

Notification of Changes to Service Provision

Changes to dsDNA Antibody Tests

**01/06/2020**

Immunology

York Teaching Hospital NHS Foundation Trust

**Introduction**

In 2018 following a competitive tender that was awarded to Werfen Limited, Autoimmune serology undertook a major laboratory equipment upgrade replacing all platforms. Currently requests for Anti-dsDNA antibodies are screened for anti-nuclear antibodies (ANA) by indirect immunofluorescence (IIF) on Hep2 slides. The samples will be processed further for Anti-ds DNA and ENA antibodies only if immunofluorescence is positive. For anti-dsDNA, the next stage would be an ELISA assay on a DS-2 analyser. From 01/06/2020 we will be changing this method and platform to the chemiluminescence method on the Werfen BioFlash analyser for detecting anti-ds DNA.

The reference ranges for this test will also change:

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| --- | --- |
| **Anti-dsDNA Ab Reference range (DS-2 ELISA) (in-house current assay)** | **Anti-dsDNA Ab Reference range (BioFlash)**  **(New assay)** |
| <17.28 IU/ml : Negative | <27.00 IU/mL : Negative |
| 17.29 – 22.64 IU/mL : Equivocal | 27.00 – 35.00 IU/mL : Equivocal |
| 22.65- 31.85 IU/ml : Low Positive | >35.00 IU/mL : Positive |
| 31.85 - 87.23 IU/ml: Positive |  |
| >87.23 IU/ml: Strong Positive |  |
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Both the current and the new methodologies for detection and quantitation of anti-dsDNA Ab are traceable to the same WHO standard. However, as the manufacturer recommended cut-off for the new assay is higher than that of the current method, the new method may be less sensitive for the detection of anti-dsDNA than the previous assay. Therefore, please interpret all dsDNA Ab results in the context of ANA IIF and clinical details.

If you require further advice on the interpretation of these result please email [**Leedsth-tr.immunologyclinicalenquiry@nhs.net**](mailto:Leedsth-tr.immunologyclinicalenquiry@nhs.net)

Here is a summary of the dsDNA data. Overall agreement 86.5% (Equivocal results for both assays interpreted as negative). Review of clinical details for discrepant results suggest that the newer Bioflash assay is less sensitive in some cases but more sensitive in other cases. However, in those instances where the Bioflash assay was less sensitive and provided clinical details were suggestive of CTD, the ANA was positive by IIF at a high titre. Therefore, results of anti-dsDNA should be interpreted along with ANA by IIF particularly in patients with clinical features of CTD.

**Please note:**

Although the new assay has gone through a rigorous verification process, it is pending UKAS accreditation until further notice.

As the reference range has changed, we are aware that this could impact on patient treatment thus the immunology department will also offer a dsDNA value from the previous method on patients known to have CTD for a short period of time.

If you have any queries regarding the content of this notification then please do not hesitate to contact the laboratory using the contact details below.

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