HOTLINE: Effective December 6, 2021

MEDICARE COVERAGE OF LABORATORY TESTING

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
4. Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
5. Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for CPT codes are available through the Centers for Medicare & Medicaid Services (CMS) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

The CPT Code(s) for test(s) profiled in this bulletin are for informational purposes only. The codes reflect our interpretation of CPT coding requirements, based upon AMA guidelines published annually. CPT codes are provided only as guidance to assist you in billing. ARUP strongly recommends that clients reconfirm CPT code information with their local intermediary or carrier. CPT coding is the sole responsibility of the billing party.

The regulations described above are only guidelines. Additional procedures may be required by your fiscal intermediary or carrier.

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
8	2005018	Celiac Disease (HLA-DQ2, and HLA-DQ8) Genotyping												x
3	3004445	Celiac Disease *HLA-DQ* Genotyping											x	
4	0099470	Heavy Metals Panel 3, Blood					x							
4	0020584	Heavy Metals Panel 4, Blood					x							
4	0020745	Lead, Blood (Capillary)					x	x						
5	0020098	Lead, Blood (Venous)					x	x						
7	0025016	Lead, Industrial Exposure Panel, Adults					x	x						
7	0098819	Melanocyte Stimulation Hormone, Alpha (a-MSH)				x								

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
8	2012255	Polycystic Kidney Disease, Autosomal Dominant (*PKD1* and *PKD2*) Sequencing												x
8	2012250	Polycystic Kidney Disease, Autosomal Dominant (*PKD1* and *PKD2*) Sequencing and Deletion/Duplication												x

New Test **3004445** **Celiac Disease *HLA-DQ* Genotyping** **HLACELIAC**

Click for Pricing

Methodology: Polymerase Chain Reaction/Massively Parallel Sequencing, or Polymerase Chain Reaction/Sequence-Specific Oligonucleotide Probe Hybridization

Performed: Mon-Fri

Reported: 8-15 days

Specimen Required: Collect: Lavender (EDTA). Also acceptable: Yellow (ACD Solution A).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens collected in Yellow (ACD Solution B). Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background Information for Celiac Disease *HLA-DQ* Genotyping:

Characteristics: Celiac disease is a systemic autoimmune disease of the gastrointestinal system caused by exposure to cereal gluten in genetically susceptible individuals.

Incidence: On average, 1 in 133 individuals in the United States is affected.

Inheritance: Multifactorial.

Cause: The presence of either *HLA-DQ2* or the *HLA-DQ8* alleles in combination with dietary gluten.

Clinical Sensitivity: greater than 99 percent.

Methodology: Polymerase Chain Reaction/Massively Parallel Sequencing, or Polymerase Chain Reaction/Sequence-Specific Oligonucleotide Probe Hybridization.

Analytical Sensitivity and Specificity: greater than 99 percent.

Limitations: Rare diagnostic errors may occur due to primer site mutations. Other genetic and nongenetic factors that influence celiac disease are not evaluated. In cases where an *HLA* allele cannot be resolved unambiguously, the allele assignment will be reported as the most common, based on allele frequencies from the common, intermediate and well-documented alleles catalogue version 3.0.0 (Hurley CK et al, 2020).

Alleles tested: *HLA-DQA1* and *HLA-DQB1* alleles.

Most celiac disease patients (approximately 90 percent) carry HLA-DQ2.5 heterodimers encoded by HLA-DQA1*05 and HLA-DQB1*02 alleles. The remaining 5-10 percent of the patients carry HLA-DQ8, encoded by HLA-DQB1*03:02 allele, most commonly in combination with HLA-DQA1*03 alleles. A minority of patients negative for the above genotypes may carry HLA-DQB1*02 but without the DQA1*05 alpha chain, most commonly with DQA1*02. The presence of the DQB1*02 allele in combination with either DQ2.5 or DQ8 may further increase celiac disease risk.

Stratified overall genetic risk for patients carrying the celiac disease-associated HLA-DQ genotypes:

Genotype	Risk*
DQ2.5 homozygous	Very High (greater than 1:10)
DQ2.5 + DQB1*02	Very High (greater than 1:10)
DQ2.5 + DQ8	High (greater than 1:20)
DQ8 homozygous	High (greater than 1:20)
DQ8 + DQB1*02 (without DQA1*05)	Intermediate (greater than 1:50)
DQ2.5 heterozygous	Intermediate (greater than 1:50)
DQ8 heterozygous	At risk (greater than 1:100)
Population risk for unknown genotype	1:100
DQB1*02 (without DQA1*05)	Low
DQA1*05 (without DQB1*02)	Minimal
Negative for DQ2 and DQ8	Not at risk

* Risk is provided from the references below, and defined according to HLA allele combinations, considering a disease prevalence of 1:100. However, these alleles are common in the general population and the majority of individuals positive for celiac-associated alleles do not develop the disease. Detection of these alleles can support a clinical diagnosis but should not be interpreted as diagnostic of celiac disease.

References:

1. Megiorni F, Mora B, Bonamico M, et al. HLA-DQ and risk gradient for celiac disease. Human Immunology. 2009;70:55-59.
2. Pietzak MM, Schofield TC, McGinnis MJ, et al. Stratifying risk for celiac disease in a large at-risk United States population by using HLA alleles. Clinical Gastroenterology and Hepatology. 2009;7:966-971.
3. Almeida LM, Gandolfi L, Pratesi R, et al. Presence of DQ2.2 associated with DQ2.5 increases the risk for celiac disease. Autoimmune Diseases, 2016. 2016:5409653.
4. Vader W, Stepniak D, Kooy Y, et al. The HLA-DQ2 gene dose effect in celiac disease is directly related to the magnitude and breadth of gluten-specific T cell responses. PNAS. 2003;100:12390-12395.

Disclaimer Information:

This test was developed and its performance characteristics determined by the Histocompatibility& Immunogenetics laboratory at the University of Utah Health. It has not been cleared or approved by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Histocompatibility& Immunogenetics laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

Performed at: Histocompatibility& Immunogenetics Laboratory, University of Utah Health, 417 Wakara Way, Suite 3220, Salt Lake City, UT 84108.Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

CPT Code(s): 81382 x2

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.

0099470 Heavy Metals Panel 3, Blood — HY MET B

Reference Interval:

Test Number	Components	Reference Interval	
0099045	Arsenic, Blood	Less than or equal to 12.0 µg/L	
0099305	Mercury, Whole Blood	Less than or equal to 10.0 µg/L	
0020098	Lead, Blood (Venous)	Effective December 6, 2021	
		Age	**Reference Interval**
		0-5 years	Less than or equal to 3.4 µg/dL
		6 years or above	Less than or equal to 4.9 µg/dL

0020584 Heavy Metals Panel 4, Blood — HY MET B4

Reference Interval:

Test Number	Components	Reference Interval	
0099045	Arsenic, Blood	Less than or equal to 12.0 µg/L	
0099675	Cadmium, Blood	Less than or equal to 5.0 µg/L	
0099305	Mercury, Whole Blood	Less than or equal to 10.0 µg/L	
0020098	Lead, Blood (Venous)	Effective December 6, 2021	
		Age	**Reference Interval**
		0-5 years	Less than or equal to 3.4 µg/dL
		6 year or above	Less than or equal to 4.9 µg/dL

0020745 Lead, Blood (Capillary) — LEAD CAP

Reference Interval:
Effective December 6, 2021

Age	Reference Interval
0-5 years	Less than or equal to 3.4 µg/dL
6 year or above	Less than or equal to 4.9 µg/dL

Interpretive Data:
Elevated results may be due to skin or collection-related contamination, including the use of a noncertified lead-free collection/transport tube. If contamination concerns exist due to elevated levels of blood lead, confirmation with a venous specimen collected in a certified lead-free tube is recommended.

Repeat testing is recommended prior to initiating chelation therapy or conducting environmental investigations of potential lead sources. Repeat testing collections should be performed using a venous specimen collected in a certified lead-free collection tube.

