LifePoint Inc.

WRITTEN COMMENTS REGARDING FDA DRAFT GUIDANCE FOR "OVER THE COUNTER (OTC) SCREENING TESTS FOR DRUGS OF ABUSE: GUIDANCE FOR PREMARKET NOTIFICATIONS" [Docket No. 99D-1020]

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LifePoint, Inc. (Ontario, Calif.) is a late development stage company currently in the process of commercializing a unique on-site product that will test for both alcohol *and* drugs without the use of breath, blood or urine (see Exhibit). The LifePoint test system uses a special patented flow immunosensor technology, for which the company holds an exclusive worldwide license from the United States Navy Research Laboratories. When used in conjunction with saliva as the test specimen, this unique technology has made it possible for LifePoint to develop a broadly applicable, non-invasive, on-site diagnostic test system that is capable of providing completely automated results for up to10 analytes in under 5 minutes.

When applied to substance of abuse testing, the LifePoint product brings the advantages of observable, non-invasive collection, quantitative results that may prove to be evidential for alcohol, and significantly more sensitive and specific results than that which is provided by current immunological urine drug tests (either on-site or lab based). The system, completely automated from collection and processing of the specimen, testing, analysis, result readout and interpretation, almost eliminates the chances for operational or interpretive error and potential specimen mix-up, and, therefore, should provide legally defensible results.

All of these benefits can mean significant cost savings and operational improvements for substance of abuse testing in the workplace, insurance and sports. The use of drug testing in these environments is usually conducted by trained professionals under the supervision of a Medical Review Officer (MRO). Furthermore, it is apparent that the standards set for the regulated workplace through the Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS) (similar to the oversight provided by the Department of Transportation (DOT) for alcohol testing) are being widely adopted as the standards by professionals in the non-regulated workplace arena.

During the past year, LifePoint has presented its technical findings at numerous conferences and seminars. LifePoint has presented at the Drug and Alcohol Testing Industry Association, the International Chiefs of Police Drug Recognition Expert Conference, the Mid-Atlantic Association of Forensic Toxicologists, the Northwest Association of Forensic Toxicologists, the International Association of Forensic Toxicologists, the Society of Forensic Toxicologists, and the American College of Emergency Physicians. LifePoint presented a paper to the International Congress of Alcohol, Drugs and Traffic Safety in Stockholm. Based on the presentations made at the International Congress of Alcohol, Drugs and Traffic Safety, LifePoint was invited to present to the European Union project on roadside drug testing (the ROSITA project). In both instances, LifePoint's presentations were well received. In fact, audiences of employers, law enforcement officials, government representatives, medical professionals, scientists and researchers have consistently shown a great deal of interest in the flow immunosensor technology and the first product under development by LifePoint. LifePoint will be initiating field evaluations shortly.

With such a tremendously positive response to LifePoint's saliva-based, on-site simultaneous test for drugs of abuse and alcohol, we feel it necessary to comment on the recently published "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications". While we acknowledge that there may be a need to set guidelines for OTC products in environments where there are casual, infrequent users, such as in home use, the application of these same guidelines to the more routine, *professional use* in the workplace, sports and insurance is not appropriate. The unintentional consequences of duplicate and onerous requirements on both the user and the manufacturer by FDA, in conjunction with the current and proposed DOT and SAMHSA guidelines, will have significant, undesired effects on drug testing in general. Not only will there be a significant increase in the total delivery cost of a test, but the proposed guidelines will also be in conflict with the standards of practice already established and controlled by SAMHSA and the DOT.

Additionally, some of the newer products and technologies under development have already addressed many of the concerns raised by this document. It is critical, therefore, for FDA to take into consideration the newer technologies and products that will be shortly available, that can revolutionize substance abuse testing practices, and finally provide the ability to obtain lab-quality results easily, quickly, and cost-effectively on-site by non-technical users. The complexity of the test itself should also be addressed as is currently done by FDA in laboratory regulation by defining products as CLIA-88 waived, moderate complexity, or high complexity and using appropriate regulation based on the complexity of the product itself.

