Interpreting urine drug test (UDT) results is difficult, especially considering how frequently false-positive and false-negative results occur. Surrounded by a backdrop of contention among the courts and third-party payers for what constitutes “medically necessary” in-office testing, required frequency, and confirmation by more expensive definitive lab analysis, providers are at a loss as to how to adhere to standards, which remain undefined. While legal court battles continue against various laboratory companies for encouraging precise testing by chromatography, perhaps software apps can help discern when more comprehensive testing is in fact medically indicated.

Practical Pain Management talked with Jeffrey Fudin, PharmD, DAAPM, FCCP, FASHP, developer of a new app called Urintel that helps clinicians better analyze UDT results and make clinical decisions when they find unexpected results.

**Q**: What is the Urintel application, and how is it designed to help pain practitioners?

**Dr. Fudin**: Urintel is a software application that was created to help pain practitioners and other health care providers interpret UDT results from an immunoassay test performed at the point of care or a laboratory. One of the key reasons we developed this app is because immunoassay is a qualitative test that lacks specificity for any unique drug; therefore, false-positive or false-negative results are common, and patients may be falsely accused of drug abuse/misuse when they haven’t done anything wrong.

There are no standards to help practitioners interpret the results of UDTs by immunoassay, or to ascertain when false-positive or false-negative results could or should happen. In addition, providers are not trained to interpret immunoassays considering specific drug doses, medicinal chemistry, drug, chemical, and food interactions.

Urintel guides practitioners toward appropriate actions to take when faced with an unexpected result that yields illicit substances or false-positive or false-negative results and suggests when it is appropriate to quantify results using definitive gas or liquid chromatography mass spectrometry. The app is available for use on office computers as well as the Apple iPhone and Android-based phones (eg, Motorola’s Droid, HTC, and Samsung).
**Q**: How does this application fit into daily practice?

**Dr. Fudin**: The thought is that when a provider receives UDT results, either the provider or a staff member could enter the information into the Urintel software application. The computer app is intuitive and has 3 steps:

- Enter all medications and doses prescribed to the patient using drop down menus (Figure 1)
- Select results from a UDT (Figure 2)
- The app analyzes the results and presents recommendations that can be saved/printed as a PDF or copied to clipboard for quick “paste” into the electronic health record (EHR) (Figure 3, page 86)

The printed report can be handed to the patient upon triage or when the patient enters the examination room, allowing the information to be communicated in a nonconfrontational way. The patient will see the results as well as the list of potential medications that can cause a false-positive or false-negative result. The health care provider then can educate the patient about what the test results mean.

**Q**: Is Urintel compatible with EHRs?

**Dr. Fudin**: A huge benefit is that the software platform for in-office use allows for a printable report that can be copied and pasted into an EHR, saved as a PDF, and attached to the EHR, or faxed to a third-party payer to document the need for definitive testing by chromatography. This report offers detailed explanations that justify the need for definitive testing by quantitative confirmation, and the printed report can be faxed immediately to a third-party payer.

I recently received an email from a provider who had a very difficult time having confirmatory testing by chromatography approved by a certain insurance provider under which several of his patients were covered. The insurance company never approved the physician’s request for further confirmatory testing. With a recent patient, the provider used Urintel to analyze the UDT results, faxed the report to the insurance company, and received approval without question.

**Q**: How does this app help secure approvals and payment for definitive testing by chromatography from third-party payers?

**Dr. Fudin**: Doctors are having more and more difficulty getting third-party payers to pay for definitive testing by chromatography. This report offers detailed explanations that justify the need for definitive testing by quantitative confirmation, and the printed report can be faxed immediately to a third-party payer.
Q: What are examples of cases in which the Urintel app would be helpful in explaining false-positive results on UDT?

Dr. Fudin: I receive emails all the time from patients begging me to help them because they’ve received a letter from their doctor stating that they are being discharged from clinic because their UDT was positive for cannabinoids, when in fact the positive result was due to their taking the proton-pump inhibitor omeprazole (Prilosec, others).

Last week, a woman told me about her 81-year-old mother who was discharged from her physician’s care because her UDT was positive for amphetamines, cannabinoids, and phencyclidine (PCP). The woman was taking omeprazole (which would give a false positive for cannabinoids), the antidepressant venlafaxine (Effexor, others), which would give a false positive for PCP, and the anti-Parkinson combination carbidopa/levodopa (Sinemet, others) (which would give a false positive for amphetamines). She received a discharge letter without any confirmation testing being conducted. This happens all the time. So, Urintel is beneficial and educational for providers and patients. Patients can use the smartphone app to open a dialogue with their doctor regarding the legitimacy of their unexpected results and how to interpret them.

From a health care provider’s perspective, the Urintel app would give the provider an opportunity to make a clinical judgment. In the case of the 81-year-old woman, the Urintel report would state that the patient’s positive result for PCP, for example, is not unexpected because the venlafaxine prescribed can cause a false-positive test.

The user also can see a full list of medications that can cause false-positive results for PCP, which helps the clinician ask appropriate open-ended questions about whether the patient is taking any medications of which the clinician is unaware.

Next, the report will recommend “discussing findings with the patient, using clinical judgment, and if indicated, definitive testing by quantitative confirmation.”

