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PROVIDER REFERENCE MODULE

Laboratory Services

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Laboratory Services

*Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the **fee-for-service (FFS)** delivery system.*

*For information about services provided through the **managed care** delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect, Hoosier Healthwise or Indiana PathWays for Aging (PathWays) services – providers must contact the member's managed care entity (MCE) or refer to the MCE provider manual. MCE contact information is included in the [IHCP Quick Reference Guide](#) at in.gov/medicaid/providers.*

For updates to information in this module, see [IHCP Bulletins](#) at in.gov/medicaid/providers.

Introduction

The Indiana Health Coverage Programs (IHCP) defines a *clinical laboratory* as a place where materials derived from the human body are tested, measured or examined to provide information on diagnosis, monitoring, prevention or treatment of disease or information about impairment or assessment of health. IHCP reimbursement is available for most clinical diagnostic laboratory procedures performed in a physician's office, by an independent laboratory or by a hospital laboratory for its outpatients. Laboratory procedures are subject to the rules and regulations of the Clinical Laboratory Improvement Amendments (CLIA).

To be eligible for IHCP reimbursement, a laboratory service must be ordered in writing by an IHCP-enrolled physician or other IHCP-enrolled practitioner authorized to do so under state law, and the order must include a condition-related diagnosis that necessitates the laboratory service.

Clinical Laboratory Improvement Amendment Regulations

For IHCP reimbursement of laboratory services falling under CLIA regulations, the rendering provider must obtain a CLIA number and have a valid copy of the CLIA certificate on file with the IHCP provider enrollment contractor. The IHCP reimburses these providers only for lab codes allowed by the certificate.

CLIA certification types are as follows:

- Certificate of Waiver – This certificate is issued to a laboratory to perform only waived tests.
- Certificate for Provider-Performed Microscopy (PPM) Procedures – This certificate is issued to a laboratory in which a physician, dentist or other qualified practitioner performs no test other than the PPM procedures. This certificate permits the laboratory to also perform waived tests.
- Certificate of Registration – This certificate is issued to a laboratory that enables the entity to conduct moderate or highly complex laboratory testing (or both) until the entity is determined by survey to be in compliance with the CLIA regulations.
- Certificate of Compliance – This certificate is issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.
- Certificate of Accreditation – This certificate is issued to a laboratory on the basis of the laboratory's accreditation by an organization approved by the Centers for Medicare & Medicaid Services (CMS).

For information about the procedures that are eligible for reimbursement under specific CLIA certificates, go to the CMS CLIA [Categorization of Tests](#) webpage at cms.gov.

The CLIA program is intended to ensure that providers performing laboratory procedures do so in accordance with federal regulations. For more information about CLIA, contact the Indiana Department of Health (IDOH). See the [Clinical Laboratory \(CLIA\) Licensing and Certification Program](https://www.in.gov/health/clinical-laboratory-clia-licensing-and-certification-program) webpage at [in.gov/health](https://www.in.gov/health) for contact information.

Hospital Outpatient Defined for Laboratory Services

The IHCP defines *hospital outpatient* as a member whom the hospital has not admitted as an inpatient but who is registered in hospital records as an outpatient and receives services directly from the hospital. If personnel not employed by the hospital take a tissue sample, blood sample or specimen and send it to the hospital for tests, the IHCP classifies the tests as *nonpatient* (rather than outpatient) hospital services, because the patient did not directly receive services from the hospital.

Independent Diagnostic Testing Facilities

An independent diagnostic testing facility (IDTF) is a diagnostic testing facility (entity) that is independent of a physician's office or hospital (that is, it is not owned by a hospital, individual physician or physician group). An IDTF furnishes diagnostic tests and does not use test results to directly treat patients. IDTFs are distinguished from facilities that provide similar services by their ownership structure and the types of services they perform. IDTFs must be enrolled in Medicare before enrolling in the IHCP.

Example of non-IDTF: A radiologist-owned or hospital-owned office that bills for professional interpretations and rarely bills for purchased interpretations or technical components only of diagnostic tests is *not* an IDTF.

An IDTF must employ one or more supervisory physicians who are proficient in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. A physician group practice cannot be considered a supervisory physician. In accordance with *Code of Federal Regulations 42 CFR 410.33 (b)(2)*, Medicare IDTFs have discretion in determining the qualifications required of a supervisory physician if the physician is not certified in a medical specialty.

