

2026 Gravity Diagnostics Annual Physician Notice

Gravity Diagnostics is dedicated to ensuring that all business conducted follows all federal, state and local agencies' laws and regulations. The Office of Inspector General (OIG) recommends clinical laboratories send notices to physicians and other providers who use their services, at least once a year, to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services. This Annual Notice is provided pursuant to that recommendation. The following information is intended to promote awareness of federal regulations and to explain the requirement for ordering providers to furnish appropriate documentation when ordering testing services. If you have questions about the contents of this notice, we encourage you to contact us for more information. You may also visit [the OIG website](#).

Authorized Ordering Providers

A clinical laboratory may examine a specimen only when the test has been ordered by a licensed physician, a qualified practitioner or non-physician practitioner authorized by law to order laboratory testing. All ordering providers must have a valid National Provider Identifier (NPI#), available [here](#).

Medicare requires individuals referring orders for laboratory services to be registered in the CMS Provider Enrollment, Chain and Ownership System (PECOS) Providers may access the [PECOS website](#).

It is your responsibility to stop ordering tests and to immediately notify Gravity if:

- (a) your license has been revoked or suspended;
- (b) you have been excluded from the Federal Programs;
- or (c) if your enrollment in Federal Programs has been revoked or suspended.

All orders shall consist of either

- (a) handwritten signature of name or initials,
- or (b) electronic or computer-generated signature of name or unique identifier acceptable to the Centers for Medicare and Medicaid Services (CMS).

Medical Necessity and Diagnosis Codes

Federal Programs will only pay for tests that meet coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. The medical need for testing must be based on patient-specific factors as determined during their clinical assessment and documented by the ordering provider in the patient's medical record and/or treatment plan. You can access more information about Medicare's Laboratory documentation requirements on the [CMS MLN Site](#). Note that other third-party payors may have additional documentation requirements. Gravity Diagnostics reserves the right to request patient records from our providers when requested by any payor or for internal auditing purposes.

Tests used for routine screening of patients without regard to their individual need are not usually covered and therefore are not reimbursed. As a Medicare provider, Gravity Diagnostics has a responsibility to educate ordering providers and to implement ordering procedures to help ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. As the ordering provider, you are responsible for ordering tests only when they are medically necessary, for documenting medical necessity in the patient's permanent medical record, and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity to Gravity Diagnostics. Medicare billing and coding guidelines for toxicology testing may be found [here](#).

All other policies can be found on the [CMS website](#).

Please note that laboratories are prohibited from using diagnostic information provided by the provider from earlier dates of service, and from inserting diagnosis codes based on their own evaluation of the patient's probable or most likely diagnosis, or from speaking with a patient.

The OIG takes the position that an ordering provider who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.

Test Ordering

All tests are available for order by test requisition forms and secure electronic ordering option. A Gravity Diagnostics requisition form (whether via electronic ordering or in paper form) must always be used when ordering tests. The Gravity Diagnostics requisition forms are designed to emphasize patient specific ordering of only medically necessary tests. Medicare regulations require that all orders for laboratory tests be in writing. If an ordering provider or his/her authorized representative orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. As necessary, Gravity Diagnostics will contact ordering providers to have them resubmit the test order on a Gravity Diagnostics test requisition form or otherwise clarify each specific test being ordered. Only tests that are ordered will be reported and billed.

Patient Specific Ordering

Policy changes and guidance from Medicare Administrative Contractors, other government regulatory authorities and commercial insurers discourage, if not outright prohibit, clinicians' use of non-patient-specific panels, including "custom profiles," when ordering laboratory drug testing. Gravity Diagnostics supports these efforts to help ensure testing is medically necessary based on individual patient specific elements identified during the clinical assessment. Gravity Diagnostics does not accept non patient specific panels, including "custom profiles" or "standing orders".

Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), Gravity Diagnostics is a health care provider and a covered entity. It is our policy to fully comply with the HIPAA privacy and security standards.

Clinical Consultations

Physicians and other clinicians authorized to order tests have access to clinical consultations with Gravity

Diagnostics specialist where they can review results and answer questions. This team can be reached by calling our main number at (855) 841-7111 during normal business hours.

Prohibited Practices

It is the policy of Gravity Diagnostics to comply with all aspects of the laws and regulations governing physician self-referral, most notably including the federal Stark law (also known as the physician self-referral law). The Stark law's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers), and the relationship does not fit into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory, and (b) the laboratory may not bill Medicare for services referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include, but are not limited to the lease or rental of equipment and the purchase of medical or other services by a laboratory from a referring physician.

