

Annual Notice to Clients

February 25, 2021

At NeoGenomics Laboratories, Inc. (“NeoGenomics”), we are committed to full compliance with all applicable federal and state laws and regulations, third party payer requirements, and industry best practices. To that end, and consistent with recommendations of the Office of the Inspector General (“OIG”) for the U.S. Department of Health and Human Services Compliance Program Guidance for Clinical Laboratories, the purpose of this annual letter is to inform you about certain important laboratory practices and the regulations governing them.

Medical Director Clinical Support

For laboratory testing questions, we encourage you to contact NeoGenomics’ Client Services Department for assistance with any concerns that may arise. Our Medical Team members are also available for professional consultation on global tests performed (testing inclusive of technical component (“TC” or “Tech-Only”) and professional component (“PC”). Questions regarding Tech-Only testing should be directed to our Client Services Department, as our Medical Team members are unable to provide professional consultation on Tech-Only cases. Our assigned Medical Directors for each of our major laboratory facilities and other important contact information is listed below for your convenience:

- California (Aliso Viejo) Medical Director: **Vladislav Chizhevsky, M.D. – 949.445.7300, ext. 3289**
- California (Carlsbad) Medical Director: **Yin Xu, M.D. – 949.445.7300, ext. 5142**
- California (San Diego): **Steven Brodie, Ph.D – 239.768.0600, ext. 2300**
- Florida (Fort Myers) Medical Director: **Derek Lyle, M.D. – 760.516.5145**
- Florida (Tampa/Temple Terrace) Lab Director: **John McGill, Ph.D. – 239.768.0600, ext. 2311**
- Georgia (Atlanta) Medical Director: **Yin Xu, M.D. – 949.445.7300 ext. 5142**
- Tennessee (Nashville) Medical Director: **Christopher Mixon, M.D. – 615.574.6090**
- Texas (Houston) Medical Director: **Tricia Peters, M.D. – 713.528.4363, ext. 6424**
- **Billing: 866.776.5907, ext. 2**
- **Client Services: 866.776.5907, ext. 3**

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Medical necessity

Consistent with coverage requirements issued by the Centers for Medicare and Medicaid Services (“CMS”), we require a completed laboratory test requisition form with each specimen submitted to us for testing that includes a diagnosis from the licensed ordering physician supporting medical necessity before we can perform a laboratory test. CMS also requires a signed physician order be maintained in the patient record for each test ordered or the signature of the ordering physician/pathologist on the test requisition form attesting to the medical necessity of each test, or panel of tests ordered. While NeoGenomics does not accept standing orders or custom profiles, our requisitions have been designed in a manner to allow clients the ability to order the combination of testing that is medically necessary for each patient’s specific diagnosis or condition. When ordering panels of testing, clients should ensure that all components of the panel are medically necessary for the specific patient’s diagnosis and if not, individual tests or a less inclusive panel that do meet medical necessity should be ordered. Components of all panels can be found on the [NeoGenomics](#) website. **It is important to note that the OIG takes the position that physicians and other authorized individuals who order medically unnecessary tests or who knowingly causes a false claim to be submitted to any federally funded program may be subject to sanctions or remedies available under civil, criminal and administrative law.**

CMS has also developed specific National Coverage Determinations (“NCDs”) for certain laboratory tests, which can be accessed on the [CMS website](#). Further, CMS’ Medicare Access Contractors (“MACs”) and fiscal intermediaries have published Local Coverage Determinations (“LCD”) for certain laboratory tests that are specific to a patient’s geographic location or jurisdiction. Laboratory tests that do not meet applicable NCD or LCD coverage requirements are considered “non-covered tests” and, depending on the circumstances, the patient may be financially responsible. However, in order for the laboratory to bill the patient, Medicare (and other payers) require that a patient sign an [Advance Beneficiary Notice \(“ABN”\)](#) informing them of the non-covered status of a test prior to the test being performed. Since we do not interact directly with patients, **it is the responsibility of the ordering physician to be familiar with applicable NCD and LCD coverage rules, including ABN requirements, to ensure that informed medical necessity determinations, which take into consideration a patient’s financial ability, are made for each patient and are supported by a signed order in the patient’s medical record.**

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Requisition requirements

Each test requisition form must contain complete patient demographic information including the patient's full legal name, date of birth ("DOB"), gender, hospital status (inpatient/outpatient/nonpatient), and insurance information, if applicable. If there are two insurances (e.g., Medicare and a secondary payer), all insurance information is required for both payers. For all test requisition forms that indicate that we should bill a third party payer, do also include a copy of the patient's insurance card with each requisition form. Please note that if any required information is missing on a test requisition form, it may impact turnaround time for the test results while we gather the missing information.

Reflex tests

NeoGenomics offers medically necessary reflex testing to facilitate effective and efficient patient care while remaining compliant with state and federal regulations governing the ordering of laboratory tests. A reflexed test is any test that automatically results in the order of one or more secondary tests based on preset criteria applied to the initial test. The secondary tests are almost always an additional charge above the initial test. When ordering a reflexed test, clients are given the ability, on the requisition, to opt-out of the secondary tests when they are not medically necessary for the specific patient and for the specific situation in which the order is placed. Certain reflex testing has been predetermined based on specific criteria accepted as standard-of-care by the medical community. These tests will always reflex because the initial test result is not useful without the reflex test result.

Specimen requirements

Clients are responsible for submitting specimens which are properly labeled and have two patient identifiers in addition to meeting the submission requirements for all testing requested. For your convenience, a listing of all [specimen requirements](#) may be found on our website. **Please do not send any specimens with biopsy needles, syringes, blades, or any other foreign objects in the tubes. We are unable to extract tissue from these tubes, which will result in disposal of the foreign objects which can leave less specimen for processing, and can delay turnaround time.** If you send two blocks for us to choose from, but do not indicate "select best" on the test requisition form, both blocks will be processed. In such case, you may be charged for duplicate processing and testing if the specimen is being submitted as a client-bill specimen. For TC testing, the client must indicate which block should be used for testing in order to avoid turnaround delays.

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Infectious disease testing

NeoGenomics cannot accept Category A infectious substances as defined by IATA (Dangerous Goods Regulations), which include, but not limited to, specimens that may harbor variant Creutzfeldt-Jakob disease (CJD - Mad Cow Disease), variant Creutzfeldt-Jakob disease, or tissue cultures of Mycobacterium Tuberculosis. FFPE, fresh blood or bone marrow specimens, and body fluids are acceptable from patients with tuberculosis. We will attempt to find another qualified testing lab that can pick up and process any infected specimens sent in error. Specimens from other patients received in the same package will be considered potentially contaminated and handled in the same way, regardless of origination. If no options are available, specimens will be disposed as biohazardous waste after client notification. Please refer to [IATA Dangerous Goods Regulations](#) for a complete list of Category A Infectious Specimens.

Medicare reimbursement fee schedules

Medicare reimburses laboratory testing services through either the Physician Fee Schedule or the Clinical Lab Fee Schedule, depending on the type of test. If you would like a copy of either of these fee schedules, please refer to the Medicare Fee-for-Service Payment section of CMS's website. Medicaid reimbursement is generally equal to or less than the amount of Medicare reimbursement.

Client billing

Unless a client indicates that it should be billed on the test requisition form or otherwise has a contract with NeoGenomics providing for a 100% client bill arrangement, we will, whenever possible and permitted by law, directly bill and collect from all insurers. One notable exception to this policy is that we must bill hospital clients for any technical component services for Medicare or payers following Medicare guidelines on in-patients and some out-patients. Additionally, NeoGenomics is required to bill Medicare for certain molecular tests ordered for hospital outpatients. You can find detailed information about these topics on our [Client Billing](#) website.

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Patient billing

Clients are advised that patients will receive invoices from NeoGenomics in certain situations. Although, we are an “in-network” or contracted laboratory services provider with over 225 national and regional third party payers, there are certain plans with which we do not have a contract (“out-of-network”). If we are an out-of-network laboratory with a payer and the payer makes payment directly to a patient for the lab services we perform, we must invoice the patient for such services to obtain payment. In addition, in situations in which we are an in-network provider with a patient’s insurance company or government payer such as Medicare, we are contractually obligated to invoice patients for any co-payment, co-insurance or deductible that a payer determines is the patient’s responsibility. Some payers for which we are an in-network laboratory may also deny payment for certain tests that we offer including, but not limited to, some of our newer and more expensive molecular profile panels, because they have not yet established reimbursement for such services or have otherwise determined that they are “non-covered services”. In such situations, we are legally required to make good faith efforts to collect on any amounts due directly from the patients. Although we may offer discounts and/or payment plans to patients in accordance with applicable law, many patients are concerned about the expense of such tests. As stated previously, it is the responsibility of the treating physician to inform each patient of any tests that may not be covered by their insurance and, for Medicare patients, to ask that they sign an ABN which lists the non-covered tests and pricing. This allows each patient to make informed decisions on their care with full knowledge of the financial responsibility they may incur. You can find more information on our [Patient Billing](#) website.

California Consumer Protection Act

In an effort to provide our clients important information about other therapeutic options for their patients, physician contact information provided with test orders may be shared with third parties, including companies that sponsor clinical trials, and these companies may contact the physician directly in connection with clinical trials that they sponsor. NeoGenomics may also sell the physician’s identifiable contact information to companies that sponsor clinical trials, and physicians who are California residents have the right to opt out of such sale, under the California Consumer Protection Act, at any time by visiting our [website](#).

Thank you for your attention in these important matters of mutual concern. To the extent you have questions, please feel free to contact our Compliance & Ethics Department at **239.768.0600** or **compliance@neogenomics.com**.