IDTF services are billed with place-of-service (POS) code 81 – *Independent laboratory* on a professional claim (CMS-1500 claim form, IHCP Provider Healthcare Portal [IHCP Portal] professional claim or 837P electronic transaction).

Reimbursement Methodology for Laboratory Services

Most clinical diagnostic laboratory procedures performed in a physician's office, by an independent laboratory, or by a hospital laboratory for outpatients are reimbursed at the rate on the applicable IHCP Fee Schedule (professional or outpatient) or at the submitted charge, whichever is lower. (The IHCP Fee Schedules are accessible from the [IHCP Fee Schedules](https://www.in.gov/medicaid/providers) webpage at [in.gov/medicaid/providers](https://www.in.gov/medicaid/providers).)

The IHCP uses Medicare resource-based relative value scale (RBRVS) methodology to price laboratory procedures that are listed on the [Medicare Physician Fee Schedule](#) with relative value units (RVUs).

However, some procedures do not have RVUs on the Medicare Physician Fee Schedule, because the procedure meets one of the following criteria:

- Associated with special restrictions
- Carrier-priced
- Excluded from the definition of physician services
- Excluded from the Medicare Physician Fee Schedule
- Noncovered by Medicare
- Not valid for Medicare

For laboratory procedures on the Medicare Physician Fee Schedule that do **not** have RVUs, IHCP reimbursement is based on the [Medicare Clinical Laboratory Fee Schedule](#) – or on manual pricing methodology, if a rate has not yet been established by Medicare.

For laboratory procedures not covered by the Medicare Physician Fee Schedule as not meeting the definition of physician-provided services, the IHCP reimburses from the Medicare Clinical Laboratory Fee Schedule. For codes for which Medicare has not yet established a specific rate in the Medicare Physician Fee Schedule or the Medicare Clinical Laboratory Fee Schedule, the IHCP reimburses through manual pricing until Medicare assigns a rate.

Pursuant to Section 1903(i)(7) of the *Social Security Act*, Medicaid reimbursement for individual clinical laboratory procedures cannot exceed the Medicare rate of reimbursement. In accordance with the clinical laboratory reimbursement methodology set out in *Indiana Administrative Code 405 IAC 5-18-1* and in the approved Indiana Medicaid State Plan, the IHCP adopts the Medicare rates for any clinical laboratory procedure code for which the IHCP's current reimbursement rate exceeds the Medicare rate. This analysis is performed typically at the beginning of each calendar year; thus, any rate changes are effective for dates of service on or after January 1 of the current year.

Note: Outpatient laboratory services, defined as the procedure codes listed on the [Medicare Clinical Laboratory Fee Schedule](#), are not eligible for Hospital Assessment Fee (HAF) adjustments. See the [Hospital Assessment Fee](#) module for more information about the HAF program.

Billing Procedures for Laboratory Services

Laboratory services must be ordered in writing by an IHCP-enrolled physician or other IHCP-enrolled practitioner authorized to do so under state law. Laboratories performing the services must bill the IHCP (or the appropriate managed care entity) directly, unless otherwise approved.

*Note: Regulations require that the **laboratory analyzing the specimen** submit the charge to the IHCP. It is **not** appropriate for a physician to bill using **modifier 90 – Reference (outside) laboratory** for a laboratory service that was analyzed by an outside laboratory.*

Providers that submit specimens to an outside laboratory may be eligible for reimbursement of handling and conveyance expenses, as described in the [Handling and Conveyance of Specimens From Doctor's Office to Laboratory](#) section.

When billing laboratory services, providers should use the pathology and laboratory guidelines noted in the Current Procedural Terminology (CPT^{®1}) and Healthcare Common Procedure Coding System (HCPCS) codes. Clinical diagnostic laboratory services include all laboratory tests listed in CPT codes 80047 through 89331, as well as some G, P and Q codes listed in the HCPCS Level II Code book.

Providers may submit only one claim when providing multiple laboratory services. If the provider administers the procedure to a member more than one time in the same day, the provider should bill it as only one line item, with an indication of the number of units of service given that day.

