

Tumour Markers (CA Series)

Accreditation Status:	UKAS Schedule of Accreditation												
Date Scheme started:	1988												
Clinical Applicability:	Diagnosis and management of malignant disease												
Analytes:	Ovarian Markers (CA125) (SER/021) Gut Markers (CA199) (SER/022) Breast Markers (CA153) (SER/023) Lung Markers (NSE) (SER/024) Chromogranin A (SER/049) All analytes are available separately												
Units for Reporting:	kU/L (CA series markers), µg/L (NSE), ng/mL and nmol/L (Chromogranin A)												
Samples Distributed:	Liquid format. Normal and pathological human serum												
Number of Distributions per year:	6												
Number of Samples per Distribution:	10 (2 x CA125, 2 x CA15-3, 2 x CA19-9, 2 x NSE, 2 x Chromogranin A)												
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 also show method and manufacturer specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, and MRVIS. Because of marked differences in antigenic potency of some commercial kits, the Designated Value (DV) for calculation of VI is the Method Laboratory Trimmed Mean (MLTM). Chosen Coefficient of Variation: <table><tr><td>CA125 and Ovarian markers</td><td>7%</td></tr><tr><td>CA15-3 and Breast markers</td><td>10%</td></tr><tr><td>CA19-9 and GI markers</td><td>10%</td></tr><tr><td>NSE and Lung markers</td><td>12.5%</td></tr><tr><td>Chromogranin A (pilot analyte)</td><td>30.0%</td></tr></table>	CA125 and Ovarian markers	7%	CA15-3 and Breast markers	10%	CA19-9 and GI markers	10%	NSE and Lung markers	12.5%	Chromogranin A (pilot analyte)	30.0%		
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Performance Scoring:	MRVIS												
Criteria of Performance:	Laboratory performance is classified in terms of the MRVIS over a running analytical window of 6 Distributions (12 months) <table><tr><td>Ideal</td><td>MRVIS</td><td><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>>200 or SDBIS >200</td></tr></table>	Ideal	MRVIS	<50	Good		50 - 100	Adequate		101 - 200	Poor		>200 or SDBIS >200
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												
Cancer Treatment Trials:	Participation in these EQA programmes is often a requirement for laboratories providing analytical services to clinicians wishing to enter patients. Such laboratories will be required to agree to the organiser releasing their performance data to the relevant Trials Office												