



October 5, 2018

Dear Valued Client,

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**

To assist with 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 (technical component ("TC" or "Tech-Only") testing inclusive of professional component ("PC") testing, collectively, a "Global Test"). 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: Lawrence Weiss, M.D. - (626) 227-6438**
- **Florida (Fort Myers) Medical Director: Adrian Padurean, M.D. - (239) 768-0600, ext. 2342**
- **Tennessee (Nashville) Medical Director: Christopher Mixon, M.D. - (615) 574-6090**
- **Texas (Houston) Medical Director: David Morgan, M.D. - (713) 528.4363, ext. 2313**
- **Director of Billing: Deena Murphy - (239) 768-0600, ext. 3151**
- **Client Services: 866-776-5907, ext. 3**

### **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 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 back of the requisition or on [www.neogenomics.com](http://www.neogenomics.com). **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.**

We continue to see a significant increase in the number of requests from payers for patient records relating to laboratory tests. Such inquiries almost always include verification of medical necessity for the tests ordered. When we receive such a request, if the requisition forms relating to the tests in question have not been signed by the ordering physician, we are required to contact the patient's treating physician in order to obtain the signed order in the patient's medical record or refer such payer to the treating physician's office. This can be a burdensome and time-consuming exercise for the physician, but can be avoided if the ordering physician simply signs the test requisition in the upper left for the physician's office box of the form verifying the validity and medical necessity of the tests ordered.

In addition to medical necessity requirements, CMS has developed specific National Coverage Determinations (“NCDs”) for certain laboratory tests, which can be accessed on the CMS website at <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. 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.**

### **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 at <https://www.cms.gov/Medicare/Medicare.html>. Medicaid reimbursement is generally equal to or less than the amount of Medicare reimbursement.

### **Proficiency Test Handling**

In accordance with applicable regulations under the Clinical Laboratory Improvement Act of 1988, as amended (“CLIA”), we are unable to accept client proficiency testing (“PT”) requests. As a rule, any aspect of PT should be exclusively performed by clients at their facilities. It is our policy to immediately return any specimens received for PT to the referring client to ensure CLIA compliance. However, there is an exception whereby we can assist with PT if slide staining or image analysis is necessary for a client to complete the interpretive portion of a PT. In such cases, we may assist with the TC portion of the staining/image analysis of the PT testing and bill the client accordingly.

### **Patient Privacy (HIPAA)**

Under the Health Insurance Portability and Accountability Act (HIPAA), NeoGenomics is a health care provider and a covered entity. It is our policy to fully comply with the HIPAA privacy and security standards. Our privacy policy is available at: <http://neogenomics.com/company/regulatory-and-licensing/health-privacy-practices>.

### **Patient Requests for Test Results**

In 2014, federal regulations were changed to allow patients to obtain their test results directly from a laboratory. For Global Tests performed by NeoGenomics, we are required to provide a copy of any patient test reports within thirty (30) days of the date on which a patient makes the request in writing. However, we will not explain the results of any such report to a patient as any explanation should come from the patient’s treating physician. In the event that we have only performed the TC testing on a specimen, the patient will be directed to your office to obtain the final test report.

### **Informed Consent**

Some state laws require physicians ordering genetic testing to obtain informed consent from the patient (or legally authorized representative). Although the requirements vary by state, typically, these requirements relate to hereditary or germline cancer tests. It is the treating physician’s responsibility to be knowledgeable of all state laws and/or regulations regarding the appropriate disclosures and documentation necessary for obtaining a patient’s informed consent. To facilitate this, a sample informed consent form can be found on our website at <https://neogenomics.com/sites/default/files/neogenomics/neo-consenthereditarycancer-form.pdf>. Please note that this is only a sample form for informational purposes, and should be tailored by the provider to the specific state laws and patients at issue. We do not make any representations regarding the legal sufficiency of this sample form. We recommend that providers discuss the informed consent form with each patient and have them sign the form prior to sending any samples to NeoGenomics for germline genetic testing.

### **Requisition Requirements**

In addition to having a patient diagnosis indicating the medical necessity for testing (in ICD-10 or narrative description format), each test requisition form must also 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, please 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.

### **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 at <https://neogenomics.com/sites/default/files/Brochure/Specimen-Requirements.pdf>. Please be advised that if you send us 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, if more than one block is submitted, in order to avoid turnaround delays.

### **Technical Component/Professional Component Testing**

Federal regulations require that any pathologist who performs PC testing be appropriately trained and credentialed for the specialty being tested. The laboratory location releasing the final interpretative test results must also be CLIA certified or possess equivalent state licensure and specialty credentialing. To ensure compliance with applicable law, we are unable to provide services to clients that do not meet these professional and regulatory requirements. It is the responsibility of each of our clients to be knowledgeable of, and current with, applicable federal regulations and state licensing requirements in order to perform PC interpretations on any TC tests ordered from NeoGenomics.

