

2023 Laboratory Compliance Program NOTICE TO PHYSICIANS AND AUTHORIZED PROVIDERS

UCLA Health Clinical Laboratories is providing this notice in accordance with the Office of Inspector General (OIG) of the Department of Health and Human Services. The laboratory advises the physicians and clients on updates related to federally-funded healthcare programs that affect both the physician, laboratory and <u>UCLA</u> <u>Health's Code of Conduct</u> including laboratory policies for test ordering, billing, and other information regarding the laws, rules, and regulations governing laboratory services.

Providers ordering tests through UCLA Health Clinical Laboratories are responsible for adhering to all applicable federal and state regulations concerning provision of health care services. Medicare works with medical review contractors such as the OIG to review the Statutes and Laws under the Compliance Program.

LICENSED PHYSICIANS and NON-PHYSICIANS PRACTITIONERS (NPP)

Laboratory may only bill Medicare for testing ordered by the treating physician or qualified non-physician practitioner. Services are medically reasonable and necessary and meet all CLIA regulations. If your physician license has been revoked or suspended, immediately notify the laboratory (LabRegulatoryAffairs@mednet.ucla.edu).

<u>MEDICAL NECESSITY</u>

Tests that are medically necessary for the diagnosis or treatment of a Medicare patient are covered and may be reimbursed by Medicare. Routine screening of patients without regard to their individual need are not usually covered by the Medicare Program. Test panels must only be ordered when every test in that panel is medically necessary. If all components of the panel are not medically necessary, individual tests or a panel that contains only the medically necessary tests should be ordered.

 The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIC) issued a fraud alert on fraudulent genetic testing (with focus on telemedicine schemes). A primary concern of OIG is the fact that the beneficiary receives a testing kit even if the testing is not medically necessary and is not ordered by a physician.

INFORMED CONSENT/PRE-AUTHORIZATION

Payers may have pre/prior authorization requirements in place for certain laboratory testing including certain genetic carrier biomarkers and infectious disease panels. In addition, when required by law requiring consent from the patient (or legally authorized representative) for certain tests, it is the treating provider's responsibility to provide the consent or pre-authorization number. If not received at the time of test ordering, it risks delay to the patient's testing.

<u>CMS CLINICAL LABORATORY FEE SCHEDULE</u>

The 2023 Clinical Laboratory Fee Schedule is available at:

https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched



Los Angeles, CA 90095

TEST ORDERING

Laboratory tests orders must be in writing or electronically through CareConnect. UCLA Health test requisition (CareConnect or paper form) should be used when ordering tests. Documentation in the medical record must show intent to order and medical necessity for the testing. A non-UCLA Health requisition form or an incomplete requisition form may result in delayed processing or cancellation of the test. As necessary, UCLA Health laboratories may contact physicians to resubmit a test order that is incomplete or request clarification for a specific order. Only orders that are complete, signed, and dated will be performed.

Routine orders are for services and treatments that apply to patients with the same or similar medical condition(s). These frequently called "routine, protocol or standing orders" are based on an assessment of a given condition in patients with medical illness or injury.

- Medicare defines any order(s) that does not specifically address an individual patient's unique illness, injury or medical status, as not reasonable and necessary.
- As required by law, Medicare does not accept such "standing orders" as supporting medical necessity for the individual patient.

AMA APPROVED ORGAN or DISEASE ORIENTED PANELS

American Medical Association (AMA) has grouped certain tests into panels for coding purposes. If one orders tests in addition to those specifically indicated for a particular panel, those tests are billed separately in addition to the panel code. A valid diagnosis code must be provided for each AMA-approved panel ordered.

It is the responsibility of the Provider to accurately describe the patient's condition (ICD-10 code or a narrative diagnostic information) on the date of service in the patient's medical record: ICD-10 code (or a narrative diagnostic information) supported by the patient's medical record, for each test ordered, including all tests listed as part of organ or disease-oriented panels. Providers will be contacted for requisitions that do not include this required information.

FALSE CLAIM ACT

The OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.

VERBAL TEST ORDERS

Medicare regulations require that all orders for laboratory tests be in writing. If a provider orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. UCLA Health Clinical Laboratory will require the ordering clinician to send a written confirmation of the verbal order request for its records within thirty (30) days of the verbal request.

LABORATORY TEST DIRECTORY

The <u>UCLA Health Laboratory Test Directory</u> provides guidelines for test ordering and specimen collection for laboratory services, policies and procedures, and shipping to ensure the specimen is viable when it arrives at the performing laboratory. Additionally, the Laboratory Test Directory provides information on established Turnaround Time (TAT), including laboratory-defined STAT tests.

NOTE: The current Laboratory Information System (LIS) setting allows the provider to order STAT on all available tests. However, a STAT request will ONLY apply to the laboratory-defined STAT tests. Routine turn-around-times will apply for STAT orders for tests that are not defined as STAT under the TAT section.