Lastly, and most importantly, FDA's mission, as authorized by law (21 USC § 393) is to " protect the public health by ensuring that... there is reasonable assurance of the safety and effectiveness of devices intended for human use." " The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals..." (21 USC § 321h). The inclusion of workplace, sports and insurance testing is not within the charter of FDA. Additionally, the results of these tests are not used for diagnosis or treatment, and this position has been upheld both by the courts and Congress, which has been explicit on this point in the Americans with Disabilities Act of 1990.

We recognize the mammoth effort that the draft represents on the part of FDA. While we appreciate your effort, we also appreciate the opportunity to submit these comments and respectfully petition your full consideration of the following:

ON-SITE TESTING

The development of simple, easy-to-use drug testing products should enhance substance abuse detection and allow for more reliable, accurate, and faster testing methods without increasing the cost of such testing. There is no real attempt to include these new and improved technologies; the draft guideline only focuses on current urine drug tests.

Additionally, the proposed guidelines lean very heavily toward laboratory-type Prescription Use Product oversight and control, which is not relevant to use in OTC markets. In fact, some of the draft guidelines appear to require more quality control of on-site testing than that required for moderately complex laboratory products or lab-based testing.

If the intent of these guidelines to discourage the use of on-site testing then this draft guideline will accomplish such a goal. However, if instead the goal of these guidelines is to improve the overall accuracy, effectiveness, and efficiency of OTC testing, then the use of Prescription Use Product oriented regulations and oversight requirements for such simple on-site testing products is overkill. We need only look back to the late 1980s to see how such over-regulation can actually harm the public good rather than help it. Prior to the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), most physician offices performed a wide variety of tests that enhanced the physician's ability to provide immediate diagnosis to their patients. The patients and physicians both enjoyed the benefits of this process. With the passage of CLIA-88 and the requirement for physician office labs (often using very simple and automated test products designed for physician office use) to meet the same standards as commercial labs (including hiring laboratory professionals) 85% of physician offices that were doing on-site testing for moderately complex tests stopped doing testing (CDC data).

SALIVA TESTING

Saliva as a drug test specimen represents a viable alternative for drug testing programs. The use of saliva rather than urine makes it possible to address a number of burdensome issues that have plagued drug testing for many years. For example, saliva is, by far, a much less invasive specimen for collection purposes. Few people find it offensive to provide a saliva sample versus urine. Saliva also makes it possible to conduct an observed collection *every time* without requiring anyone to watch a donor urinate.

Because of saliva's window of detection of several hours to a day, depending on the drug and dosage level, it makes for an excellent indicator of "under the influence" status. This makes it particularly effective as a more accurate post-accident, reasonable suspicion test, and even fit-for-duty testing. Additionally, all urine and saliva-based drug tests are "recent use" tests and as such have the capability to be used for pre-employment, random, and return-to-duty testing; in

fact, with some drugs (e.g., cocaine, amphetamines and THC) , depending on dose level and assay sensitivity, the window of detection for saliva will definitely overlap that of urine*. Saliva has already been validated and approved in many states as a viable specimen for use in the criminal justice system. Law enforcement officials are specifically allowed by law to use saliva as a specimen for DUI drug testing purposes in 9 states, while 10 other states allow the use of "other bodily substances" besides breath, urine and blood. Lastly, several participants in the European Union-funded ROSITA project have published the results of their studies and have defined the "perfect on-site drug test" as a saliva-based, instrumented (for objectivity and elimination of user interpretation), panel test, with results in 5 minutes.

Interest in the use of saliva for drug testing purposes is growing rapidly and the guideline should not only reflect this, but also be careful not to inadvertently restrict or discourage its use. This is especially true at a time when adulteration and substitution problems associated with urine testing are beginning to impact the integrity of the drug testing process overall, and the use of a specimen that can be observed every time significantly reduces the opportunity for substitution and adulteration.

THE DRAFT GUIDELINE POINT-BY-POINT

The following are recommendations that LifePoint believes should be considered by FDA.

INTRODUCTION

This draft only addresses urine testing and does not address the newer products and technologies, or the alternate specimens (hair, sweat and saliva) now being considered by SAMHSA and DOT in their workplace drug testing draft guidelines.

