

# Laboratory Tests and Services

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[Instructions for Use](#)

Table of Contents	Page
<a href="#">Coverage Guidelines</a> .....	1
• <a href="#">General Coverage</a> .....	1
• <a href="#">Covered Clinical Diagnostic Laboratory Tests and Services</a> .....	2
• <a href="#">Home Blood Draws (Venipunctures)</a> .....	2
• <a href="#">Molecular Diagnostic Tests</a> .....	2
• <a href="#">Vitamin D Assays</a> .....	2
• <a href="#">B-type Natriuretic Peptide Measurements</a> .....	3
• <a href="#">Chemosensitivity and Chemoresistance Assays</a> .....	3
• <a href="#">HIV Serologic Testing</a> .....	3
• <a href="#">Sweat Test for Diagnosis of Cystic Fibrosis</a> .....	3
• <a href="#">Obsolete and Unreliable Diagnostic Tests</a> .....	3
• <a href="#">Hair Analysis</a> .....	3
• <a href="#">Cytotoxic Food Tests</a> .....	3
• <a href="#">Heartsbreath Test for Heart Transplant Rejection</a> .....	3
• <a href="#">Non-Covered Laboratory Tests and Services</a> .....	4
<a href="#">Definitions</a> .....	4
<a href="#">Supporting Information</a> .....	4
<a href="#">Policy History/Revision Information</a> .....	6
<a href="#">Instructions for Use</a> .....	6

- Related Medicare Advantage Policy Guidelines**
- [Clinical Diagnostic Laboratory Services](#)
  - [Histocompatibility Testing \(NCD 190.1\)](#)
  - [Human Tumor Stem Cell Drug Sensitivity Assays \(NCD 190.7\)](#)
  - [Lymphocyte Mitogen Response Assays \(NCD 190.8\)](#)
  - [Obsolete or Unreliable Diagnostic Tests \(NCD 300.1\)](#)
  - [Pharmacogenomic Testing for Warfarin Response \(NCD 90.1\)](#)
  - [Qualitative Drug Testing for Indications Other Than Mental Health](#)
  - [Serologic Testing for Acquired Immunodeficiency Syndrome \(AIDS\) \(NCD 190.9\)](#)
  - [Vitamin D Testing](#)

## Coverage Guidelines

Laboratory tests and services are covered when Medicare coverage criteria are met.

COVID-19 Public Health Emergency Waivers and Flexibilities: In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain laboratory services. For a comprehensive list of coronavirus waivers and flexibilities, refer to <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>. (Accessed April 14, 2021)

### General Coverage

Laboratory services (inpatient or outpatient) are covered in support of basic health care services to be used in the screening or detection of disease and determined to be reasonable and medically necessary.

Refer to the [Medicare Benefit Policy Manual, Chapter 15, §80.1 – Clinical Laboratory Services](#).

For quality standards for all laboratory testing, see the Medicare Clinical Laboratory Improvement Amendments (CLIA) website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>. (Accessed April 14, 2021)

## Covered Clinical Diagnostic Laboratory Tests and Services

The following are examples of clinical diagnostic laboratory tests and services that are covered when criteria are met. Applicable NCDs for these tests are available at the [Lab National Coverage Determinations \(NCDs\) Alphabetical Index](#). (Accessed April 14, 2021)

- Alpha-fetoprotein; refer to the Coverage Summary titled [Genetic Testing](#)
- Blood counts; refer to the National Coverage Determination (NCD) for Blood Counts (190.15)
- Blood glucose testing; refer to the NCD for Blood Glucose Testing (190.20)
- Carcinoembryonic antigen; refer to the NCD for Carcinoembryonic Antigen (CEA) (190.26)
- Collagen cross link; refer to the NCD for Collagen Crosslinks, any Method (190.19)
- Digoxin therapeutic drug assay; refer to the NCD for Digoxin Therapeutic Drug Assay (190.24)
- Fecal occult blood test; refer to the Coverage Summary titled [Preventive Health Services and Procedures](#)
- Gamma glutamyl transferase; refer to the NCD for Gamma Glutamyl Transferase (GGT) (190.32)
- Glycated hemoglobin/glycated protein; refer to the NCD for Glycated Hemoglobin/Glycated Protein (190.21)
- Hepatitis panel; refer to the NCD for Hepatitis Panel/Acute Hepatitis Panel (190.33)
- Human chorionic gonadotropin (hCG); refer to the NCD for Human Chorionic Gonadotropin (hCG) (190.27)
- HIV testing (diagnosis); refer to the NCD for Human Immunodeficiency Virus (HIV) Testing (Diagnosis) (190.14)
- HIV testing (prognosis and monitoring); refer to the NCD for Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring) (190.13)
- Lipid testing; refer to the NCD for Lipid Testing (190.23)
- PTT (partial thromboplastin time); refer to the NCD for Partial Thromboplastin Time (PTT) (190.16)
- Prostate specific antigen; refer to the Coverage Summary titled [Genetic Testing](#)
- Prothrombin test; refer to the NCD for Prothrombin Time (PT) (190.17)
- Serum iron studies; refer to the NCD for Serum Iron Studies (190.18)
- Thyroid testing; refer to the NCD for Thyroid Testing (190.22)
- Tumor antigen by immunoassay-CA 125; refer to the Coverage Summary titled [Genetic Testing](#)
- Tumor antigen by immunoassay-CA 15-3/CA 27.29; refer to the Coverage Summary titled [Genetic Testing](#)
- Tumor antigen by immunoassay-CA 19-9; refer to the Coverage Summary titled [Genetic Testing](#)
- Urine culture, bacterial; refer to the NCD for Urine Culture, Bacterial (190.12)

## Home Blood Draws (Venipunctures)

Medically necessary home blood draws (venipunctures) by an independent laboratory technician are covered in the following circumstances:

- Patient is confined to home or other place of residence used as his or her home when the specimen is a type which would require the skills of a laboratory technician (e.g., where a laboratory technician draws a blood specimen). For definition of homebound, refer to the [Medicare Benefit Policy Manual, Chapter 7, §30.1.1 – Patient Confined to the Home](#).
- Patient's place of residence is an institution, only if:
  - The patient was confined to the facility; and
  - The facility did not have on duty personnel qualified to perform the service.

Note: Specimen which would require only the services of a messenger and would not require the skills of a laboratory technician (e.g., urine or sputum,), a specimen pickup service would not be considered medically necessary.

Refer to the [Medicare Benefit Policy Manual, Chapter 15, §80.1.3 – Independent Laboratory Service to a Patient in the Patient's Home or an Institution](#). (Accessed April 14, 2021)

## Molecular Diagnostic Tests (MDT)

Refer to the Coverage Summary titled [Genetic Testing](#).

## Vitamin D Assays (CPT code 82306)

Medicare does not have a National Coverage Determination (NCD) for vitamin D assays. Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist for all states/territories and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for [Vitamin D Assay Test](#).

## **B-type Natriuretic Peptide (BNP) Measurements (CPT code 83880)**

Medicare does not have a National Coverage Determination (NCD) for B-type natriuretic peptide (BNP) measurements. Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist for all states/territories and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for [B-type Natriuretic Peptide \(BNP\) Measurements](#).

## **Chemosensitivity and Chemoresistance Assays (CSRAs)**

### ***Human Tumor Stem Cell Drug Sensitivity Assay***

The NCD for Human Tumor Stem Cell Drug Sensitivity Assay (190.7) addresses 2 distinct types of assays:

- Human Tumor stem cell drug sensitivity assays, and
- Fluorescent Cytoprint Assays.

Human tumor drug sensitivity assays are considered experimental, and therefore, not covered under Medicare at this time. The clinical application of the assay, based on testing in tumor micro organs rather than in clones derived from single cells, is considered experimental, and therefore, not covered under Medicare at this time.

Refer to the [NCD for Human Tumor Stem Cell Drug Sensitivity Assay \(190.7\)](#). (Accessed April 14, 2021)

### ***Other Chemosensitivity and Chemoresistance Assays (CSRAs)***

Examples include but are not limited to Oncotech Extreme Drug Resistance (EDR) assay, DiSC (Differential staining cytotoxicity) assay, ATP (Adenosine Triphosphate) assay, MTT (Methyl Thiazolyl Tetrazolium) assay, HYDRA<sup>®</sup> (AntiCancer Inc) assay, EVA-PCD (Rational Therapeutics) assay, and ChemoFx<sup>®</sup> assay.

Medicare does not have a National Coverage Determination (NCD) for CSRAs. Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for [Other Chemosensitivity and Chemoresistance Assays](#).

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled [Chemosensitivity and Chemoresistance Assays in Cancer](#).

Note: After checking the [Other Chemosensitivity and Chemoresistance Assays](#) table and searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

## **HIV Serologic Testing**

Refer to the [NCD for Serologic Testing for Acquired Immunodeficiency Syndrome \(AIDS\) \(190.9\)](#). (Accessed April 14, 2021)

## **Sweat Test for Diagnosis of Cystic Fibrosis**

Refer to the [NCD for Sweat Test \(190.5\)](#). (Accessed April 14, 2021)

## **Obsolete and Unreliable Diagnostic Tests**

Refer to the [NCD for Obsolete or Unreliable Diagnostic Tests \(300.1\)](#). (Accessed April 14, 2021)

## **Hair Analysis**

Refer to the [NCD for Hair Analysis \(190.6\)](#). (Accessed April 14, 2021)

## **Cytotoxic Food Tests**

Refer to the:

- [NCD for Cytotoxic Food Tests \(110.13\)](#). (Accessed April 14, 2021)
- Coverage Summary titled [Allergy Testing and Allergy Immunotherapy](#)

## **Heartsbreath Test for Heart Transplant Rejection**

Refer to the NCD for [Heartsbreath Test for Heart Transplant Rejection \(260.10\)](#). (Accessed April 14, 2021)

## Non-Covered Laboratory Tests and Services

Laboratory tests and services that are not reasonable and necessary are not covered. Refer to the [Medicare Benefit Policy Manual, Chapter 16, §20 – Services Not Reasonable and Necessary](#). Examples include but are not limited to

- Autopsy
- Employer or legally required drug or alcohol testing
- Genetic testing to determine predisposition to an inherited disease (carrier status) or when the test will not be used to determine the care of member
- Serum testing for genetic predisposition for Huntington’s Chorea
- Pre-marital blood testing
- School admissions and athletic requirement for laboratory testing

Also refer to the Coverage Summaries titled [Preventive Health Services and Procedures](#) and [Genetic Testing](#).

## Definitions

**Laboratory:** Any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. [Medicare Benefit Policy Manual, Chapter 15, §80.1 – Clinical Laboratory Services](#). (Accessed April 14, 2021)

## Supporting Information

**Important Note:** When searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the applicable referenced default policy below for coverage guidelines.

Vitamin D Assay Test				
Accessed August 23, 2021				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L33996 (A56798)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	CGS Administrators, LLC	KY, OH
L33771 (A56841)	<a href="#">Vitamin D; 25 hydroxy, includes fraction(s), if performed</a>	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L37535 (A57736)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	National Government Services, Inc.	CT, IL, MN, NY, ME, MA, NH, RI, WI, VT
L34051 (A57719)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT WY
L36692 (A57718)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L34914 (A56416)	<a href="#">Assays for Vitamins and Metabolic Function</a>	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L33418 (A56485)	<a href="#">Assays for Vitamins and Metabolic Function</a>	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L34658 (A57484)	<a href="#">Vitamin D Assay Testing</a>	Part A MAC	Wisconsin Physicians Service Insurance Corporation	AK*, AL*, AR*, AZ*, CA*, CO*, CT*, DE*, FL*, GA*, HI*, IA, ID*, IL*, IN, KS, KY*, LA*, MA*, MD*, ME*, MI, MO, MS*, MT*, NC*, ND*, NE, NH*, NJ*, NM*, NV*, OH*, OK*, OR*, PA*, RI*, SC*, SD*, TN*, TX*,

