ANTI-TNF DRUGS AND ANTIBODIES (Pilot)

Accreditation Status: *currently not accredited to ISO 17043*

Date Scheme started: 2024

Clinical Applicability: Assist with drug and antibody monitoring of anti-TNF therapies

Analytes: TNF Adalimumab drug and antibody **(SER/065)**
TNF Infliximab drug and antibody **(SER/066)**

Units for Reporting: ug/mL (drugs), AU/ml or ng/mL (antibodies)

Samples Distributed: Liquid format. Normal and pathological human serum

Number of Distributions per year: 4

Number of Samples per Distribution: 1 set of Adalimumab samples (1 x drug, 1 x antibody)
1 set of Infliximab samples (1 x drug, 1 x antibody)

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 21 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics

Data Analysis: Reports show method or kit related statistics. Qualitative responses are recorded and assessed in relation to the designated response.

All Laboratory Trimmed Mean (ALTM) with truncation at 2SD, SD, and CV%. Reports also show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, MRVIS and OMIS

Performance Scoring: MRVIS
MI scoring based on Consensus Designated Response

Criteria of Performance: Laboratory performance is classified in terms of the MRVIS and OMIS over a Running analytical window of 4 Distributions (12 months)

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

	Total MIS
Good	Zero
Adequate	1-2
Poor	>2

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