More importantly, there are significant inconsistencies in these proposed guidelines that conflict with standards that are already applied in certain industries which are already regulated by the US Government: SAMHSA and DOT already regulate drug testing in the workplace (similar to DOT regulation of alcohol testing), and SAMHSA is currently in the second year of a major effort to increase that oversight. We continue to see that testing in the workplace is moving toward professional use in both the regulated and non-regulated workplace. Additionally, oversight is provided to drug testing in sports medicine through the International Olympic Committee (IOC) and the National College Athletic Association (NCAA).

*Cone, Edward J. in Malamud, D. and Tabak, L. (eds) Saliva as a Diagnostic Fluid. "Saliva Testing for Drugs of Abuse". Annals N.Y Academy, Sci., vol. 694 (1993), pp. 91-127.

Additionally, the application of OTC guidelines, which are designed for the infrequent, non-professional user, to more routine, frequent use by trained professionals in the workplace, sports and insurance is not appropriate.

Lastly, there is no consideration given to the complexity of the product being used; for example, it is not clear how CLIA-88 waived type products would be used in an OTC environment compared with moderate complexity products. FDA needs to consider how the complexity of the products being used would change the oversight requirements in these environments. Since CLIA waived products assure an accurate result by a non-technical user, many of the proposed regulations are again inconsistent in the application of such products in an OTC environment.

We recommend that FDA consider only OTC home usage issues in this document, and consider the professional use of these products for drug testing in the industrial workplace, sports medicine and insurance testing as a separate professional use (but not a laboratory) category.

LifePoint recommends that FDA ultimately consider several different levels of oversight to any testing process, depending on both the user level of familiarity with testing procedures in general, and the complexity of the product being used. For example, there may be the need for several levels of oversight and control such as:

1) OTC Home Use – non-experienced user.
   a) Simple or automated product with no user interpretation (such as CLIA waived products)
   b) Products that are somewhat complex and that require user interpretation
2) Workplace, Sports Medicine and Insurance Testing – Testing done by professionals under the oversight and control of SAMHSA, DOT, the NCAA, and the IOC.
   a) Simple or automated products with no user interpretation (such as CLIA waived products)
   b) Products that are somewhat complex and that require user interpretation
3) Laboratory Based Testing
   a) CLIA Waived Products
   b) Moderate Complexity Products
   c) High Complexity Products

SAMHSA is already addressing these issues in the workplace and currently has draft guidance that takes into consideration the complexity of various products and the environments in which they will be used.

OTC SETTINGS

OTC products are mostly used in environments where there are casual and infrequent operators of the product(s), and because of that, these users may require more assistance from the manufacturer of a product.

Within the professional use settings of workplace, sports and insurance, there may be a need to provide data that shows inexperienced users can use a specific product with reliable results, similar to the types of studies used for CLIA waver. But, within that context, it should be adequate to show: 1) a product gives results similar to a predicate device, and 2) a non-trained user will obtain results similar to a trained professional. The test system should provide both the non-trained user and the professional equal ability to obtain valid test results and should not require any correlation to a reference method (this is in the prescription part of the guidelines).

However, the application of these same guidelines to more routine, frequent use by trained professionals in the workplace, sports and insurance is not appropriate. Additionally, many of these applications are already regulated by other agencies such as the DOT and SAMHSA, IOC, NCAA, etc. and oversight by a second US agency, often with discrepant requirements, would be confusing to the professionals that provide testing services and to the recipients of these test results.

The unintentional consequences of duplicate and onerous regulatory requirements on the user and the manufacturer by FDA, in conjunction with the proposed DOT and SAMHSA guidelines, will have significant, undesired effects on drug testing in general by significantly increasing the cost, and decreasing the amount of testing being done. It has been validated numerous times that testing routinely for drugs is the best deterrent for drug use. We firmly believe, therefore, that melding FDA's guidelines within the framework of the guidelines that already exist, such as those of SAMHSA and DOT, will do more to further promote public health and safety.