In this case, the clinician will have a full comprehensive report to add to the patient’s chart justifying their decisions.

Q: Can you give an example of a case in which Urintel helped detect a patient with a substance abuse problem?

Dr. Fudin: A patient who is prescribed low-dose oxycodone (Roxicodone, others) (5 mg, 4 times per day) would not be expected to have a positive result on an opiate screen. If the results come back positive, the Urintel report would note that the dose is likely too low to test positive and that this result is unexpected.

Furthermore, the report will note that there is a high probability that this patient is taking a higher oxycodone dose than prescribed or that the patient is taking another drug, such as morphine or heroin. The report will suggest discussing the finding with the patient, using clinical judgment and if indicated, ordering definitive testing by quantitative confirmation.

If the outcome is that the patient actually was using another substance, then, hopefully, the patient will be sent to a substance abuse clinic for treatment. This allows the patient to get the help he or she needs, which may not have occurred had the substance abuse not been identified.

In this case, Urintel helps the provider accurately assess the risk for substance abuse and offers protection from a liability perspective. From an altruistic perspective, the app helps patients who need counseling and substance abuse rehabilitation to be identified and then counselled on how to best deal with their substance abuse.
Dr. Fudin: I think Urintel would be extremely useful in primary care, internal medicine, and obstetrics and gynecology practices, pain clinics, urgent care facilities, and emergency departments. It also would be useful for police laboratories and those doing employment screens.

I foresee Urintel being used in large health care systems, in which the software can be embedded into the EHR system. In this way, once the laboratory adds in the UDT results, Urintel will automatically generate a report using information in the system about the patient's current medications. This would only work if the provider can be reasonably sure that all of the medications were prescribed from that same health care system as the labs. In smaller offices in which providers may not be aware of all of the medications that a patient has been prescribed, the report will give you an entire list of drugs that can cause a false-positive or false-negative result; this can prompt the provider to ask the patient “Are you taking any other medications? Do you have a prescription for pain medicines from anywhere else?”

Urintel also can be incorporated into laboratory company software packages so laboratories can send the report along with test results to the health care provider or other client.

Dr. Fudin: I get bombarded with emails and phone calls every day and night from clinicians all over the country asking me for help interpreting UDT results. I want to help everyone, but answering hundreds of emails at night after working all day is impossible. For a very long time, I’ve thought about writing a software application to help providers understand what UDT results indicate. I write a little bit of code and knew it could be done. I envisioned in my mind the best way to do it while ensuring it was user friendly.

A couple of years ago, Nadia Shahzad, PharmD, was a student on a pain rotation with me and she started making recommendations about how to tweak my Website. After her rotation, she made those changes for me, and I saw that she was very good at Website design and information technology. It also turns out that her husband, Nicholas W.D. Jarrett, PhD, is an expert in developing and integrating Website-based applications, statistics, randomized dimension reduction, and statistical science. I thought, ‘this is the perfect storm!’ We all worked together to develop Urintel.

For 3 people to come together who have this expertise was a huge coincidence, as if it were meant to be.

When I first started developing this app, I had no intention of selling it. I developed the app to help patients and providers. If the app does become profitable, I want to hire 24/7 clinical support, so that all these calls that I get—and I get a lot of them—can be answered by PharmDs who are well-trained in UDT and can give clinicians the help they need.

Dr. Fudin: I am working with a separate team of experts to develop mathematical models that eventually will culminate into Kinetel, which will be based on complex mathematical models that integrate pharmacokinetics with pharmacogenetics to calculate individualized opioid dosing strategies based on patient phenotypes. I also am working on developing a comprehensive pharmacogenetic application called Phenotel that offers guidance for implementing, justifying, and ordering phenotype and genotype analysis. The app is designed to provide therapeutic decision algorithms for individualized therapy selection using information about pharmacotherapeutic drug category and disease state.

Our last application planned is Dialytel, which will predict opioid dosing prior to dialysis, during dialysis, and post-dialysis to keep the patient at steady-state blood concentrations throughout and following dialysis. If we could expand this beyond analgesic therapy, it would be a huge asset to patients and providers because there is no standard, and it is something that clinicians wrestle with daily.

A demo of Urintel for PC or Mac, smartphones, and/or tablet are available at http://www.remitigate.com/urintel/.

Author’s Bio: Jeffrey Fudin, PharmD, DAAPM, FCCP, FASHP, is an Adjunct Associate Professor of Pharmacy Practice & Pain Management at Albany College of Pharmacy and Health Sciences and Western New England University College of Pharmacy, in Springfield, Massachusetts. He also is an Assistant Professor of Pharmacy Practice at the University of Connecticut School of Pharmacy, in Storrs, Connecticut, and a Clinical Pharmacy Specialist and the Director of the PGY2 Pain & Palliative Care Pharmacy Residency at the Stratton VA Medical Center, in Albany, New York.

Dr. Fudin has disclosed that he is on the speakers’ bureau and is a consultant for Millennium Health, LLC. He is also CEO and owner of Remitigate, LLC. Statements are the sole opinion of Dr. Fudin and do not reflect the opinion of employers, employee affiliates, and/or pharmaceutical companies.