ACL Laboratories
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Test Bulletin

February 2025

ACL Implements New In-House Test
Solid tumor 159 Genes NGS Panel (Test Order Code LAB12423)

Effective Tuesday, February 18, 2025, ACL Laboratories implemented a new test Solid Tumor 159 Genes NGS Panel (OCAplus) (Test Order Code LAB12423). The new panel will expand to 159 genes which includes ESR1, POLE, BRCA1 & 2, among others. See chart below. Red diamond – indicates new FDA biomarkers added since 2019.

Clinical Indication: Molecular profiling with the OCAplus for Solid Tumors allows for the accurate and sensitive detection of common variants such as SNV, CNV, indels and fusions in Breast, Bladder, Colorectal, GIST, Glioma, HCL, Melanoma, NSCLC, Ovarian, Thyroid, allowing the determination of drug response, aiding the diagnosis and providing prognosis information.

Test Method: This test will be performed by ACL Laboratories using a laboratory developed test method based on Next Generation Sequencing.

Specimen Requirements: Formalin-fixed paraffin embedded cell block (FFPE) OR fine needle biopsy (FNA)

Specimen Preparation: FFPE block must be cut in the following order:

- One H&E slide (4 µm)
- 4 slides (4 µm thick), de-paraffinized
- Two scrolls (10 µm thick) placed in labeled 1.5 mL micro tube

Blocks selected for analysis must contain at least 20% malignant cells.

Transport: Ambient

Performing Sites: ACL Illinois Central Laboratory

Reporting Time: Final within 14 days

Next Generation Sequencing Solid Tumor Panel 50 (Test Order Code LAB10599) was discontinued **effective Tuesday, February 18, 2025.**

The new assay can detect most common variants such SNV, CNV, indels and fusions in the following genes:

Hotspot Genes (87)			
AKT1	ESR1 ◆	KIT	PDGFRB
AKT2	EZH2 ◆	KNSTRN	PIK3CA
AKT3	FGFR1	KRAS	PIK3CB
ALK ◆	FGFR2	MAGOH	PPP2R1A
AR	FGFR3	MAP2K1	PTPN11
ARAF	FGFR4	MAP2K2	RAC1
AXL	FLT3 ◆	MAP2K4	RAF1
BRAF	FOXL2	MAPK1	RET
BTK	GATA2	MAX	RHEB
CBL	GNA11	MDM4	RHOA
CCND1	GNAQ	MED12	ROS1
CDK4	GNAS	MET	SF3B1
CDK6	H3F3	MTOR	SMAD4
CHEK2 ◆	HIST1H3B	MYC	SMO
CSF1R	HNF1A	MYCN	SPOP
CTNNB1	HRAS	MYD88	SRC
DDR2	IDH1	NFE2L2	STAT3
EGFR	IDH2	NRAS	TERT
ERBB2	JAK1	NTRK1 ◆	TOP1
ERBB3	JAK2	NTRK2 ◆	U2AF1
ERBB4	JAK3	NTRK3	XPO1
ERCC2	KDR	PDGFRA	

Copy Number Variants (43)	
AKT1	FGFR4
AKT2	FLT3
AKT3	IGF1R
ALK	KIT
AR	KRAS
AXL	MDM2
BRAF	MDM4
CCND1	MED12
CCND2	MET
CCND3	MYC
CCNE1	MYCN
CDK2	NTRK1
CDK4	NTRK2
CDK6	NTRK3
EGFR	PDGFRA
ERBB2	PDGFRB
ESR1	PIK3CA
FGF19	PIK3CB
FGF3	PPARG
FGFR1	RICTOR
FGFR2	TERT
FGFR3	

Fusion Drivers (51)		
AKT2	KRAS	RB1
ALK	MDM4	RELA
AR	MET	RET
AXL	MYB	ROS1
BRAF	MYBL1	RSPO2
BRCA1	NF1 ◆	RSPO3
BRCA2	NOTCH1	TERT
CDKN2A	NOTCH4	
EGFR	NRG1	
ERBB2	NTRK1	
ERBB4	NTRK2	
ERG	NTRK3	
ESR1 ◆	NUTM1	
ETV1	PDGFRA	
ETV4	PDGFRB	
ETV5	PIK3CA	
EZH2	PPARG	
FGFR1	PRKACA	
FGFR2	PRKACB	
FGFR3	PTEN	
FLT3	RAD51B	
JAK2	RAF1	