DESCRIPTION OF DEVICE

The development of newer technologies and products has significantly increased the level of accuracy that can be obtained from some on-site test systems. It is inappropriate to classify all on-site methods as "less accurate" than lab based methods. In fact, some of the newer methods may be as accurate as lab-based methods. Additionally, some drugs (cocaine, PCP or THC) being tested rarely, if ever, get either laboratory false positives or positives from prescription medications. Therefore, if an on-site test is as accurate as a lab-based test, then a confirmation test should be performed only as desired by the user. The requirement that ALL tests must be confirmed and included in the cost of the initial test only adds unnecessary expense to the testing process, and could cause the unintended result of reduced testing or inaccessibility of testing to

those that would like to perform testing. We suggest the requirement for language that indicates that presumptive positive results for certain drugs (for example opiates and amphetamines) may be caused by prescription or OTC drugs and a confirmation test is strongly suggested.

#2

The language used needs to be consistent for all applications of a product – the use of "presumptive positive" has been proposed for the preliminary screen result by DOT and SAMHSA. Since many drug testing products are used in multiple markets, the language used for a "not as yet confirmed positive" screen test needs to be consistent. If not, the requirement will become confusing to service providers that may perform testing in multiple markets. We strongly recommend that FDA work with the DOT and SAMHSA to develop consistent language in all guidance.

Additionally, the use of "uncertain", "maybe" or "inconclusive" may be misleading or confusing. The initial screening test results are most often correct and the use of these terms may undermine the confidence in good initial test results.

#4

We strongly believe that FDA should not require that a confirmation test be included in the cost of the initial screen. This is one of the main areas of divergence between home testing for occasional users and the routine use by professionals in the workplace, insurance, and sports. In these environments, there are regulations which dictate under what circumstances a test needs to be confirmed (for example, in follow-up monitoring where only one test is done on a known user there is no need to confirm). Additionally, the requirement for confirmatory testing conflicts with certain state regulations.

The inclusion of a confirmation test will significantly increase the cost of the initial screen – manufacturers will need to assume that all tests will require a confirmation. Depending on the environment in which a product is used, the positivity rate can be extremely variable. Additionally, the requirements for collection and transport to the lab will also add additional unnecessary expense. The inclusion of a specific laboratory will either require regional packaging or long distance transportation for a majority of specimens.

Additionally, the mandatory confirmation requirement when applied to the professional use in the workplace, insurance, and sport, where there are procedures already established in the processing of test specimen, is contradictory and not consistent with current practice. For example, the due process afforded employees by the requirement to have an MRO involved in the testing process is eliminated.

The bottom line is that this requirement cannot be implemented in the workplace, insurance, or sports without adding significant cost and labeling confusion, with the potential for an unintended result of a significant decrease in drug of abuse testing being performed.

We strongly recommend that any environments where professionals use the on-site drug testing products routinely and frequently do not fall under this guideline. We also recommend that the requirement for the inclusion of a confirmation be only for home use.

We recommend that a statement to consult with a healthcare professional be used rather than a mandatory confirmation test.

2. SAMPLE TYPE AND DISTRIBUTION

We believe that it is inappropriate to legislate and pre-determine the sampling and distribution of the clinical study. The types of data that need to be collected will vary significantly depending on the type of specimen, the assay technology, the intended use of the product, the predicate device, and the manufacturers' claims for their product. We recommend that the structure of field evaluations be dictated by the sample matrix, assay sensitivity, accuracy and precision, as is currently done with most FDA cleared products. Consider that the LifePoint test system requires no user interpretive skills even around the cutoffs. This is not true for the visual membrane-based immunoassay systems. The clinical study sampling should certainly reflect this key difference. The sampling grid in the guideline appears to single out the problems specifically associated with visual membrane-based systems.

6. DESCRIPTION OF CERTIFIED LAB

This may be impossible if a regional approach is used. Again, this requirement should be limited to home use testing only. Confirmation of drug testing in regulated environments is already done by NIDA certification of laboratories.

LABELING

We recommend that labeling for workplace, insurance, and sports follow the labeling guidance for prescription use assays. These users are trained personnel who should be informed of the device's performance data.

3. LIMITATION OF SCREENING

We recommend the consistent use of labeling across DOT, SAMHSA, FDA, etc. (See our comments under Description of Device)

The statement "laboratory test is more accurate" may not be completely true and therefore, misleading. Some on-site test methods are actually more accurate than some methods that are used in a laboratory. We do not recommend the use of such wording.