Hospitals must bill laboratory services on an institutional claim (UB-04 claim form, IHCP Portal institutional claim or 837I electronic transaction) using the most appropriate HCPCS or CPT code. Revenue codes billed without the appropriate HCPCS or CPT procedure code are denied. Providers must bill the professional component of a laboratory service performed in an outpatient hospital setting on the professional claim (CMS-1500 claim form or electronic equivalent) with the appropriate HCPCS or CPT code and modifier **26 – Professional component**.

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See the [Claim Submission and Processing](#) module for general billing instructions.

*Note: Hospice providers must not include costs for services such as laboratory and X-rays with the attending physician's billed charges. The daily hospice care rates that the IHCP pays include these costs, which are expressly the responsibility of the hospice provider. However, if an IHCP hospice member requires laboratory services **not related to the terminal illness**, the hospice provider is not responsible for these laboratory services. The IHCP allows for separate reimbursement of non-hospice-related laboratory treatment in these circumstances. IHCP providers billing for the treatment of nonterminal conditions are reminded that they are responsible for obtaining IHCP prior authorization (PA) for any nonhospice services that require PA.*

Billing for Professional and Technical Components

Some clinical diagnostic laboratory procedures have both professional and technical components of service. A physician typically performs the professional component of the lab procedure. The IHCP reimburses the physician for the professional component when the physician bills the appropriate CPT lab code along with modifier 26 – *Professional component*.

When billing only the technical component of the procedure, providers should append modifier TC – *Technical component* to the appropriate CPT lab code. When billing for both professional and technical components of service, providers should use no modifiers.

Providers should bill the appropriate lab code only. The [Medicare Physician Fee Schedule](#) at cms.gov includes information about lab codes billed using these modifiers.

Clinical Laboratory Interpretation Services

The CMS has identified certain procedures as clinical lab tests that frequently require physician interpretation. The physician can bill for this interpretation service using the applicable laboratory code along with modifier 26.

Multiple Component Rebundling

As part of the Multiple Component Rebundling enhanced code auditing, the IHCP applies component rebundling logic to physician and institutional claims. This claim-editing process identifies claims containing two or more procedure codes used to report individual components of a service when a single, more comprehensive procedure code exists that more accurately represents the service performed. During component rebundling, individual unbundled procedures will be denied.

Lab Panels

Organ- or disease-oriented lab panels were developed to allow for coding of a group of tests. Providers are expected to bill the lab panel when all the tests listed within each panel are performed on the same date of service. When one or more of the tests within the panel are not performed on the same date of service, providers may bill each test individually. Providers may not bill for a panel *and* all the individual tests listed within that panel on the same day. However, *other* tests performed in addition to those listed on the panel on the same date of service may be reported separately, in addition to the panel code. Providers must follow CPT coding guidelines when reporting multiple panels. For example, providers cannot report basic panel code 80048 with comprehensive panel code 80053 on the same date of service, because all the lab tests in 80048 are components of 80053.

Consultative Pathology Services

The IHCP covers consultative pathology laboratory services if the following conditions are met:

- The member's attending physician requested the service in writing.
- The service relates to a test result that lies outside the clinically significant normal or expected range in view of the condition of the member.
- The service results in a written narrative report in the member's medical record.
- The service requires the exercise of medical judgment by the consulting physician.

Specimen Collection

The IHCP allows a minimal fee to be reimbursed for separate charges made by physicians, independent laboratories or hospital laboratories for the drawing or collecting of specimens. The IHCP covers these specimen collection services only when the provider draws a blood sample through venipuncture or collects a urine sample by catheterization.

Providers must itemize specimen collection fees when billing for them. The IHCP allows only one charge per day, per member for venipuncture. The IHCP allows a charge for catheterization for each patient encounter; it does not limit this service per day or per claim.

Travel for Specimen Collection

The IHCP reimburses allowable units (miles) of HCPCS code P9603 – *Travel allowance one way in connection with medically necessary laboratory specimen collection drawn from home bound or nursing home bound patient; prorated miles actually travelled* at a maximum-fee rate (indicated on the Professional Fee Schedule) rather than manually priced at a percentage of the amount billed. In no situation will the laboratory be reimbursed for billing more miles than are reasonable, or for miles that are not actually traveled by the laboratory technician.

The per-mile travel allowance is to be used in situations when the average trip to the patients' homes is farther than 20 miles round trip, and is to be prorated in situations when specimens are drawn from non-Medicaid members (patients) in the same trip.

