|SN|74279-1^IGNF neg cntrl Bld^LN^IGNFNC^IGNF Negative
Control^L^2.63^U||^7|{#}^number^UCUM||||F ...
OBX|3|SN|74278-3^M TB IGNF.ESAT-6 Ag Bld^LN^ESAT6^IGNF ESAT
6Ag^L^2.63^U||>^16|{#}^number^UCUM||||F ...
OBX|4|SN|74277-5^M TB IGNF.CFP10 Ag Bld ^LN^CPF10^IGNF
CFP10Ag^L^2.63^U||>^16|{#}^number^UCUM||||F ...
OBX|5|CE|71773-6^M TB IGNF Bld QI^LN^IGNFQI^IGNF
Interpretation^L^2.63^U||10828004^Positive^SCT||Negative|
A^Abnormal^HL70078^A^Abnormal^L^2.7^V1||F ...
SPM|1|...