

C1 Esterase Inhibitor and Functional Complement Assays

Accreditation Status:	UKAS Schedule of Accreditation
Date Scheme started:	2002
Clinical Applicability:	Diagnosis of Hereditary Angioedema and monitoring of complement activation
Analytes:	Performance will be monitored in the antigenic and functional assays for C1 Esterase Inhibitor. Laboratories are required to return data on Complement C3 and C4 to permit the interpretation of the C1 Esterase Inhibitor levels (SER/033)
Units for Reporting:	g/L in relation to relevant international standards, functional activity (%)
Samples Distributed:	Liquid format. Normal and pathological human serum Additional materials may be produced by the addition of purified C1 Esterase Inhibitor, C3 or C4 to an analyte free serum matrix
Number of Distributions per year:	4
Number of Samples per Distribution:	2
Frequency of Distributions:	Every three 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:	All Laboratory Trimmed Mean (ALTM) with truncation at 2SD, SD, and CV%. Reports also show method and manufacturer specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, and MRVIS. The Designated Value (DV) for calculation of VI is the All Laboratory Trimmed Mean (ALTM) Chosen Coefficient of Variation is 10%
Performance Scoring:	MI scoring and MRVIS

Criteria of Performance:

Laboratory performance for the qualitative element of the Scheme is assessed over a running analytical window of 4 Distributions (12 months)

Good	OMIS = 0
Adequate	OMIS = 1 -2
Poor	OMIS = >2

Individual laboratory performance over a running analytical window of 4 Distributions (12 months) 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