



# MEMORANDUM

To: All Regional Medical Laboratory, Inc. (RML) Clients  
 From: Regional Medical Laboratory, Inc.  
 Sonya Bruening, BS, MLT (AMT), Manager of Immunology  
 Gerald C. Miller, PhD, Chief of Immunology and Microbiology  
 Date: July 3, 2019  
 Subject: **New Mini Anti-Nuclear Antibody Analyzer**

**Regional Medical Laboratory is pleased to announce the addition of a new analyzer algorithm for the determination of the presence of Anti-Nuclear Antibodies (ANA).** This new analyzer follows a different pathway than the original ANA analyzer. The mini-ANA analyzer was designed to provide for the different needs of client’s preferences and what each desires as the most appropriate for their patients. If in doubt, order the ANA analyzer or contact the physician to whom you will be referring.

The ANA Analyzer and Mini-ANA Analyzer both begin with an ANA Screen done by indirect immunofluorescence (IFA) for the detection of autoantibodies to cellular components/antigens. A positive ANA screen alone is insufficient for diagnosis of systemic autoimmune disease and should be further evaluated to determine the presence of any known specific autoantibody(s). To aid in efficient and appropriate further evaluation of such autoantibodies, the ANA analyzer and Mini-ANA analyzer were created to trigger additional testing based on the ANA screen findings.

The existing ANA analyzer (test code: 5524250) triggers different pathways of testing based upon the specific ANA screen pattern(s) and titers found – See RML Online for more details on this analyzer. **The new Mini-ANA analyzer was designed to provide a more consolidated and predictable approach to reflex testing of Positive ( $\geq 1:160$ ) ANA screens.** The Mini-ANA analyzer includes anti-ds DNA testing and an ENA screen on most positive ANA screens. It does not include reflex testing to C3/C4 at any point in the algorithm.

**The Mini-ANA Analyzer is designed to work as follows:**

Begin with an ANA Screen

- Negative ( $< 1:80$ ) --- Report, No Further Testing
- Positive ( $1:80$ ) --- Report, No Further Testing
- Positive ( $\geq 1:160$ ) and Dense Fine Speckled (DFS) Pattern --- Report, No Further Testing
- Positive ( $\geq 1:160$ ) and any pattern other than DFS --- Reflex to both:
  - Anti-ds DNA
  - ENA Screen, if positive reflex to Autoantibody Titers

ANA screen results and subsequent add on autoantibody results must always be interpreted in consideration with the clinical history of the patient.

**The Mini-ANA Analyzer will be available for use effective July 8, 2019, using the following test build information:**

Test Name	Mnemonic	Test Code	Specimen	Handling
Mini-ANA Analyzer	MINI-ANA AN	6907869	4.5 mL (2 mL min) Serum from clot activator SST.	Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transport refrigerated.

CPT codes will vary based on add on testing indicated. See RML Online for a complete listing of potential add on CPT codes.

For questions, concerns or additional information, please contact Dr. Gerald Miller at 918-744-2553 x15543 or Sonya Bruening at 918-744-2500 x18213.