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<u>REFLEX TESTING</u>

Reflex testing and confirmatory testing may be medically indicated when initial test results fall within certain parameters. UCLA Health Clinical Laboratories use Medical Executive Committee-approved testing algorithms to avoid delays in patient care. UCLA Health's <u>Reflex Test List</u> provides information on tests and test results that may generate additional testing and the conditions under which they are performed. Some reflex testing may result in additional charges. For reference laboratory testing, reflex testing policies are defined by each reference laboratory.

• REFERENCE RANGE, ABNORMAL FLAGS AND CRITICAL VALUES FOR SOGI

UCLA Health provides the opportunity for patients to share information about their sexual orientation or gender identity (SOGI). Providers who are informed of their patients' SOGI are better able to provide relevant, specific and compassionate care in a patient-centered environment. In CareConnect, non-binary genders are defined as "Unknown" or "Unspecified". In patients where SOGI is non-binary, the following parameters are utilized for laboratory tests that have sex-based reference ranges:

- Both Male & Female reference ranges will be added to the laboratory test result as a result comment.
- Abnormal flag and critical value limits are based on the highest value of the lower limit and the lowest value of the higher limit of the male and female defined reference ranges (the most conservative algorithm).

PATIENT PRIVACY (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA) UCLA Health is a healthcare provider and a covered entity. It is our policy to fully comply with the <u>HIPAA privacy standards</u>.

The HIPPA Privacy Rule permits disclosure of protected health information without beneficiary authorization to carry out treatment, payment or health care operations. The A/B MACs perform health care operation as agents of the CMS. Providing the requested documentation is in keeping with the HIPPA Privacy Rule.

• <u>ANTI-KICKBACK STATUTE</u> [Section 1128B (b) of the Social Security Act]

It is a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward referrals of items or services reimbursable by a Federal health care program and should be reported to the UCLA Health Office of Compliance Services.

PHYSICIAN SELF-REFERRAL LAW (STARK LAW) [42 CFR 411.355]

It is the policy of UCLA Health to comply with all aspects of the laws and regulations governing physician self-referral (federal Stark law).

The Stark Law prohibits a physician from referring for certain designated health services payable by Medicare to an entity where the physician (or an immediate family member) has an ownership/investment interest or a compensation arrangement, unless an exception applies.

DE-IDENTIFIED TEST DATA

From time to time, de-identified test result data may be made available to pharmaceutical companies and other entities engaged in healthcare research. In accordance with applicable regulations under HIPAA, we



are permitted to de-identify protected health information (PHI) and provide such de-identified information to third parties. None of the data provided to third parties shall contain any PHI protected under HIPAA.

<u>CONTACTS</u>

Laboratory Directors, Clinical Consultants, and other Scientific Directors are available to discuss appropriate testing and proper test ordering. For assistance, contact the Laboratory Director accordingly.

Clinical Laboratory	Laboratory Director	Telephone	Email
Ronald Reagan UCLA Medical Center	Alyssa Ziman, MD	310-267-8090	AZiman@mednet.ucla.edu
Santa Monica-UCLA Medical Center and Orthopaedic Hospital	Steven Hart, MD	424-259-8123	SHart@mednet.ucla.edu
UCLA Medical Center Clinical Laboratories	Bita Naini, MD	310-825-0863	BNaini@mednet.ucla.edu
BURL- Panorama City	Thomas Drake, MD	310- 825-6975	TDrake@mednet.ucla.edu



AMA ORGAN / DISEASE ORIENTED PANELS - CPT 2023

American Medical Association (AMA) defined ORGAN OR DISEASE PANELS		
BASIC METABOLIC PANEL		80048
Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565)	Glucose (82947) Potassium (84132) Sodium (84295) Urea Nitrogen (BUN) (84520)	
COMPREHENSIVE METABOLIC PANEL		80053
Albumin (82040) Bilirubin, total (82247) Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947)	Phosphatase, alkaline (84075) Potassium (84132) Protein, total (84155) Sodium (84295) Transferase, alanine amino (ALT) (SGPT) (84460) Transferase, aspartate amino (AST) (SGOT) (84450) Urea Nitrogen (BUN) (84520)	
ELECTROLYTE PANEL		
Carbon dioxide (bicarbonate) (82374) Chloride (82435)	Potassium (84132) Sodium (84295)	
LIPID PANEL		80061
Cholesterol, serum, total (82465) Lipoprotein, direct measurement, HDL c	Triglycerides (84478) holesterol (83718)	
HEPATIC FUNCTION PANEL		80076
Albumin (82040) Bilirubin, total (82247) Bilirubin, direct (82248) Phosphatase, alkaline (84075)	Protein, total (84155) Transferase, alanine amino (ALT) (SGPT) (84460) Transferase, aspartate amino (AST) (SGOT) (84450)	
ACUTE HEPATITIS PANEL		
Hepatitis A antibody (HAAb), IgM antibo Hepatitis B core antibody (HBcAb), IgM Hepatitis B surface antigen (HBsAg) (87 Hepatitis C antibody (86803)	antibody (86705)	
RENAL FUNCTION PANEL		
Albumin (82040) Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565)	Glucose (82947) Phosphorus inorganic (phosphate) (84100) Potassium (84132) Sodium (84295) Urea Nitrogen (BUN) (84520)	