

**Redefining On-Site Screening
for Drugs of Abuse
Solution White Paper**

NOVX[®]

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Executive Summary

To be effective, substance abuse programs must have a reliable way of testing participants for program compliance. In the US and Canada, drug courts, treatment centers, pain management clinics, and employment testing groups are finding that drug screening is a difficult and resource-draining task. Many of these organizations struggle with getting accurate, reliable, on-site results and consolidating them with other critical information so that an informed decision can be made quickly.

The process itself – collecting the urine sample, performing the drug screen, interpreting the results, communicating the findings, and making a decision based on the full case history – is a logistical challenge. The difficulty of this challenge is further compounded by regulatory mandates, privacy and chain of custody concerns, resource limitations, and the inherent unpleasantness of handling urine samples.

NOVX provides a comprehensive solution that redefines on-site screening for drugs of abuse. By integrating the iMDx™ automated drug screening platform with PatientVu™ and ClientVu™ software for electronic health record management and case management, NOVX provides judges, physicians, and employers with accurate, timely results presented in the context of a complete case history. NOVX delivers the accuracy of laboratory screening with an easy-to-use, automated, on-site system that minimizes time demands on staff and key decision makers.

Redefining On-Site Screening for Drugs of Abuse

Drugs of Abuse Testing

The abuse of addictive substances is, without question, a pressing concern in today's society. From the court room, to the boardroom, to the 12-step meeting room, the need to identify and help drug users is growing more urgent.

One indication of how critical this need has become is the continued expansion of drug courts that are set up to help offenders break the cycle of addictive drug use. The first drug court opened in Florida in 1989; today, there are more than 1900 drug courts operating in the U.S.¹ – representing an almost tenfold increase over the past decade.

Drug courts are by no means the only institutions for which drug screening is imperative. Effective drug screening is vital to the success of any organization involved in addiction treatment, workplace testing, or chronic pain management.

As more and more organizations begin drug screening initiatives, they are rapidly discovering that managing the drug screening process can be unexpectedly difficult, time-consuming, and labor-intensive.

Challenges in Point-of-Collection Testing

Any drug screening process starts by collecting samples from program participants and ultimately ends with someone making an informed decision based on test results from those samples and the participant's case history. What happens between those end points, though, varies widely from organization to organization.

Some send the samples out to a third-party laboratory for processing. While labs deliver accurate results, the costs and relatively long turn-around time required by this approach make it unfeasible for many drug courts and treatment centers.

Others have chosen to perform the test at the point-of-collection with single-use urine dipsticks.

¹According to National Drug Court Institute Statistics

This approach, many have found, comes with its own set of drawbacks. The results are only qualitative; they provide a simple positive/negative indication of drug use. Further, these tests have greater margin for error and are more likely to produce incorrect results. Perhaps most importantly, this approach is messy. It requires a staff member to handle open samples of urine and examine the soaked dipsticks.

Equally important are the steps required to get the test results to the judge, case worker, or physician that must make a decision regarding the participant's continued care. Manually transcribing results from dipstick tests or lab reports is a tedious and error-prone task. Compiling those results and presenting them in context with other information on the participant is also time-consuming, but it is a step that cannot be bypassed. To make a well-informed decision, you must have not only current results, but also past test results and case history.

In both on-site and off-site approaches there are additional screening requirements that further complicate the process. Drug screening demands strict adherence to security and privacy practices to protect personal information. Records of test results must be carefully secured to protect participant privacy and ensure the results are not altered. Organizations must establish and rigorously follow such practices to comply with Health Insurance Portability and Accountability Act (HIPAA) regulations in the U.S. and Personal Information Protection and Electronic Documents Act (PIPEDA) guidelines in Canada.

The NOVX Solution

Clearly, there is a critical need to simplify, streamline, and accelerate the entire drug screening process, from the collection of samples to the making of a sound decision based on accurate results.

To meet this need, NOVX Systems has developed a complete and powerful drug screening solution that enables judges, physicians, employers, and other



Figure 1: NOVX redefines on-site drug screening

decision makers to make an informed, timely decision based on accurate on-site results in the context of a complete case history. Designed for non-laboratory settings and non-technical personnel, the NOVX solution reduces the workload and staff demands at the point-of collection. It offers the simplicity of dipstick tests without the mess and it delivers the accuracy of the lab without the wait. The NOVX solution is founded upon the iMDx automated drug screening platform and integrated PatientVu/ClientVu software for electronic health record and case management (see Figure 1). By combining the accuracy of laboratory results with the convenience of on-site testing, NOVX is redefining the drug screening process, from where it is conducted, to how results are managed and interpreted, to the experience of the point-of-collection worker.

Accurate On-site Results

Many drug screening centers today rely on urine dipstick tests to obtain a qualitative result on the presence of drugs of abuse in a participant's system. While these tests can be conducted on-site, they lack the accuracy and detail of lab results, and therefore provide less value in helping decision makers reach a fair and reasonable conclusion.

Quantitative results can be obtained by sending samples to a laboratory. This approach resolves the

accuracy problem, but it introduces additional delay, chain-of-custody issues, privacy concerns, and the potential for sample quality to degrade over time.

The iMDx Analyzer provides reliable, accurate results in an easy-to-use, on-site environment. It is approved for use in clinics and other near-patient settings. The iMDx has FDA 510(k) clearance and is licensed by Health Canada as a Class III Medical Device. It requires no special plumbing or electrical sources, only an Internet connection and a standard electrical supply.

Because barcoded urine samples are handed directly from the program participant to the staff and placed immediately into the analyzer, chain-of-custody and sample degradation concerns are eliminated. iMDx also eliminates transcription errors and patient privacy issues because test results are forwarded directly and securely into the integrated PatientVu/ClientVu case management system where they can be accessed only by authorized personnel. In addition, iMDx automatically performs self-checks to ensure accurate results, including carefully monitoring reagents and thermal variations within the instrument. The samples themselves can also undergo adulterant testing to ensure that they have not been diluted or tampered with in an attempt to mask drug use.

Complete Case Histories

Making an informed decision requires a view of the complete picture that includes the participant’s previous results, appointment attendance record, medical details, and case history along with comments and notes from others that may have reviewed the case previously.

A complete view of the history of each case is vital, because compliance with drug screening requirements over time is the key factor in most decisions. Tracking, reporting, and auditing of this compliance history is a crucial capability for any organization that relies on drug screening. In treatment centers, patient compliance is required for continued therapy. In drug courts, compliance is required to avoid incarceration. And in employment testing, compliance is required by professional licensing boards, or in some organizations, to secure and maintain employment.

Drug court judges can see up to 50 cases a day and sometimes more. Similarly, treatment center physicians and HR directors may have to review dozens of cases daily. All of them must make decisions that can have a profound impact on the lives of program participants. Few have free time to spend searching for and collating test results with other case information.

PatientVu/ClientVu provides a comprehensive case history including past and current test results in a single, intuitive interface (see Figure 2). It can integrate with other back-end systems to access additional information. PatientVu/ClientVu is a fully functional Electronic Medical Record (EMR) and case management system; it was designed to meet the specific needs of the drug screening community. PatientVu/ClientVu automatically integrates new results with the existing case history as soon as iMDx completes a sample run. Results are available immediately, and are free from transcription errors and subjective interpretation of dipstick readings. PatientVu/ClientVu also facilitates collaboration and information sharing, making it easier for multiple decision makers to provide consistent case management by sharing notes, comments, and other information across different locations and over multiple visits.

PatientVu/ClientVu is compliant with HIPAA and PIPEDA privacy guidelines, providing secure role-based access to authorized personnel only. Further, PatientVu/ClientVu sends all results electronically and only produces paper reports upon request, minimizing the need to carefully track and shred papers detailing confidential information.

The PatientVu/ClientVu interface is designed for ease-of-use and can be securely accessed from remote locations using a Web browser or BlackBerry® mobile handheld device. PatientVu/ClientVu allows judges, physicians, and employers to make sentencing, treatment, or employment decisions quickly and with confidence from virtually any location and at any time.



Figure 2: PatientVu/ClientVu integrates sample results with a complete case history

Scale without Complexity

It is clear that handling dozens of open urine samples, waiting for dipsticks to show results, and transcribing results is a time-consuming effort. How time consuming? Informal studies have found that it takes up to 30 minutes to screen fourteen samples with dipsticks, and that is only the time to produce raw data. Additional effort is required to gather, collate, and present the data.

