# Changes to York and Scarborough Immunology Laboratory Service

Following the formation of the combined Scarborough, Hull and York Pathology Service (SHYPS), the Immunology laboratory service has been consolidated onto a single site within the Blood Sciences Department at Hull Royal Infirmary.

Many elements of the Immunology of the service offered in York and now tested in Hull are the same but the main differences are highlighted below:

## Tests for Anti-nuclear antibody (ANA) \*Please note updated Aptiva multiplex screen and reference ranges in place form 9.10.2023 – see Appendix

Previously in York, ANA were screened using indirect immunofluorescence. If positive, specific ANA antibodies were reflex tested by the laboratory. These included dsDNA antibody and a panel of ENA antibodies (extractable nuclear antigens, eg Ro, La, Sm, RNP, Scl-70 and Jo-1).

In Hull, samples are screened for ANA using particle-based multi-analyte technology (PMAT, multiplex) on the Werfen Aptiva analyser. The Werfen Aptiva ANA assay can simultaneously detect the presence of autoantibodies to the following autoantigen specificities: DNA, Ro (SS-A) 60, Ro (SS-A) 52, La (SS-B), Sm, RNP, Scl-70, Jo-1, centromere (CENP-B) and ribosomal P. These specific ANA have greater association with connective tissue diseases. The reference ranges and units for ENA will change.

We have implemented a borderline range for the following autoantibody specificities:

* Borderline Ro, La, Sm, RNP, and Jo-1 will have confirmatory ENA immunoblot.

In rare instances where there is a strong clinical suspicion of underlying systemic autoimmune disease, but where the autoimmune screen by multiplex analyser produces a negative result, we can perform additional ANA testing by indirect immunofluorescence. If these are required clinically, arrangements can be made after discussion with the Immunology laboratory in Hull

Please see the separate advice document for advice on requesting and interpretation of ANA results.

## Testing for Coeliac Disease

Patients with suspected Coeliac disease will be tested for IgA anti-tissue transglutaminase (tTG) antibody on the Werfen Aptiva analyser. This method contains an integral IgA verification test which will flag any samples that are potentially IgA deficient. It is therefore unnecessary to request immunoglobulins when screening for Coeliac disease.

The Aptiva IgA tTG Ab test has a different normal range and reporting units to those previously reported by York.

In children 4 years of age and under, requests for coeliac screen in these patients will also generate IgG tTG Ab request. These tests will be automatically requested in the laboratory.

## Anti-CCP Antibody and Rheumatoid Factor

CCP

The same methodology is used for testing Anti-CCP Ab in Hull as previously used in York.

Hull report an indeterminant range between 10-19 CU. Positive CCP Ab are 20 CU and above as previously reported by York.

Rheumatoid factor will be tested on the Beckman chemistry analysers in Hull. The reference range will change from <5 IU/mL to **<15 IU/mL**.

Please see the NICE Clinical knowledge skills guidance on diagnosis and management of rheumatoid arthritis.

https://cks.nice.org.uk/topics/rheumatoid-arthritis/diagnosis/investigations-for-suspected-ra/

## ANCA Screen Testing

The initial ANCA screen will detect anti-MPO and PR3 antibodies on the Werfen Bioflash analyser. The reference ranges and reporting units will stay the same as previously reported by York.

ANCA (MPO/PR3) negative results will be reported and no further action taken.

ANCA positive for anti-MPO and PR3 Ab will be authorized with the comment ANCA by indirect immunofluorescence to follow.

## Urgent Samples (ANCA and GBM antibody)

The York/Scarborough Blood Sciences laboratory must be informed via phone of any urgent requests for immunology testing.

The requesting clinician, location and contact details (full phone number and nhs.net email address) MUST be provided on the request form to ensure timely reporting of the results.

The Immunology laboratory at Hull does not provide an out of hours service – the laboratory is open 08.30 – 17.00 hrs Monday – Friday therefore samples received in York or Scarborough after 2pm will be testing on the next working day.

## Laboratory Contact Information

York Blood Sciences

Laboratory (01904 72) 6802

Scarborough Blood Sciences

Laboratory: (01723 34) 2625

Hull Immunology

Laboratory: 01482 607768

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## Appendix

**Anti-nuclear Antibody Screen – Aptiva multiplex assay**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Reference ranges | | |  |
| Antibody | Negative | Intermediate/Borderline | Positive | Units |
| Anti-dsDNA antibody | <27 | 27-35 | > =  35 | IU/mL |
| Anti-Ro60 (SSA) Antibody | <15 | 15-30 | ≥ = 30 | U |
| Anti-Ro52 antibody | <5 | 5-30 | ≥ = 30 | U |
| Anti-La (SSB) antibody | <5 | 5-30 | ≥ = 30 | U |
| Anti-Sm antibody | <5 | 5-30 | ≥ = 30 | U |
| Anti-RNP antibody | <15 | 15-30 | ≥ = 30 | U |
| Anti-Jo-1 antibody | <5 |  | ≥ = 5 | U |
| Anti-Scl-70 antibody | <15 | 15-30 | ≥ = 30 | U |
| Anti-centromere antibody | <5 |  | >=5 | U |
| Anti-Ribosomal P antibody | <5 | 5-15 | ≥ = 15 | U |

Borderline ENA results (except Ribosomal P antibodies) are confirmed by ENA immunoblot method.

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| --- | --- |
| **Test** | **New reference range/units** |
| **Coeliac Screen** |  |
| IgA tissue transglutaminase | Negative <5 Units  Positive ≥5 Units |
| IgG tissue transglutaminase | Negative <5 Units  Positive ≥5 Units |
| **Anti-phospholipid antibodies** |  |
| IgG cardiolipin | Negative <20 CU  Positive ≥20 CU |
| IgG Beta-2-glycoprotein 1 | Negative <20 CU  Positive ≥20 CU |
| **Anti-CCP Ab** | Negative <10 CU  Indeterminant 10-20 CU  Positive ≥20 CU |
| **Rheumatoid Factor** | Negative <15 IU/mL |
| **ANCA MPO and PR3 Ab** | Negative <20 CU  Positive ≥20 CU |
| **Anti-GBM Ab** | Negative <20 CU  Positive ≥20 CU |