Full Exon Coverage (48)		
ARID1A	NF1	STK11
ATM ◆	NF2	TP53
ATR	NOTCH1	TSC1
ATRX	NOTCH2	TSC2
BAP1	NOTCH3	
BRCA1 ◆	PALB2 ◆	
BRCA2 ◆	PIK3R1	
CDK12 ◆	PMS2 ◆	
CDKN1B	POLE ◆	
CDKN2A	PTCH1	
CDKN2B	PTEN	
CHEK1 ◆	RAD50	
CREBBP	RAD51	
FANCA	RAD51C ◆	
FANCD2	RAD51D	
FANCI ◆	RAD51B ◆	
FBXW7	RB1	
MLH1	RNF43	
MRE11	SETD2	
MSH2	SLX4	
MSH6 ◆	SMARCA4	
NBN	SMARCB1 ◆	

Red diamond – indicates new FDA biomarkers added since 2019.

If you have any questions, please contact:
ACL Molecular Pathology Department at Rosemont (847.349.7182 or ACL Client Services (800.877.7016)

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at https://www.acllaboratories.com/providers/test-directory/.

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Metal Free Transport Tube Change

ACL Laboratories offers a variety of metal tests that are either performed internally or referred to ARUP, our primary reference lab partner. Several of the metal tests require the specimen to be transported in a Trace Element - Free transport tube. ACL is transitioning the transport tube currently used to a new product to meet requirements of having metal free labeling on each individual tube.

Effective immediately, providers should place an order for the new Metal Free labeled tube following their normal supply ordering practice. The new product is listed as 7.0 mL Metal Free transport tube. Once your practice receives the new tube supply, **please discard the old blue cap transport tube.**

Current tube:
Item # 1109426-IL
Item # 1109426-WI

New tube:
Item # 3054438-IL
Item # 3054438-WI

ACL Laboratories tests impacted:

Test Name	Test Order Code	Performing Lab
Copper, Blood	LAB10042	ACL
Zinc	LAB8904	ACL
Magnesium, RBC	LAB9664	ARUP
Selenium, Plasma	LAB9812	ARUP
Zinc, RBC	LAB9899	ARUP
Iodine, Serum	LAB9633	ARUP
Iodine, Urine	LAB10455	ARUP
Chromium, Serum	LAB9440	ARUP
Chromium, Urine	LAB9438	ARUP
Cobalt, Serum	LAB9452	ARUP
Aluminum, Serum	LAB9335	ARUP
Nickel, Serum	LAB9716	ARUP
Manganese, Serum	LAB9666	ARUP

Miscellaneous Test

Miscellaneous Test (Test Order Code LAB10119), updated Collection Requirements and Shipping/Handling instructions to include verbiage: **For irretrievable or bone marrow specimens, indicate "Special Handling" on the specimen transport bag.**

Listeria Antibody

Effective Tuesday, February 18, 2025, Listeria Antibody (Test Order Code LAB9651) has been inactivated. No replacement test is available.

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at https://www.acllaboratories.com/providers/test-directory/.

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Updated Referral Testing Orderable Codes

Effective Tuesday, February 18, 2025, the following send out assays have been updated as identified in the chart on the following pages.

COVID-19 IgG (Spike), Semi-Quantitative by CIA

	Current (Deactivated 2.18.2025)	Replacement (Activated 2.18.2025)
Test Name	COVID-19 IgG (Spike), Semi-Quantitative by CIA	SARS-CoV-2 Semi-Quant IgG Antibody, Spike
Test Order Code	LAB11958	LAB12841
Performing Lab	ARUP	LabCorp
Specimen Type	Serum	Serum 0.5 mL (minimum 0.4mL)
Collection Tube	Gold Gel	Gold Gel
Temperature	Refrigerated	Refrigerated
Stability	1 week	14 days
Methodology	Semi-Quantitative Chemiluminescent Immunoassay	Chemiluminescent Immunoassay (CLIA)
TAT	3 days	4 days

