Indigenuity Clinical Laboratory Inc.

2025 Annual Physician Notice

OFFICE OF INSPECTOR GENERAL

The Office of Inspector General (OIG) recommends that clinical laboratories provide annual notices to physicians and other healthcare providers using their laboratory services to inform participating healthcare networks and ordering practitioners, collectively called clients, of the policies and procedures for ordering diagnostic testing and billing requirements. The annual notice provides compliance information about federal and state legal monitoring requirements governing independent clinical laboratories. The information contained within this notice is intended to create awareness of all federal and state regulations. If you have questions, contact us for more details.

PRIVACY AND SECURITY RULES

Indigenuity Clinical Lab Inc., hereafter Indigenuity, is a healthcare provider and a covered entity under the Health Insurance Portability and Accountability Act (HIPAA). Indigenuity complies with all federal privacy and security rules.

ANTI-KICKBACK LAWS

Federal law prohibits offering or paying any remuneration to induce or reward the referral of clinical laboratory testing covered by CMS or any other federal health care programs, including the Indian Health Services, 638 Tribal Health programs, and Urban Indian Health programs. Any form of a kickback, payment, or other remuneration (e.g., anything of value) intended to secure a federal health care program referral is strictly prohibited and should be reported to Native American Development Corporation's compliance department by calling 406.259.3804.

STARK LAWS

Indigenuity complies with all aspects of the Stark law, also called the physician self-referral law. The Stark law(s) prohibits all financial relationships between a physician, a physician's immediate family, and a laboratory. Unless the relationship meets the criteria for the Stark law's exceptions, a physician may not refer Medicare patients to the laboratory, and the laboratory may not bill Medicare for services from the referring physician. Examples of financial relationships include but are not limited to monetary incentives, leasing or renting space or equipment, and purchasing medical or other services by the laboratory from a referring physician.

MEDICAL NECESSITY INFORMATION

At Indigenuity, we strive to empower our client accounts to order only those lab tests deemed medically necessary for the individual patient. We ensure the convenience of ordering standard panels and custom profiles does not impact this ability. While we recognize the value and importance of convenience, indiscriminate use of panels and profiles leads to ordering tests that are not considered medically necessary. Therefore, all tests ordered in our panels and profiles can be individually ordered. A component test not listed separately on the request form may be written in the requisition section. We recommend that physicians and nonphysician practitioners order individual tests or a less inclusive profile when not all tests are included in the panel or profile.

The Centers for Medicare and Medicaid Services (CMS) sets the standard for medical necessity and only pays for laboratory testing that meets the coverage criteria deemed medically necessary and appropriate for the effective diagnosis and treatment of the individual patient. The medical necessity for drug testing is based on patient-specific criteria identified within the patient's medical assessment, and documentation is provided by qualified and licensed physicians, nonpractitioner physicians, and other authorized healthcare providers.

As a participating CMS program, ordering providers must understand and implement compliant test ordering procedures. Tests must be ordered, performed, and billed consistently with all federal and state laws and compliance regulations. Ordering providers are responsible for ordering laboratory tests deemed medically necessary, documenting the need within the patient's medical record, and providing appropriate diagnostic information within the narrative using appropriate procedure codes. Under the False Claims Act, any ordering provider who orders medically unnecessary laboratory testing for which CMS provides reimbursement may be subject to civil penalties.

NATIONAL AND LOCAL COVERAGE DETERMINATIONS

Indigenuity is subject to the Medicare National Coverage Determination (NCDs) and Local Coverage Determinations (LCDs) of the Part B Medicare Administrative Contractor (MAC) for jurisdiction via Noridian Healthcare Solutions. These policies specify the conditions for which included testing is considered covered and reimbursable or considered a non-covered service. For more information, please visit http://cms.gov.

PRIOR AUTHORIZATION

Some payers may require prior authorization for laboratory services. The ordering provider's office should complete any required prior authorization approval before submitting the laboratory test order. A copy of the prior authorization approval documentation should be provided with the order.

