K011610

JUN - 8 2001

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

The sponsor, Pan Probe Biotech, Inc., has developed, manufactured, and tested under GMP guidelines, an in vitro diagnostic device for the qualitative testing of urine samples for the presence of Methamphetamine, its analogs or metabolites in a screening format.

The trade names of these devices are the Pan Probe Biotech LiveSure™ Methamphetamine Screen Test Card and Test Strip, having a designated common name of Methamphetamine Test Systems and classification as Class II devices as per listing 21 CFR 862.3610. These devices are intended for medical/forensic screening of urines for Methamphetamine.

The Pan Probe Biotech LiveSure™ Methamphetamine Screen Test and Test Strip (i.e., LiveSure™ Methamphetamine) are rapid qualitative competitive chromatographic immunoassays in which a chemically labeled drug conjugate competes with Methamphetamine drug, analogs or metabolites that may be present in test urinary samples for limited specific antibody binding sites. LiveSure™ Methamphetamine devices contain a unique membrane that has been pre-coated both with Methamphetamine drug conjugate at the test band, and have a built-in reference band with second antibody as a system control band. A pink colored anti-Methamphetamine monoclonal antibody-colloidal gold conjugate pad is placed on the right side of the test strip. In the absence of Methamphetamine drug, analogs or metabolites in the test urine, the pink colored antibody-colloidal gold conjugate moves chromatographically along with the urinary sample on the membrane by the capillary action. The antibody-colloidal gold conjugate binds to drug conjugate, forming an antibody-antigen complex. This complex binds to drug conjugate as a captured reagent at the test region and produces a visible pink colored band. When Methamphetamine is present in a test urine, that drug, analog or metabolite antigen competes with Methamphetamine conjugate at the test band region for the limited antibody sites on the antibody-colloidal gold conjugate. When a sufficient concentration of urinary Methamphetamine drug is present, it blocks limited antibody binding sites. This blockage-binding prevents attachment of pink colored antibody-colloidal gold conjugate to the Methamphetamine drug conjugate zone located at the LiveSure™ Methamphetamine test band region. To serve as a procedural control, a pink colored band in a control region will always appear regardless of presence of Methamphetamine in samples. Thus, negative urine samples produces two pink colored bands, while positive urine samples produce only one pink colored band.

In-house testing of LiveSure™ Methamphetamine Screen Test Card and Test Strip devices against EMIT® II Assay as a predicate provided data essentially showing equivalency between these devices and the predicate EMIT® II Assay. Additionally, independent clinical testing of 300 urine samples against LiveSure™ Methamphetamine Screen Test Card and Test Strip devices, as well as EMIT® II Assay at an external reference laboratory resulted in a 100% percent agreement with all GC/MS quantitative positive results. Moreover, LiveSure™ Methamphetamine Test Card gave a 98.2 agreement and the Test Strip gave a 97.0% agreement with GC/MS negative results, whereas EMIT II® yielded only a 96.4% correlation with GC/MS negatives. In comparing the Test Card and Test Strip positives with EMIT® II positives, a 97.8% and a 99.3% respective agreement with EMIT® II was found. Specificity of Test Card and Test Strip negatives with EMIT® II negatives was shown to be 98.2% of both. In terms of overall accuracy of values at and below the ±25% range of the NIDA/SAMHSA cut-off of 1000 ng/ml of Methamphetamine, however, the LiveSure™ Methamphetamine Screen Test Card and Strip yielded no false positives or false negative, but EMIT® II resulted in 1 false positives values for urine samples with GC/MS results below 750 ng/ml of Methamphetamine, and 3 false negative values for urine samples with GC/MS results above 1001 ng/ml of Methamphetamine. Finally, the LiveSure™ Methamphetamine Test Card and the Test Strip gave overall accuracy results of 297/300 (99.0%) and 295/300 (98.3%), respectively, versus GC/MS data, whereas 291/300 (97.0%) accuracy was obtained with EMIT®II. Thus, as judged against GC/MS results from an independent laboratory, the LiveSure™ Methamphetamine Test Card and Test Strip were determined to be equivalent in performance to each other and somewhat superior in capability versus assays with EMIT®II.

Additional information on this submission may be obtained by contacting Alice Yu, Vice President, Pan Probe Biotech, Inc. at: 858-689-9936 - or by fax at 858-689-6896.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 8 2001

James M. Barquest, Ph. D.
Acting Chief
Pan Probe Biotech, Inc.
c/o California Department of Health
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, CA 94234

Re: 510(k) Number: K011610
Trade/Device Name: Pan Probe Biotech LiveSure™ Methamphetamine Screen Tests
Regulation Number: 862.3610
Regulatory Class: II
Product Code: LAF
Dated: May 21, 2001
Received: May 25, 2001

Dear Dr. Barquest:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011610

Device Name: Pan Probe Biotech LiveSure™ Methamphetamine Screen Tests

INDICATIONS FOR USE STATEMENT:

The Pan Probe Biotech LiveSure™ Methamphetamine Screen Test Card and Test Strip devices are rapid *in vitro* diagnostic (IVD) qualitative lateral flow immuno-chromatographic competitive urinary assays for detection of Methamphetamine (MET) in human urine at the at the NIDA (National Institute on Drug Abuse) and SAMHSA (Substance Abuse and Mental Health Services Administration) cut-off level of 1,000 ng MET/ml. These tests are intended for visual, qualitative IVD screening, for professional use only, and are not intended for quantitative results, nor for over the counter sales. These screen tests for Methamphetamine, analogs and metabolites provide only preliminary qualitative analytical data. A more specific quantitative alternative method must be used in order to obtain a confirmed analytical result. NIDA and SAMHSA have established gas chromatographic/mass spectrometry (GC/MS) as the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011610

Prescription Use: ✓ **or** **Over-the-Counter Use:** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**