Allergens Food, Egg Components IgE

	Current (Deactivated 2.18.2025)	Replacement (Activated 2.18.2025)
Test Name	Allergens Food, Egg Components IgE	Allergen: Egg Protein Component Panel
Test Order Code	LAB11877	LAB11370
Performing Lab	ARUP	ACL
Specimen Type	Serum	Serum 1.0 mL (minimum 0.5 mL)
Collection Tube	Gold Gel	Gold Gel
Temperature	Refrigerated	Refrigerated
Stability	2 weeks	1 week
Methodology	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
TAT	Final within 5 days	Final within 3 days

Allergen, Food, Milk (Cow's) Component Ige

	Current (Deactivated 2.18.2025)	Replacement (Activated 2.18.2025)
Test Name	Allergen, Food, Milk (Cow's) Component Ige	Allergen: Milk Protein Component Panel
Test Order Code	LAB12271	LAB11371
Performing Lab	ARUP	ACL
Specimen Type	Serum	Serum 1.0 mL (minimum 0.5 mL)
Collection Tube	Gold Gel	Gold Gel
Temperature	Refrigerated	Refrigerated
Stability	2 weeks	1 week
Methodology	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
TAT	Final within 5 days	Final within 3 days

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Allergen, Food, Ovomucoid Ige

	Current (Deactivated 2.18.2025)	Replacement (Activated 2.18.2025)
Test Name	Allergen, Food, Ovomucoid Ige	Allergen: Ovomucoid, Egg Protein, IgE
Test Order Code	LAB11881	LAB11378
Performing Lab	ARUP	ACL
Specimen Type	Serum	Serum 1.0 mL (minimum 0.5 mL)
Collection Tube	Gold Gel	Gold Gel
Temperature	Refrigerated	Refrigerated
Stability	2 weeks	1 week
Methodology	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
TAT	Final within 5 days	Final within 3 days

Allergen, Pediatric Profile

	Current (Deactivated 2.18.2025)	Replacement (Activated 2.18.2025)
Test Name	Allergen, Pediatric Profile	Allergen:Peds Perennial Panel and Allergen: Pediatric Food Group
Test Order Code	LAB9258	LAB11363 and LAB12522
Performing Lab	CCL	ACL
Specimen Type	Serum	Serum 4.0 mL (minimum 2.5 mL)
Collection Tube	Gold Gel	Gold Gel
Temperature	Refrigerated	Refrigerated
Stability	30 days	1 week
Methodology	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
TAT	Final within 4 days	Final within 3 days

Glycohemoglobin (Test Order Code LAB8266) Methodology Changes

Effective Monday, February 17, 2025, ACL Laboratories changed the test methodology for Glycohemoglobin (Test Order Code LAB8266). ACL transitioned from High-performance liquid Chromatography (HPLC) testing on the Bio-Rad D100 instrument to Protein Separation via capillary electrophoresis on the Sebia Capillarys instrument. As result of this change, specimen transport and stability will change to:

- Ambient: 3 Days
- Refrigerated: 7 days
- Frozen: Unacceptable

We do not expect any changes to results or interpretation, results between methods are comparable.

Reference ranges will remain unchanged:

- Non Diabetic: <5.7%
- Increased Risk: 5.7%- 6.4%
- Diagnostic for Diabetes: >6.4%

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at https://www.acllaboratories.com/providers/test-directory/.

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Streck Tube Label Update

Effective immediately, the label for the Streck Cell-Free DNA BCT tube has been updated. The stopper color of the tube has changed from mottled to tan. Please see image to the right.

This is a label change ***only*** – there are no changes to the product or procedures.

If you have the mottled stopper tubes in your inventory, continue using up your inventory. **Please ensure you order the tan stopper tubes when you re-order.**

What's Changing on the Cell-Free DNA BCT® Tube

Methodology Changes for Epstein Barr Virus and Syphilis Antibody Testing

Effective Tuesday, February 18, 2025, ACL Laboratories changed the testing platforms for both Epstein Barr Virus antibody and Syphilis antibody testing. As a result of this test methodology change, reference ranges and specimen transport requirements will change. The assays are currently performed on the Bio-Rad Bioplex using Multiplex Flow Immunoassay and will transition to the DiaSorin Liaison XL using chemiluminescent immunoassay (CLIA) technology.