LABORATORY TESTING AND PATIENT-SPECIFIC ORDERS

CMS governs all covered indications, limitations, and/or medical necessity for clinical laboratory testing, which must be conducted using written orders. Testing will only be performed with signature confirmation on the accompanying order.

All tests can be ordered by hard copy requisition form or within Orchard Enterprise Outreach, a web-based portal. Both formats are designed for individualized testing of patient-specific and medically necessary orders. Indigenuity does not accept laboratory test orders from other requisition forms or

incomplete orders. As required, Indigeneity may contact the ordering providers to request a resubmission of the requisition form or web-based order.

DEFINITIVE URINE DRUG TESTING

Based on the patient's historical use and risk factors trends, physician-directed definitive drug testing is reasonable and necessary when ordered for an individual patient. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive urine drug testing orders should be individualized based on clinical history and risk assessment and documented in the medical record. Medical necessity criteria for urine drug testing must be based on patient-specific elements identified during the clinical evaluation and must be documented by the clinician in the patient's medical record and minimally include:

a. Patient history, physical examination, and previous laboratory findings.
b. A signed and dated order or intent to order is noted in the medical record.
c. Current treatment plan.
d. Prescribed medication(s).
e. Risk assessment.

Tests used for routine and non-medical screening, also called non-medical forensic or compliance testing, without regard for medical treatment are considered non-covered testing by CMS. An independent clinical laboratory may charge 115% of the Medicare rate for non-covered testing as a self-pay option.

CODING GUIDELINES

One presumptive drug testing code may be billed once per patient per day, as indicated by the code description, and should only be billed at one unit regardless of the provider.

One definitive drug testing code may be billed once per patient per day, as indicated by the code description, and should only be billed at one unit regardless of the provider.

The documentation should support the medical necessity of the drug testing ordered and the clinical indicators that led to the test ordering.

DOCUMENTATION REQUIREMENTS

All documentation must be maintained in the patient's medical record and available to the contractor upon request. Every record page must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)), and the name of the physician or non-physician practitioner responsible for providing the care to the patient. The submitted medical record should support using the selected diagnosis code(s) with the submitted CPT/HCPCS code describing the service performed.

The medical record documentation (e.g., history, physical, and progress notes) maintained by the ordering physician/treating physician must indicate the medical necessity for performing a drug test. The treating provider must order all tests in writing, and all drugs/drug classes must be shown in the order.

If the service provider is not the ordering/referring physician, that service provider must maintain hard copy documentation of the lab results, along with copies of the ordering/referring physician's order for

the drug test. The physician must include the clinical indication/medical necessity in the order for the drug test.

MEDICO-LEGAL TESTING

Medical Forensic testing is not available through the Indigenuity clinical laboratory. We refer these lab requests to each State's Medical Examiner's office. If a specimen analysis may have unusual legal implications, please consult the laboratory director or manager at 406.794.2809.

NON-MEDICAL FORENSIC USE ONLY TESTING

Non-medical forensic use-only testing is most used for legal compliance related to criminal investigations, court conditions, and probation and parole status checks. However, it is not currently available through Indigenuity. Indigenuity is exploring the addition of non-medical forensic urine drug testing for our community partners.

NO CHARGE FOR TESTING

Indigenuity clinical laboratory bills appropriately for all tests performed. Any test not performed for any reason will be promptly and appropriately credited.

The test is canceled per client, and the test results are before the credit request.

If a client has ordered the test and we run it per their request, it is too late to cancel once any results are entered into our laboratory reporting system. The bill should be sent to the ordering provider location rather than the patient or their insurance.

The test has been canceled per the client, and the test still needs to be given a result.

If results are not entered into our laboratory reporting system, we will credit the test as the client requested.

REFERRAL TO ANOTHER LAB

Tests not performed in the Indigenuity clinical laboratory can be referred to another qualified, licensed reference laboratory. If a lab is referred to another reference lab, Indigenuity staff will inform the ordering provider of the specimen's location and storage requirements. Indigenuity will send a report to the ordering physician or qualified non-physician (e.g., P.A., Nurse Practitioner, Advanced Practice Nurse Practitioner).

REFLEXIVE TESTING

Some tests can be ordered as reflex panels, and additional testing is done automatically in response to the initial results. When further testing is done, the user has chosen a reflexive panel; the fees for the additional testing can be found in the Indigenuity fee schedule.

REPEAT TESTING

Whenever there is a question about the validity of a test result, a repeat test will be performed upon request at no extra cost.

REPORTING

As a test result becomes available, it is entered into the laboratory information system and immediately accessible for transmission to providers to look up results via our outreach portal.

Results may also be printed and mailed or faxed (per client's request) the next business day. Providers can call Client Support Services at 406.794.2809 if needed sooner for a verbal result. Requesting laboratory values via telephone directly to the laboratory reduces the time available for technical tasks and hinders the availability and efficiency of the laboratory staff. Please direct your calls to CSS; they will forward them to the laboratory if appropriate.

The following results cannot be faxed unless the patient's name is coded/de-identified or with a patient-signed authorization for use and disclosure:

- Drugs of abuse
- Toxicology screens
- Communicable disease results

STAT TESTING

There is no STAT fee. The online testing guide indicates that many procedures are available STAT 24 hours daily. Others may be treated as STAT after consultation with a Laboratory Manager or Director. Confirmatory toxicology test results may be available between 24 to 72 hours. The Laboratory Manager can be reached at 406.794.2809.

Local Courier Service Expectations: The drop-off cut-off time is 3:30 p.m. Monday through Friday.

Non-Local Courier Service Expectations: Shipped specimens may be delivered Monday through Friday, 8:00 a.m. to 4:30 p.m.

Results shall be provided within 24 to 72 hours from when the specimen is prepared for analysis.

SUPPLIES

Some supplies (e.g., requisition forms, specimen bags, etc.) are routinely provided to outside clients at no charge. Please call Client Support Services at 406.794.2809 for more information.

STANDARD TEST TURN AROUND TIME

Confirmatory toxicology testing requires extensive sample preparation. Depending on the complexity of the testing, results are available within 24 to 72 hours.

Presumptive toxicology testing requires minimal preparation, and results are available within 24 hours.

Complete blood count (CBC) hematology testing requires minimal sample preparation, and results are available within 24 hours.

Repeat testing may take additional time.

Indigenuity observes several federal holidays. These include New Year's Day, Martin Luther King Jr.'s birthday, President's Day, Juneteenth, Independence Day, Labor Day, Veteran's Day, Indigenous People's Day, Thanksgiving, and Christmas.

Client Support Services will operate regular courier service and observe usual office hours on these days. However, since these are holidays for Indigenuity, the laboratory will be on holiday staffing, and test run schedules may be altered.

HOW TO SEND A SPECIMEN/UNACCEPTABLE CONDITIONS

Indigenuity requires our users and clients to place at least two patient identifiers on every specimen's label to meet the patient safety goals. The most common and appropriate patient identifiers are Name, Birth date, Assigned Patient ID Number, and Assigned Specimen ID Number. The patient's floor, clinic, hospital, provider, or the specimen's collection date are invalid identifiers.

The identifiers must appear on the specimen and the requisition paperwork. The laboratory cannot accept responsibility for identifying unlabeled/mislabeled specimens. If a specimen is unlabeled/mislabeled:

1. The provider facility ordering location will be notified.
2. For specimens originating through the Outreach portal, the requested lab work will be canceled, except in rare cases where recollection of the specimen would place the patient in danger and the specimen is reasonably identifiable. In those rare instances, the originating person(s) must receive authorization from the chief medical officer, medical director, chief nursing officer, or authorized on-call designee. If authorized, the originating person must identify the specimen(s) and sign the original requisition indicating acceptance of responsibility for the identification. The specimen will be processed in this rare event, and the laboratory will complete an "Unusual Incident Report" documenting the event.

