



ALFA NEWSLETTER

*Your partner for
quality, rapid
diagnostic products.*

MANUFACTURED IN OUR 40,000 SQ. FT.
U.S. FACILITY.



Did you know?

We now offer
Adulteration Strips
(Specimen Validity Tests)
& Cotinine Test Devices.

Contact your Alfa Sales or
Customer Service Rep for
further details.

Mark your calendars!

Drug Free Work Week

will be held
October 20-26, 2008.
For more detailed
information visit:
<http://www.dol.gov/asp/programs/drugs/workingpartners/dfww-introduction.asp>



13200 Gregg Street
Poway, CA, 92064
PH: 858-513-3888
FX: 858-513-8388

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Editor: Alison Adduono
aadduono@alfascientific.com

Just What Is CLIA?

Often we are asked by distributors why it is important for a test to be CLIA-waived. Well to answer that it is first best to explain what CLIA stands for.

What Is CLIA?

The Clinical Laboratory Improvement Amendments of 1988 specifies that laboratory requirements must be based on the complexity of the test performed. As a result they established provisions for

categorizing a test as waived.

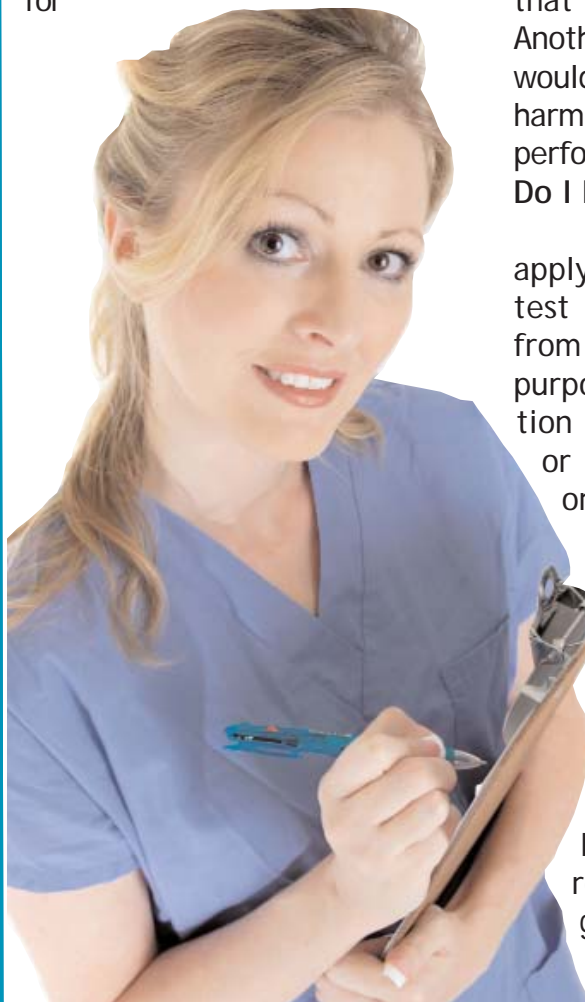
If tests meet the requirements set by this statute, then they may be waived from regulatory oversight. On February 28, 1992, regulations were published to implement CLIA.

Waived tests were defined as simple laboratory procedures that are cleared by the FDA for home use and that incorporate methodologies that are so easy and accurate that it is unlikely that mistakes would occur. Another requirement is that they would pose no reasonable risk of harm to a patient if they were performed incorrectly.

Do I Need A CLIA-Waived Test?

CLIA requirements do apply to entities that perform test on ..."materials derived from the human body for the purpose of providing information for diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If the tests are performed for these purposes, the organization doing so is considered under CLIA to be a laboratory and must register with the CLIA program. In these instances,

Continued on page 2





Understanding CLIA-Waived Tests

Continued from page 1

the advantage of using a "CLIA waived" test is that it "waives" you from having to comply with a long list of laboratory requirements (such as quality control, training, etc).

CLIA regulations do not apply to settings such as Correctional (i.e. jails, prisons, probation, courts, etc.) or even Workplace markets. However

CLIA-waived tests can still be sold to them as if they were not waived at all.

As distributors typically sell to multiple end user markets, having a selection of CLIA-waived tests is advantageous as it avoids limiting their sales avenues.