Reference the summary below for each impacted test code:

T. Pallidum Total IgG/IgM, Reverse Syphilis Screen Algorithm (Test Order Code LAB8563)		
Component(s), Reference Range, and Interpretation	**Component**	**Ref Range**
	Treponema Pallidum Antibody, IGG and IGM	Non-reactive
Specimen Collection Details (specimen type, amount)	One gold gel (SST) 5.0 mL OR One red (plain) 6.0 mL	
Transport Temperature	One 1.0 mL (Min: 0.5 mL) serum refrigerated	
Methodology	Chemiluminescent Immunoassay	

Epstein Barr Virus VCA Antibody, IgM (Test Order Code LAB8478)			
Component(s), Reference Range, and Interpretation	**Component**	**Ref Range**	**Interpretation**
	Epstein-Barr Virus, Antibody to Viral Capsid Antigen, IGM	<36.0 U/mL	< 36.0 U/mL Negative 36.0 - 43.9 U/mL Equivocal >= 44.0 U/mL Positive
Specimen Collection Details (specimen type, amount)	One gold gel (SST) 5.0 mL OR One red (plain) 6.0 mL		
Transport Temperature	One 1.0 mL (Min: 0.5 mL) serum frozen		
Methodology	Chemiluminescent Immunoassay		

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Epstein Barr Virus Chronic Panel (Test Order Code LAB8476)			
Component(s), Reference Range, and Interpretation	**Component**	**Ref Range**	**Interpretation**
	Epstein-Barr Virus, Antibody to Viral Capsid Antigen, IGG	<18.0 U/mL	< 36.0 U/mL Negative 36.0 - 43.9 U/mL Equivocal >= 44.0 U/mL Positive
	Epstein-Barr Virus, Antibody to Viral Capsid Antigen, IGM	<36.0 U/mL	< 36.0 U/mL Negative 36.0 - 43.9 U/mL Equivocal >= 44.0 U/mL Positive
	Epstein-Barr Virus, Antibody to Early D Antigen, IGG	<9.0 U/mL	< 9.0 U/mL Negative 9.0 - 10.9 U/mL Equivocal >= 11.0 U/mL Positive
	Epstein-Barr Virus, Antibody to Nuclear Antigen, IGG	<18.0 U/mL	< 18.0 U/mL Negative 18.0 - 21.9 U/mL Equivocal >= 22.0 U/mL Positive
Specimen Collection Details (specimen type, amount)	One gold gel (SST) 5.0 mL OR One red (plain) 6.0 mL		
Transport Temperature	One 1.0 mL (Min: 0.5 mL) serum frozen		
Methodology	Chemiluminescent Immunoassay		

Epstein Barr Antibody Screen (Test Order Code LAB8521)			
Component(s), Reference Range, and Interpretation	**Component**	**Ref Range**	**Interpretation**
	Epstein-Barr Virus, Antibody to Viral Capsid Antigen, IGG	<18.0 U/mL	< 18.0 U/mL Negative 18.0 - 21.9 U/mL Equivocal >= 22.0 U/mL Positive
	Epstein-Barr Virus, Antibody to Viral Capsid Antigen, IGM	<36.0 U/mL	< 36.0 U/mL Negative 36.0 - 43.9 U/mL Equivocal >= 44.0 U/mL Positive
Specimen Collection Details (specimen type, amount)	One gold gel (SST) 5.0 mL OR One red (plain) 6.0 mL		
Transport Temperature	One 1.0 mL (Min: 0.5 mL) serum frozen		
Methodology	Chemiluminescent Immunoassay		

Epstein-Barr Virus Antibody to Viral Capsid Antigen IgG (Test Order Code LAB8477)			
Component(s), Reference Range, and Interpretation	**Component**	**Ref Range**	**Interpretation**
	Epstein-Barr Virus, Antibody to Viral Capsid Antigen, IGG	<18.0 U/mL	< 18.0 U/mL Negative 18.0 - 21.9 U/mL Equivocal >= 22.0 U/mL Positive
Specimen Collection Details (specimen type, amount)	One gold gel (SST) 5.0 mL OR One red (plain) 6.0 mL		
Transport Temperature	One 1.0 mL (Min: 0.5 mL) serum frozen		
Methodology	Chemiluminescent Immunoassay		

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at https://www.acllaboratories.com/providers/test-directory/.