K010001

510k Submission for
LiveSure™ THC SCREEN TEST
FEB - 5 2001

Pan Probe Biotech, Inc. Revision A, November 13, 2000

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 Cannabinoids and their metabolites (THC) in a screening format.

The trade name of the device is Pan Probe Biotech LiveSure™ THC Screen Test, having a designated common name of THC Test System and a classification as a Class II device per 21 CFR 862.3870. This device is intended for medical/forensic screening of urines for THC.

The Pan Probe Biotech LiveSure™ THC Screen Test (i.e., LiveSure™ THC) is a rapid qualitative competitive chromatographic immunoassay in which a chemically labeled drug conjugate competes with any THC drug that may be present in test urinary samples for limited specific antibody binding sites. LiveSure™ THC devices contain a unique membrane that has been pre-coated both with THC drug conjugate at the test band, and followed by a built-in reference band with 2nd antibody as a system control band. A pink colored anti-THC monoclonal antibody-colloidal gold conjugate pad is placed on the right side of the test strip. In the absence of THC drug 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 the drug conjugate as a captured reagent at the test region and produces a visible pink colored band. When THC drug is present in a test urine, that drug or metabolite antigen competes with THC drug conjugate at the test band region for the limited antibody sites on the antibody-colloidal gold conjugate. When a sufficient concentration of urinary THC drug is present, it blocks the limited antibody binding sites. This blockage-binding prevents attachment of pink colored antibody-colloidal gold conjugate to the THC drug conjugate zone located at the LiveSure™ THC test band region. To serve as a procedural control, a pink colored band in the control region will always appear regardless of the presence of THC in samples. Negative urine samples produces two pink colored bands, while positive urine samples produce only one pink colored band.

In-house clinical testing of LiveSure™ THC resulted in a 100% percent agreement with both the EMIT® II and GC/MS positives, a 97.0 % a percent agreement within EMIT® II negatives, and accuracy agreement of 97.9% versus EMIT® II results on samples shown to be positive by GC/MS. Independent external clinical testing consisting of 395 samples was performed and the combined data produced a percent agreement within positives for LiveSure™ THC of 92.5% versus EMIT® II results. It was noted that the EMIT® II tests falsely detected 8 more positives than either LiveSure™ THC or GC/MS methods. Also in this independent study, the percent agreement within negatives was 99.6%, with an accuracy of 97.5% for LiveSure™ THC results versus EMIT® II THC results. By comparison with EMIT® II and GC/MS results, all LiveSure™ THC positives were 107/107 or 100% confirmed. Finally, the LiveSure™ THC vs. the GC/MS relative specificity of result (i.e., agreement of results within negatives) was 283/288 or 98.3%, while the LiveSure™ THC vs. the GC/MS accuracy with positives was 390/395 or 98.7%.

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
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2001

Pan Probe Biotech, Inc.
James M. Barquest, Ph.D.
c/o California Department of Health Services
P. O. Box 942732 (MS-357)
Sacramento, California 94234-7320

Re: K010001
Trade Name: PanProbe Biotech LiveSure™ THC Screen Test
Regulatory Class: II
Product Code: LDJ
Dated: January 22, 2001
Received: January 23, 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 (for the indications for use stated in the enclosure) to legally marketed predicate 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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): Not yet assigned

Device Name: Pan Probe Biotech LiveSure™ THC Screen Test

INDICATIONS FOR USE STATEMENT:

Pan Probe LiveSure™ THC Screen Test is an in vitro diagnostic qualitative lateral flow immuno-chromatographic urinary assay for rapid detection of the Cannabinoids and metabolites, mainly: 11-nor-Δ9-THC-9-carboxylic acid (i.e., Δ9-THC-9-COOH) at the National Institute on Drug Abuse, and Substance Abuse and Mental Health Services Administration (NIDA/SAMHSA) cut-off level of 50 ng THC/ml. This test is designed to give visual, qualitative results and intended for professional use only. It is not intended for quantitative results, nor for over the counter sales. The test provides only preliminary analytical data. A more specific alternative method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method of the NIDA/SAMHSA. 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)

(Division Sign-Off) for Jean Cooper
Division of Clinical Laboratory Devices
510(k) Number 010001

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