

# Liver Disease Antibodies

<b>Accreditation Status:</b>	<a href="#">UKAS Schedule of Accreditation</a>								
<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 <a href="#">Distribution Schedule</a>								
<b>Schedule of Analysis:</b>	<a href="#">Data entry</a> 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>	Reports show method or kit related statistics. Qualitative responses are recorded and assessed in relation to the designated response.  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								
<b>Performance Scoring:</b>	MI scoring based on Consensus Designated Response								
<b>Criteria of Performance:</b>	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)  The categories of performance are: <table><thead><tr><th></th><th><u>Total MIS</u></th></tr></thead><tbody><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></tbody></table>		<u>Total MIS</u>	Good	Zero	Adequate	1-2	Poor	>2
	<u>Total MIS</u>								
Good	Zero								
Adequate	1-2								
Poor	>2								
	A OMIS of >2 (out of a possible six in the defined time window) for any one analyte will also be classified as poor performance.								
<b>Persistent Poor Performance:</b>	Defined as being in the Poor Performance category for two or more successive Distributions								