

TEST UPDATE

New Autoantibody Testing for VASCULITIS and IBD

UVMMMC

On 12/6/23, the UVMMMC Immunology Laboratory will be transitioning its ELISA-based, autoantibody testing on the Dynex DSX to a new chemiluminescent immunoassay platform, the Inova Diagnostics Bioflash. This will affect the following autoantibody tests: **dsDNA, tTG IgA, SSA, SSB, Sm, and RNP**. In addition, we will be bringing MPO and PR3 autoantibody testing in-house instead of sending the testing to Mayo Clinic Laboratories. This testing will now be offered daily M-F instead of batched and run 2-3 times per week. Comparison studies performed between the old Dynex DSX and new Inova Bioflash platform show good correlation.

| Test | Old Reference Range (All ages) | New Reference Range (All ages) |
|--|---|--|
| dsDNA Ab, IgG | Negative: <30.0 IU/mL Borderline Positive: 30.0-75.0 IU/mL Positive: >75.0 IU/mL | Negative: <27 IU/mL Indeterminate: 27-35 IU/mL Positive: >35 IU/mL |
| Tissue Transglutaminase (tTG) Ab, IgA | Negative: <4 U/mL Weak Positive: 4-10 U/mL Positive: >10 U/mL | Negative: <20 CU Weak Positive: 20-30 CU Positive: >30 CU |
| SSA Ab, IgG (now Ro52 Ab, IgG and Ro60 Ab, IgG) | Negative: <20 Units Weak Positive: 20-39 Units Moderate Positive: 40-80 Units Strong Positive: >80 Units | For Both Ro52 and Ro60 Negative: <20 CU Positive: >= 20 CU |
| SSB (La) Ab, IgG | Negative: <20 Units Weak Positive: 20-39 Units Moderate Positive: 40-80 Units Strong Positive: >80 Units | Negative: <20 CU Positive: >= 20 CU |
| Sm (Smith) Ab, IgG | Negative: <20 Units Weak Positive: 20-39 Units Moderate Positive: 40-80 Units Strong Positive: >80 Units | Negative: <20 CU Positive: >= 20 CU |
| RNP Ab, IgG | Negative: <20 Units Weak Positive: 20-39 Units Moderate Positive: 40-80 Units Strong Positive: >80 Units | Negative: <20 CU Positive: >= 20 CU |
| Myeloperoxidase (MPO) Ab, IgG | Negative: <0.4 U Equivocal: 0.4-0.9 U Positive: >= 1.0 U | Negative: <= 5.97 IU/mL Positive: > 5.97 IU/mL |
| Proteinase 3 (PR3) Ab, IgG | Negative: <0.4 U Equivocal: 0.4-0.9 U Positive: >= 1.0 U | Negative: <= 5.0 IU/mL Positive: > 5.0 IU/mL |

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The primary difference is how SSA testing is performed. In the current assay, the Ro52 and Ro60 kDa proteins are combined and these are not differentiated in a positive SSA result. On the Inova Bioflash, Ro52 and Ro60 are resulted individually. This allows the clinician to distinguish the Ro52 antibodies seen in higher frequency among patients with systemic sclerosis and idiopathic inflammatory myopathies.

| Orderable to be Inactivated | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|-----------------------------|-----------|------------|----------------|-------------|----------|
| SSA Abs by ELISA | LAB2377 | SSAA | FAH5607 | 33569-5 | 86235 |

| New Orderable | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|--|-------------|-------------|----------------|--------------|----------|
| Ro52 Ab, IgG | LAB17611 | LAB17611 | FAH6102 | 70257-1 | 86235 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Ro52 Ab, IgG | 12301020075 | 12301020075 | FAH6122 | 70257-1 | |
| Specimen Requirements: | | | | | |
| Container | Specimen | Temp | Collect Vol | Submit Vol | Min Vol |
| SST (preferred) or Red Top | Serum | Frozen | 2.0 mL | 1.0 mL | 0.5 mL |
| Collection Instructions: | | | | | |
| Serum should be separated from the clot within 4 hours of collection. Store samples at room temperature no longer than 8 hours . If the assay will not be completed within 8 hours , refrigerate the sample at 2-8°C. If the assay will not be completed within 48 hours , or for shipment of the sample, freeze at -20°C or lower. | | | | | |

