Immunology Tests

Coeliac Disease Tests
Following a review of current trends the following changes will be implemented. All Coeliac requests will have tissue transglutaminase IgA (tTg IgA) and Deamidated Gliadin Peptide IgG (DGP IgG) tested. Any positive tTg IgA will also have an Endomysial IgA (EMA IgA) test performed. However we will be looking at the relevance of continuing with the EMA IgA test.
The tTg IgA and DGP IgG methodology will be changed from the current ELISA methodology to the Phadia 250 ImmunoCap Elia analyser. This utilizes a Fluoroenzymeimmunoassay principle. The Elia is very similar in principle to the standard ELISA.
Expected values generated by the Phadia 250 for both the tTg IgA and DGP IgG will be about half those currently reported from the ELISA test.
Result interpretation for both tTg IgA and DGP IgG is:
   Negative <7, Equivocal 7 - 10 and Positive >10
The sensitivity of this new assay may also enable the detection of an IgA deficiency. When this is suspected we will do a total serum IgA.

Anti CCP
This test will change from the Abbott Architect CMIA test to the Phadia 250 ImmunoCap Fluoroenzymeimmunoassay method.
Expected values generated by the Phadia 250 will be about twice of those currently reported from the Architect.
Result interpretation is - Negative <7, Equivocal 7 - 10 and Positive >10

ANCA
The screen test will change from the current ELISA methodology to the Indirect ImmunoFluorescence Antibody test (IFA). Any screen test that is not clearly negative will then have the individual MPO and PR3 tests. These tests will change from the current ELISA methodology to the Phadia 250 ImmunoCap Fluoroenzymeimmunoassay method.
Expected values generated by the Phadia 250 will be about 40% less than those currently reported from the current ELISA method.
Result interpretation is –
MPO - Negative <3.5 , Equivocal 3.5 – 5.0 and Positive >5.0
PR3 - Negative <2.0 , Equivocal 2.0 – 3.0 and Positive >3.0

dsDNA
This test will change from the current ELISA methodology to the Phadia 250 ImmunoCap Fluoroenzymeimmunoassay method.
Expected values generated by the Phadia 250 will be about ± 20% of those currently reported from the ELISA method.
Result interpretation is - Negative <10, Equivocal 10 – 15 and Positive >15
ANA
Following a meeting of the local (Waikato, Bay of Plenty and Rotorua) Rheumatologists in early July the following changes have been proposed.
When considering an ANA request only the following clinical presentations are deemed to be relevant.

When to request ANA
- Systemic inflammatory signs that are not related to infection
- Mouth ulcers, hair loss
- Chronic suggestive rashes or erythema (photosensitive, urticarial)
- Inflammatory Arthritis
- Sicca Symptoms (Xerostomia, Xerophthalmia)
- Unexplained serositis (pleuritis/pericarditis)
- Possible autoimmune liver disease
- Glomerular disease (haematuria/casts, proteinuria)
- Myositis (raised CK and weakness)
- Skin thickening
- Raynaud’s phenomenon
- Interstitial lung disease
- Leukopenia, lymphopenia or haemolytic anaemia

When not to request ANA
- For monitoring a connective tissue disease
- Screening for CTD when someone already has another autoimmune condition such as Coeliac disease, type 1 Diabetes or Autoimmune Thyroid disease.
- “Tiredness”
- Other forms of arthritis
  - Gout
  - OA
- Other symptoms/signs that remains unexplained.

For demand management of ANA, ENA and anti dsDNA to encompass the following
- ANA/ENAs: Two requests will be allowed initially. After that an ANA will only be performed after 9 months. Serum will be stored for 14 days if required but will need discussion with the Immunology department at Pathlab Waikato prior to additional testing.
- Anti-dsDNA antibodies no more frequently than 6 weeks and again serum will be stored for 14 days.
- Anti-dsDNA antibodies, will only be performed if previously positive, on known SLE patients or if ANA is positive. Serum will be stored for 14 days.
- ENA will only be performed if ANA positive but we will check that this can be validated. If no previous ANA result available then the ANA test will be added. Only if this ANA result is positive will the ENA test be performed. Note the biggest risk is around Jo-1 and missing a subtle cytoplasmic pattern.
- If requests under the following are received – Auto-immune Profile/Screen, Autoantibody Profile/Screen, Renal Autoimmune screen, Autoantibodies then the following comment will be reported together with the ANA result.
  “Autoimmune/Autoantibody screen- This type of request is not helpful for the laboratory to determine the exact tests that are needed. However, an ANA test has been completed. The sample will be stored for 14 days should further testing be required.
- ANA positive screens will be titred. However if high titres are encountered they will be reported as >1280.
- ENA and dsDNA tests will not be automatically added to any Positive ANA results.
Tissue Antibody Requests
Requests for these tests will now only generate Parietal Cell Antibody/Gastric Parietal Cell (PCA/GPC), Anti Mitochondrial Antibody (AMA) and Smooth Muscle Antibody (SMA) tests. The other tests (ANA and Thyroid antibody) can still be requested individually if required.

Requests for Tissue Autoantibody screen will have the Tissue antibody tests completed and the following comment. “Ordering “Tissue Autoantibodies” is discouraged as it is better to order the specific autoantibodies related to the diagnosis in question. The sample will be stored for 14 days. If further testing would be helpful please contact the Immunology department at Pathlab Waikato.

Cytoplasmic Staining
When Reticulin staining is observed in tissue MKS slides then this staining pattern will no longer be commented on. However past test history will be reviewed. As approximately 60% of Coeliac patients exhibit Positive Reticulin antibodies, if no previous coeliac testing has been done then these tests will be added.

When Vimentin staining is observed in Hep 2 ANA slides then this staining pattern will no longer be specifically noted. It will simply be reported as cytoplasmic staining present. However when Actin staining is observed then this will still be specifically reported.

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