

The Paradigm Shift

Issue 2, June 2020

Welcome to The Paradigm Shift, a newsletter dedicated to client education about the value of laboratory data to you and your staff. April and May were busy months and many of our client responded positively to our new Benchmark OFT® drug testing platform, which can be used while patients remain at home and are seen via telemedicine.

Message from Paradigm’s President, Catherine Veal



What a whirlwind this Spring has been for us all! At Paradigm, we’ve stayed very busy throughout the COVID-19 public health emergency and we’re looking forward to helping our clients as they continue telemedicine visits and return to in-person encounters with their patients. Our Benchmark® Presumptive LC-MS/MS testing platforms (oral and urine) continue to serve as efficient and cost-effective tools to mitigate risks associated with treating patients with controlled medication or treating them for substance use disorders. Whatever your practice background, we hope you will continue to look to us for quality toxicology testing.

We are dedicating this issue of *The Paradigm Shift* to providing you with an overview of the laboratory data we compile for client use in evaluating their patient population and controlled substance prescribing compliance efforts. We are very proud of our Information and Client Services Department and the data we compile to facilitate client education and improved laboratory test ordering.

We hope this information facilitates discussion between you and your Paradigm Account Executive about your practice needs and Paradigm’s laboratory services can better serve you and your patients. If you have a topic you would like us to discuss or a question, let us know. We look forward to continuing to serve you and working together to get through these challenging times!

Best,

Catherine Veal

Department Feature – Brandon S. Prince, Director of Information and Client Services

Brandon S. Prince is Paradigm’s Director of Information and Client Services. He has been employed with Paradigm since 2015 and has extensive experience operating LC-MS/MS instrumentation and working with laboratory information systems.

Brandon received his Bachelor of Science in Biological Sciences from North Carolina State University and his Masters in Business Administration from the University of North Carolina at Greensboro.



Brandon has a collective total of 13 years’ clinical laboratory services, with 10 years’ direct experience in toxicology.

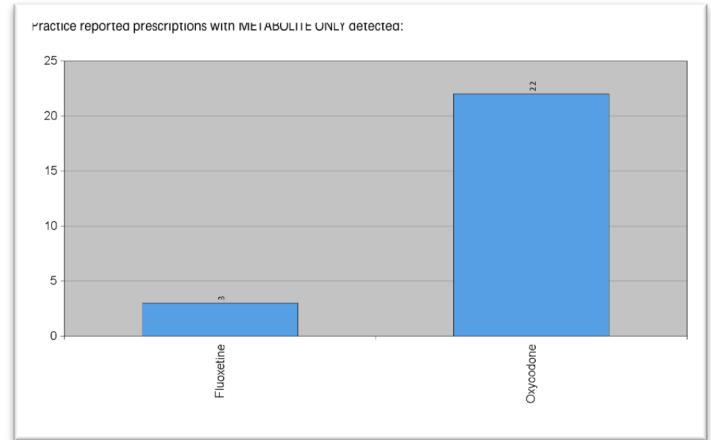
At Paradigm, Brandon is the keeper of all things laboratory – from laboratory test orders to test reports, as well as data showing your testing patterns and specific drugs of abuse challenges in your practice. Using Paradigm’s on-line, laboratory information management system, Horizon, Brandon and the Paradigm team have established a practice overview report for Paradigm customers. The rest of this issue highlights key features for these reports, as related by Brandon during an interview for this newsletter.

Question – What types of laboratory data does Paradigm have and use with its customers?

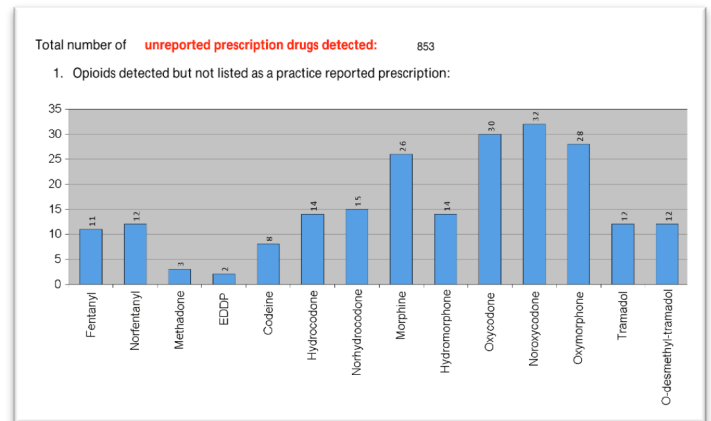
Answer. Paradigm has a robust practice overview report for its clients. Using our Horizon data reporting system, Paradigm can provide detail to each client on:

1. Percentage of overall specimens by analyte type and focusing on positive results. *See Example 1, shown on last page below.*
2. Total Number of Consistent Findings (Consistent with Reported Medication). *See Example 2, below.*
3. Total Number of Samples with a Parent Drug Only Detected. *See Example 3, below.*
4. Total Number of Samples with a Metabolite Only Detected. *See Example 4, below.*
5. Total Number of UNREPORTED* Drugs Present. *Unreported means the drugs detected in a sample were not tied back to a prescription drug listed on the patient's medication list. *See Table 5, below.*
6. Total Number of Samples with Illicit Drugs Detected. *See Table 6, below.*