| New Orderable | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|--|-------------|-------------|----------------|--------------|----------|
| Ro60 Ab, IgG | LAB17612 | LAB17612 | FAH6103 | in process | 86235 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Ro60 Ab, IgG | 12301020076 | 12301020076 | FAH6123 | in process | |
| Specimen Requirements: | | | | | |
| Container | Specimen | Temp | Collect Vol | Submit Vol | Min Vol |
| SST (preferred) or Red Top | Serum | Frozen | 2.0 mL | 1.0 mL | 0.5 mL |
| Collection Instructions: | | | | | |
| Serum should be separated from the clot within 4 hours of collection. Store samples at room temperature no longer than 8 hours . If the assay will not be completed within 8 hours , refrigerate the sample at 2-8°C. If the assay will not be completed within 48 hours , or for shipment of the sample, freeze at -20°C or lower. | | | | | |

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The ENA Panel (LAB3983) and SSA/SSB Panel (LAB3356) but will still be available as stand-alone orderables, with Ro52 and Ro60 replacing the SSA result.

| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|-------------------------|-------------|-------------|----------------|--------------|----------|
| ENA Antibody Panel | LAB3983 | LAB3983 | FAH6111 | in process | 86235x5 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Ro52 Ab, IgG | 12301020075 | 12301020075 | FAH6122 | 70257-1 | |
| Ro60 Ab, IgG | 12301020076 | 12301020076 | FAH6123 | in process | |
| SS-B (La) Ab, IgG | 12301020072 | 12301020072 | FAH6124 | 29965-1 | |
| Sm (Smith) Ab, IgG | 12301020070 | 12301020070 | FAH6125 | 33564-6 | |
| RNP Ab, IgG | 12301020071 | 12301020071 | FAH6126 | 29958-6 | |

| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|-------------------------|-------------|-------------|----------------|--------------|----------|
| SSA/SSB Panel | LAB3356 | LAB3356 | FAH6168 | in process | 86235x3 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| SS-B (La) Ab, IgG | 12301020072 | 12301020072 | FAH6124 | 29965-1 | |
| Ro52 Ab, IgG | 12301020075 | 12301020075 | FAH6122 | 70257-1 | |
| Ro60 Ab, IgG | 12301020076 | 12301020076 | FAH6123 | in process | |

| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|-------------------------|-------------|-------------|----------------|--------------|----------|
| Sm (Smith) Ab, IgG | LAB2373 | LAB2373 | FAH6109 | 33564-6 | 86235 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Sm (Smith) Ab, IgG | 12301020070 | 12301020070 | FAH6125 | 33564-6 | |

| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|-------------------------|-------------|-------------|----------------|--------------|----------|
| RNP Ab, IgG | LAB772 | LAB772 | FAH6110 | 29958-6 | 86235 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| RNP Ab, IgG | 12301020071 | 12301020071 | FAH6126 | 29958-6 | |

| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|-------------------------|-------------|-------------|----------------|--------------|----------|
| SS-B (La) Ab, IgG | LAB2378 | LAB2378 | FAH6108 | 29965-1 | 86235 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| SS-B (La) Ab, IgG | 12301020072 | 12301020072 | FAH6124 | 29965-1 | |

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We are bringing the MPO and PR3 testing in-house to align with the 2017 and 2020 international consensus on testing of ANCA's in systemic vasculitis and non-vasculitis conditions^{1,2} and offering the new tests/panel below.

| New Orderable | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|--|-------------|-------------|----------------|--------------|----------|
| Myeloperoxidase Antibody, IgG | LAB17602 | LAB17602 | FAH6098 | 97996-3 | 83516 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Myeloperoxidase Antibody, IgG | 12301020047 | 12301020047 | FAH6119 | 97996-3 | |
| Specimen Requirements: | | | | | |
| Container | Specimen | Temp | Collect Vol | Submit Vol | Min Vol |
| SST (preferred) or Red Top | Serum | Frozen | 2.0 mL | 1.0 mL | 0.5 mL |
| Collection Instructions: | | | | | |
| Serum should be separated from the clot within 4 hours of collection. Store samples at room temperature no longer than 8 hours . If the assay will not be completed within 8 hours , refrigerate the sample at 2-8°C. If the assay will not be completed within 48 hours , or for shipment of the sample, freeze at -20°C or lower. | | | | | |

