

Department of Origin: Integrated Healthcare Services	Effective Date: 10/18/23
Approved by: Chief Medical Officer	Date Approved: 10/13/23
Clinical Policy Document: Laboratory Tests	Replaces Effective Clinical Policy Dated: 09/27/22
Reference #: MP/L001	Page: 1 of 3

PURPOSE:

The intent of this clinical policy is to provide coverage guidelines for laboratory testing.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

COVERAGE:

- I. The test is ordered and submitted from or under the direction of a provider working within their scope of practice; and
- II. Each test has been approved for its intended use by the appropriate regulatory/oversight body (implies analytic validity); and
- III. Each test has sufficient sensitivity or specificity (*clinical validity*) for targeting the member's specific clinical condition; and
- IV. The result of each test has appropriate evidence that it will directly impact clinical decision-making and clinical care (clinical utility); and
- V. Laboratory tests are covered when the individual test or panel meets the Plan's definition of a *standard laboratory test*, as reflected in this policy.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:

Analytic Validity:

How accurately and reliably the test measures the genotype of interest. A major component in the validation of an analytical technique is the technique's ability to accurately determine the presence of the substance it is seeking. It must measure the target substance without a great range of variation over a number of trials. The technique also must be proven to work reliably at multiple labs to be validated by this testing.

Clinical Laboratory Improvement Amendments (CLIA):

United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research.

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Clinical Utility:

How likely the test is to significantly improve patient outcomes. The evidence of improved measurable clinical outcomes, and its usefulness and added value to patient management decision-making compared with current management without the testing.

Clinical Validity:

How consistently and accurately the test detects or predicts the intermediate or final outcomes of interest.

Companion Diagnostic:

A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The test helps a health care professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks.

In Vitro Diagnostics (IVD):

Those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVDs are regulated by the US Food and Drug Administration (FDA) under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). IVDs are medical devices subject to premarket and postmarket approval, depending on their risk profiles. Use of IVDs in a laboratory setting to deliver clinical results is regulated by the Centers for Medicare and Medicaid Services (CMS) under the 1988 Clinical Laboratory Improvement Amendments (CLIA). Devices are classified into 3 separate risk categories: class I (low risk), II (moderate risk), class III (high risk), which determines their pathway to FDA marketing authorization. FDA regulation of IVDs focuses on safety and effectiveness of the device, primarily as demonstrated through clinical and analytic performance, whereas CMS regulation through CLIA focuses on laboratory quality.

Laboratory Developed Test (LDT):

Some IVDs are known as LDTs. LDTs, also known as home brew or in-house tests, are developed in and by laboratories in a variety of settings (e.g., hospital-based laboratories, independent laboratories) and are then offered only by those laboratories, compared with traditional laboratory tests, which represent most of the market and are typically marketed commercially as kits and distributed to several laboratories. These kits often include all of the necessary components to perform testing in a CLIA-certified laboratory. These traditional laboratory tests, which are broadly available commercially, are subject to FDA regulation per the FD&C Act. Depending on the risk profile of the test, a premarket review process may apply. Certain low-risk tests are exempt from premarket review; moderate-risk tests generally are require test manufacturers to provide evidence that their test are "substantially equivalent" to existing tests under the 510(k) program, and high-risk tests generally are reviewed for safety and effectiveness under the more rigorous premarket approval (PMA) process, reserved for class III IVDs.

Non-Standard Laboratory Test:

Not meeting the criteria of a standard laboratory test defined below or possessing one of the following attributes:

- A test proposed for the diagnosis and/or monitoring of a condition or disease state which is inconsistent with medical standards and accepted practice parameters of the community.
- A test using a methodology other than that employed in standard medical practice (eg, spectroscopy analysis instead of a standard culture for microorganisms).
- A test using a specimen type other than that employed in standard medical practice (eg, saliva specimen instead of a standard blood collection).

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- Panels comprised of numerous analytes – a high number of which do not impart clinical utility to the diagnosis or management of the disease or condition under consideration (eg, a hormone panel measuring multiple analytes when two analytes are recognized as standard medical practice).
- Test results reported in laboratory reporting values not recognized as national or international values employed in standard laboratory practice (eg, low-medium-high versus micrograms/liter).
- Test is performed at a frequency or volume that is not consistent with medical standards and accepted practice parameters of the community.

Standard Laboratory Test or Panel:

A test/panel performed in a *CLIA*-certified clinical laboratory setting; and recognized as clinically valid by at least one of the following professional organizations (Note: list may not be exhaustive)

- American Society of Clinical Pathology (ASCP)
- Association for Molecular Pathology (AMP)
- Clinical and Laboratory Standards Institute (CLSI)
- College of American Pathologists (CAP)
- National Committee for Clinical Laboratory Standard (NCCLS)

REFERENCES:

1. Clinical Policy: Coverage Determination Guidelines MP/C009
2. Clinical Policy: Levels of Evidence (LOE) and the Evaluation of Health Care Services MP/L004
3. In Vitro Companion Diagnostic Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on: August 6, 2014. Content current as of: 09/27/18. Retrieved from <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm262327.pdf>. Accessed 09-07-23.

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Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).