Information sources for blood lead reference intervals and interpretive comments include the CDC's "Childhood Lead Poisoning Prevention: Recommended Actions Based on Blood Lead Level" and the "Adult Blood Lead Epidemiology and Surveillance: Reference Blood Lead Levels (BLLs) for Adults in the U.S." Thresholds and time intervals for retesting, medical evaluation, and response vary by state and regulatory body. Contact your State Department of Health and/or applicable regulatory agency for specific guidance on medical management recommendations.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Group	Concentration	Comment
Children	3.5-19.9 µg/dL	Children under the age of 6 years are the most vulnerable to the harmful effects of lead exposure. Environmental investigation and exposure history to identify potential sources of lead. Biological and nutritional monitoring are recommended. Follow-up blood lead monitoring is recommended.
	20-44.9 µg/dL	Lead hazard reduction and prompt medical evaluation are recommended. Contact a Pediatric Environmental Health Specialty Unit or poison control center for guidance.
	Greater than 44.9 µg/dL	Critical. Immediate medical evaluation, including detailed neurological exam is recommended. Consider chelation therapy when symptoms of lead toxicity are present. Contact a Pediatric Environmental Health Specialty Unit or poison control center for assistance.
Adults	5-19.9 µg/dL	Medical removal is recommended for pregnant women or those who are trying or may become pregnant. Adverse health effects are possible. Reduced lead exposure and increased blood lead monitoring are recommended.
	20-69.9 µg/dL	Adverse health effects are indicated. Medical removal from lead exposure is required by OSHA if blood lead level exceeds 50 µg/dL. Prompt medical evaluation is recommended.
	Greater than 69.9 µg/dL	Critical. Immediate medical evaluation is recommended. Consider chelation therapy when symptoms of lead toxicity are present.

0020098 **Lead, Blood (Venous)** **LEAD-WB**

Reference Interval:
Effective December 6, 2021

Age	Reference Interval
0-5 years	Less than or equal to 3.4 µg/dL
6 year or above	Less than or equal to 4.9 µg/dL

Interpretive Data:
Elevated results may be due to skin or collection-related contamination, including the use of a noncertified lead-free tube. If contamination concerns exist due to elevated levels of blood lead, confirmation with a second specimen collected in a certified lead-free tube is recommended.

Information sources for blood lead reference intervals and interpretive comments include the CDC's "Childhood Lead Poisoning Prevention: Recommended Actions Based on Blood Lead Level" and the "Adult Blood Lead Epidemiology and Surveillance: Reference Blood Lead Levels (BLLs) for Adults in the U.S." Thresholds and time intervals for retesting, medical evaluation, and response vary by state and regulatory body. Contact your State Department of Health and/or applicable regulatory agency for specific guidance on medical management recommendations.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Group	Concentration	Comment
Children	3.5-19.9 µg/dL	Children under the age of 6 years are the most vulnerable to the harmful effects of lead exposure. Environmental investigation and exposure history to identify potential sources of lead. Biological and nutritional monitoring are recommended. Follow-up blood lead monitoring is recommended.
	20-44.9 µg/dL	Lead hazard reduction and prompt medical evaluation are recommended. Contact a Pediatric Environmental Health Specialty Unit or poison control center for guidance.
	Greater than 44.9 µg/dL	Critical. Immediate medical evaluation, including detailed neurological exam is recommended. Consider chelation therapy when symptoms of lead toxicity are present. Contact a Pediatric Environmental Health Specialty Unit or poison control center for assistance.
Adult	5-19.9 µg/dL	Medical removal is recommended for pregnant women or those who are trying or may become pregnant. Adverse health effects are possible. Reduced lead exposure and increased blood lead monitoring are recommended.
	20-69.9 µg/dL	Adverse health effects are indicated. Medical removal from lead exposure is required by OSHA if blood lead level exceeds 50 µg/dL. Prompt medical evaluation is recommended.
	Greater than 69.9 µg/dL	Critical. Immediate medical evaluation is recommended. Consider chelation therapy when symptoms of lead toxicity are present.