If an organization needs to scale and expands its drug screening operation, it has few good options. It can try to find more and more workers willing to do a job that few want. Or, it can increase the workload of its existing staff, likely forcing even higher turnover rates, more transcription errors, and more errors due to subjective variability in interpreting results.

Even organizations that send samples to a lab for testing can have difficulty scaling. Problems with delays, lost samples, sample degradation, chain-of-custody, and getting data in a useable form can rapidly become unmanageable as the screening effort scales.

When the results come back from a lab in higher volumes, the staff is tasked with gathering and coordinating the results into a useful form. It is important to note that in both dipstick and lab testing, an organization cannot skip this step that takes raw data as input and produces easily understood information as output. If it is not done before the data reaches already burdened judges, physicians, and case workers, then they are forced to spend more of their time analyzing raw data.



Figure 3: Designed to minimize time demands

NOVX enables your organization to scale drug screening without this complexity. The iMDx Analyzer and PatientVu/ClientVu are designed to increase productivity by requiring only a fraction of your staff's time. To test up to 14 samples, an individual needs only five minutes to load the iMDx and start the run. Results automatically flow into PatientVu/ClientVu where they are available to decision makers as a part of a comprehensive case history in less than an hour. There is no manual transcription of results that can introduce errors. Sample handling is kept to a minimum – the staff member simply removes the cap from sample cup and loads it into a carousel. There are no open urine samples sitting on workbenches. After loading the samples and cartridge-based reagents into iMDx, the staff member starts the run, and walks away – free to work on other job responsibilities until the next run.

With a simple touch screen interface, the iMDx has been designed to be easy to use. Typically, a new staff member can be fully trained to use iMDx in an hour and is proficient after one or two sample runs. System maintenance is also kept to a bare minimum. The iMDx requires only a single one-hour calibration process per month, a procedure similar to a sample run.

The iMDx system itself is continually monitored by NOVX. This enables NOVX to ensure the system is always operating efficiently to produce accurate results. Further, this monitoring enables NOVX to streamline and simplify inventory management for its customers by tracking the use of reagents, sample containers, and other supplies. When customer inventory for any of these supplies falls below a set threshold, NOVX can automatically ship a new supply.

For organizations with limited IT resources on-site, NOVX also offers a hosting service. With this service, PatientVu/ClientVu runs on secure servers maintained and operated by NOVX, further reducing the workload for point-of-collection staff and eliminating the need for dedicated IT personnel. NOVX also provides a customer support hotline and ensures reliable access to data with real-time backups and hardware redundancy. NOVX can also perform follow-up confirmatory testing of positive samples.

Steps in a Sample Run

To illustrate how NOVX solutions redefine on-site drug screening, let's take a step-by-step look at a typical workflow.

Scheduling

The process begins with scheduling the participant visit. PatientVu/ClientVu supports three different approaches to scheduling:

- a fixed schedule, for example every Monday and Friday
- a random schedule in which participants are called and asked to provide a sample within a pre-defined number of hours
- a random keyed schedule in which participants call in and listen to pre-recorded information to find out when they must come in to provide a sample

Sample Collection

At the point-of-collection, PatientVu/ClientVu helps the staff manage the arrival and processing of program participants, showing everyone who is expected to provide a sample that day, whether they have arrived, and their current status.

PatientVu/ClientVu also enables the senior provider to pre-select the specific panel of tests to be performed on each sample.

