**Issues the Coeliac Disease Antibody Screening Test: February 2024**

1. Coeliac Disease Antibody Screening Test: Low IgA Concentration

2. Coeliac Screen (anti-IgA tTG antibody): Patient less than 3 years of age

1. Coeliac Disease Antibody Screening test: Low IgA Concentration

An issue has been identified with our coeliac disease screening test, IgA-Anti-tissue transglutaminase (tTG) antibody.

The method for detecting IgA-anti-tTG antibody has an in-built control to flag samples with low concentrations of IgA as an assay verification step. We have identified this control flag is only highlighting samples that are deficient in IgA (<0.02 g/L) but not those with a measurable but low concentration of IgA (0.2 g/L of IgA or less).

In patients found to have low IgA or are IgA deficient, a second line IgG-anti-tTG antibody test is usually performed, as a deficient or low IgA concentration invalidates the IgA method.

**There is therefore a risk that false negative anti-IgA tTG results may have been reported in patients for whom the second line IgG anti-tTG antibody test was not performed.**

The current coeliac screen was introduced in January 2023. If you have a patient with a high degree of clinical suspicion for coeliac with a negative IgA TTG result and no IgG TTG or IgG EMA result, then please consider repeat testing (and also check immunoglobulins).

Going forward, we are confident that the IgA anti-tTG antibody test will detect IgA deficient patients. For all children under 4 years of age, the second line IgG anti-tTG antibody test will be requested, IgA will be measured on all paediatric patients (<17 years), and any patient found to have an IgA concentration <0.2g/L will have IgG TTG antibody measured.

2. Coeliac Screen (anti-IgA tTG antibody): Patient less than 3 years of age

The ESPGHAN New Guidelines for the Diagnosis of Paediatric Coeliac Disease (2022) recommends the combination of total IgA and IgA class antibodies against transglutaminase 2 (tTG-IgA) for initial testing. In children with low total IgA concentrations (low for age or <0.2 g/L above the age of 3 years), an IgG-tTG test should be performed as a second step.

Prior to the York Immunology service transferring to Hull in March 2023, for the coeliac screen, all children under 16 years of age would also have IgA requested. If a low/undetectable IgA concentration was detected, patients would have second line IgG endomysial Ab.

The method for detecting IgA-anti-tTG antibody in Hull has an in-built control to flag samples with low concentrations of IgA as an assay verification step, therefore IgA is not routinely requested as part of the Coeliac screen. In addition, in Hull, patients under 4 years of age have both IgA and IgG anti-tTG antibodies tested, so not to miss any potential patients with low IgA concentration.

Between July 2023 and January 2024, we have not automatically performed IgG TTG in children <4yrs of age. Therefore, we have some concerns that false negative anti-IgA TTG results may have been reported without second line IgG TTG testing being performed. The risk is very low, <0.5%. Out of 427 patients less than 4 years of who had had both IgA and IgG tTG antibody test, 2 had a negative IgA tTG and positive IgG tTG.

**If you have a patient with a high degree of clinical suspicion for coeliac with a negative IgA TTG result and no IgG TTG or IgG EMA result, then please consider repeat testing (and check immunoglobulins).**

The second line IgG tTG test is now requested on all patients under 4 years and additionally IgA will be measured on all request for patients under 17 years of age (Please also see the communication re: issues identified with the low IgA flag).

If you have any questions or to discuss, please contact the Immunology via email: anna.mchugh@nhs.net