ALFA SCIENTIFIC DESIGNS, INC.

White Paper

ALFA's Patented
Drug Screening Devices

Accuracy at the Speed of ALFA

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Introduction and Background

The drug testing market is growing rapidly, from a $4 billion industry in 2014 to an estimated $6.3 billion by 2019. Among the factors driving this growth are increased use/abuse of prescription drugs by a growing, aging population, federal funding for drug testing, passage of stringent laws in developed nations, and increased awareness of drug testing in developing nations.[1] In addition, the American Society of Addiction Medicine (ASAM) has pointed out the underutilization of drug testing in health care for "the prevention and treatment of addiction" and "highlight[s] the wide range of applications in which drug testing can promote prevention, early detection, and lifelong recovery from addiction in the interests of individual and public health."[2]

From the initial gas chromatographic "tox screens" employed in death investigations in the 1950s to today's rapid, point-of-care (POC), lateral flow-based immunoassays (IAs) ubiquitous throughout modern employment, clinical, and corrections environments, drug screening technologies have evolved significantly. Now, multiple sample matrices (blood, urine, oral secretions) may be tested in mere minutes for the presence of drugs and their metabolites. In keeping with these advancements, Alfa Scientific Designs, Inc. offers a wide array of Instant-view® Drug Tests for rapid drug testing of urine and saliva samples. With advanced technologies that enhance assay specificity and decrease analysis time while controlling testing costs, Instant-view® Drug Tests provide 'Accuracy at the Speed of ALFA'

Current Drug Screening Practices

At present, drug screening is utilized in four primary settings: (1) addiction treatment programs, (2) emergency, pain management, and psychiatric clinics, (3) law enforcement and correctional institutions, and (4) under the terms of employment of many industries and the military. While confirmatory tests involving GC-MS or LC-MS/MS are required for positive tests in most cases, rapid IAs are the standard for initial screening in all of the indicated environments thus contributing to this already sizeable market.

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Recommended Expansion of Drug Screening

ASAM has provided an extensive guidance[1] regarding the expansion of drug screening in a number of clinical environments; hence, market expansion is likely to arise from three specific areas.

The Clinic

A study of patients, prescribed controlled substances, who were drug tested showed that only 40% of patients take the pharmaceuticals as prescribed, with the remaining 60% falling into categories of abstinence or potential abuse as shown in Figure 1.[3]

While data were gathered across a spectrum of primary care, pain management, and psychiatric clinics, it is a clear indicator that many patients are either not receiving the benefits of their prescriptions or are risking unmanaged drug interactions by self-medicating, and potentially abusing prescription or illicit drugs. Without testing protocols, clinicians lack a full picture of their patients' drug use and potential for abuse.

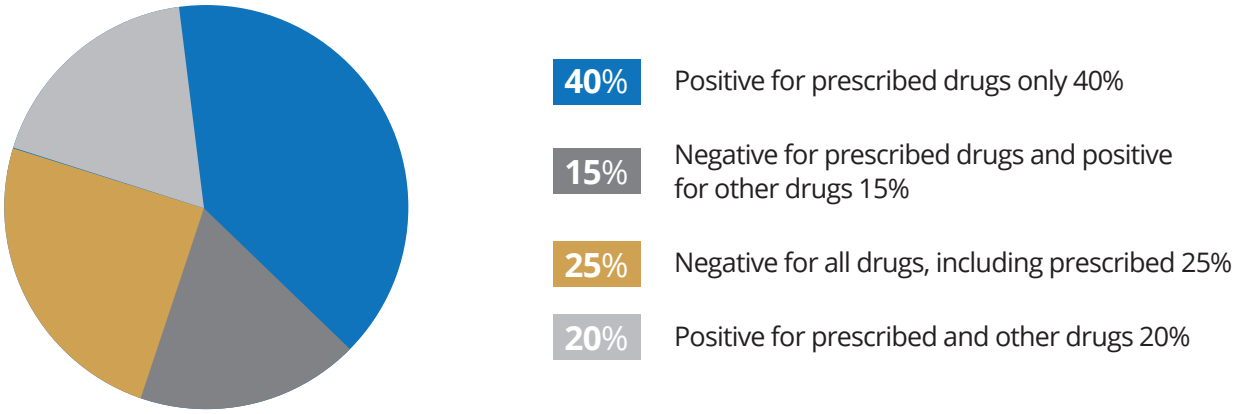

Figure 1: Distribution of patients testing positive or negative for prescribed medications, non-prescribed medications, and illicit drugs (adapted from CESAR Fax).[3]

Obstetrics

Another area of concern within the medical field centers on obstetrics. With half of all opioid and benzodiazepine use going unreported by patients[4], a testing protocol is likely to help physicians refer at-risk expectant mothers to treatment programs to combat the 300% rise, from 2000 to 2009, in neonatal abstinence syndrome (withdrawal).[5]

Law Enforcement and Corrections

Finally, a New Paradigm is being employed by innovative criminal justice systems[1] which calls for frequent, random drug testing with immediate, but non-draconian, consequences for non-compliance. One study[6] found that program participants showed a 55% lower incidence of recidivism, a clear indication the New Paradigm should be widely adopted.

With these target markets in mind, Instant-view® Drug Tests, developed and manufactured in the USA, can fulfill the growing need for accurate, simple, and cost-effective drug screening.