When multiple specimens are collected at a single site (a nursing home, for instance), the travel payment component is prorated based on the number of specimens collected in that trip, for both Medicaid and non-Medicaid members.

The following examples are provided to explain how to bill for the travel allowance (assuming a fixed rate for P9603 of \$1.31 per 1-mile unit):

Example 1: A laboratory technician travels 60 miles round trip from the laboratory in a city to a remote rural location, and back to the laboratory to draw one Medicaid member's blood. The claim submitted should indicate 60 units of P9603, with a charged amount of \$78.60 ($60 \times \1.31).

Example 2: A laboratory technician travels 30 miles from the laboratory to a Medicaid member's home to draw blood, next travels an additional 10 miles to a separate residence to draw blood from two non-Medicaid patients, and then travels 20 miles to return to laboratory. The total distance traveled is 60 miles, which averages to 30 miles per collection site, thus meeting the required minimum average (greater than 20 miles per site) for billing the service. When billing the service, the total mileage for the trip is prorated by the number of individuals served. Thus, the claim submitted for the Medicaid member should indicate 20 units ($60 \div 3$) of P9603, with a charged amount of \$26.20 ($20 \times \1.31).

The travel allowance is intended to cover the provider's estimated travel costs for collecting a specimen, including the laboratory technician's salary and travel expenses. Applicable specimen collection fees (as described in the [Specimen Collection](#) section) are separately reimbursable on the claim, in addition to the travel allowance.

Handling and Conveyance of Specimens From Doctor's Office to Laboratory

The IHCP reimburses for handling and conveyance of a specimen to a laboratory if services are billed by a physician, chiropractor, podiatrist or other attending provider authorized to do so under state law. The IHCP reimburses providers for no more than two conveyance fees (procedure code 99000) per member, per provider, on the same date of service. Providers can charge this fee only if the physician, chiropractor, podiatrist or other authorized attending provider has an expense involved in conveyance.

Policies and Procedures for Specific Laboratory Services

The following sections include coverage, billing and reimbursement information for various types of laboratory services. For information about laboratory services related to a specific type of provider, service or program, see the appropriate module:

- For genetic tests, including molecular pathology, cytogenetics and multianalyte assays with algorithmic analyses (MAAA), see the [Genetic Testing](#) module.
- For laboratory services related to renal dialysis, see the [Renal Dialysis Services](#) module.
- For newborn screening blood tests, see the [Inpatient Hospital Services](#) module.
- For prenatal laboratory services and cervical cancer screening, see the [Obstetrical and Gynecological Services](#) module.
- For laboratory services covered under the Family Planning Eligibility Program, see the [Family Planning Eligibility Program](#) module.

To determine whether a specific laboratory code requires prior authorization, see the IHCP Fee Schedules, accessible from the [IHCP Fee Schedules](#) webpage at in.gov/medicaid/providers.

HIV Testing

The IHCP covers routine laboratory testing for human immunodeficiency virus (HIV) when it is done to establish an HIV diagnosis. HIV testing is covered only in circumstances when a blood sample is drawn through venipuncture or when a urine sample is collected by catheterization. The IHCP does not cover oral HIV testing methods.

The United States Preventive Services Task Force (USPSTF) has found evidence that identification and treatment of HIV infection is associated with a markedly reduced risk for progression to acquired immune deficiency syndrome (AIDS), AIDS-related events and death in individuals with immunologically advanced disease. Providers are encouraged to follow USPSTF guidelines.

Note: Providers should be aware that CPT code 86703 (Antibody; HIV-1 and HIV-2, single result) is not currently recognized as a “CLIA-waived” procedure code under Centers for Disease Control and Prevention (CDC) guidance, despite manufacturer and common coding guidance indicating that a CLIA-waived HIV test kit may be performed and billed with this particular code. This has led to claim denials for some IHCP providers that used this code to bill for HIV testing performed with a CLIA-waived test kit. The IHCP reminds providers that HCPCS code G0433 (Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening) is a CLIA-waived test under CDC guidance, allowing IHCP providers with only a Certificate of Waiver to be reimbursed for this service.

Lead Testing

For lead testing in the office setting, the coverage and reimbursement rate for code 83655 includes tests administered using filter paper and handheld testing devices. Providers should bill using the appropriate procedure code and modifier combination:

- 83655 – *Lead, quantitative; blood*
- 83655 U1 – *Lead, using filter paper*
- 83655 U2 – *Lead, handheld testing device*

See the [Early and Periodic Screening, Diagnostic and Treatment \(EPSDT\) Services](#) module for blood lead testing policies and procedures specific to EPSDT-eligible members.

