

Notification of Changes to Service Provision

Changes to Rheumatoid Factor Antibody Tests

**19/10/2020**

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 Rheumatoid factor antibodies (IgM) are screened for by ELISA on the Dynex DS2. From the week commencing the 19/10/2020 we will be changing the Rheumatoid factor method and platform to the chemiluminescence method on the Werfen BioFlash analyser.

 The reference ranges for this test will also change:

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| --- | --- |
| **Anti-Rf Ab Reference range (DS-2 ELISA) (in-house current assay)** | **Anti-Rf Ab Reference range (BioFlash)****(New assay)** |
| <18.5 IU/ml : Negative | <5.00 IU/mL : Negative |
| 18.51 – 25.01 IU/mL : Equivocal | ≥5.00 IU/mL : Positive |
| 25.01- 34.5 IU/ml : Low Positive |  |
| 34.6 – 123.0 IU/ml: Positive |  |
| >123.0 IU/ml: Strong Positive |  |
|  |  |

The manufacturer recommended cut-off for the new assay is lower than that of the current method. Please interpret all Rf Ab results in the context of clinical details.

If you require further advice on the interpretation of these results please email steveholding@nhs.net

**Please note:**

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

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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