| New Orderable | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|--|-------------|-------------|----------------|--------------|----------|
| Proteinase 3 Antibody, IgG | LAB17603 | LAB17603 | FAH6099 | 74106-6 | 83516 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Proteinase 3 Antibody, IgG | 12301020048 | 12301020048 | FAH6120 | 74106-6 | |
| Specimen Requirements: | | | | | |
| Container | Specimen | Temp | Collect Vol | Submit Vol | Min Vol |
| SST (preferred) or Red Top | Serum | Frozen | 2.0 mL | 1.0 mL | 0.5 mL |
| Collection Instructions: | | | | | |
| Serum should be separated from the clot within 4 hours of collection. Store samples at room temperature no longer than 8 hours . If the assay will not be completed within 8 hours , refrigerate the sample at 2-8°C. If the assay will not be completed within 48 hours , or for shipment of the sample, freeze at -20°C or lower. | | | | | |

| New Orderable | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|--|-------------|-------------|----------------|--------------|----------|
| Myeloperoxidase and Proteinase 3 Antibodies Vasculitis Panel | LAB17645 | LAB17645 | FAH6167 | 90230-4 | 83516x2 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Myeloperoxidase Antibody, IgG | 12301020047 | 12301020047 | FAH6119 | 97996-3 | |
| Proteinase 3 Antibody, IgG | 12301020048 | 12301020048 | FAH6120 | 74106-6 | |
| Specimen Requirements: | | | | | |
| Container | Specimen | Temp | Collect Vol | Submit Vol | Min Vol |
| SST (preferred) or Red Top | Serum | Frozen | 2.0 mL | 1.0 mL | 0.5 mL |
| Collection Instructions: | | | | | |
| See individual tests (above). | | | | | |

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With MPO and PR3 testing being brought in-house, an additional testing option for Anti-Neutrophil Cytoplasmic Antibodies (ANCA) will be available. This is again in alignment with the 2017 and 2020 international consensus on testing of ANCAs in systemic vasculitis and non-vasculitis conditions.^{1,2} The new test, Anti-Neutrophil Cytoplasmic Antibody Vasculitis Profile IFA with MPO and PR3, is the recommended test for patients being investigated for granulomatosis with polyangiitis, microscopic polyangiitis, anti-GBM, idiopathic interstitial pneumonia, and infective endocarditis with nephritis. MPO and PR3 testing will always be performed in addition to the ANCA IFA.

| New Orderable | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|--|-------------|-------------|----------------|--------------|-----------------------------------|
| ANCA Vasculitis Profile IFA with MPO and PR3 | LAB17604 | LAB17604 | FAH6104 | 90230-4 | 83516x2, 86036, 86037 (if approp) |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| ANCA Interpretation | 12301002588 | ANCAI | FAH5734 | 21419-7 | |
| ANCA Titer pattern 1 | 12301002590 | ANCAP1 | FAH5735 | 51924-9 | |
| ANCA Titer pattern 2 | 12301002614 | ANCAP2 | FAH5736 | 51924-9 | |
| Myeloperoxidase Antibody, IgG | 12301020047 | 12301020047 | FAH6119 | 97996-3 | |
| Proteinase 3 Antibody, IgG | 12301020048 | 12301020048 | FAH6120 | 74106-6 | |
| Specimen Requirements: | | | | | |
| Container | Specimen | Temp | Collect Vol | Submit Vol | Min Vol |
| SST (preferred) or Red Top | Serum | Frozen | 2.0 mL | 1.0 mL | 0.5 mL |
| Collection Instructions: | | | | | |

Serum should be separated from the clot within 4 hours of collection. Store samples at room temperature no longer than **8 hours**. If the assay will not be completed within **8 hours**, refrigerate the sample at 2-8°C. If the assay will not be completed within **48 hours**, or for shipment of the sample, freeze at -20°C or lower.

| Orderable to be Inactivated | Epic Code | Atlas Code | Mayo Test ID | Order LOINC | CPT Code |
|------------------------------|-----------|------------|--------------|-------------|----------|
| Myeloperoxidase Abs, IgG, S. | LAB2365 | MYL | MPO | 48404-8 | 83516 |
| Orderable to be Inactivated | Epic Code | Atlas Code | Mayo Test ID | Order LOINC | CPT Code |
| Proteinase 3 Abs, IgG, S. | LAB2369 | PR3AB | PR3 | 74106-6 | 83516 |

Anti-Neutrophil Cytoplasmic Antibody, IFA (LAB458), which currently reflexes if positive to MPO and PR3 testing at Mayo Clinical Laboratories, will no longer reflex to these assays. The test name will be updated to reflect this change. This test is the recommended test for patients being evaluated for ulcerative colitis or Crohn's disease when there is diagnostic uncertainty, or for autoimmune hepatitis lacking conventional autoantibodies. Only an ANCA IFA will be performed.

