



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 27 2001

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Carl A. Mongiovi
Vice President of Operations
Phamatech, Inc.
9265 Activity Road
Suite #112-113
San Diego, California 92126

Dear Mr. Mongiovi:

Test systems cleared by the Food and Drug Administration (FDA) for over-the-counter (OTC) use qualify for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The following test system is now waived under this process:

Test System Name: Pharmatech At Home Drug Test (Model 9150)

Analyte Names: Cannabinoids (THC)
Opiates
Cocaine Metabolites
Methamphetamine
Amphetamine

Re: K003858

Waived status is applicable to OTC test systems and their instructions cleared by the FDA. We recommend that the test system instructions 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.