Vitamin D Assay Test

Accessed August 23, 2021

LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
				UT*, VA*, VT*, WA*, WI*, WV*, WY* Note: States notated with an asterisk should follow the other available state-specific LCD/LCA listed in this table. This WPS LCD/LCA only applies to states without asterisk.
L34658 (A57484)	<a href="#">Vitamin D Assay Testing</a>	Part B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE

[Back to Guidelines](#)

B-type Natriuretic Peptide (BNP) Measurements

Accessed August 23, 2021

LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L33943 (A56425)	<a href="#">B-type Natriuretic Peptide (BNP) Testing</a>	Part A and B MAC	CGS Administrators, LLC	KY, OH
L33267 (A57649)	<a href="#">B-Type Natriuretic Peptide (BNP)</a>	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L33573 (A56826)	<a href="#">B-type Natriuretic Peptide (BNP) Testing</a>	Part A and B MAC	National Government Services, Inc.	CT, IL, MN, NY, ME, MA, NH, RI, WI, VT
L34038 (A57084)	<a href="#">B-type Natriuretic Peptide (BNP) Testing</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT WY
L35526 (A57083)	<a href="#">B-type Natriuretic Peptide (BNP) Testing</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L34410 (A56605)	<a href="#">B-type Natriuretic Peptide (BNP) Testing</a>	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L33422 (A56565)	<a href="#">Brain Natriuretic Peptide (BNP) Level</a>	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L36523 (A57559)	<a href="#">MoIDX: Biomarkers in Cardiovascular Risk Assessment</a>	Part A MAC	Wisconsin Physicians Service Insurance Corporation	AK*, AL*, AR, AZ*, CA*, CO, CT*, DE, FL*, GA*, HI*, IA, ID*, IL*, IN, KS, KY*, LA, MA*, MD, ME*, MI, MO, MS, MT*, NC*, ND*, NE, NH*, NJ, NM, NV*, OH*, OK, OR*, PA, RI*, SC, SD*, TN*, TX, UT*, VA*, VT*, WA*, WI*, WV*, WY* Note: States notated with an asterisk should follow the other available state-specific LCD/LCA listed in this table. This WPS LCD/LCA only applies to states without asterisk.

### B-type Natriuretic Peptide (BNP) Measurements

Accessed August 23, 2021

LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L36523 (A57559)	<a href="#">MoIDX: Biomarkers in Cardiovascular Risk Assessment</a>	Part B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE

[Back to Guidelines](#)

### Other Chemosensitivity and Chemoresistance Assays

Accessed August 23, 2021

LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L37628 (A56071)	<a href="#">In Vitro Chemosensitivity and Chemoresistance Assays</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L37630 (A56073)	<a href="#">In Vitro Chemosensitivity and Chemoresistance Assays</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT WY
L34554 (A56871)	<a href="#">In Vitro Chemosensitivity and Chemoresistance Assays</a>	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV

[Back to Guidelines](#)

## Policy History/Revision Information

Date	Summary of Changes
04/20/2021	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>Reformatted policy; transferred content to new template</li> </ul> <p><b>Coverage Guidelines</b></p> <p><i>Non-Covered Laboratory Tests and Services</i></p> <ul style="list-style-type: none"> <li>Modified content heading; previously titled [Other Laboratory Tests and Services (Non-Covered)]</li> </ul>

## Instructions for Use

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare

Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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