We recommend the use of a different approach. "Since certain OTC and prescription drugs may provide a positive result, a confirmation via a GC/MS may provide further clarification as to the causative agent of the presumptive positive result. We recommend that you consult with a health care provider to further clarify results."

Additionally, if the result obtained using an on-site test is equal to or better than results generated by a lab-based method, then we also recommend that a confirmation test be required only when a confirmation would be required for the lab-based method.

9. READING AND UNDERSTANDING TEST RESULTS

We again recommend consistency in the use of words for results. FDA, SAMHSA, DOT and any other agencies that regulate testing should agree on the terminology to be used.

10. The provision of pharmacokinetic data may not be appropriate or useful for screening assays since most of the data found in the literature cites GC/MS results on samples obtained from single dose studies. We recommend that such data should not be included because the clearance rates are the result of multifactorial influences including, level of drug dose, method of drug delivery, metabolic rate of subject and the sensitivity of the assay system used for drug detection. The inclusion of such data may be not only misleading, but, under some circumstances, incorrect.

17. OUTSIDE BOX LABELING

We recommend consistent labeling in defining "presumptive positive" results.

ADDITIONAL ISSUES LISTED AT THE END OF THE GUIDELINE:

#1

The provision of pharmacokinetic data may not be appropriate or useful for screening assays since most of the data found in the literature cites GC/MS results on samples obtained from single dose studies. We recommend that such data should not be included because the clearance rates are the result of multifactorial influences including, level of drug dose, method of drug delivery, metabolic rate of subject and the sensitivity of the assay system used for drug detection. The inclusion of such data may be not only misleading, but, under some circumstances, incorrect.

#2

The use of a product for either pre-employment testing or incidence testing should NOT require different studies. The user is the same and the test is the same. This requirement would possibly require a user to use different products for different types of tests, which could increase confusion and jeopardize test result accuracy. This would again add unnecessary cost to the testing programs and probably have the unintentional effect of reducing testing and thereby once again impact public health and safety.

#3

The requirement to test for false negatives would significantly increase the cost of the testing programs. Additionally, this proposed requirement is not even currently required of labs. Therefore, this would be asking the on-site test to perform QC testing at higher levels than those required of a laboratory.

#4

Alcohol testing is normally done under DOT requirements and under state law for forensic use. In both situations, a second test is often considered a confirmation test. (This approach has been validated by the courts and is currently accepted by DOT and SAMHSA). The requirement for an additional confirmation would again add unnecessary cost to the process. Additionally, since breath cannot be transported, this would also require the collection of a blood test, an onerous requirement in many testing situations.

#6

The required labeling described in this section is unnecessary. The organizations that follow SAMHSA or DOT are fully aware of their requirements.

QUESTIONS PRESENTED TO THE CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL, NOV. 13, 2000 MEETING

1. We strongly believe that FDA should not require that confirmation testing be a mandatory component in the design and cost of the screening test for workplace, insurance, and sports settings. This requirement should be only be considered for home use. However, the inclusion of a mandatory confirmation test for positive results will require that manufacturers assume that all tests will positive and include the cost of the confirmation in the product. This *will* significantly increase the price of a test to the user (estimated to be an additional $30-50 per test for sample collection, transport, confirmation testing by GC/MS, and reporting, with the probably negative consequence of reduced testing. Since testing has been proven to be the best deterrent to drug abuse, this may result in the unintentional consequence of increased drug use.

   Instead we propose that FDA consider a mandatory confirmation not be required, but that the labeling include a statement similar to the following: "Since certain OTC and prescription drugs may provide a presumptive positive result, a confirmation via GC/MS may provide further clarification. We recommend that you consult with a health care provider to further clarify results."

2. The studies and labeling guidance for workplace, insurance, and sports should take into consideration the fact that the user is a *professional* and routinely uses the product. Product complexity should also be taken into consideration so that easy-to-use, error-proof products can be used by non-technical personnel, without significant oversight, similar to FDA guidance for CLIA waived products.