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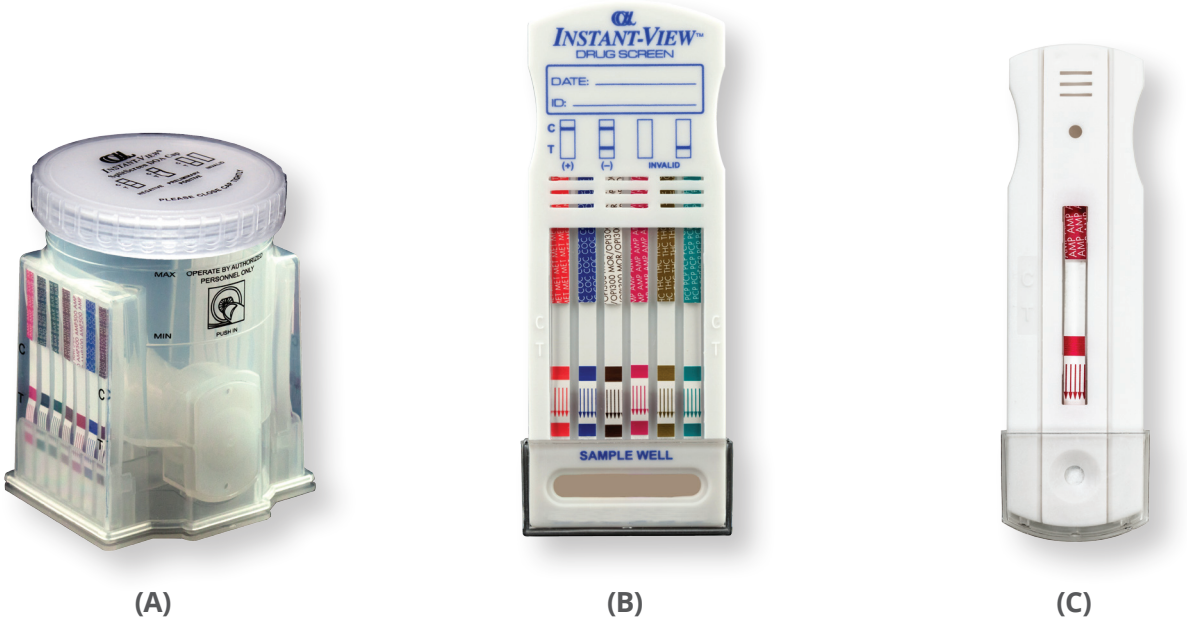
Registration of the Instant-view® Drug Tests

Available in three formats (Figure 2), Instant-view® Drug Tests are US FDA 510(k) cleared for professional/over-the-counter (OTC) use and CLIA-waived for 14 analytes, with adulterant tests available for creatinine, nitrites, glutaraldehyde, pH, specific gravity, and oxidants.



(A) (B) (C)

Figure 1: Instant-view® Urine Drug Tests are available in (A) Push Button SplitScreen Cup, (B) Multi-Drug Dual Cassette, and (C) Single-Drug Dip Cassette formats.

Instant-view® Urine Drug Tests Provide Accurate Results

Of key importance in any drug testing protocol is the accuracy of the test itself. When the analyte of interest is present in concentrations near the detection cutoff, rapid point-of-care drug tests sometimes return false positive or false negative results. Instant-view® Urine Drug Tests are proven to minimize these occurrences near the cutoff to a high degree. Testing performed at 3rd party locations returned MS confirmed results at rates from 92% for amphetamine, a notoriously difficult analyte to accurately detect, all the way up to 99.8% for barbiturates.[6]

Instant-view® Urine Drug Tests also have a proven track record with published reports indicating a reliance on these tests in forensic cases[7,8] and academic studies.[9] One report even demonstrates that Instant-view® Urine Drug Tests outperform a competitor's point-of-care drug test in a side-by-side comparison of sensitivity.[10]

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All-In-One Sample Collection and Testing

The Instant-view® Push Button SplitScreen collection and testing device goes a step further toward ensuring both accuracy and sensitivity. The scientists at Alfa Scientific Designs, Inc. have designed and patented an integrated collection and testing cup that allows the user/tester to collect, seal, and record the temperature of a sample in an external chamber of the device. From there, the simple push of a button introduces a metered amount of sample to the isolated testing chamber containing 14 individual test strips, which may include a screen for adulterants. Accurate results are ready for documentation as quickly as 4-7 minutes with the cup's flat surface allowing the user/tester to photo-copy the results for easy documentation purposes. By running the test in this closed environment following sample collection, problems with environmental contamination or spillage are completely averted, meaning fewer repeated tests and more reliable results.

Instant-View® SplitScreen Devices Ensure Sample Integrity

Regardless of the inherent accuracy and sensitivity of a given drug screen, confirmatory testing must be completed in the event of a positive test. With a two-chamber design, the Instant-view® Push Button SplitScreen device maintains segregation between the sample and the test reagents. This physical separation guarantees that the untested sample remains uncontaminated by test reagents. In addition, as the collection cup remains sealed from the environment and isolated from the test reagents, the entire device may be stored and transported for confirmatory testing. Once again, this robust arrangement eliminates the possibility of environmental contamination or spillage during transfer to a separate container.

Summary

Instant-view® Urine Drug Tests are well suited to a range of point-of-care drug screening needs. With a suite of product formats, a high degree of accuracy, excellent sensitivity, and a reasonable price-point, Alfa Scientific Designs, Inc. offers an excellent solution to current drug screening needs. The patented Instant-view® Push Button SplitScreen device offers excellent accuracy and sensitivity with the added benefit of industry-leading sample security.

With these tools, Alfa Scientific Designs, Inc. facilitates improved rehabilitation efforts for those struggling with addiction, allows medical professionals to more closely monitor and effectively treat their patients, and helps officers drastically reduce the recidivism rates plaguing our overburdened corrections system. With Alfa Scientific's dedication to enhancing the performance of point-of-care drug tests while maintaining a reasonable price-point, Instant-view® Urine Drug Tests are truly "Where Value Meets Quality in Diagnostics."™

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