

Diabetic Markers

Accreditation Status:	UKAS Schedule of Accreditation								
Date Scheme started:	2011								
Clinical Applicability:	Aiding the clinical diagnosis of type I diabetes								
Analytes:	<p>Islet cell (ICA), Glutamic Acid Decarboxylase (GAD) and Protein Tyrosine Phosphatase (IA2), Insulin antibody (IA), Zinc Transporter 8 Antibody (ZnT8), Diabetic Marker Autoantibody Screen (SER/047)</p> <p><i>The sample analytes included will depend on their prevalence in the general population, therefore not all analytes may be covered during the year</i></p>								
Units for Reporting:	<p>Islet cell: qualitative (titre) or U/mL</p> <p>GAD: U/mL</p> <p>IA2: U/mL</p> <p>IA: U/mL % Binding ZnT8: U/mL</p> <p>Diabetic Marker Autoantibody Screen: U/mL</p>								
Samples Distributed:	Liquid format. Normal and pathological human serum								
Number of Distributions per year:	6								
Number of Samples per Distribution:	2								
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 28 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics								
Data Analysis:	Qualitative responses are recorded for each analyte and assessed in relation to the designated response. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported								
Performance Scoring:	MI scoring								
Criteria of Performance:	<p>Laboratory performance is classified in terms of OMIS over a running analytical window of 6 Distributions (12 months). Cumulative performance scores are based on qualitative response</p> <p>The categories of performance are:</p> <table><thead><tr><th></th><th><u>Total MIS</u></th></tr></thead><tbody><tr><td>Good</td><td>zero</td></tr><tr><td>Adequate</td><td>1 - 3</td></tr><tr><td>Poor</td><td>>3</td></tr></tbody></table>		<u>Total MIS</u>	Good	zero	Adequate	1 - 3	Poor	>3
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Good	zero								
Adequate	1 - 3								
Poor	>3								
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions								