



To: Penn Medicine Physicians and Staff

Date: 5/15/2023

From: Eline T. Luning Prak, MD, PhD
Joyce Gonzalez, BS, M(ASCP)

Re: Updated Reportable Range and Reporting for Antinuclear Antibody (ANA) Test

Beginning on May 18, 2023, Penn Medicine Pathology and Laboratory Medicine will be performing the Antinuclear Antibody Assay (ANA) using the automated Werfen QUANTA-lyser 3000 IFA analyzer, which replaces the current manual Indirect Immunofluorescence Antibody method. Validation studies showed good correlation between the two assays.

The reference range has changed from a positive titer cutoff of 1:160 for the old assay, to a positive titer of 1:80 for the new assay. The end point titer will now be 1:2560 for the new assay, instead of 1:20480.

Interpretive information for the new assay is as follows:

Negative: Negative

Weak positive: 1:80, 1:160

Positive: 1:320 or greater

In addition, comments for specific ANA patterns, both nuclear and cytoplasmic, have been updated, in accordance with recommendations from the International Consensus on ANA Patterns initiative.

The order codes and tube type (SST) will not change.

For clinical questions related to this change, please contact the Immunology Resident at 215-980-9871. For operational questions related to this change, please contact Joyce Gonzalez at Joyce.Gonzalez@pennmedicine.upenn.edu or 215-662-6023.