IMMF358 Version 2

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Dear RUH Immunology Laboratory Service Users,

## Changes to systemic autoimmune rheumatic disease autoantibody testing in Bath from 27th May 2026

As has been proposed across the region for the past few years, the testing pathway for the investigation of suspected systemic autoimmune rheumatic diseases / connective tissue disease (SARD/CTD) is changing. This includes autoantibody testing for the investigation of Sjogren disease (SjD), systemic sclerosis (SSc), inflammatory myositis, anti-synthetase syndrome (ASyS), systemic lupus erythematosus (SLE) and mixed connective tissue disease (MCTD). This does not include rheumatoid arthritis serology.

In addition to the changes in the testing pathway, the site of testing will also switch from RUH Bath Immunology to the Immunology & Immunogenetics department at Southmead Hospital, North Bristol Trust (NBT).

### 1. Primary Care Changes (RUH-facing GP practices)

From the date specified, **anti-nuclear antibodies (ANA)** will no longer be provided by indirect immunofluorescence (IIF) using the HEp-2 cell substrate. CTD antibody testing will instead be provided using a multi-antibody immunoassay (Thermofisher Scientific EliA CTD screen). The new method will detect the following panel of autoantibodies: anti-U1-RNP, Ro60/SS-A, Ro52, La/SS-B, centromere, Scl-70, Jo-1, U3-RNP, RNA-Pol III, Ribo-P, PM-Scl, PCNA, Mi2, Sm (Smith) and double stranded DNA antibodies.

These changes will introduce automation to the antibody serology laboratory and shorten results turnaround times. In addition, we expect the changes to reduce the number of weak positive clinically insignificant ANAs generated in primary care that can result in diagnostic uncertainty and unnecessary referrals to secondary care.

**Negative results generated by the new GP SARD/CTD testing pathway:** The EliA CTD screen includes a selection of the most common autoantibodies found in SARD/CTD. As with current testing methods, a negative result does not entirely exclude SARD/CTD, especially the autoimmune myositis and systemic sclerosis spectrum. **If a high index of suspicion for autoimmune rheumatic disease remains (e.g. late-onset Raynaud's, unexplained elevated creatine phosphokinase, pulmonary fibrosis, photosensitive rashes, unexplained proteinuria and/or any other features consistent with SARD/CTD), then please contact the NBT Immunology & Immunogenetics laboratory to arrange further investigations and discuss with Rheumatology team via the Advice & Guidance system.**

**Positive results generated by the new GP SARD/CTD testing pathway:** Samples with positive EliA CTD screens will receive further investigation in the laboratory to confirm the results and determine the specificity of the autoantibody in question, this will include, but not be limited to, indirect immunofluorescence (IIF) using the HEp-2 cell substrate, extractable nuclear antigen (ENA) antibody screening, double stranded DNA (dsDNA) antibodies as well multi-analyte autoantibody immunoblotting where appropriate (autoantibody immunoblotting is detailed below).

These changes will only apply to GP practices that currently use the laboratories at Royal United Hospitals, Bath from the date specified.

## 2. Secondary Care Changes (RUH)

The principles of autoantibody testing for suspected systemic autoimmune rheumatic disease will remain the same for secondary care, with initial investigations based on the ANA screen using indirect immunofluorescence (IIF) on a HEp-2 cell substrate. However, some of the laboratory methods and instruments used to deliver this pathway are changing:

- **ANA testing**: EUROImmun HEp-2 cell using digital indirect immunofluorescence by EUROPattern Live digital microscopy. Reporting using International Consensus on ANA patterns (ICAP) terminology.
- **ENA screening**: Thermofisher Scientific EliA Symphony immunoassay (inc. Ro60/SS-A Ro52, La/SS-B, U1RNP, Sm, centromere, Scl-70 and Jo-1).
- **ENA typing**: EUROImmun EUROLINE ANA5 immunoblot (inc. anti-nRNP/Sm, Sm (Smith), U1-RNP (RNP70, RNPA, RNPC), Ro-60 (SS-A), Ro-52, La (SS-B), Scl-70, PM-Scl, Jo-1, centromere CENP-B, *PCNA**, *dsDNA**, *nucleosomes**, *histones**, *ribosomal P-proteins** & *AMA-M2**).

  **Please note that these antibodies are not part of the routine ENA typing antibody panel and are only reported under specific circumstances.*
- **Systemic sclerosis antibody panel**: EUROImmun EUROLINE SSc immunoblot (inc. anti-Scl-70, CENP-A, CENP-B, RNA polymerase III (RP11 & RP155), U3-RNP (Fibrillarin), NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, NVL & Ro-52).
- **Myositis antibody panel**: EUROImmun EUROLINE myositis immunoblot (inc. anti-Mi-2 alpha, Mi-2 beta, TIF1g, MDA5, NXP2, SAE1, Ku, PM-Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52, cN-1A, Ha, Ks & Zo).
- **Crithidia**: EUROImmun *Crithidia luciliae* indirect immunofluorescence by EUROPattern Live digital microscopy.
- **Double stranded DNA (dsDNA) antibody testing**: Thermofisher Scientific EliA dsDNA IgG immunoassay.

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**Please note that the numerical results generated by the new dsDNA method (reported in IU/mL) will not be comparable to the values generated by the current RUH dsDNA methods.** This is particularly important for established SLE patients who receive sequential monitoring of dsDNA antibody titres. In these cases, the patients should be tested using the new method to establish their current baseline dsDNA antibody concentration.

The reference intervals (ranges) for dsDNA antibodies are also changing. Your current ranges are being replaced by the following:

- **Negative: <10 IU/mL**
- **Equivocal: 10 - 15 IU/mL**
- **Positive: >15 IU/mL**

Please note that the well-established limitations concerning dsDNA antibody testing by immunoassay remain: A diagnosis of SLE should not be made on the basis of a positive dsDNA antibody result in isolation and SLE is not excluded by a negative dsDNA result. All dsDNA results should continue to be interpreted in the context of the clinical picture as well as supporting laboratory information including ANA (HEp-2 indirect immunofluorescence), ENA, serum complement C3 and C4 levels and *Crithidia luciliae* fluorescence, where appropriate.

**When?** Changes to the RUH SARD/CTD autoantibody testing pathway will go live on **Wednesday 27th May**.

We accept that this represents a significant amount of change to your historical antibody testing pathways. Please feel free to contact us if you wish to discuss these changes further.

Kind regards

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