Survey for Antinuclear Antibodies (ANA)

EQA Provider: ESfEQA GmbH Heidelberg

Survey Coordinator: Dr. H. Depner

Instructions for Use

Notes:

The samples should be considered as potentially infectious. The usual precautions in the laboratory for potential hazardous samples apply for these samples. The blood donations used for production were found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. They should be applied by trained personnel only.

WARNING: Contains methylisothiazolones. H317 May cause allergic skin reaction.

This product contains human source material and should be considered as potentially infectious.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeqa.eu

1. Intended Use

The samples are intended for use as qualitative and quantitative control material for External Quality Assessment (EQA) in medical laboratories for the following parameters:

- ANA detection/screen
- ANA – IIFT Hep2 Pattern
  - General Pattern
  - Specific Nuclear Patterns
  - Specific Cytoplasmatic Patterns
- ANA titer (dominant pattern)
- ANA identification (qualitative, semi-quantitative, quantitative)
  - Anti-CENP-A
  - Anti-CENP-B
  - Anti-dsDNA
  - Anti-Jo1
  - Anti-RNP
  - Anti-Scl70
  - Anti-Sm
  - Anti-SSA (Ro)
  - Anti-SSB (La)

Please note that, in general, we will not issue a certificate of successful participation for the quantitative determination since the target values are reagent-specific and a bias to the calculated consensus value does not necessarily represent a poor laboratory performance. The statistical evaluation is for information purposes only.

2. Product Description

The liquid samples derive from defibrinated human plasma and are ready-to-use.

3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated below.

4. Sample Preparation and Analysis

Allow the sample to equilibrate to room temperature for 15 minutes prior to testing. Directly before use, agitate the sample by gently inverting the vial several times.

All samples should be treated the same way as patient samples and analysed in accordance with the instructions of the instrument and reagent manufacturer.

Users are encouraged to select the corresponding ANA-IIFT Hep2 Pattern according to the ICAP guidelines (these can be found on https://www.anapatterns.org/).

Users can select one or more of the following categories to describe the general staining pattern(s) observed: Negative, Nuclear, Cytoplasmic, Mitotic, or Unclassified. Where applicable, users are encouraged to further characterise the sample by selecting one or more specific Nuclear and/or Cytoplasmic patterns from the available options. If further characterisation is not applicable due to the nature of the sample, please select “Not applicable.”

Please note, that due to technical limitation the specific nuclear patterns options are divided into two sections.

5. Dates and Submission of Test Results

Testing Periods: Please refer to the sample labels. Results can be submitted anytime within the testing period indicated on the sample labels.

For the evaluation of survey results, please indicate the reagent and method used - indication of the instrument is optional - and submit your results electronically to ESfEQA at https://teqa-labv2.esfeqa.eu/

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance for the registration, configuration and result submission in TEQA. Alternatively, though not preferred, use the fax form provided on the ESfEQA website. In both cases indicate the reagent and method used for the analysis of the samples - indication of the instrument is optional.

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In TEQA, all entries are confirmed by pressing the button "confirm". The successful transmission of the results is indicated by “data saved”.

6. Deadline for Data Submission

The deadline for submitting results is indicated on the sample labels (time zone GMT +1).

7. Reports and Certificates

The data will be evaluated by ESfEQA. The individual laboratory reports and certificates can be retrieved online at https://teqa-labv2.esfeqa.eu/

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