Interferon Gamma Release Assays

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 2009

Clinical Applicability: Test for latent tuberculosis infection and a useful aid for diagnosing M. tuberculosis complex infection

Analytes: IGRA TB **(SER/0039)**

Units for Reporting: Qualitative responses (Positive, Negative and Indeterminate), Quantitative responses (IU/mL), number of T-spots, Clinical and Technical Interpretations

Samples Distributed: Normal and pathological human serum
Distributions are linked to cases on the UK NEQAS for Immunology, Immunochemistry & Allergy Interpretative EQA Scheme (iEQA) website

Number of Distributions per year: 6

Number of Samples per Distribution: 2 sets of 4 (Nil, TB1 antigen, TB2 antigen and Mitogen), or one pre-incubated microtiter strip consisting of two samples

Frequency of Distributions: Every two months as outlined in the **Distribution Schedule**

Schedule of Analysis: **Data entry** 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

Data Analysis: 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

Performance Scoring: MRVIS / MI scoring

Criteria of Performance: OMIS for qualitative results over a running analytical window of 6 Distributions (12 months)

Good	OMIS	Zero
Adequate		1
Poor		>1

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

Ideal	MRVIS	<50
Good		50 – 100
Adequate		101 – 200
Poor		>200 or SDBIS >200

Persistent Poor Performance: Defined as being in the Poor Performance category for two or more successive Distributions