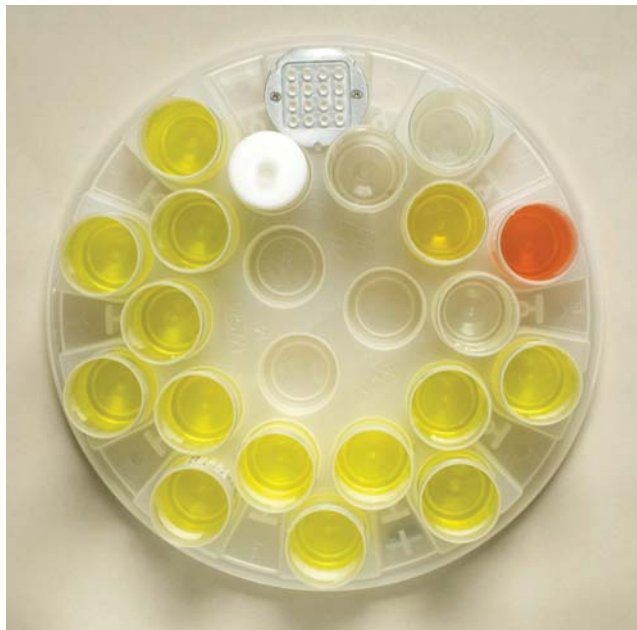


Figure 4: The iMDx carousel



Figure 5: Barcoded cartridge-based reagent

When a participant is ready to provide a sample, the staff member uses PatientVu/ClientVu to print out a label with the tests to be performed encoded in a barcode. This label is affixed to a sample cup, and handed to the participant. Because the barcode contains no information that identifies the patient, the iMDx results are inherently secure.

Loading the iMDx Analyzer

After the participant fills the sample cup, the sample is placed in the iMDx carousel along with up to 13 other samples to be processed in the same run. The staff member also loads the carousel with pH calibrators and an optional control sample provided by NOVX.

On the iMDx touch screen, the staff member is directed to load the carousel into iMDx, remove the sample caps, and close the door. iMDx then reads all the barcodes, ensures there is enough sample in each cup to conduct the tests, and checks that everything in the carousel is ready for the run.

Once the first self-check is completed, iMDx directs the staff member to load the specific cartridges it needs for that run. Consumables are uniquely barcoded, enabling iMDx to verify, for example, that the correct cartridge has been loaded, that it has not past its expiration date, and that it has not been used previously.

After iMDx verifies that the carousel and each cartridge have been loaded correctly, it presents a "Run" button on the touch screen interface. The staff member presses this button, and can now move onto other job responsibilities.

The three step process, loading the carousel, loading the consumables, and starting the run takes about five minutes.

Inside the iMDx Analyzer

Using the same technology applied in specialized, off-site labs, the iMDx Analyzer is designed to provide highly accurate results with a minimum of staff involvement. Once a run has started, iMDx ensures accurate results with precision timing of the chemical reactions and careful monitoring of the reaction environment.

The iMDx Analyzer can further validate results using a Control sample which contains known concentrations of each substance to be tested. Accurate analysis of the Control sample certifies the balance of the run as accurate.

To detect attempts at skewing results through sample adulteration, iMDx can also measure creatinine and pH levels and ensure they are within a normal range.

Viewing Results

The iMDx process can be monitored remotely with PatientVu/ClientVu. The software shows the current operational status, including how long a test has been running and how much time is remaining in the run.

Test results flow automatically from iMDx to PatientVu/ClientVu, and are ready to be accessed by decision makers in the context of a complete case history within an hour. Because there is no manual transcription of results and no data entry, the main sources of human error are eliminated.

Drug Screening Redefined

As the need for drug screening increases, more drug courts, treatment centers, and employers are discovering firsthand how difficult and resource-intensive the process can be. From ensuring compliance with regulatory mandates and privacy guidelines to reducing staff turnover and maintaining morale, there are a host of secondary issues that compound the primary challenge inherent in drug screening: getting accurate, reliable, and timely results to decision makers in the context of a complete history.

NOVX provides a complete solution that redefines on-site screening and enables organizations to implement an efficient process that maximizes the productivity of point-of-collection staff and key decision makers.

About NOVX Systems Inc.

NOVX Systems provides a complete and powerful drug screening solution that allows an informed decision to be made on-site. To make this decision – and make it immediately – judges, physicians, employers, and other decision-makers must have everything they need in one place. They need accurate on-site results. They need to see the complete case history to put the results in the proper context. And they need to be able to scale their operation without adding complexity. Only NOVX Systems has developed a complete screening solution for use in non-laboratory settings and by non-technical staff. NOVX – On-Site Screening Redefined.

The iMDx Analyzer provides semi-quantitative results and a more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when the preliminary test result is positive.

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