

## Interferon Gamma Release Assays (Mycobacterium tuberculosis) IGRA TB

<b>Accreditation Status:</b>	<a href="#">UKAS Schedule of Accreditation</a>																					
<b>Date Scheme started:</b>	2009																					
<b>Clinical Applicability:</b>	Test for latent tuberculosis infection and a useful aid for diagnosing M. tuberculosis complex infection																					
<b>Analytes:</b>	IGRA TB																					
<b>Units for Reporting:</b>	Qualitative responses (Positive, Negative and Indeterminate), Quantitative responses (IU/mL), number of T-spots, Clinical and Technical Interpretations																					
<b>Samples Distributed:</b>	Normal and pathological human serum Distributions are linked to cases on the UK NEQAS for Immunology, Immunochemistry & Allergy Interpretative EQA Scheme (iEQA) website																					
<b>Number of Distributions per year:</b>	6																					
<b>Number of Samples per Distribution:</b>	2 sets of 4 (Nil, TB1 antigen, TB2 antigen and Mitogen), or one pre-incubated microtiter strip consisting of two samples																					
<b>Frequency of Distributions:</b>	Every two months as outlined in the <a href="#">Distribution Schedule</a>																					
<b>Schedule of Analysis:</b>	<a href="#">Data entry</a> is via the web for the submission of results. Data analysis is commenced 21 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics																					
<b>Data Analysis:</b>	All Laboratory Trimmed Mean (ALTM) with truncation at 2SD, SD and CV%. Reports show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS and MRVIS Chosen Coefficient of Variation for Interferon gamma is 20% Qualitative responses are assessed in relation to the designated response																					
<b>Performance Scoring:</b>	MRVIS / MI scoring																					
<b>Criteria of Performance:</b>	OMIS for qualitative results over a running analytical window of 6 Distributions (12 months) <table border="0" style="margin-left: 40px;"> <tr> <td style="padding-right: 20px;">Good</td> <td style="padding-right: 20px;">OMIS</td> <td>Zero</td> </tr> <tr> <td>Adequate</td> <td></td> <td>1</td> </tr> <tr> <td>Poor</td> <td></td> <td>&gt;1</td> </tr> </table> <p>Individual laboratory performance over a running analytical window of 6 Distributions (12 months) for Interferon Gamma Release Assay quantitation is expressed in terms of MRBIS, SDBIS and MRVIS</p> <table border="0" style="margin-left: 40px;"> <tr> <td style="padding-right: 40px;">Ideal</td> <td style="padding-right: 20px;">MRVIS</td> <td>&lt;50</td> </tr> <tr> <td>Good</td> <td></td> <td>50 – 100</td> </tr> <tr> <td>Adequate</td> <td></td> <td>101 – 200</td> </tr> <tr> <td>Poor</td> <td></td> <td>&gt;200 or SDBIS &gt;200</td> </tr> </table>	Good	OMIS	Zero	Adequate		1	Poor		>1	Ideal	MRVIS	<50	Good		50 – 100	Adequate		101 – 200	Poor		>200 or SDBIS >200
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<b>Persistent Poor Performance:</b>	Defined as being in the Poor Performance category for two or more successive Distributions																					