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| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|--|-------------|------------|----------------|--------------|-----------------------------|
| ANCA IFA (IBD and Autoimmune Hepatitis) NOT FOR VASCULITIS | LAB458 | ANCAIF | FAH5733 | 21419-7 | 86036, 86037 (if approp) |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| ANCA Interpretation | 12301002588 | ANCAI | FAH5734 | 21419-7 | |
| ANCA Titer pattern 1 | 12301002590 | ANCAP1 | FAH5735 | 51924-9 | |
| ANCA Titer pattern 2 | 12301002614 | ANCAP2 | FAH5736 | 51924-9 | |

Lastly, we will be transitioning our dsDNA Ab, IgG assay and our Tissue Transglutaminase Ab, IgA assay to the Inova Diagnostics Bioflash. Tissue Transglutaminase Ab, IgA is not only a stand-alone orderable but is also included in the Celiac Disease Panel (LAB2736).

| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|---------------------------------|-------------|-------------|----------------|--------------|----------|
| dsDNA Ab, IgG | LAB648 | LAB648 | FAH6106 | 33799-8 | 86225 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| dsDNA Ab, IgG | 12301020100 | 12301020100 | FAH6127 | 33799-8 | |
| | | | | | |
| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
| Tissue Transglutaminase Ab, IgA | LAB723 | LAB723 | FAH6107 | 46128-5 | 86364 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Tissue Transglutaminase Ab, IgA | 12301020069 | 12301020069 | FAH6132 | 46128-5 | |

| Updated Orderable build | Epic Code | Atlas Code | Mayo Access ID | Order LOINC | CPT Code |
|---------------------------------|-------------|-------------|----------------|--------------|-----------------|
| Celiac Disease Panel | LAB2736 | LAB2736 | FAH6169 | 94494-2 | 86225, 86364 |
| Result Component(s) | Epic Code | Atlas Code | Mayo Access ID | Result LOINC | Notes |
| Tissue Transglutaminase Ab, IgA | 12301020069 | 12301020069 | FAH6132 | 46128-5 | |
| IgA | 12301002021 | IGAS | FAH5813 | 2458-8 | |
| Celiac Disease Interpretation | 12301000618 | CDSP1 | FAH5798 | 69048-7 | |

If you have any questions or concerns about these changes, please contact the Medical Director of Immunology at UVMMMC, Dr. Clayton Wilburn, at (clayton.wilburn@uvmhealth.org).

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References:

1. Bossuyt X, Cohen Tervaert JW, Arimura Y, Blockmans D, Flores-Suárez LF, Guillevin L, Hellmich B, Jayne D, Jennette JC, Kallenberg CGM, Moiseev S, Novikov P, Radice A, Savige JA, Sinico RA, Specks U, van Paassen P, Zhao MH, Rasmussen N, Damoiseaux J, Csernok E. Position paper: Revised 2017 international consensus on testing of ANCA in granulomatosis with polyangiitis and microscopic polyangiitis. *Nat Rev Rheumatol*. 2017 Nov;13(11):683-692. doi: 10.1038/nrrheum.2017.140. Epub 2017 Sep 14. PMID: 28905856
2. Moiseev S, Cohen Tervaert JW, Arimura Y, Bogdanos DP, Csernok E, Damoiseaux J, Ferrante M, Flores-Suárez LF, Fritzler MJ, Invernizzi P, Jayne D, Jennette JC, Little MA, McAdoo SP, Novikov P, Pusey CD, Radice A, Salama AD, Savige JA, Segelmark M, Shoenfeld Y, Sinico RA, Sousa MJ, Specks U, Terrier B, Tzioufas AG, Vermeire S, Zhao MH, Bossuyt X. 2020 international consensus on ANCA testing beyond systemic vasculitis. *Autoimmun Rev*. 2020 Sep;19(9):102618. doi: 10.1016/j.autrev.2020.102618. Epub 2020 Jul 12. PMID: 32663621.

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