Annual Notice to Clients - 2025

January 27, 2025

To Our Clients:

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:

Main Laboratory Locations:

13103 E Mansfield, Spokane Valley WA
221 Wellsian Way, Richland WA
55 W Tietan St, Walla Walla WA
500 W Broadway St, Missoula MT
2811 South 102nd, Ste 170, Tukwila WA
15912 E Marietta Ave, Ste 200, Spokane Valley WA
750 N Syringa, Ste 101, Post Falls ID

Collection Centers:

9631 N Nevada St, Ste 210, Spokane WA
105 W Prairie Shopping Ctr, Hayden ID
750 N Syringa, Ste 101, Post Falls ID
55 W Tietan St, Walla Walla WA
20 East J Street, Deer Park, WA
315 W Dalton Ave, Coeur d'Alene ID
1129 S 2nd Ave, Ste B, Walla Walla, WA
185 W 4th Ave, Ste B, Post Falls, ID
105 W 8th, Ste 6020, Spokane, WA
221 Wellsian Way, Richland WA
318 E Rowan Ave, Ste 205, Spokane WA
22180 Olympic College Way NW, Poulsbo WA
3001 St Anthony Way, Ste 107, Pendleton, OR
905 East D Street, Deer Park, WA
7173 E Super 1 Loop, Ste A, Athol, ID
1551 E Mullan Ave, Bldg A, Ste 102, Post Falls, ID
980 W Ironwood Dr, Ste 101 Coeur d'Alene, ID

MedicoLegal Specimens

Incyte does not accept, process, or transport any specimens collected for medicolegal purposes.

Requisition Requirements

In addition to having an accurate patient diagnosis (narrative and/or ICD-10 supported in the patient's medical records) 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 test, gonorrhea and/or chlamydia testing. When a PAP test or HPV test is ordered, 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 when it is necessary to 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.

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.

Medical Necessity

Per applicable CMS regulations and most third-party payer guidelines, 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 both the intent to order laboratory or pathology testing and to support medical necessity.

For pathology and laboratory testing a signed requisition is not required; however, all orders must be supported via signed chart notes and made available upon request.

Complying with Signature Requirements for Diagnostic Tests

Title	Complying with Signature Requirements for Diagnostic Tests
Date	2013-05-31

Issue: Medicare is denying an increasing number of claims because documentation submitted for diagnostic tests does not include signed test orders or evidence of intent (MD progress notes listing tests needed) and evidence of medical necessity (description of clinical conditions and treatment showing the need for the testing).

Guidance: While the physician's signature is not required when initially ordered for clinical diagnostic tests, upon review by Medicare contractors, there must be evidence to support the physician's intent to order the tests performed and documentation of medical necessity is required. Claims may be denied if signatures, evidence of intent, and medical necessity are missing. If the physician signature is not legible on an order or progress note, providers may submit a signature log or attestation statement to support the identity of the illegible signature. For more information, please refer to the Medicare Learning Network® publication titled Complying With Medicare Signature Requirements Fact Sheet (PDF) .

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceLabServices-Fact-Sheet-ICN909221.pdf#:~:text=requisition%2C%20or%20a%20medical%20record%20supporting%20the%20physician%E2%80%99s,laboratory%20services%20documentation%20includes%20the%20order%20%28including%20standing

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 test) 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 an ABN is required for other clinical laboratory tests.

NCD SECTION	NCD TITLE
190.25	Alpha-fetoprotein
190.15	Blood Counts
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

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 to ensure reimbursement. Corresponding billing and coding articles may also be useful.

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

No Surprises Act

For non-insured and self-pay patients, please contact us at GoodFaithEstimates@incdx.com or call 509-892-2784 (Monday-Friday 8 a.m. – 2 p.m.) for a good faith estimate. Estimates will be provided within 1 business day.

To assist with meeting the requirements of the balanced billing provisions under the Federal No Surprises Act, hospital clients may reference our list of contracted payers provided on our website.

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.

Proficiency Testing

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

Creutzfeldt – Jakob, Prion or Mad-Cow Disease

Incyte Diagnostics will not perform any testing on specimens (except for cerebral spinal fluid (CSF)) or patients with known or suspected prion disease, such as CJD or TSE (Transmissible Spongiform Encephalopathy). This includes brain biopsies, spinal cord biopsies or autopsies. This includes tissue that is fresh, frozen or fixed in formalin or alcohol. In addition, specimens other than CSF of patients with or suspected of having TSE will be sent to a facility that specializes in handling these types of specimens. Incyte should be notified of possible CJD or other TSE infected patient cases before any specimen/tissue is sent to Incyte.

For additional information, please visit our website at http://incytediagnostics.com.