North Bristol NHS Trust

IMMF358 Version 2

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Dear RUH Immunology Service Users,

IgG coeliac autoantibodies: notification of change in method and site of testing

What is changing? IgG coeliac antibody testing is currently provided by RUH Bath Immunology laboratory using indirect immunofluorescence methods. From 20th April this service will be moving to the Immunology & Immunogenetics laboratory, Southmead Hospital at North Bristol Trust. We will also be switching from the current anti-endomysial IgG antibodies by indirect immunofluorescence (primate oesophagus tissue, Inova Diagnostics) to the EliA IgG Celikey anti-human tissue transglutaminase (IgG-tTG) immunoassay (Thermofisher Scientific).

Please note this change only refers to the IgG coeliac antibody tests that are reflexed in the laboratory in the context of a low serum Immunoglobulin A (IgA) concentration. This change does not concern the coeliac antibodies you would request as part of routine coeliac antibody screening (IgA anti-tissue transglutaminase testing).

The new methods will introduce assay automation and increase testing capacity, reduce result turnaround times and should also provide a greater level of diagnostic accuracy by reducing assay interference (from other autoantibodies and pro-zoning). The assay switch will also align us with the majority of other UK clinical laboratories using automated immunoassays for IgG coeliac antibody testing.

Will I notice any differences to my IgG coeliac antibody results? How the test is used is not changing: IgG coeliac serology will remain an infrequent reflex test used by the laboratory when a low serum Immunoglobulin A (serum IgA <0.2 g/L) is detected in the context of coeliac antibody testing.

Once the new assay is implemented, IgG coeliac serology will be reported as a numerical value in U/mL. The reference ranges are listed below:

- **Negative: < 7 U/mL**
- **Equivocal: 7 – 10 U/mL**
- **Positive: >10 U/mL**

Please note that some of the limitations around IgG coeliac serological results will remain:

- All **IgG coeliac antibody** tests have widely variable clinical sensitivity (13-99%)[1]; therefore, a negative test result does not reliably exclude coeliac disease. In the case of negative IgG-tTG results (in the context of a low serum IgA concentration <0.2 g/L), if a high index of suspicion remains the patient should be considered for referral to a GI specialist for further investigations.

- A positive IgG coeliac serology result (even at high titres) is insufficient in isolation to make a diagnosis of coeliac disease. Patients with positive IgG coeliac serology should be referred to a GI specialist for confirmatory investigations if clinically indicated.

- Unlike IgA-tTG antibodies, the relationship between IgG-tTG antibodies and coeliac disease activity and/or dietary compliance is uncertain. We do not recommend IgG-tTG antibody levels are serially monitored to determine coeliac disease activity nor patient compliance to a gluten-free diet.

When? The new method for measuring IgG antibodies in coeliac disease will go live for RUH users on **20th April 2024**.

Please feel free to contact me if you wish to discuss this matter further.

Kind regards

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1) Fasano A, Catassi C. Clinical practice. Celiac disease. N Engl J Med. 2012 Dec 20;367(25):2419-26