Federal law prohibits offering or paying any remuneration, meaning anything of value, to induce or reward the referral of tests that are covered by Medicare, Medicaid or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited and should be reported to the Gravity Diagnostics compliance department via Verify Comply by visiting report.complyline.com; Organization PIN 593633; Site ID 812 or by calling (800) 928-0084. ***All reports can be made anonymously.***

Patient Billing Policy

Insured patients are billed deductibles, co-insurance and co-payments as required by their insurance provider. Gravity Diagnostics reserves the right to use resources available to search for active insurance if information is not provided or if the order is marked "Self Pay" "Uninsured" or "Patient Does Not Have Insurance Coverage." Under HIPAA, patients may opt out of using their insurance benefits to prevent reporting this service to their insurance carrier. Gravity Diagnostics offers a patient self-pay option for patients who wish to waive insurance benefits and pay a flat, out-of-pocket rate for testing services. Patients seeking testing services who do not wish to use their insurance coverage must sign a patient Opt Out of Insurance Coverage Application Form & Agreement or Advanced Beneficiary Notice (Medicare patients only) at the time of ordering. Gravity Diagnostics must be informed at the time of ordering if the patient is choosing this option and prepayment will be expected at the out-of-pocket rate for services performed. In the event, pre-payment is not received the patient will be billed directly. If payment for such service is not received from the patient within 30 days, Gravity Diagnostics will bill the patient's insurance to secure reimbursement. Patients should contact us if they have questions about their bill or need to establish payment arrangements at 855-841-7111 Option 2.

Financial Hardship Program

Gravity Diagnostics understands that providing quality patient care has a related cost, which in some situations may be a financial burden for patients and results in some patients avoiding certain necessary services because they are concerned about the expense. Gravity Diagnostics is committed to delivering the best patient care to all and has established a financial hardship program.

Providers should notify Gravity, at the time of order, if they believe a patient will qualify for the program. Our

dedicated team will work with these patients to determine if they meet the qualifications and resolve these balances in accordance with federal guidelines. Patients that receive bills from Gravity that feel they are unable to pay the balance are encouraged to contact our team at 855-841-7111 Option 2.

Prior Authorizations

Certain payers may require pre-authorization for Gravity Diagnostics' services. Any required pre-authorization paperwork should be completed by the ordering provider's office before the lab test order is submitted. Please include the pre-authorization paperwork and/or Prior authorization number with the test order. In the event, services are denied for needing prior authorization, our team may reach out to your office to initiate the process to receive retroactive Prior Authorization.

Medicare & Medicaid Rates

Gravity Diagnostics' test list with CPT and HCPCS G-Codes and Calendar Year 2025 are attached in Attachment A. The rates for these charges can be found [here](#). These rates are updated at least once yearly but often quarterly. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

Medicare National and Local Coverage Determinations

For certain tests, Gravity Diagnostics is subject to Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) of the Part B Medicare Administrative Contractor (MAC) for Jurisdiction 15, Celerian Group Solutions "CGS". Note that regardless of the state the specimen originates from, Gravity Diagnostics must bill our MAC as services are performed in Kentucky.

These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare, typically by reference to specific ICD-10 codes that are deemed to support coverage. These documents can be accessed on the [Medicare Coverage Database "MDC"](#).

Toxicology related LCD documents may be found [here](#).

Services provided for Medicare Recipients in Opioid Treatment Programs

Effective January 1, 2020, Section 2005 of 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 Opioid Treatment Programs ("OTPs") as defined by Medicare in 42 CFR 410.67(c). Toxicology testing by an OTP is bundled for OUD treatment services in an episode of care provided to people with Medicare Part B medical insurance and can only be billed by the OTP. More information can be found on the [Medicare website](#).

Note that many states also follow a bundled rate for SUD and Addiction recovery services that include payment for toxicology services. Any client that bills a bundled service must notify Gravity Diagnostics LLC to initiate a laboratory service agreement "LSA". Note clients will be financially responsible for any services included in a bundled reimbursement by Medicare and Medicaid plans.

Any questions related to this document may be sent to info@gravitydiagnostics.com.