3. FDA should not impose tighter accuracy requirements for OTC products than is required for similar technologies in a laboratory setting. Additionally, the accuracy requirement should also depend on the cut-off level. For example, a requirement for +/-50% the cutoff is very different for urine samples with cutoffs at 300 to 2000 ng/ml as versus oral fluid with cutoff level of 4 ng/ml to 160 ng/ml. At 300, a +/- 50% requirement allows for 150 to 450 ng/ml, while the same requirement at 5 ng/ml requires performance between 3ng/ml and 7 ng/ml. For any analyte with a cutoff below 50 ng/ml, there should be nothing less than a +/- 50% requirement for on-site tests or laboratory based tests.

4. Performance data specific to the type of specimen and the product being used should be included in the labeling for workplace, insurance, and sports settings. These users are trained personnel who should be informed about the performance data of the product.

5. We recommend that the structure of field evaluations be dictated by the sample matrix, assay sensitivity, accuracy, and precision, as is currently done with most FDA cleared products. Consider that the LifePoint test system

requires no user interpretive skills even around the cutoffs. This is not true for the visual membrane-based immunoassay systems. The clinical study sampling should certainly reflect this key difference. The sampling grid in the guideline appears to single out the problems specifically associated with visual membrane-based systems.

6. If the sponsor has already obtained FDA prescription clearance, only studies required for CLIA waived status should be performed for workplace, insurance, and sports settings. This would model the validation procedures required of clinical assays being conducted outside of a central lab.

7. There should be no obligation to restrict FDA clearance to products meeting SAMHSA cutoffs. SAMHSA only applies to the federally regulated workplace. Other regulatory bodies oversee the sports and insurance industries, and SAMHSA cutoffs may not be appropriate for those uses. FDA should not impose ANY cutoffs for results interpretation for drug of abuse testing. As with all other FDA cleared products, the recommended cutoffs for each product should be established and validated by the manufacturer of the product and then the final cutoff selected by the user, based on the use of the product. With drugs of abuse testing, the cutoffs selected will vary significant depending on the use of the product (for example, there will be very different "cutoffs" for an overdose in the ER as versus the testing for law enforcement which is also often done in the ER. The SAMHSA guidelines may be appropriate for SAMHSA regulated markets only, and should not be automatically used by FDA in other applications.

8. There should always be performance requirements especially around the cutoff.

OTC Alcohol Tests

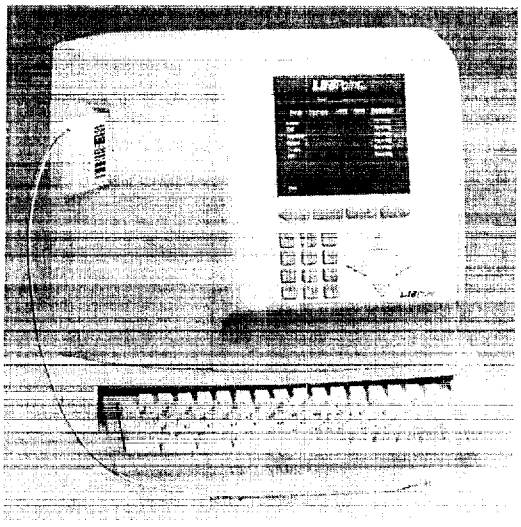
1. The Department of Transportation approach to alcohol testing should certainly be considered by FDA for workplace, insurance, and sports settings. FDA regulation of this market will be duplicative and potentially onerous, costly, and confusing to the users and manufacturers. Likewise, FDA should consider SAMHSA approach to drugs of abuse testing for workplace and the IOC and NCAA regulation of sports testing. Similarly, FDA regulation of these markets will be mostly duplicative and potentially onerous, costly, and confusing to the users and manufacturers. These markets already have standards of practice that have been used successfully for a long time, and have been supported by state and federal courts and legislatures.

2. For alcohol testing, a second test should be considered a confirmation test. This approach has been accepted by DOT, SAMHSA and the courts.