SAMPLE RETURNS

Indigenuity's Client Support Services occasionally receives requests to return specimens to clients. These requests will be reviewed and may be honored if the circumstances fit into an appropriate category. The procedure for returning samples is outlined below.

1. Samples may be returned to the ordering location only. If the request comes from another entity, they will be referred to the ordering location.
2. A sample may be returned only if it is in the original container we received it in, with the client labeling intact. The Laboratory Director must approve exceptions.
3. The client must cover the cost of returning a sample. If returned using a shipping company, the client's account number should be given as the payer. We will use our courier or the client's courier to return the sample when possible.
4. The client database will record the date requested, the date returned, the patient's name, ID number (indicating location), contact person, specimen type, and shipping temperature.
5. Requests from legal entities will be forwarded to the laboratory legal representative.

Please note that Indigenuity does not accept requests for human samples for research testing.

DISCREPANCY BETWEEN SPECIMEN LABEL AND REQUISITION ORDER OR FORM

A requisition order form must accompany the specimen(s) sent to the laboratory. The patient's name and participating healthcare provider information on the requisition form must match the name and number on the specimen container. The ordering provider's name and NPI (National Provider Identifier) must be included on the requisition.

When a discrepancy exists, specimens are deemed unacceptable, and the policy followed is the same as that described above for unlabeled/mislabeled specimens.

Please ship specimens to Indigenuity Clinical Lab, 502 N. 30th St, Billings, MT 59101.

We will notify you promptly if discrepant specimens or paperwork are received in our processing area.

The provider's ordering location will be notified if a specimen is considered unacceptable for testing. Each specimen will be discarded with notifying the ordering location.

LABORATORY SUPPORT AND CONTACTS

Technical and clinical inquiries on assays performed at Indigenuity Clinical Laboratory should first be directed to Client Support Services at 406.794.2809. If necessary, they can redirect the inquiry as appropriate.

The Laboratory Director Pathologist is available to assist our participating healthcare providers select and interpret laboratory tests. The Laboratory Director Pathologist is an intermediary between those professionals involved in direct patient care and the laboratory staff. Documentation is maintained on each request for service or information, and changes in laboratory services are determined, in part, by suggestions in this record.

MEDICARE AND MEDICAID FEE SCHEDULE

Indigenuity clinical laboratory diagnostic and treatment testing lists the Medicare and Medicaid CPT and HCPCS G-Codes and reimbursement rates for the calendar year. In most cases, Medicare reimbursement is equal to or less than the Medicare reimbursement rate. Exhibit A provides the current CMS reimbursement rates and covered procedure codes.

AFFORDABLE CARE ACT

Indigenuity recognizes that the Affordable Care Act (ACA), the healthcare law, created expanded access to affordable healthcare coverage for all Americans, lowering costs to improve quality and care coordination. The ACA requires individuals to maintain health insurance that meets the minimum essential coverage requirements, qualify for an exemption from a shared responsibility payment, or file a tax exemption. Members of federally recognized tribes may access care from the Indian Health Service, Tribal 638 Health Programs, or Urban Indian Health Programs and claim an exemption to the shared responsibility payment for care received through an I/T/U.

Section 1402 (d)(1) indicates that issuers of qualified health plans (QHPs) must eliminate all cost-sharing (e.g., co-payments and deductibles) for members of federally qualified tribes and shareholders in Alaska Native regional or village corporations with a household income of less than 300 percent of the federal poverty level if insurance is obtained through the Health Insurance Exchange.

American Indian and Alaska Native people may also be eligible for Medicaid and other Medicaid programs (e.g., HMK, CHIP, etc.). Medicaid programs increase access to services that a local Indian Health Care Program (I/T/U) might not be able to provide, such as reference laboratory testing.

American Indian and Alaska Native people may qualify for zero or limited cost-sharing plans, reducing out-of-pocket costs and deductibles when receiving care from Indian Health Care Providers. However, AIANs enrolled in US federally recognized tribes with a household income between 100 and 300 percent of the federal poverty level may have to pay premiums.

American Indian and Alaska Native people with an income between 300 and 400 percent of the federal poverty level may be eligible for a sliding fee or discount premium tax credit and limitations on cost sharing. The Health Insurance Exchange can allow tribes, tribal organizations, and urban Indian organizations to pay premiums for enrolled members of federally recognized tribes and Alaska Native shareholders.

Please notice that there is no cost share for any American Indian or Alaska Native for any item or service obtained directly through the I/T/U or referrals under contract health services without regard to household income.

FINANCIAL ASSISTANCE PROGRAMS

Indigenuity recognizes that quality healthcare has related costs, which may create a cost burden among patients or prevent some patients from seeking care to avoid necessary treatment. Indigenuity is dedicated to delivering the best healthcare services to promote high-quality patient care. Indigenuity offers a financial assistance program to ensure affordable access to laboratory services when a specific exemption does not apply.

PATIENT ACCOUNT BILLING POLICY

Indigenuity Clinical Lab Inc. reserves the right to use resources available to search for active insurance information on all orders. At Indigenuity, insured patients without an allowable ACA exemption are billed deductibles, co-insurance, and co-payments as required by their health insurance plan.

Under HIPAA, patients may opt out of using their insurance benefits to prevent reporting services to their insurance provider. Indigenuity offers patients self-pay options for those who want to waive their insurance benefits and pay the out-of-pocket rate for laboratory services. When a patient waives their insurance benefit, they must sign an Opt-out of Insurance Coverage Application Form and Agreement or, for Medicare patients, the Advanced Beneficiary Notice when the order is placed. Indigenuity must be informed of this decision at the time of ordering and must be provided with the patient's insurance information. The patient will then be billed the out-of-pocket rate for the laboratory service. If payment for services is not received within 60 days, Indigenuity will bill the patient's insurance to secure reimbursement.

Testing service coverage varies depending on the type of laboratory test ordered, individual insurance plan, and patient benefits. Some laboratory testing services may not be covered under a particular patient's insurance plan due to local coverage determinations or insurance coverage policies and limitations of benefit.

Patients should contact PGM Northstar, our billing service team, if they have questions about their bill or need to establish a payment agreement. Please call 888.336.8283 extension 267 for patient accounts or 877.646.9237 extension 214 for customer service.

LABORATORY SERVICES PROVIDED HOSPITALS AND SKILLED NURSING FACILITIES

To ensure appropriate billing practices, hospitals and skilled nursing facilities must notify Indigenuity when ordering laboratory services for a hospital patient or resident. Per the Medicare Claims processing manual, Chapter 16, Section 40.3, only the hospital can bill for hospital outpatient laboratory services provided to Medicare beneficiaries. Per the Medicare Outpatient Prospective Payment System, payment for clinical diagnostic laboratory procedures provided to hospital outpatients is typically a packaged payment. Per the Medicare Inpatient Prospective Payment System, payment for clinical diagnostic laboratory procedures is packaged into the admissions payment. Payment packaging policies also apply to skilled nursing patients covered by Medicare.

LABORATORY SERVICES PROVIDED TO OPIOID TREATMENT PROGRAMS

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by certified Opioid Treatment Programs (OTPs) as defined in 42 CFR 410.67(c). Toxicology testing for OPTs is a bundled service for OUD treatment and can only be billed by the OTP for Medicare Part B.

QUESTIONS

Questions regarding toxicology and hematology procedures may be directed to Client Support Services at 406.794.2809.

