DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 29 2002

Carl A. Mongiovi
Vice President
Phamatech
9530 Padgett St., Suite 101
San Diego, CA 92126

Re: K993165/A4
Device Name: Phamatech QuickScreen Pro Multi Drug Screening Test
(Model 9177 and 9178)
Received: August 15, 2002

Dear Mr. Mongiovi:

We have completed the evaluation of your professional use labeling for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Based upon the information submitted, the professional use device qualifies for waived status. The following test system is now waived:

Test System: Phamatech QuickScreen Pro Multi Drug Screening Test
(Model 9177 and 9178)
Analytes: Methamphetamine
Cannanbinoids (THC)
Phencyclidine (PCP)
Amphetamine
Cocaine
Opiates

Waived status is applicable to Professional Use test systems and instructions cleared by the FDA. The test system instructions should include a statement that the test system is waived under CLIA.

Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for evaluation of waiver.

This categorization is effective as of the date of the notification; will be reported on FDA's home page http://www.fda.gov/cdrh/clia; may be provided to the user of the commercially marketed test system or assay as specified for the analyte(s) indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal