

Paradigm's Laboratory Credentials

Paradigm Labs is both CAP and CLIA-Accredited

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 applies to facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. The CLIA Program sets standards for clinical laboratory testing and issues certificates. The Centers for Medicare and Medicaid Services (CMS) recognizes 7-independent laboratory organizations and allows a laboratory that has successfully undergone inspection and other laboratory accreditation steps through one of them to also receive CLIA-Accreditation.

The College of American Pathologists (CAP) is one of the organizations recognized by CMS as upholding the standards necessary to accredit clinical laboratories. CMS granted the CAP Laboratory Accreditation Program “deeming” authority, which allows a laboratory to undergo CAP inspection in lieu of a CMS inspection. CAP Laboratory Accreditation helps laboratories:

- Maintain accuracy of test results and ensure accurate patient diagnosis
- Meet required standards from CLIA, FDA and OSHA. CAP requirements commonly exceed the standards, bolstering patient care and safety.
- Manage rapidly evolving changes in laboratory medicine and technology
- Exchange ideas and best practices among pathology and laboratory medicine peers
- Offer professional development and learning opportunities for laboratory staff

Paradigm has successfully completed the CAP-Accreditation program for laboratories performing clinical toxicology and continues to undergo on-site CAP-inspections every two years to assess its compliance with program requirements. To confirm Paradigm's CAP-Accreditation, use this [link](#) and search under “laboratory” using Paradigm Labs as the laboratory entry and Georgia as the state entry. More information about CLIA and Paradigm may be found at <https://npiprofile.com/npi/1184041949>.

Paradigm's Executive Laboratory Staff

Paradigm's laboratory staff is experienced, and its testing is dedicated to toxicology. Below are brief biographical overviews of a few of our laboratory staff members.

Catherine Sue Brown, PhD, MBA – Laboratory Director

PhD, Toxicology and MBA (Virginia Commonwealth University)
BHS, Medical Technology (Duke University)

Dr. Brown is the Laboratory Director for Paradigm Labs and a senior laboratory executive with technical and business expertise. Dr. Brown has more than 25 years' experience in the field of toxicology and holds Director level positions in five production drug testing laboratories, three of which she has guided from start-up. Dr. Brown has served as a consultant to SAMHSA and participated in the development of SAMHSA regulatory guidelines.

Nicholas Rhodes, PhD – Director of Research and Development

PhD, Bioinorganic Chemistry (University of Alabama)
BS, Chemistry (University of West Georgia)

Dr. Rhodes is the Director of Research and Development at Paradigm Labs. Dr. Rhodes' training has been very interdisciplinary, and occurs at the crossroads of chemistry, biology, and medicine. Dr. Rhodes focuses on method development in the clinical, wellness replacement therapy, and forensic toxicology fields using Agilent LC/MS/MS* systems and MassHunter data acquisition and qualitative and quantitative analytical software. Dr. Rhodes' work with Agilent's LC/MS/MS systems includes use of LC 1260 systems and several MS triplequad systems 6420 and 6460. Together with Dr. Brown, Dr. Rhodes also manages Paradigm's laboratory staff.

Andrea Fox, Certifying Scientist-Team Lead

MS in Forensic Toxicology (University of Florida)

Andrea has more than 15 years' clinical and forensic toxicology experience, including direct laboratory experience and experience as a Laboratory Supervisor and Certifying Scientist. She is an active member of Society of Forensic Toxicologists (SOFT).

*LC/MS/MS = Liquid Chromatography with Mass Spectrometry

Brandon S. Prince, MBA, Dir. of Information & Client Services
MBA (University of North Carolina at Greensboro)
BS in Biological Sciences (North Carolina State University)

Brandon has a collective total of 13 years' clinical laboratory services, with 10 years' direct experience in toxicology. Brandon has extensive experience in laboratory information management and client services and is very experienced in the value of LC/MS/MS data to healthcare professionals. Using Paradigm's on-line, laboratory information management system, Horizon, Brandon and the Paradigm team have established a practice overview report for its customers. This report enables healthcare practitioners to see emerging drug-abuse trends and drug use patterns in their practice and to identify individual patient behaviors in a timely fashion to ensure clinically appropriate use of drug test results in the patient treatment plan and care coordination.

Paradigm's Science – the Paradigm Difference

Paradigm's scientists have constructed accurate and complete clinical toxicology testing for healthcare practitioners. Paradigm's flagship testing platforms are its Benchmark OFT™ (30+ specific drug analytes in oral fluid) and Benchmark UDT™ (65+ specific drug analytes in urine). Paradigm's Benchmark tests use LC/MS/MS* for both presumptive and definitive testing. Significantly, however, Paradigm's presumptive LC/MS/MS Benchmark tests have greater clinical utility and result in more cost-effective definitive testing because Paradigm uses the presumptive LC/MS/MS phase to examine more specific drug analytes than can be evaluated using immunoassay. Paradigm's fee for LC/MS/MS presumptive testing is the same as it is for standard laboratory (independent or physician office laboratory) immunoassay testing.

For each Benchmark test, presumptive positives and/or presumptive negatives of prescribed medication “reflex” to definitive LC/MS/MS testing and are resulted using quantitative values for those analytes detected in the patient sample. Through this platform, Paradigm's Benchmark testing enables the healthcare provider to *maximize the number of specific drugs and drug classes examined by presumptive LC/MS/MS and to minimize the number of drug classes that “reflex” to definitive LC/MS/MS examination; This also improves the provider's ability to demonstrate how the drugs/drug classes that reflex to definitive testing are directly relevant to the patient's plan of care.* **Paradigm's Benchmark OFT™ and UDT™ closely align with payor coverage and reimbursement policies for drug testing while also preserving the provider's ability to mitigate risks and promote patient safety.**

Paradigm continues to offer traditional “confirmation” LC/MS/MS testing following provider-performed immunoassay testing to accommodate healthcare providers who perform immunoassay testing in their office or through a physician-owned laboratory. However, Paradigm's laboratory data shows that its Benchmark tests offer the provider a more clinically significant examination of patient drug-use and/or abuse behaviors at a significant cost-savings to the health plan and the patient. Paradigm encourages providers to use one of the Benchmark test platforms for new patients and for testing established patients who have been evaluated as high risk for abuse and diversion, or high risk for a drug-drug interaction due to medical conditions and medication regimen.

Paradigm's scientists are available to discuss the responsible use of both presumptive and definitive LC/MS/MS testing. Paradigm reports all testing within **24 to 48 hours from receipt of the specimen**. More information about Paradigm's testing services is available at www.paradigm.healthcare.

Paradigm's Payor Network - Basics

Paradigm participates in Medicare and various Medicaid plans. Paradigm also has network contracts with BCBS individual state plans and many other major commercial plans. Paradigm is committed to promoting cost-effective, patient-centered testing that meets the needs of healthcare practitioners to keep patients safe and the needs of payors to contain healthcare costs. Paradigm keeps a library of payor policies and other clinical guidelines, position statements, and licensing board materials. These items are available upon request via email to compliance@paradigm.healthcare.

Paradigm is proud to serve you and your patients.
For additional information, email:

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call **912.342.2443**

*LC/MS/MS = Liquid Chromatography with Mass Spectrometry