Laboratory Services
Important Test Announcement

DNA PLOIDY ANALYSIS

Starting immediately, DNA Ploidy Analysis will resume in-house testing. This test has been sent out to ARUP due to a manufacturer backorder. Please note that ***frozen samples will once again be accepted.***

Test Code: DNAP **Live Date:** 4/3/2025

- **Methodology:** Quantitative Flow Cytometry
- **Performed:** Monday - Friday
- **Turnaround Time: 5** days
- **Specimen Required:**
  - **Collect** :
    - Bone marrow or peripheral blood in green (sodium heparin) or lavender (EDTA)
    - Tissue: Paraffin-embedded tissue block enriched with tumor
    - Tissue: Fresh tissue in culture transport media
    - Tissue: Frozen in sterile container
  - **Specimen Volume: 3**mL (Minimum 1 mL)
  - **Storage/Transport/Temperature/Conditions:**
    - Tissue (paraffin embedded): Ambient: Indefinitely; Refrigerated: Indefinitely;
    - Tissue (Frozen): 60 months
    - Tissue (Fresh): Refrigerated: 24 hours
    - Peripheral blood or bone marrow: Ambient: 24 hours; Refrigerated: 72 hours;
  - **Unacceptable Conditions:**
    - Not received within specified time frame
    - Delayed or improper handling
    - Not received at proper temperature

DISCONTINUATION OF ADENOVIRUS ANTIBODY, SERUM TESTING

Test Code: XADEV **Discontinued Date:** 4/7/2025

Effective 4/7/2025, the reference lab for Adenovirus Antibody, Serum has discontinued testing. There is currently no equivalent alternative available.

A related in-house test option may be Adenovirus Blood by PCR, Qual (**ADVBLD**). PCR testing detects current infection by identifying viral genetic material, while antibody testing determines if the patient has been infected in the past (as antibodies are produced as a response to the virus), and may decrease over time.

ADENOVIRUS BLOOD BY PCR, QUALITATIVE

Test Code: ADVBLD

- **Methodology:** Real-time Polymerase Chain Reaction (PCR)
- **Performed:** Sunday-Friday
- **Turnaround Time:** 2 days
- **Specimen Required:**
  - **Collect:** 3 mL Purple tube (EDTA)
  - **Specimen Volume:** 3 mL
  - **Specimen Preparation:** N/A
  - **Storage Transport/Temperature/Conditions:** Transport to lab as soon as possible. If delay in transport is greater than 1 hour, refrigerate.

- **Unacceptable Conditions:** Wrong collection tube, over or under-filled tube
- **Stability:**
  - Whole blood: Room temperature 6 hours, Refrigerated 6 days
  - Plasma: Refrigerated 3 days, Frozen Indefinite weeks
- **Comments:**
  - Specimens received after 0900 will be done on the next day of testing.

SOMATIC DISEASE/GERMLINE COMPARATOR EXOME UPDATES

Test Code: SDGC **Live Date:** 4/7/2025

Effective 4/7/2025, Somatic Disease/Germline Comparator Exome (**SDGC**) version 2 will be released. Enhancements to this test include the ability to utilize lower input samples (25 nanograms of DNA) through the incorporation of a new methodology for sample preparation. This method also supports the genomic analysis of samples decalcified with EDTA, as well as Formical. FFPE specimens processed using strong acid decalcification remain unacceptable for testing.

In addition, this test will now report tumor mutational burden (TMB). The TMB value serves as a biomarker in consideration of the potential applicability of therapies targeting immune checkpoint inhibition. TMB values of greater than or equal to 10 are described as ***TMB high***, values less than or equal to 5 are described as ***TMB low***, and **values between those ranges** are defined as ***TMB intermediate***. Tumors with a high TMB can generate neoantigens, representing abnormal proteins that can trigger an immune response. For this reason, TMB-high tumors may be more likely to respond to immunotherapy. TMB is used to inform the cancer patient population who would be more likely to benefit from immune checkpoint inhibitors.

In the setting of high-TMB (defined in this context as 10 mutations/Mb), the FDA has approved pembrolizumab for adult and pediatric patients with advanced-stage solid tumors following disease progression on standard-of-care therapy who lack an alternative treatment option. Dozens of other immunotherapies have been approved in various cancer contexts. In some contexts, the ability to report TMB may be tumor specimen dependent. Please contact the laboratory for further information.

Type I and II Interferon Signature Quantitation in Monocytes by Flow Cytometry

Test Code: T1A2MP **Live Date:** 4/8/2025

On April 8, 2024, the normal range for Type I and II Interferon Signature Quantitation in Monocytes by Flow Cytometry will be updated as shown in the chart below.

Updated Reference cut-offs for CD169 and CD274 parameters were derived from ROC (receiver operating characteristic) curve analysis, which defines sensitivity and specificity of a clinical test, for all reported parameters. For ROC analysis, both healthy adult and pediatric cohorts were utilized, along with a positive patient cohort, to identify the cut-offs for each parameter with the highest sensitivity and specificity. Healthy adult and pediatric controls were segregated into independent categories. The % and MFI CD14 Bright monocyte normal ranges are not changing and were derived utilizing the 5th-95th percentile.

Type I and II Interferon Signature Quantitation in Monocytes by Flow Cytometry

Adult Normal Range

Immune Cell Subsets	Old Normal Range	New Normal Range	Unit
% CD14 Bright Monocytes (% Total Monocytes)	90-98	90-98	%
MFI CD14 Bright Monocytes	195848 - 322434	195848 - 322434	MFI
%CD14 Bright CD169 +(%CD14 Bright Monocytes)	0-2	<3	%
MFI CD14 Bright CD169+	1112-5155	<5306	MFI
%CD14 Bright CD274+ (%CD14 Bright Monoctes)	0-1	<2	%
MFI CD14 Bright CD274_	651-2266	<3089	MFI
CD169 MFI Ratio (CD169/Isotype)	1.42 - 4.53	<3	MFI Ratio
cCD274 MFI Ratio (CD274/Isotype)	0.42 - 0.85	<1	MFI Ratio

Pediatric Reference Range

Immune Cell Subsets	Old Reference Range	New Reference Range	Unit
% CD14 Bright Monocytes (% Total Monocytes)	83 - 97	83 - 97	%
MFI CD14 Bright Monocytes	182142 - 340869	182142-340869	MFI
%CD14 Bright CD169 +(%CD14 Bright Monocytes)	0-2	<3	%
MFI CD14 Bright CD169+	1205 - 8343	<6067	MFI
%CD14 Bright CD274+ (%CD14 Bright Monoctes)	0-1	<2	%
MFI CD14 Bright CD274_	781 - 4585	<3968	MFI
CD169 MFI Ratio (CD169/Isotype)	2.00-4.70	<3	MFI Ratio
CD274 MFI Ratio (CD274/Isotype)	0.00 - 1.00	<1	MFI Ratio

If you have any additional questions about testing, please refer to the Laboratory Test Directory or call Client Services at 614-722-5477.