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Roche

Diagnostics

July 1, 2004

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AGENCY: Substance Abuse and Mental Health Services, HHS

Re: Federal Register Docket 04-7984 (Vol. 69, No.71 /April 13, 2004)

Response to *"Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs"*

Introduction

The purpose of this document is to respond to the above listed document. This response is formatted into the following sections:

Overview
Specific comments to the Subpart C - Drug and Validity Tests - section of the document related to recommendations on using single or separate tests for the detection of amphetamines and MDMA.

Overview

Roche Diagnostics Corporation (RDC) is one of the world's leading developers of *In Vitro* Diagnostic tests. We have been in the Drugs of Abuse Testing market for over 30 years. It is from this perspective that we address the proposed revised mandatory guidelines.

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Comments to Subpart C

Statement: Recommendations on using a single amphetamine test kit or the need to use separate kits are requested.

Comment:

The question of using single or separate test kits for the detection of amphetamines and ecstasy is ultimately a question of how specific such tests are. The concern is that the "all encompassing" assay for amphetamines will also have increased specificity to amphetamine-related over-the-counter and prescription drugs, which will result from the selection of antibodies that have broad cross-reactivity characteristics.

The less than desirable assay specificity and resulting false-positives are a general problem for all amphetamine assays currently on the market. It is the industry's common experience that the reactivity towards over-the-counter and prescription amphetamine-related compounds is the cause of the assay specificity issues, and it is difficult to avoid due to structural similarity of the legally available and abused drugs. Samples containing sufficiently high quantities of ephedrine, pseudoephedrine, phentermine and/or tyramine will likely produce false-positives in amphetamine test kits currently on the market. This is an ongoing issue for amphetamine screening tests, and it is independent of the test's ability to detect ecstasy-class compounds.

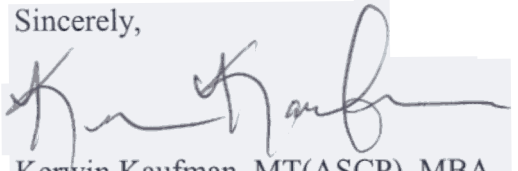
Although antibodies developed specifically to detect amphetamine or methamphetamine, in our experience, will have some degree of cross-reactivity to designer drugs MDMA, MDA, or MDEA, specificity of these antibodies might not be enough to deliver the necessary performance in a test kit designed to detect amphetamine and designer compounds. In this case, a third antibody, developed to detect designer drugs, will have to be incorporated into such a test. These antibodies are unlikely to be a source of significant cross-reactivity to over-the-counter and prescription drugs due to the design of their immunogens, and do not have to exacerbate the cross-reactivity to other over-the counter drugs.

If two independent assays are desired, it will not be practical to have an amphetamine / methamphetamine test that has cross-reactivity to ecstasy compounds. In this case, the existing antibodies for amphetamine / methamphetamine may not be suitable due to their cross-reactivity to ecstasy. Two separate assays will lead to additional costs and complexity for testing laboratories. In addition to the cost of two reagents, testing laboratories will need to run separate calibrators and controls for amphetamine / methamphetamine and ecstasy. Two assays will also result in the utilization of another channel on the instrument.

Comments to Subpart C, continued

It is for these reasons that we highly recommend that manufacturers provide a single test for all amphetamine-class drugs, which meets all previously proposed SAMHSA requirements.

Sincerely,



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