Comprehensive Environmental Lead Investigation

The IHCP covers initial and follow-up comprehensive environmental lead investigation services for members with a confirmed blood lead reference value (BLRV) at or greater than 3.5 µg/dL.

Comprehensive environmental lead investigation services must be billed with one of the following HCPCS codes:

- T1029 – *Comprehensive environmental lead investigation*
- T1029 TS – *Comprehensive environmental lead investigation; follow up*

The services must be billed by an IHCP-enrolled public health agency (provider type 13) with specialty 130 – *County Health Department*. Providers must adhere to current IDOH guidelines per 410 IAC. Licensed risk assessors or lead inspectors, as defined in 410 IAC 29-1, are not recognized as IHCP billing providers. These entities must work with the appropriate health departments for services to be covered.

Services are limited to one unit, per member, per rolling 12-month period. Prior authorization is not required for initial or follow-up comprehensive environmental lead investigation.

All comprehensive environmental lead investigation services are carved out of managed care, which means these services will be reimbursed through the fee-for-service (FFS) delivery system, including for members enrolled in managed care programs.

Oncology (Colorectal) Screening

The IHCP covers CPT code 81528 – *Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result (Cologuard)*. Coverage is available for individuals ages 45 through 75 and is limited to once every three years.

Reimbursement and coverage information is included in the IHCP Fee Schedules (both outpatient and professional), accessible from the [IHCP Fee Schedules](https://in.gov/medicaid/providers) webpage at in.gov/medicaid/providers.

For information on colorectal cancer screenings using computerized tomography (CT) colonography screening, see the [Radiology Services](#) module.

Urine Drug Testing

The IHCP covers the following types of urine drug testing (UDT) when medically necessary:

- Presumptive UDT – CPT codes 80305–80307
- Definitive UDT – HCPCS codes G0480–G0483, G0659

Providers are encouraged to use *presumptive* drug testing methods, as these are clinically appropriate for detecting nearly all prescription opioids, benzodiazepines and illicit drugs.

The use of *definitive* testing should be based on the need to detect specific substances that cannot be identified on presumptive UDTs, or in the presence of unexpected UDT results. For example, presumptive drug testing may be problematic for the accurate detection of amphetamines, and therefore definitive testing may be necessary for unanticipated results. Providers may also use definitive testing to assess for drug metabolites which may help identify if the member has been consistently taking prescribed medications as intended.

PA is required for all definitive drug panels with 15 or more drug classes (HCPCS codes G0482 and G0483). PA will also be required for definitive testing performed beyond 16 cumulative units per member per calendar year. Otherwise, PA is not required for the first 16 units of definitive UDT of under 15 drug classes. For presumptive testing performed beyond 52 cumulative units per member per calendar year, providers must maintain medical necessity documentation supporting the need for more than 52 units in a calendar year within the member's record. Presumptive drug testing codes differ based on the level of complexity of the testing methodology. Only one code from this range may be reported per date of service. See Table 1 for a summary of these limits and requirements.

Providers performing validity testing on urine specimens used for drug testing shall not separately bill for validity testing of the specimen. For example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed.

Providers should **not** test for substances for which results would not affect patient management. UDT is **not covered** for any of the following circumstances:

- Unnecessarily frequent drug testing without consideration for a specific drug's window of detection
- Testing for the same drug with both a blood or saliva test and a urine specimen simultaneously (multiple tests seeking the same outcome)
- Testing for legal intervention or employment

Table 1 – Urine Drug Testing Limits and Requirements

Limits and Requirements	Procedure Code	Description
Only one code from this range allowable per date of service Medical necessity documentation required in member's record if over 52 units per calendar year	80305	Testing for presence of drug, read by direct observation
	80306	Testing for presence of drug, read by instrument assisted observation
	80307	Testing for presence of drug, by chemistry analyzers
PA required if over 16 cumulative units (combined for all three codes in this group) per calendar year	G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays [e.g., IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods pe.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
	G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays [e.g., IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [e.g., alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
	G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Limits and Requirements	Procedure Code	Description
PA required	G0482	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods [e.g., alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed
	G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods [e.g., alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed