

# Liver Disease Antibodies

<b>Accreditation Status:</b>	<b>UKAS Schedule of Accreditation</b>								
<b>Date Scheme started:</b>	General Autoimmune Serology Started 1982, reconfigured 2025								
<b>Clinical Applicability:</b>	Diagnosis and monitoring of autoimmune liver disease								
<b>Analytes:</b>	Identification of antibodies associated with autoimmune liver disease ( <b>SER/004</b> ) To include Mitochondrial antibodies, Liver Kidney Microsomal (LKM) antibodies, Smooth Muscle Antibodies (SMA) and other liver antibodies (PML, Ro-52)								
<b>Units for Reporting:</b>	IU/ml or U/mL in relation to the appropriate International Reference Preparations, or titre. Qualitative responses or interpretation of quantitative results recorded as POSitive or NEGative								
<b>Samples Distributed:</b>	Liquid format. Normal and pathological human serum								
<b>Number of Distributions per year:</b>	6								
<b>Number of Samples per Distribution:</b>	1								
<b>Frequency of Distributions:</b>	Every two months as outlined in the <b>Distribution Schedule</b>								
<b>Schedule of Analysis:</b>	<b>Data entry</b> is via the web for the submission of results. Data analysis commences 21 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics.								
<b>Data Analysis:</b>	<p>Reports show method or kit related statistics. Qualitative responses are recorded and assessed in relation to the designated response.</p> <p>Quantitative results show Method Laboratory Trimmed Mean (MLTM), the range of results reported, SD and CV%. MRVIS, MRBIS and SDBIS are also provided for quantitative results</p>								
<b>Performance Scoring:</b>	MI scoring based on Consensus Designated Response								
<b>Criteria of Performance:</b>	<p>Laboratory performance is classified in terms of OMIS for qualitative responses for analytes for which the laboratory is registered over a running analytical window of 6 Distributions (12 months)</p> <p>The categories of performance are:</p> <table><tr><td></td><td><u>Total MIS</u></td></tr><tr><td>Good</td><td>Zero</td></tr><tr><td>Adequate</td><td>1-2</td></tr><tr><td>Poor</td><td>&gt;2</td></tr></table> <p>A OMIS of &gt;2 (out of a possible six in the defined time window) for any one analyte will also be classified as poor performance.</p>		<u>Total MIS</u>	Good	Zero	Adequate	1-2	Poor	>2
	<u>Total MIS</u>								
Good	Zero								
Adequate	1-2								
Poor	>2								
<b>Persistent Poor Performance:</b>	Defined as being in the Poor Performance category for two or more successive Distributions								