Example 4 – Total # Specimens w/Drug Metabolite Only

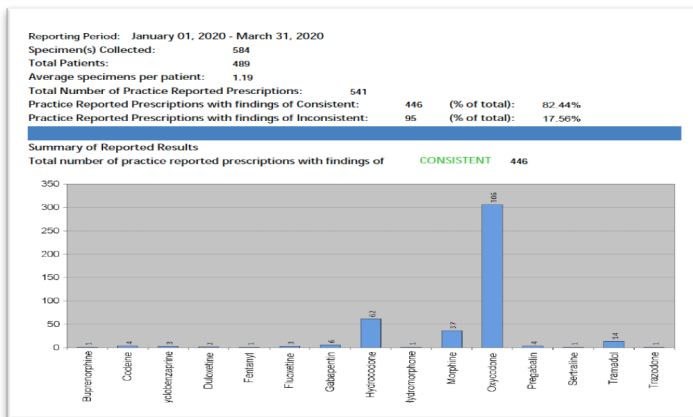


Example 5 – Total # UNREPORTED Drugs Detected (Not Identified as in corresponding medication list)

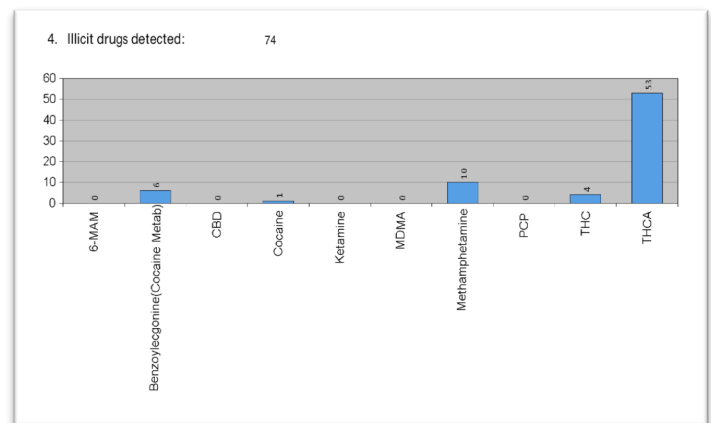


Note: The phrase “Practice Reported Prescriptions” used below in Examples 2 through 5 refers to the medication list provided to Paradigm by the ordering practitioner/medical staff.

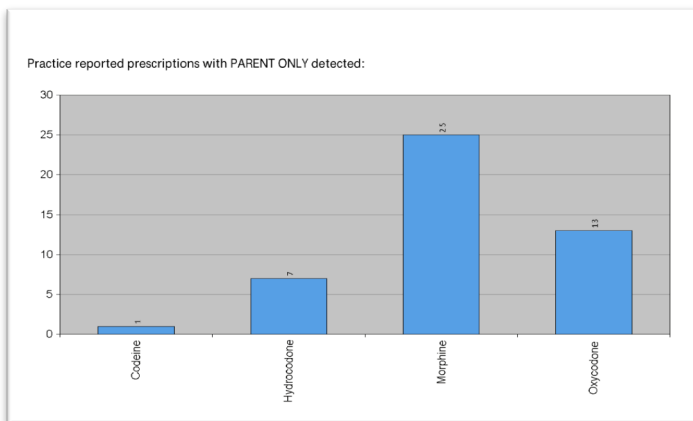
Example 2 – Total # Findings Consistent w/Reported Meds



Example 6 – Total Number of Illicit Drugs Detected



Example 3 – Total # Specimens w/ Parent Drug Only



Question - How do I gain access to and use this information?

Answer: Clients should contact their Paradigm sales representative to obtain a practice overview report and to review the data in detail. As Director of Information and Client Services, I am also available to Paradigm clients and their representatives to review these reports.

I encourage practitioners to review the practice overview data in light of their current test orders and consider the following questions:

1. Am I over or undertesting my patients in terms of frequency and drugs tested in light of each patient's individual medical needs?
2. Am I keeping and providing updated medication lists to the laboratory with my test orders?
3. Am I targeting the right drugs of abuse for my patient population? Are there drugs that have never appeared positive in my patient population? If so, how does this data impact my test orders? What if I perform presumptive testing and only send out for definitive testing?
4. Is there a benefit to using Benchmark OFT® or Benchmark UDT® platform over the traditional in-house screen and send out for LCMS test confirmation?
5. How do I better individualize my testing for each patient?
6. How will this data help me demonstrate compliance with applicable clinical standards and payor policies for medical necessity?

Experience tells us that a deep dive into the data will not only help practitioners see their patient population through a different lens but will also help practitioners make improved test order decisions to stay in line with payor policies and applicable standards of care.

Question - What is Benchmark OFT®?

Answer: Paradigm's Benchmark OFT® uses a simple oral fluid swab to collect the patient's sample and LC-MS/MS testing for both presumptive and definitive (quantitative, where appropriate). Paradigm's Benchmark OFT® test examines 33 specific drugs (17 total drug classes).