THE GRIEVANCE PROCESS

As an independent clinical laboratory, Indigenuity understands customers, ordering providers, healthcare facility administrators, and patients may have an actual or perceived wrong or other cause for complaint or protest specific to patient care and safety, confidentiality, harm, or another adverse event concern. In the event of an actual or perceived concern, Indigenuity uses a formal grievance procedure for prompt and equitable resolutions of complaints that incorporate due process and compliance standards. Please contact the NADC Administrative Office at 406.259.3804 to request the clinical laboratory grievance report forms.

EXHIBIT A | CMS FEE SCHEDULE

Code Description	Procedure Code	Medicare Allowable	Uninsured Contract Allowable
Urine Drug Testing, Definitive, 1-7 drug classes*	G0480	$114.43	$35.00
Urine Drug Testing, Definitive, 8-14 drug classes*	G0481	$156.59	$50.00
Urine Drug Testing, Definitive, 15-21 drug classes*	G0482	$198.74	$60.00
Urine Drug Testing, Definitive, 22 or more drug classes*	G0483	$246.92	$75.00
Gapapentin, whole blood serum, or plasma	80171	$21.67	$7.00
Urine Drug Testing, Presumptive, any number of classes	80305	$12.60	$4.00
Urine Drug Testing, Presumptive, any number of classes	80306	$17.14	$6.00
Urine Drug Testing, Presumptive, any number of classes	80307	$62.14	$20.00
Blood count; automated differential WBC count	85004	$6.47	$3.00
Blood count; blood smear, microscopic examination with manual differential WBC count	85007	$3.80	$3.00
Blood count; blood smear, microscopic examination without manual differential WBC count	85008	$3.43	$3.00
Blood count; hematocrit (Hct)	85014	$2.37	$3.00
Blood count; hemoglobin (Hgb)	85018	$2.37	$3.00
Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count	85025	$7.77	$6.00
Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)	85027	$6.47	$6.00
Blood count, manual cell count (erythrocyte, leukocyte, or platlet) each	85032	$4.31	$3.00
Blood count; red blood cell (RBC), automated	85041	$3.02	$3.00

***Urine drug testing classes include any classes provided in Exhibit B.**

EXHIBIT B | TOXICOLOGY DEFINITIVE DRUG CLASSIFICATION REFERENCE

Drug/Analyte	Drug Classification	Procedure Code
Ethyl Glucuronide/Ethyl Sulfate	Alcohol Biomarkers	**80321**
Amphetamines, Methamphetamines, Phentermine	Amphetamines	**80324-80326**
Methamphetamine – d/l Isomers	Stereoisomer	**80374**
Fluoxetine, Sertraline	Antidepressants, serotonergic class	**80332-80334**
Bupropion	Antidepressants, NOS	**80338**
Aripiprazole, Clozapine, Haloperidol, Olanzapine, Quetiapine, Risperidone	Antipsychotics, NOS	**80341-80344**
Alprazolam, Clonazepam, Lorazepam, Oxazepam, Temazepam	Benzodiazepines	**80346-80347**
Buprenorphine	Buprenorphine	**80348**
Marijuana, THC	Cannabinoids, natural	**80349**
Benzoylecgonine (cocaine metabolite)	Cocaine	**80353**
Fentanyl and analogues (Fentanyl, Norfentanyl, 4-ANPP	Fentanyl	**80354**
Gabapentin	Gabapentin	**80355**
6-MAM (Heroin metabolite)	Heroin Metabolite	**80356**
Ketamine	Ketamine	**80357**
Methadone/EDDP (methadone metabolite)	Methadone	**80358**
MDMA	Methylenediozyamphetamine	**80359**
Methylphenidate, Ritalinic Acid	Methylphenidate	**80360**
Codeine, Hydrocodone, Hydromorphone, Morphine	Opiates	**80361**
Naloxone, Natrexone	Opioids and opiate analogs	**80362-80364**
Oxycodone, Oxymorphone	Oxycodone	**80365**
Phencyclidine	Phencyclidine	**83992**
Pregabalin	Pregabalin	**80366**
Tramadol	Tramadol	**80373**
Xylazine	NOS	**80375-80377**