

Digital ANA (dANA) - image based

Accreditation Status:	UKAS Schedule of Accreditation								
Date Scheme started:	2021								
Clinical Applicability:	Recognition of HEp-2 patterns seen in autoimmune disease in accordance with International Consensus on Antinuclear Antibody (ANA) Patterns (ICAP).								
Analytes:	<p>A digital based image programme. Includes identifying the presence and identification of staining patterns in HEp-2 cell lines using the ICAP system (DA/601)</p> <p><i>Multiple digital users can be registered.</i></p>								
Units for Reporting:	N/A								
Samples Distributed:	A set of 3 digital images (magnification 1x100, 1x200, 1x400) from healthy donors or patients with autoimmune connective tissue disease.								
Number of Distributions per Year:	4								
Number of Samples per Distribution:	2 digital samples per distribution								
Frequency of Distributions:	Every 12 weeks as outlined in the Distribution Schedule								
Schedule of Analysis:	Access to the digital images is via the web and includes the submission of interpretations. Data analysis is commenced 21 days after release of case. Late returns cannot be accepted.								
Data Analysis:	Qualitative responses are assessed in terms of MI scoring for each scoring element in relation to the Designated Response.								
Performance Scoring:	MI scoring								
Criteria of Performance:	<p>Laboratory performance is classified in terms of OMIS derived from the qualitative responses for:</p> <ul style="list-style-type: none">• HEp-2 Cell Staining• Cell location of staining• Description of Nuclear staining pattern (Level 2)• Description of Nuclear staining pattern (Level 3) <p>over a running analytical window of 4 Distributions (12 months)</p> <p>The categories of performance are:</p> <table><tr><td>Total MIS</td><td></td></tr><tr><td>Good</td><td>zero</td></tr><tr><td>Adequate</td><td>1 - 2</td></tr><tr><td>Poor</td><td>>2</td></tr></table> <p>An OMIS of 2 or more for any one analyte will be classed as poor performance</p>	Total MIS		Good	zero	Adequate	1 - 2	Poor	>2
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Good	zero								
Adequate	1 - 2								
Poor	>2								
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions								