





From:

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Date:

24 July 2019

To: All COSs, DOMs & Medical staff, NTEC

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## Replacement of Indirect Immunofluorescent Assay (IFA) with Enzyme-linked Immunosorbent Assay (ELISA) for Anti-dsDNA Antibody Test Implementation Date: 29th July 2019

Antibodies against dsDNA is used as a diagnostic marker for systemic lupus erythematosus (SLE). For many years in our department, detection of such anti-dsDNA antibodies has been done by using the traditional method: *Crithidia luciliae*-based immunofluorescent assay (IFA), which requires visual interpretation and manual transcription of results. For the purpose of improving assay performance and enhancing service quality, we will be discontinuing this IFA and replacing it by an automatic ELISA (Anti-dsDNA-NcX ELISA, EUROIMMUN) for direct quantification of anti-dsDNA antibodies, with effect from 29<sup>th</sup> July 2019.

According to manufacturer's specification, this anti-dsDNA-NcX ELISA demonstrated superior sensitivity and specificity over the *Crithidia luciliae*-based IFA, or another very well recognized anti-dsDNA antibody detection method: the Farr assay. Based on our own laboratory evaluation, assay performance is comparable between the IFA method and the ELISA. For the implementation of this new ELISA method, reference interval will be revised; from <60 IU/mL to <100 IU/mL. Reportable range will also be updated from 50-1000 IU/mL to 10-800 IU/mL.

This new ELISA test can be requested electronically through the Generic Clinical Request System (GCRS) under the section <u>Immunology</u>, by the test-code <u>DNAE</u>. If there is any enquiry regarding the above modifications, please contact our Scientific Officer at 5569-9070. Thank you for your kind attention.

Sincerely yours,

Prof. Rossa WK CHIU

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