Tumour Markers

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:

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%

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)

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