Digital ANA (dANA) - image based

Accreditation Status: *accreditation to ISO 17043 pending*

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: A digital based image programme. Includes identifying the presence and
identification of staining patterns in HEp-2 cell lines usings the ICAP system
(DA/601)
Multiple digital users can be registered.

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: Laboratory performance is classified in terms of OMIS derived from the
qualitative responses for:
- HEp-2 Cell Staining
- Cell location of staining
- Description of Nuclear staining pattern (Level 1)
- Description of Nuclear staining pattern (Level 2)

over a running analytical window of 4 Distributions (12 months)

The categories of performance are:

	Total MIS
Good	zero
Adequate	1 - 2
Poor	>2

An OMIS of 2 or more for any one analyte will be classed as poor performance

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