ANNUAL NOTICE TO CLIENTS

To Our Clients:

In an effort to help laboratories comply with federal laws and regulations, the Office of the Inspector General (OIG) has issued a recommendation that all CLIA certified laboratories provide annual notification to their clients regarding pertinent issues.

Please review the following important information.

Incyte Diagnostics Locations

- 13103 E Mansfield, Spokane Valley WA
- 221 Wellsian Way, Richland WA
- 1280 116th Ave NE, STE 210, Bellevue WA
- 15912 E Marietta Ave, Suite B, Spokane Valley WA
- 21950 E Country Vista Dr, Suite 200, Liberty Lake WA
- 12615 E Mission Ave, Suite 108, Spokane Valley WA
- 1307 S Grand Blvd, Spokane WA
- 318 E Rowan Ave, Suite 205, Spokane WA

• Medical Necessity

Per applicable CMS regulations, we require all testing requisitions/orders to contain a diagnosis and/or ICD-10 code(s) supporting the tests ordered by our clients. Medicare has issued both National and Local Coverage Determinations (NCD/LCD) that outline coverage specifics. To access NCDs please visit CMS' website at www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

In addition, LCDs for our area can be accessed on Noridian's website at https://med.noridianmedicare.com/web/jeb/policies/lcd/active

In some instances, it may be necessary to obtain additional medical records from our clients to support medical necessity.

• Prior Authorization

Many payers are now requiring prior authorization (PA) before testing will be reimbursed. Please consult with individual payers for PA requirements prior to sample collection. Prior authorization numbers should be included on the requisition.

• Advanced Beneficiary Notice

Medicare requires Advanced Beneficiary Notice be given to the patient prior to the collection of a testing sample for some tests including cervical cancer screening (PAP smear) and Human Papilloma Virus (HPV) screening when not performed in accordance with Medicare NCDs 210.2 and 210.2.1. English and Spanish versions are available at https://www.incytediagnostics.com/client-support/abn/

Please consult the following NCDs to determine whether or not an ABN is required for other clinical laboratory tests.

Flow Cytometry and molecular tests are also covered under LCDs which can be found at the Noridian website listed above. If testing is to be performed outside the guidelines set forth in the LCDs, a valid ABN must accompany the request in order to ensure reimbursement.

• Requisition Requirements

In addition to having an accurate patient diagnosis (narrative and/or ICD-10) indicating the medical necessity for testing, each requisition form must also include complete patient demographic information including the patient's full legal name, date of birth (DOB), gender, and current insurance information.

For gynecological testing, the requisition must also include all testing being requested for each patient including a PAP smear, HPV, gonorrhea and/or chlamydia testing. When a PAP smear or HPV test is order, the requisition must also include the source (cervical v. vaginal), LMP date and any other clinically significant information. Please note that if any required information is missing on a requisition, it may impact turnaround time while we contact the client for the missing information.

• Specimen Labeling

Regulations require that each primary specimen be clearly labeled with at least 2 patient identifiers. A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. This may be in the form of a specimen collection tube, syringe, swab, slide or other form of specimen storage.

For prepared slides submitted to a laboratory, if the slides only contain one identifier, they must be securely submitted in a container labeled with two identifiers. If specimen containers are not appropriately marked, turnaround time could be impacted while we contact the client to confirm specimen labeling information.

• Technical Component/ Professional Component Testing

Federal guidelines require that any pathologist who performs the professional component (PC) of testing be appropriately trained and credentialed for that specialty. All Incyte pathologists meet this requirement. Each of our laboratory locations is CLIA certified and participates in regular CAP or state inspections.

• Billing Information

Unless Incyte has agreed ahead of time to "client-bill" for testing, we will attempt to bill directly and collect from third party insurers, health maintenance organizations, and federal and state health insurance programs (Medicare and Medicaid).

Per regulation we are required to bill hospitals for the clinical lab and technical pathology services provided to Medicare inpatients and outpatients of a hospital or its provider-based clinics.

• Proficiency Testing

Per CLIA regulations, Incyte Diagnostics is unable to accept client proficiency testing (PT) requests. Under most circumstance, all aspects of PT testing should be performed by the client at their facility. As a result, Incyte will not accept PT testing.

• Patient Requests for Records

In 2014, Federal HIPAA regulations were changed and allow patients to call the laboratory directly to obtain their test results. We are required under Washington state law to accommodate these requests within 15 business days.

As a courtesy to our clients, we will attempt to inform our clients when we have been requested to release lab results to the patient prior to releasing them if the patient makes the request within one week of the results being released to the client.

• Creutzfeldt – Jakob, Prion, or Mad-Cow Disease

Incyte does not offer any testing on tissue or fluid samples from the central nervous system obtained from patients with a suspected diagnosis of Creutzfeldt – Jakob, Prion or Mad-Cow Disease. It is our policy to immediately return any such specimen to the client.

NCD Section	NCD Title
190.25	Alpha-fetoprotein
190.15	Blood Counts
190.20	Blood Glucose Testing
190.26	Carcinoembryonic Antigen
190.19	Collagen Crosslinks, any Method
190.24	Digoxin Therapeutic Drug Assay
190.34	Fecal Occult Blood Test
190.32	Gamma Glutamyl Transferase
190.21	Glycated Hemoglobin/Glycated Protein
190.33	Hepatitis Panel/Acute Hepatitis Panel
190.27	Human Chorionic Gonadotropin
190.14	Human Immunodeficiency Virus (HIV) Testing (Diagnosis)
190.13	Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)
190.23	Lipid Testing
190.16	Partial ThromboplastinTime (PTT)
190.31	Prostate Specific Antigen
190.17	Prothrombin Time (PT)
190.18	Serum Iron Studies
190.22	Thyroid Testing
190.28	Tumor Antigen by Immunoassay - CA 125
190.29	Tumor Antigen by Immunoassay - CA 15-3/CA 27.29
190.30	Tumor Antigen by Immunoassay - CA 19-9
190.12	Urine Culture, Bacterial