# Delays to Anti-nuclear antibody testing – Update 16th May 2023

We have been experiencing significant technical and analytical issues with the new multiplex ANA screen since its introduction in mid-January 2023.

We have noted issues with high rates of positivity and with dual positivity between dsDNA and Centromere and/or Scl-70 antibodies.  We therefore took the decision to stop processing and reporting ANA results from the Aptiva ANA screen until we were able to verify a second method for confirming positive results generated on the multiplex ANA method.

Negative ANA screen results will be reported with no further laboratory testing.  There is currently a 3 week delay in reporting these result.

Positive results will have confirmatory testing on a second analytical platform until issues with the multiplex method are resolved.  Our expected timeline for reporting positive ANA results is 4-6 weeks.

For patients where there is doubt over the diagnosis or where treatment is to be initiated, please send us a repeat sample so that we may confirm the results on a secondary ANA method or arrange referral of the sample to another laboratory if indicated.   Please discuss any urgent requests with the laboratory.

For patients tested between 16th January and 2nd May on the new ANA multiplex screen, consider repeat testing where results are inconsistent with previous results or if there is doubt over diagnosis.

Repeat testing is not indicated where positive ENA results were not confirmed by ANA by indirect immunofluorescence (IIF) and/or ENA immunblot (ie Negative ANA IIF and/or negative ENA antibody profile on immunoblot).  Repeat testing is not indicated where dsDNA Ab was positive but Crithidia or ANA by indirect immunofluorescence were negative.  These results suggest the positivity detected on the Aptiva multiplex screen are likely false positive.  However, if there is still a suspicion of connective tissue disease, please repeat the ANA screen.

For reported borderline positive ANA results please see the confirmatory ENA immunoblot /IIF results (higher specificity). Repeat ANA testing is not indicated where positive results are confirmed by ENA immunoblot / IIF methods.

Our apologies to you and your patients for any delay and worry caused by these issues with the ANA screen.  To discuss please contact either Drs Sujoy Khan or Pavels Gordins, or myself.

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