The Paradigm Difference

Effective Toxicology. Patient-Centered.

Laboratory Testing Services - 2020

Paradigm offers effective LC/MS/MS toxicology testing that is patient-centered and provider-focused. Our Benchmark OFT™ (30+ specific drug analytes in oral fluid) and Benchmark UDT™ (65+ specific drug analytes in urine) testing platforms offer in-depth LC/MS/MS presumptive and definitive for healthcare practitioners who need to determine whether their patients are following their treatment plans and to demonstrate compliance with applicable standards of practice. We also offer traditional "confirmation" LC/MS/MS definitive testing following provider-performed immunoassay testing to accommodate those who perform in-office or physician office laboratory testing. This document describes our basic testing services and other items relevant to your selection of a laboratory partner.

Paradigm is a CAP-Accredited and CLIA-Accredited independent clinical laboratory offering high complexity testing; Our laboratory personnel are very experienced in toxicology and understanding the needs of healthcare professionals in behavioral health, family and general practice, and pain and other specialty practices. We look forward to serving you and your patients!

Important Terminology Used by Paradigm

Presumptive testing is used when medically necessary to determine the presence or absence of drugs or drug classes in a test sample; Results are expressed as negative or positive; Testing may be performed using immunoassay test methods (IA), or, in the case of Paradigm's Benchmark OFT™ and UDT™, via liquid chromatography with mass spectrometry (LC/MS/MS). If IA test methods are used, presumptive testing cannot identify specific drug analytes.

Definitive testing is used when medically necessary to identify specific drugs and reporting involves quantitative values of parent drugs and drug metabolites in concentrations of ng/mL. Unlike GC/MS/MS and LC/MS/MS, IA test methods DO NOT qualify as definitive testing. Paradigm's Benchmark UDT™ definitive LC/MS/MS yields a quantitative assessment of specific analytes found to be positive via presumptive LC/MS/MS, while also offering certain drug classes as traditional direct to LC/MS/MS definitive testing because the scientific characteristics of some analytes do not allow for presumptive LC/MS/MS testing.

Reflex testing is understood laboratory testing performed by an independent clinical laboratory *prior to sample reporting* and is used to further identify significant diagnostic information for appropriate patient care. An example of Paradigm's use of reflex testing for its Benchmark OFT™ and UDT™ is the identification of specific metabolites and quantitative values following a presumptive (positive or negative) test result. If Paradigm's Benchmark UDT™ yields a result of "positive" for oxycodone and oxymorphone, Paradigm will automatically reflex to definitive LC/MS/MS testing for these analytes and will be reported with a quantitative value. For both Benchmark OFT™ and UDT™, reflex testing occurs when a presumptive analyte yields a result outcome of "positive" and/or if the ordering practitioner reports a medication that can be tested using Paradigm's Benchmark OFT™ or UDT™ platform.

Testing Services

Provider Performs Presumptive Test (via cup or similar) and Paradigm Performs Definitive Testing

LC-MS/MS definitive testing following presumptive testing by the provider using a cassette, cup, or dip test at the point of care.

- Paradigm requires an individual test order for each LC/MS/MS definitive test
- Paradigm reports results within 24-48 hours of specimen receipt
- This platform is limited to definitive testing of urine samples

Provider Performs Presumptive Test (via chemistry analyzer) and Paradigm Performs Definitive Testing

LC-MS/MS definitive testing following presumptive testing by the provider using a chemistry analyzer in a physician-office lab.

- Paradigm requires an individual test order for each LC/MS/MS definitive test
- Paradigm reports results within 24-48 hours of specimen receipt
- This platform is limited to definitive testing of urine samples

Paradigm Performs BOTH Presumptive and Definitive Testing via Benchmark OFT™ or Benchmark UDT™

Benchmark UDT LC-MS/MS Testing (Presumptive LC-MS/MS with reflex to Definitive LC-MS/MS)

- Paradigm requires an individual test order for each Benchmark test
- Paradigm will perform a presumptive LC/MS/MS test
  - 30+ specific drug analytes for oral fluid samples
  - 65+ specific drug analytes for urine samples
- Paradigm will reflex positive presumptive LC/MS/MS test results AND unexpected (prescribed medication) negative results to LC/MS/MS definitive testing.
- Paradigm's Benchmark OFT™ involves LC/MS/MS* presumptive testing of the indicated # of specific drug analytes and includes an order to "reflex" presumptive positive results for definitive testing. Paradigm reports all presumptive "positive" analytes and reflexes presumptive "positives" and/or practice reported medications to definitive testing via LC/MS/MS.
- For Benchmark UDT™, providers may add-on a limited number of drug classes that cannot be tested using presumptive LC/MS/MS because of the scientific characteristics of the specific drug analytes within the add-on class.
- Paradigm reports results within 24-48 hours of specimen receipt.
- Paradigm bills its Benchmark tests under CPT 80307 plus G0480 or G0481, depending on individual patient circumstances and test orders. Most tests are billed using CPT 80307 plus G0480 (1-7 drug classes).

Paradigm's Benchmark tests provide significantly more detail than the standard EIA/IA to LC/MS/MS testing platform and uses the same presumptive test code, CPT 80307.

Benchmark OFT™ and UDT™ allow the ordering practitioner to maximize the number of specific analytes for presumptive LC/MS/MS testing and, for Benchmark UDT™, to minimize the number of drug classes "reflexed" for definitive LC/MS/MS testing.

Customers may seek a follow-up LC-MS/MS Definitive test ("confirmation") of unexpected positives and negative results, and a quantitative detail of prescribed controlled medications and relevant metabolites. This testing platform typically results definitive testing of less than 7 drug classes, which is a Tier 1, G0480, under the current coding system. Our Benchmark LC-MS/MS is consistent with payor policies non-covering or placing other medical necessity limitations on higher tiered definitive testing greater than 7 drug classes.

Paradigm's 2020 Fee Schedule for Laboratory Services

Presumptive LC-MS/MS (Benchmark OFT™ and Benchmark UDT™ Only)		Definitive LC-MS/MS (All lines of business)		
Code	**Paradigm Fee**	**Code**	**Used for**	**Paradigm Fee**
CPT 80307	$145.46	G0480 (1-7 drug classes)	Benchmark OFT™ or UDT™	$257.46
		G0481 (8-14 drug classes)	Provider ordered confirmation following provider-performed presumptive testing	$352.32
		G0482 (15-21 drug classes)		$447.17
		G0483 (22+ drug classes)		$555.57

Use of Laboratory Data to Facilitate Patient Drug Use Patterns

Paradigm uses its laboratory data to support provider testing decisions. Paradigm's laboratory data enables it to improve test offerings and provider testing patterns. Paradigm has a dedicated information system expert who is available to discuss practice testing patterns. Paradigm routinely evaluates its data to examine practice and regional positivity rate data to stay current with developing and existing drug use patterns. Drug use patterns are important to keeping test menus current and informing care provided by addiction and behavioral health specialists, Emergency Department personnel, and pain management practitioners.

Our goal is to build long-term, compliant relationships with healthcare practitioners to ensure patient-centered and medically necessary drug testing practices that balance the requirements of licensing board rules and payor coverage policies. Paradigm is happy to schedule a laboratory tour for you. We want to understand your needs and the best way to accomplish this is to invite you into our laboratory for an open dialogue on how to improve drug testing with the patient and quality medical care in mind.

For additional information contact:
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