Autoimmune diseases are a broad range of related diseases in which a person’s immune system produces an inappropriate response against its own cells, tissues and/or organs, resulting in inflammation and damage. There are over 80 different autoimmune diseases, and these range from common to very rare diseases. Some autoimmune diseases affect mainly one part of the body (e.g. organ-specific such as multiple sclerosis which attacks the nervous system, autoimmune thyroid disease, and Crohn’s disease which is localized to the gastrointestinal tract) whilst others are systemic (such as systemic lupus erythematosus, rheumatoid arthritis and systemic vasculitis).

Systemic autoimmune diseases can affect many body organs and tissues at the same time and they are broadly classified into rheumatological/connective tissue disease and vasculitis (inflammation of blood vessels). Autoimmune diseases collectively affect approximately 5% to 10% of the population of the developed world. Common autoimmune diseases such as thyroiditis, rheumatoid arthritis and diabetes affect more than 1 in 100 people. In contrast, a rare autoimmune disease such as Goodpasture’s disease (a form of vasculitis) affects around 1 in a million people. Autoimmune diseases disproportionately affect women at a rate of 2-9X greater than for men.

### DIAGNOSTICS

Autoimmune diseases are usually diagnosed using a combination of clinical history, blood tests (autoantibodies, inflammation, organ function) and other investigations such as x-rays. Specifically, autoantibodies act as biomarkers helping to diagnose disease subsets and monitor autoimmune diseases. Many autoantibodies have well-defined target antigens and can be detected with high analytical sensitivity for a particular disease.

<table>
<thead>
<tr>
<th>Category</th>
<th>Disease</th>
<th>Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connective Tissue Disease</td>
<td>Includes rheumatoid arthritis, systemic lupus erythematosus (SLE), scleroderma, and other systemic autoimmune diseases.</td>
<td>Anti-cytoplasmic antigens (c-ANCA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perinuclear antigens of neutrophils (p-ANCA)</td>
</tr>
<tr>
<td>Vasculitis</td>
<td>Inflammation in the blood vessels which can lead to serious consequences such as aneurysms.</td>
<td>Anti-cardiolipin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anti-β2 glycoprotein 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anti-prothrombin (aPT)</td>
</tr>
<tr>
<td>Anti-Phospholipid</td>
<td>Blood clotting disorders, such as Anti-Phospholipid Syndrome (APS) which is a hypercoagulable state caused by antiphospholipid antibodies.</td>
<td>Cardiolipin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>β2-glycoprotein 1</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Localized disorders that attack the gastrointestinal track such as Celiac Disease, Crohn’s Disease, ulcerative colitis or inflammatory bowel disease (IBS).</td>
<td>Tissue transglutaminase (tTG)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Liver-kidney microsomal type 1 (LKM-1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>pANCA</td>
</tr>
<tr>
<td>Endocrine</td>
<td>Thyroid diseases (e.g. Hashimoto’s and Graves’ diseases), diabetes, adrenal fatigue, osteoporosis, infertility, polycystic ovary syndrome, and several others. Hashimoto’s and Graves’ diseases are the most common autoimmune diseases.</td>
<td>Glutamic acid decarboxylase (GAD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tyrosine phosphatase-like islet cell antigen (IA2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thyroid peroxidase (TPO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thyroglobulin</td>
</tr>
</tbody>
</table>
### CONNECTIVE TISSUE DISEASE

<table>
<thead>
<tr>
<th>Antibody Type</th>
<th>Ag Type</th>
<th>Source</th>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNP/Sm Ag</td>
<td>Native Ag (Calf Thymus)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Human anti-RNP Ag</td>
<td>Human Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sm (Smith) Ag</td>
<td>Native Ag (Calf Thymus)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Human anti-Sm Ag</td>
<td>Human Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SS-A (Ro) Ag</td>
<td>Native Ag (Calf Thymus)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Human anti-Ro (SS-A) Ag</td>
<td>Human Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SS-B (La)</td>
<td>Rec. Ag (Insect Cells)</td>
<td>&gt;85%</td>
<td></td>
</tr>
<tr>
<td>Human anti-SS-B Ag</td>
<td>Human Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scl-70</td>
<td>Native Ag (Calf Thymus)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Human anti-Scl-70 Ag</td>
<td>Human Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jo-1</td>
<td>Native Ag (Calf Thymus)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Human anti-Jo-1 Ag</td>
<td>Human Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ribosomal P-proteins</td>
<td>Rec. Ag (Insect Cells)</td>
<td>&gt;85%</td>
<td></td>
</tr>
<tr>
<td>Human anti-Ribosomal P Ag</td>
<td>Human Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dsDNA</td>
<td>Native Ag (E.coli)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Ro52</td>
<td>Rec. Ag (Sf21 Insect Cells)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Proliferating Cell Nuclear Ag (PCNA)</td>
<td>Rec. Ag (Insect Cells)</td>
<td>&gt;85%</td>
<td></td>
</tr>
<tr>
<td>Rec. Ag (Sf21 Insect Cells)</td>
<td>&gt;90%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M1M20-912 MAb to PCNA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAM21-964 MAb to PCNA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Histone</td>
<td>Native Ag (Calf Thymus)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Complement C1q</td>
<td>(Human Plasma)</td>
<td>&gt;95%</td>
<td></td>
</tr>
<tr>
<td>Sheep anti-Complement C1q</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C3</td>
<td>Goat anti-C3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C4</td>
<td>Goat anti-C4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>U1-snRN C</td>
<td>Rec. Ag (Insect Cells)</td>
<td>&gt;85%</td>
<td></td>
</tr>
</tbody>
</table>

### VASCULITIS

<table>
<thead>
<tr>
<th>Antibody Type</th>
<th>Ag Type</th>
<th>Source</th>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annexin</td>
<td>Native Ag (Human neutrophils)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacterial permeability increasing factor (BPI)</td>
<td>Native Ag (Human neutrophils)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Cathepsin G</td>
<td>Native Ag (Human neutrophils)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactoferrin</td>
<td>Rabbit anti-Human Lactoferrin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lysozyme</td>
<td>Native Ag (Human neutrophils)</td>
<td>&gt;95%</td>
<td></td>
</tr>
<tr>
<td>Myeloperoxidase (pANCA)</td>
<td>Native Ag (Human neutrophils)</td>
<td>&gt;95%</td>
<td></td>
</tr>
<tr>
<td>Prothrombin</td>
<td>Native Ag (Human Plasma)</td>
<td>&gt;95%</td>
<td></td>
</tr>
<tr>
<td>Proteinase 3 (cANCA)</td>
<td>Native Ag (Human neutrophils)</td>
<td>&gt;90%</td>
<td></td>
</tr>
</tbody>
</table>

### ANTI-PHOSPHOLIPID SYNDROME

<table>
<thead>
<tr>
<th>Antibody Type</th>
<th>Ag Type</th>
<th>Source</th>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>β2-glycoprotein-1</td>
<td>Native Ag (Human Plasma)</td>
<td>&gt;95%</td>
<td></td>
</tr>
</tbody>
</table>

### GASTROENTEROLOGY

<table>
<thead>
<tr>
<th>Antibody Type</th>
<th>Ag Type</th>
<th>Source</th>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue Transglutaminase (tGT)</td>
<td>Rec. Ag (Sf21 Insect Cells)</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Calprotectin</td>
<td>Native Ag (Human neutrophils)</td>
<td>&gt;90%</td>
<td></td>
</tr>
</tbody>
</table>

### CHRONIC INFLAMMATORY BOWEL DISEASE

<table>
<thead>
<tr>
<th>Antibody Type</th>
<th>Ag Type</th>
<th>Source</th>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glomerular Basement Membrane (GBM)</td>
<td>Native Ag (Bovine Kidney)</td>
<td>&gt;90%</td>
<td></td>
</tr>
</tbody>
</table>

### ENDOCRINOLOGY

<table>
<thead>
<tr>
<th>Antibody Type</th>
<th>Ag Type</th>
<th>Source</th>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thyroid Peroxidase (TPO)</td>
<td>Rec. Ag</td>
<td>&gt;95%</td>
<td></td>
</tr>
<tr>
<td>Thyroglobulin (TG)</td>
<td>Native Ag (Human Thyroid Tissue)</td>
<td>&gt;99%</td>
<td></td>
</tr>
</tbody>
</table>