Attachment A-Test Menu and CPT/HCPC

CPT/HCPC	Test Name/Description
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Toxicology Test - CMS codes

80307	Presumptive Toxicology Tests (Urine/Oral Fluid)
G0480	Definitive Toxicology tests, 1-7 drug classes
G0481	Definitive Toxicology tests, 8-14 drug classes
G0482	Definitive Toxicology tests, 15-21 drug classes
G0483	Definitive Toxicology tests, 22+ drug classes

All Other Testing Including AMA Toxicology Codes

36415	Venipuncture
80048	Basic Metabolic Panel
80050	General Health Panel
80051	Electrolyte Panel
80053	CMP
80061	LIPID PANEL
80069	Renal Function Panel
80074	Acute Hepatitis Panel
80076	HEPATIC FUNCTION PANEL
80156	Carbamazepine-Serum
80164	Valproic Acid
80175	Lamotrigine
80178	Lithium
80183	Oxcarbazepine Metabolite
80184	Phenobarbital, Serum
80299	Methadone Dolophine
80321	Alcohol
80322	DRUG SCREEN QUANT ALCOHOLS BIOMARKERS 3 OR MORE
80323	Oral Confirmation Fluid Mitragnine
80324	Oral Confirmation Fluid Methamphetamine
80325	DRUG SCREEN QUANT AMPHETAMINES 3 OR 4
80326	DRUG SCREEN QUANT AMPHETAMINES 5 OR MORE
80332	Oral Confirmation Fluid Citalopram
80333	ANTIDEPRESSANTS SEROTONERGIC CLASS 3-5

80334	ANTIDEPRESSANTS SEROTONERGIC CLASS 6 OR MORE
80335	Oral Confirmation Fluid Amitriptyline
80336	ANTIDEPRESSANTS TRICYCLIC OTHER CYCLICALS 3-5
80337	ANTIDEPRESSANTS TRICYCLIC OTHER CYCLICALS 6/MORE
80338	Oral Confirmation Fluid Venlafaxine
80339	Carbamazepine
80342	Oral Confirmation Fluid Norquetiapine
80343	ANTIPSYCHOTICS NOT OTHERWISE SPECIFIED 4-6
80344	ANTIPSYCHOTICS NOT OTHERWISE SPECIFIED 7/MORE
80345	Amobarbital
80346	Oral Confirmation Fluid Diazepam
80347	DRUG SCREENING BENZODIAZEPINES 13 OR MORE
80348	Oral Confirmation Fluid Buprenorphine
80349	Oral Confirmation Fluid THC-COOH
80353	Oral Fluid Benzoylecgonine
80354	Oral Confirmation Fluid Norfentanyl
80355	Oral Confirmation Fluid Gabapentin
80356	Oral Fluid 6-MAM
80357	Oral Confirmation Fluid Ketamine
80358	Oral Confirmation Fluid Methadone
80359	Oral Fluid MDA
80360	Oral Confirmation Fluid Ritalinic Acid
80361	Oral Confirmation Fluid Hydromorphone
80362	Oral Confirmation Fluid Normeperidine
80363	DRUG SCREENING OPIOIDS AND OPIATE ANALOGS 3 OR 4
80364	DRUG SCREENING OPIOIDS & OPIATE ANALOGS 5/MORE
80365	Oral Confirmation Fluid Oxymorphone
80366	Oral Confirmation Fluid Pregabalin
80367	Propoxyphene
80368	Oral Confirmation Fluid Zaleplon
80369	Oral Confirmation Fluid Cyclobenzaprine
80370	DRUG SCREENING SKEL MUSCLE RELAXANTS 3 OR MORE
80371	Alpha-PVP
80372	Oral Confirmation Fluid Tapentadol
80373	Oral Confirmation Fluid O-Desmethyltramadol
80374	DRUG SCREEN STEREOISOMER ANALYSIS 1 DRUG CLASS
80375	Xylazine
81003	Urinalysis

81025	hCG Pregnancy Test
81225	Gravity CYP2C19
81226	Gravity CYP2D6
81227	Gravity CYP2C9
81230	Gravity CYP3A4
81231	Gravity CYP3A5
81240	Gravity F2
81241	Gravity F5
81291	Gravity MTHFR
81328	Gravity SLCO1B1
81355	Gravity VKORC1
81400	Dihydropyrimidine Dehydrogenase (DPD)
81401	MOLECULAR PATHOLOGY PROCEDURE LEVEL 2
81418	Gravity PGx Comprehensive Profile
81479	HRT2A Rx
82040	Albumin
82150	Amylase
82172	Apolipoprotein A-1
82247	Bilirubin, Total
82248	Bilirubin, Direct
82306	Vitamin D
82310	Calcium
82374	Carbon Dioxide (CO2)
82435	Chloride
82465	Cholesterol
82533	Cortisol
82550	Creatinine Kinase
82565	Creatinine
82607	Vitamin B12
82627	DHEAS
82670	Estradiol
82728	ASSAY OF FERRITIN
82746	ASSAY OF FOLIC ACID SERUM
82947	GLUCOSE QUANTITATIVE BLOOD XCPT REAGENT STRIP
82977	Gamma-Glutamyl Transferase
83001	Follicle-Stimulating Hormone
83002	Luteinizing hormone
83036	A1c

83090	ASSAY OF HOMOCYSTEINE
83525	ASSAY OF INSULIN TOTAL
83540	Iron
83550	UIBC, Iron Binding Capacity
83615	Lactate Dehydrogenase (LDH)
83690	Lipase Ng
83718	HDL
83721	Direct LDL
83735	ASSAY OF MAGNESIUM
83880	B-Type Natriuretic Peptide
83992	Oral Fluid PCP
84075	Alkaline Phosphatase
84100	ASSAY OF PHOSPHORUS INORGANIC
84132	Potassium
84134	Prealbumin
84144	Progesterone
84146	Prolactin
84153	ASSAY OF PROSTATE SPECIFIC ANTIGEN TOTAL
84154	Free PSA
84155	Total Protein
84270	SHBG
84295	Sodium
84403	Testosterone
84436	ASSAY OF THYROXINE TOTAL
84439	Free T4
84443	ASSAY OF THYROID STIMULATING HORMONE TSH
84450	Aspartate Aminotransferase (AST)
84460	Alanine Aminotransferase (ALT)
84466	Transferrin
84478	Triglycerides
84480	ASSAY OF TRIIODOTHYRONINE T3 TOTAL TT3
84481	Free T3
84520	Urea Nitrogen (BUN)
84545	BUN
84550	ASSAY OF BLOOD/URIC ACID
84681	C-Peptide
84702	hCG (Total B-hCG)
85014	Hematocrit

85018	Hemoglobin
85025	CBCD
85027	CBC
85048	White Blood Count
85049	Platelets
85415	PAI-1
85610	Prothrombin Time
86038	ANA Screen, IFA With Reflex
86039	ANA Titer and Pattern
86140	C-Reactive Protein
86141	C-Reactive Protein, High Sensitivity
86146	Glycoprotein III (GP-III)
86376	Anti-TPO
86430	Rheumatoid Factor Screen W/ Reflex
86431	Rheumatoid Factor
86480	QuantiFERON-TB Gold Plus
86481	T-SPOT
86592	RPR
86593	Reflex RPR Titer
86694	HSV 1/2 IgG
86695	ANTIBODY HERPES SMLPX TYPE 1
86696	ANTIBODY HERPES SMLPX TYPE 2
86701	HIV AB Reflex Type 1
86702	HIV AB Reflex Type 2
86703	Geenius Antibody HIV 1&2
86708	HAV-IgG
86709	Hep A IgM
86735	Mumps Virus (IgG), Immune
86762	Rubella AB (IgG), Immune
86765	Measles AB (IgG), Immune
86780	Treponemal IgG & IgM Antibody reflex RPR & Titer
86787	VZV AB (IGG)
86803	Anti-HCV reflex HCV NAAT QUANT Confirm with + test
87077	CUL BACT AEROBIC ADDL METHS DEFINITIVE EA ISOL
87086	CULTURE BACTERIAL QUANTTATIVE COLONY COUNT URINE
87088	CULTURE BCT ISOL&PRSMPTV ID ISOLATE EA URINE
87186	SUSCEPTIBLTY STDY ANTIMICRBIAL MICRO/AGAR DILUTJ
87389	HIV Ag/Ab

87426	SARS-CoV-2 Antigen (QuickVue)
87481	CANDIDA ALBICANS
87486	CHLAMYDIA PNEUMONIAE
87491	CHLAMYDIA TRACHOMATIS
87501	INFLUENZA A
87502	INFLUENZA A and B
87511	Gardnerella Vaginalis
87521	HCV NAAT Qual Confirmation
87522	Reflex HCV NAAT
87529	HERPES SIMPLEX VIRUS
87535	HIV-1 NAAT Qual Confirmation
87536	Reflex HIV NAAT
87563	MYCOPLASMA GENITALIUM
87581	MYCOPLASMA PNEUMONIAE
87591	NEISSERIA GONORRHOEAE
87631	IADNA RESPIRATORY PROBE & REV TRNSCR 3-5 TARGETS
87632	IADNA RESPIRATORY PROBE & REV TRNSCR 6-11 TARGETS
87633	IADNA RESPIRATORY PROBE & REV TRNSCR 12-25 TARGETS
87634	RESPIRATORY SYNCYTIAL VIRUS A/B
87635	SARS-CoV-2 RT-PCR
87636	SARS-CoV-2/FluA/FluB
87640	STAPHYLOCOCCUS AUREUS
87641	MRSA
87651	STREPTOCOCCUS PYOGENES
87661	TRICHOMONAS VAGINALIS
87798	CORONAVIRUS 229E
87811	SARS-CoV-2 Antigen (BinaxNow)
87902	HCV Genotype
89999	Iron Profile
G0472	Hep C Screen
G0499	Hep B IgM