Exhibit

LifePoint, Inc. will soon be introducing a unique product – the first non-invasive, on-site testing system that will deliver blood-equivalent results without taking a blood sample. The system consists of an easy-to-use saliva collection and testing cassette, used in conjunction with a small, portable instrument. It is designed to be user friendly with minimal training required. The system is designed to quantitatively measure alcohol and test for the five National Institute on Drug Abuse (NIDA) illicit drugs (marijuana, cocaine, opiates, methamphetamine/ amphetamine and angel dust (PCP) in a single cassette from a few drops of saliva within 5 minutes. The system is an ideal intervention tool for DUI of drugs and alcohol and provides the following advantages:

- **Delivers "under the influence" results for drugs and alcohol**
- **Provides on-the-spot results**
- **Reduces chain-of-custody issues**
- **Minimizes training requirement**
- **Eliminates suspect transportation**



The small, portable instrument automatically manages all functions related to running the test panel, including:

- **Specimen collection**
- **Sample adequacy and quality checks**
- **Automatic quality control and calibration**
- **Sample processing and analysis**
- **Designed to meet CLIA waivable criteria**
- **Electronic and hard copy test results**
- **Laboratory-quality accuracy and precision performance**
- **Result interpretation**
- **Legally defensible hardcopy results**

The test cassette, packaged in a foil pouch, is ready for immediate use and disposal. The saliva specimen, test reagents and waste are contained within the cassette, thereby greatly reducing the possibility of biological contamination.

The entire test procedure, including specimen collection and result printout, takes less than five minutes. Saliva is collected via aspiration, with a device similar to those used in a dental office, and automatically transferred into the test cassette. The collection process itself takes approximately one minute, which is significantly faster than absorbent pad collection (which can take five to fifteen minutes for sample collection alone). Additionally, aspiration allows for quantitative results, which cannot be provided with absorbent pad collection.

Saliva indicates blood-equivalent or "under-the-influence" results, similar to a blood test. Saliva as a test specimen is therefore more relevant than urine for impairment related situations such as post-accident, for suspicion, random, and fit-for-duty tests. Urine as a test specimen indicates drug use over the last 2-5 days. LifePoint's system is the first on-site system to test for drugs of abuse and alcohol simultaneously, and the first on-site test for blood-equivalent "under-the-influence" results. Additionally, the entire process – collection and test – is observable and significantly reduces the possibility of adulteration.

PLATE

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Form I.D. No. 0215

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1 From This portion can be removed for Recipient's records.

Date 2/[illegible] FedEx Tracking Number 824547037590

Sender's Name KEN BERGER Phone 909 418-3000

Company LIFEPOINT INC

Address 1205 S DUPONT AVE

Dept./Floor/Suite/Room

City ONTARIO State CA ZIP 91761

2 Your Internal Billing Reference

3 To

Recipient's Name [illegible] MANAGEMENT BRANCH Phone

Company FOOD & DRUG ADMINISTRATION

Address 5630 FISHERS LANE, ROOM 1061

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(HFA-305)

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8245 4703 7590

9160445421

4a Express Package Service *Packages up to 150 lbs*

Delivery commitment may be later in some areas

- [X] FedEx Priority Overnight — Next business morning
- [ ] FedEx Standard Overnight — Next business afternoon
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [ ] FedEx 2Day* — Second business day
- [ ] FedEx Express Saver* — Third business day

* FedEx Envelope/Letter Rate not available. Minimum charge: One-pound rate

4b Express Freight Service *Packages over 150 lbs*

Delivery commitment may be later in some areas

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

* Call for Confirmation:

5 Packaging * Declared value limit $50

- [X] FedEx Envelope/Letter*
- [ ] FedEx Pak*
- [ ] Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling Include FedEx address in Section 3.

- [ ] SATURDAY Delivery — Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- [ ] SUNDAY Delivery — Available only for FedEx Priority Overnight to select ZIP codes
- [ ] HOLD Weekday at FedEx Location — Not available with FedEx First Overnight
- [ ] HOLD Saturday at FedEx Location — Available only for FedEx Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [X] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Yes — Shipper's Declaration not required
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg
- [ ] Cargo Aircraft Only

Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below.

- [X] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check
- [ ] Obtain Recip. Acct. No.

Total Packages	Total Weight	Total Charges
2		

†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

Credit Card Auth.

8 Release Signature *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

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