In the Drugs of Abuse arena, Alfa Scientific Designs, Inc. currently offers 11 different waived drug tests and they are

available in strip, cassette, dip card and cup product formats. As far as non-DOA products are concerned, we have waived tests for hCG (Pregnancy), LH (Ovulation), FSH (Menopause), and H. Pylori. For further details about these products, please contact your sales representative.

Additional information on CLIA can be found at <http://www.fda.gov/cdrh/cliawaived.html>.

Options For Oral Confirmations

Later this year, Alfa Scientific Designs, Inc. will be partnering with Western Slope Laboratory LLC to offer you another option when it comes to attaining confirmation services for oral fluid tests.

Alfa will start to sell their popular oral fluid device in two kitting formats:

- 25 tests per box
- 25 tests per box with 2 pre-paid Western Slopes oral fluid confirmations.

The pre-paid oral fluid confirmation packets will include the following:

- welcome letter
- chain of custody form
- specimen bag
- pre-paid shipping label
- shipping bag

- confirmation result information page.

Confirmation results are usually available within 2-3 days after the device/sample has been received by Western Slopes.

Western Slope began operations in 2003 and today offers confirmation services for both urine and oral fluid testing methods. Alfa currently recommends that users seek oral fluid confirmations from this laboratory as they are one of the only labs that can confirm positive results obtained from instant tests using the sample inside the test itself.

Every confirmation performed is done using LC/MS/MS methods. Liquid Chromatogra -

phy separates the drugs and inputs them through the Mass Spectrometer. Sample pass through two filters providing results that are 99.9% accurate.

For more information visit their website at www.westernslope labs.com.

Upcoming tradeshow Alfa will be at this year:

AACC www.aacc.org
July 27-31 Washington, DC

US Probation & Parole Assoc.
www.appa-net.org
Aug. 3-6 Las Vegas, NV

National Safety Council
www.congress.nsc.org
Sept. 22-24 Anaheim, CA

Medica www.mdna.com
Nov. 19-22 Germany



Setting Up A Drug Free Workplace

As a distributor, some of you may have been asked by an end user how to go about setting up a drug-free workplace program. With today's labor laws and regulations being what they are, it is very important that an employer institute a program that is efficient yet fair while meeting all state requirements.

Drug and alcohol abuse affects employer costs with increased absences, illnesses, accident, and errors and can also lead to low employee morale. Employers can take a proactive stance by maintaining safe and healthy workplaces when they establish drug-free workplace programs. The U.S. Department of Labor's Working Partners for an Alcohol and Drug-Free Workplace program is an excellent source of information on how to go about setting these up.

The Department of Labor (DOL) offers a web-based tool that helps employers build a custom-made workplace program. Information on the coverage and requirements of the Drug-Free Workplace Act of 1988 is also provided to the employer and its employees through this site.

The DOL's website is very educational. It's Substance

Abuse Information Database (SAID) has various documents detailing drug and alcohol abuse, sample policies and surveys, training materials, legal information, etc. Brochures, presentation materials, articles, posters, and facts sheets are also available through the DOL. Its resource directories provide local, state, and national lists for the following:

- summaries of state laws related to workplace drug and alcohol abuse;
- community-based organizations that assist in making workplaces drug-free;
- helplines that offer assistance to individuals who have or know someone who has a problem with drugs or alcohol.

When an employer sets out to institute a drug-free workplace program it is best if they refer to the information provided by the DOL and work to incorporate some or all of following 5 components:

- 1) Written Policy - Clearly stating the reason and purpose for its implementation and describing in detail the prohibited behaviors and the consequences for such actions. It must be shared and understood by all and applied consistently.
- 2) Employee Education - Providing employees with a

background on the effects of drug or alcohol abuse on one's workplace and personal life and where one could seek help.

3) Supervisor Training - To show supervisors how to enforce a company policy.

4) Employee Assistance Program (EAP) - Free, confidential services to help all employees resolve personal and/or workplace issues that can affect job performance. In some cases short term counseling or referrals are offered as well as training and consultations on a variety of topics (i.e. how to handle difficult co-workers, etc.).

5) Drug Testing - Any mandate or policy associated with drug testing must clearly stipulate how testing is to be done (i.e. when, what drugs are tested, etc.) and what the consequences of a positive test result would be. As local, state, and federal laws, and in some cases union agreements, may apply, legal counsel should probably be sought before starting a drug testing program.

With all of the resources they provide, the DOL is an excellent reference for setting up a drug-free workplace program. But don't just take our word for it; visit www.dol.gov/workingpartners.