### **Billing Information and 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, including health care service plans (e.g., health maintenance organizations), federal and state health care programs (e.g. Medicare and Medicaid), and other third party payers. 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 registered with such hospital. Clients should be aware that NeoGenomics may only bill Medicare and Medicaid for testing ordered by a licensed physician, or other individuals authorized by law to order laboratory tests. Physicians must be registered with PECOS (Provider Enrollment, Chain and Ownership System). If your license has been revoked or suspended, it is your responsibility to immediately notify us. Please see our website for more information regarding our specific client billing policies and procedures at <http://neogenomics.com/billing/client-billing>.

### **Billing Patients**

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 175 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. For your convenience, a form that includes a listing of common non-covered tests and the estimated patient financial responsibility can be found on our website at <https://neogenomics.com/sites/default/files/neogenomics/patient-notice-of-financial-responsibility-for-non-covered-testing.pdf>. Beginning in April 2017, we have started to enclose a letter with all patient invoices that explains these policies.

**Reflex Laboratory Tests**

Consistent with best practices and the standards of care in laboratory medicine, pathologists may order additional laboratory tests (reflex tests) on specimens based on their independent judgment and determination of medical necessity for the patient, as well as the results of other adjunct tests performed on a specimen. Please be advised that in the event you order a Global Test from NeoGenomics, any of our pathologists may, in their discretion as the interpreting pathologist, order additional reflex tests on a specimen based on their independent medical judgment and if clinically indicated for the patient. In such cases, the NeoGenomics interpreting pathologist will use commercially reasonable efforts to contact the ordering physician to discuss the case before ordering the reflex testing. Additional reflex testing on a specimen may result in additional charges to a client if the original testing was ordered on a “client bill” basis. Our discretionary authority to order reflex testing only applies to cases in which NeoGenomics is performing the PC interpretation and such reflex testing is recommended by the reviewing pathologist.

**Client Requests for Performance Data**

In the event that a regulatory body or certification agency requests test performance and/or quality assurance (“QA”) data for tests we have performed on a client’s behalf, we will use commercially reasonable efforts to provide such information. All requests should be submitted through our Client Services Department and include the exact information required, including any applicable instructions from the regulatory body or certification agency requesting the data. Please allow thirty (30) days to process your request.

**De-identified Test Data**

From time to time, we make de-identified test result data available to pharmaceutical companies and other entities engaged in cancer research. In accordance with applicable regulations under the Health Information Privacy and Accountability Act (“HIPAA”), we are permitted to de-identify protected health information (“PHI”) and provide such de-identified information to third parties. None of the data we provide to any third parties contains any PHI protected under HIPAA. If you do not wish for us to de-identify PHI provided by you or created by us from information or specimens you provided to us, or you do not wish for us to provide such de-identified information to third parties, please sign and return the enclosed “NeoGenomics De-Identified Data Opt Out Agreement”.

**Infectious Disease Testing**

NeoGenomics cannot accept category A infectious substances as defined by IATA (***Dangerous Goods Regulations 3.6.2.1.1 Definition – Infectious Substances***), including, but not limited to, specimens that may harbor variant Creutzfeldt-Jakob Disease (mad cow disease), variant Creutzfeldt-Jakob Disease, or microbiologic 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: <https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf>

Thank you for your attention in these important matters of mutual concern. To the extent you have questions, please feel free to contact any of the undersigned or Ms. Stephanie Bywater, our Compliance Officer, at (239) 768-0600, ext. 2225.

Sincerely,



Douglas VanOort  
Chief Executive Officer



Dr. Maher Albitar  
Chief Medical Officer



Stephanie Bywater  
Chief Compliance Officer

**NeoGenomics De-Identified Data Opt-Out Agreement**

From time to time, NeoGenomics Laboratories, Inc. makes de-identified test result data available to pharmaceutical companies and other entities engaged in doing research on cancer. In accordance with applicable regulations under the Health Information Privacy and Accountability Act (“HIPAA”) under 45 C.F.R. 164.502(d), we are permitted to de-identify protected health information (“PHI”) in accordance with 45 C.F.R. 164.514(a)-(c) and provide such de-identified information to third parties. None of the data provided to any third parties contains any PHI protected under HIPAA. If you do not wish for us to de-identify PHI provided by you or created by us from information or specimens you provided to us, or you do not wish for us to provide such de-identified information to third parties, please fill out the information below and sign and return this form to NeoGenomics.

**Client Name (“CLIENT”):** \_\_\_\_\_

NeoGenomics Client Numbers: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_ Zip: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Email: \_\_\_\_\_

CLIENT hereby elects to Opt-Out of allowing NeoGenomics to i) de-identify PHI provided by it to NeoGenomics, ii) de-identify PHI created by NeoGenomics from information or specimens provided by CLIENT, or iii) provide any such de-identified information to third parties. The undersigned hereby represents and warrants that he/she is authorized to make such election on behalf of CLIENT.

By: \_\_\_\_\_

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Please Return Completed Opt-Out Forms To:**

Ms. Justine Guido, Manager, Legal Contracting and Administration

NeoGenomics Laboratories, Inc.

12701 Commonwealth Dr. Suite 9, Fort Myers, FL 33913 USA

Phone: 239.768.0600 x2388

Fax: 239.432.5601

Email: justine.guido@neogenomics.com