Paradigm has educational material for both providers and their patients, explaining the oral fluid collection process during a telemedicine encounter. This material also helps the patient understand how to package the specimen for pick up (not available in all areas) or for mailing back to Paradigm using a prepaid envelope or similar.

All test orders and reporting are available online.

Billing and Medicare Clinical Lab Fee Schedule for Benchmark OFT® are as follows:

Test and Code	Medical Fee Schedule
Presumptive LC-MS/MS Oral Fluid; CPT 80307	80307 - \$62.14
Definitive LC-MS/MS Oral Fluid with quantitative results; HCPCS G0480 or G0481	G0480 - \$114.43 OR G0481 - \$156.59

Paradigm participates in Medicare and various state Medicaid programs. Paradigm also has network contracts with BCBS-North Carolina and other major commercial plans.

For more information, ask your Paradigm Representative for the Benchmark OFT® Briefing Sheet for your area.

Compliance Corner with Cynthia Wentland –



The Importance of Medication Lists to Laboratory Data and in Demonstrating Medically Necessary Testing

Payors place the burden of ordering only medically necessary testing on practitioners and re

quire practitioners to document individualized test orders, aligning the drugs tested with the patient's personal history and treatment plan. Medication lists help practitioners demonstrate compliance with payor policies. More importantly, medication lists are significantly tied to data showing the percentage of patients who are "consistent" in a practice based on drug test results. Example: If a patient is taking an anti-psychotic and this medication is identified on a medication list, the provider is able to support his/her request to add definitive testing for anti-psychotics to a test order for Paradigm's Benchmark® UDT platform.

Failure to provide a medication list with a current lab order may not only create problems with the interpretation of test results but also may make it appear that it is not medically necessary to test unlisted drugs. **Example:** If you do not include Gabapentin in your medication list, the positive result may appear "inconsistent" with the treatment plan; Failure to include Gabapentin as part of the list may also detract from the medical necessity supporting a test order that includes definitive testing for Gabapentin.

Proper disclosure of medication lists to Paradigm will not only make it easy to understand why certain drugs/drug classes need to be tested, but make it easier to reconcile test results as "consistent" or "inconsistent", thereby making the practice overview report more meaningful in terms of

your actual percentage of “consistent” patient samples. Finally, medication lists help providers gain more insight about their overall patient population and whether laboratory test results trend toward patient compliance or non-compliance with the applicable treatment plan.

Paradigm continues to stress the need for documentation of practitioner orders for laboratory test and individualization of the test menu, to ensure compliance with governing medical policies and payor standards for documentation.

Our compliance team encourages Paradigm clients to increase the frequency of communications with our representatives to ensure you stay current. If you have questions, feel free to contact your Paradigm representative or Cynthia Wentland, VP of Administration and Chief Compliance Officer. We continue to make adjustments as we work our way through the changes to our industry brought about by the COVID-19 PHE. We look forward to getting to know you better and serving you and your patients.

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Example 1 –Overall Statistical Summary of Results by Analyte Type

Non-Negative Result by Analyte Type			
Analyte Type	Number	Total Tested	% Positive
HEROIN	0	102	0.0%
AMPHETAMINES	8	103	7.8%
Amphetamine	5		
Methamphetamine	3		
Phentermine	3		
BARBITURATES	2	102	2.0%
Butalbital	2		
BENZODIAZEPINES	13	103	12.6%
7-Aminoclonazepam	3		
Alprazolam	2		
a-Hydroxylprazolam	2		
Lorazepam	1		
Nordiazepam	4		
Oxazepam	7		
Temazepam	6		
COCAINE	1	103	1.0%
Benzoylcegonine(Cocaine Metab)	1		
ALCOHOL BIOMARKERS	7	103	6.8%
Ethyl Glucuronide	7		
Ethyl Sulfate	7		
FENTANYL	4	103	3.9%
Fentanyl	4		
Norfentanyl	4		

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Non-Negative Result by Analyte Type			
Analyte Type	Number	Total Tested	% Positive
MDAS	0	102	0.0%
METHADONE	1	96	1.0%
Methadone	1		
NATURAL OPIATES	17	102	16.7%
Codeine	5		
Hydrocodone	8		
Hydromorphone	8		
Morphine	11		
Norhydrocodone	9		
NATURAL CANNABINOIDS	21	102	20.6%
THCA	21		
OPIOID ANTAGONIST	4	95	4.2%
Buprenorphine	4		
Norbuprenorphine	4		
PHENCYCLIDINE	0	102	0.0%
PREGABALIN	0	2	0.0%
SEDATIVE HYPNOTICS	0	1	0.0%
STEREISOMERS	3	3	100.0%
D-Methamphetamine	3		
SKELLETAL MUSCLE RELAXANTS	11	101	10.9%
Cyclobenzaprine	11		
SEMI-SYNTHETIC OPIOIDS	23	101	22.8%
Noroxycodone	23		
Oxycodone	19		
Oxymorphone	21		
TAPENTADOL	0	1	0.0%
TRAMADOL	7	102	6.9%
O-desmethyl-tramadol	7		
Tramadol	6		