QuantiFERON-TB Gold Plus

Patient Details

Name : ทดสอบ ชื่อภาษาไทย
DOB : {{inputDOB}}
Age (Yr) : Test {{inputAGE}}
Gender : {{inputGENDER}}
HN : {{inputHN}}

Sample Details

Date : {{inputHN}}
Collected : {{inputHN}}
Received : {{inputHN}}
Reported : {{inputHN}}

TESTS	RESULT	UNIT
QuantiFERON-TB Gold Plus		
QuantiFERON Nil Tube	0.05	IU/mL
QuantiFERON TB1 Ag Tube	0.05	IU/mL
QuantiFERON TB2 Ag Tube	0.05	IU/mL
QuantiFERON Mitogen Tube	0.05	IU/mL
QuantiFERON TB Gold Plus - Interpret.		
	Indeterminate	

<table>
<tr><th>Nil (IU/mL)</th><th>TB1 minus Nil (IU/mL)</th><th>TB2 minus Nil (IU/mL)</th><th>Mitogen minus Nil (IU/mL)*</th><th>QuantiFERON-TB Gold Plus Result</th></tr>
<tr><td rowspan="4">≤ 8.0</td><td>≥ 0.35 and ≥ 25% of Nil</td><td>Any</td><td rowspan="2">Any</td><td rowspan="2">Positive†</td></tr>
<tr><td>Any</td><td>≥ 0.35 and ≥ 25% of Nil</td></tr>
<tr><td colspan="2" rowspan="2">< 0.35 or ≥ 0.35 and < 25% of Nil</td><td>≥ 0.5</td><td>Negative</td></tr>
<tr><td>< 0.5</td><td rowspan="2">Indeterminate‡</td></tr>
<tr><td>> 8.0§</td><td colspan="2">Any</td><td>Any</td></tr>
</table>

*Responses to the Mitogen positive control (and occasionally TB Antigens) can be outside the range of the microplate reader. This has no impact on test results. Values >10 ml are reported by the QFT-Plus software as >10 IU/ml.

†Where M. tuberculosis infection is not suspected, initially positive results can be confirmed by retesting the original plasma samples in duplicate in the QFT-Plus ELISA. If repeat testing of one or both replicates is positive, the individual should be considered test positive.

‡Refer to the “Troubleshooting” section for possible causes.

§In clinical studies, less than 0.25% of subjects had IFN-γ levels of >8.0 IU/ml for the Nil value.

The Mitogen control generally elicits the greatest IFN-gamma response of the 4 samples from each subject. In some cases, the Mitogen control OD value will be above the limit of the microplate reader; this has no impact on the test interpretation. The IFN-gamma level of the Nil control is considered backgraound and is subtracted from both the TB1 and TB2 results and the Mitogen result for that subject. In clinical studies, less than 0.25% of subjects had IFN-gamma levels of > 8.0 IU/mL for the Nil control.

The cutoff for the QuantiFERON-TB Gold Plus test is 0.35 IU/mL above the Nil control (and TB1 or TB2 minus Nil is ≥ 25% of the Nil control) for either or both TB tubes. Individuals displaying a response to either or both of the TB tubes above this cutoff are likely infected with M. tuberculosis.

The magnitude of the measured IFN-γ level cannot be correlated to stage or degree of infection, level of immune responsiveness, or likelihood for progression to