0025016 Lead, Industrial Exposure Panel, Adults LEAD-IND

Reference Interval:
Effective December 6, 2021

Test Number	Components	Reference Interval
	Lead, Blood	Less than or equal to 4.9 µg/dL
	Zinc Protoporphyrin (ZPP), Whole Blood	0-40 µg/dL
	Zinc Protoporphyrin (ZPP) to Heme Ratio	0-69 µmol ZPP/mol heme

Interpretive Data:
Elevated results may be due to skin or collection-related contamination, including the use of a noncertified lead-free collection/transport tube. If contamination concerns exist due to elevated levels of blood lead, confirmation with a second specimen collected in a certified lead-free tube is recommended.

Reference interval and interpretive comments are based on the CDC's "Childhood Lead Poisoning Prevention: Recommended Actions Based on Blood Lead Level" and the "Adult Blood Lead Epidemiology and Surveillance: Reference Blood Lead Levels (BLLs) for Adults in the U.S." Thresholds and time intervals for retesting, medical evaluation, and response vary by state and regulatory body. Actions described by OSHA in 1978 and finalized in 1983 are shown below. Contact your State Department of Health and/or applicable regulatory agency for specific guidance on medical management recommendations.

Concentration	Comment
5-19.9 µg/dL	Medical removal is recommended for pregnant women or those who are trying or may become pregnant. Adverse health effects are possible. Reduced lead exposure and increased blood lead monitoring are recommended.
20-69.9 µg/dL	Adverse health effects are indicated. Medical removal from lead exposure is required by OSHA if blood lead level exceeds 50 µg/dL. Prompt medical evaluation is recommended.
Greater than 69.9 µg/dL	Critical. Immediate medical evaluation is recommended. Consider chelation therapy when symptoms of lead toxicity are present.

"Occupational Safety and Health Standards: Lead (1983). 29 CFR Part 1910.1025 App C"
Action required for workers with Elevated Lead Values OSHA, Occupational Exposure to Lead, 1978

No. of Tests	Lead	Action Required
1	Greater than or equal to 40.0 µg/dL	Notification of worker in writing; medical examination of worker and consultation.
3 (average)	Greater than or equal to 50.0 µg/dL	Removal of worker from job with potential lead exposure.
1	Greater than or equal to 60.0 µg/dL	Removal of worker from job with potential lead exposure.
2	Less than 40.0 µg/dL	Reinstatement of worker in job with potential lead exposure is based upon symptoms and medical evaluation.
OSHA requirements in effect since 1978 call for the measurement of whole blood lead and zinc protoporphyrins (ZPP) (NCCLS document C42-A, Nov. 1996) to evaluate the occupational exposure to lead. OSHA requires ZPP whole blood testing to be reported in units of µg/dL. For adults, conversion of ZPP units of µg/dL whole blood assumes a hematocrit of 45 percent. Conversion factor: µmol/mol heme x 0.584= µg/dL.		

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

0098819 Melanocyte Stimulation Hormone, Alpha (a-MSH) MSH ALPHA

Specimen Required: Patient Prep: Patient should not be on any steroid, ACTH, or hypertension medication, if possible, for at least 48 hours prior to specimen collection. Morning fasting specimens are preferred.
Collect: Lavender (K_2 or K_3EDTA) or pink (K_2EDTA).
New York State Clients: Lavender (K_2EDTA).
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL plasma to an ARUP Standard Transport Tube. (Min. 1 mL) Freeze immediately.
New York State Clients: Collect in a prechilled tube. Remove the cap from the tube and add 0.25 mL Trasylol to the whole blood. Recap the tube and invert several times. Separate from cells and freeze.
Test is not performed at ARUP; separate specimens must be submitted when multiple tests are ordered.
Storage/Transport Temperature: **CRITICAL FROZEN.**
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 24 hours; Frozen: 1 month

HOTLINE: Effective December 6, 2021

The following will be discontinued from ARUP's test menu on December 6, 2021.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2005018	Celiac Disease (HLA-DQ2, and HLA-DQ8) Genotyping	Celiac Disease HLA-DQ Genotyping (3004445)
2012255	Polycystic Kidney Disease, Autosomal Dominant (*PKD1* and *PKD2*) Sequencing	
2012250	Polycystic Kidney Disease, Autosomal Dominant (*PKD1* and *PKD2*) Sequencing and Deletion/Duplication	