K033114

APR 2 6 2004

Summary of the 510 (k) Safety and Effectiveness

September 25, 2003

The following information is provided as a summary of safety and effectiveness information for the KetoChecks. The reagent strips that are the subject of this pre-market notification contain nine reagent areas.

1. **Trade Name**: KetoChecks

2. **Common Name**: Visual Reagent Test Strip for Urinalysis

3. **Classification Name**: Urinalysis Test System
(per 21 CFR Parts 862-892)

4. **Submitter's Identification**: Neo Pharm, Inc.
10532 Walker St., Suite #B
Cypress, California 90630

5. **Contact Person**: Sung H. Pyo
10532 Walker St., Suite #B
Cypress, CA 90630
Phone: (714) 226-0070
Fax: (714) 226-0094
e-mail: xthegreat@yahoo.com

6. **Intended Use**:

The KetoChecks for Urinalysis is a dipstick with a reagent area for semi-quantitative urinalysis. The KetoChecks provides a test for Ketone (Acetoacetic acid) in urine for persons to test semi-quantitatively by visual comparison with a color chart on the bottle label.

7. **Product Description**:

KetoChecks for Urinalysis is firm plastic strips to which a reagent area is affixed. Depending on the product being used, KetoChecks provides a test for Ketone (Acetoacetic acid) in Urine. Test results may provide information regarding the status of carbohydrate metabolism. Please refer to the outside box and bottle label for the specific test parameters of the product you are using.

KetoChecks is packaged along with a drying agent in a plastic bottle with a twist-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. The directions must be followed exactly. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. Accurate timing is essential to provide optimal results. To obtain optimal results, it is necessary to use fresh, well-mixed, and uncentrifuged urine. No calculations or laboratory instruments are needed.

TEST PRINCIPLE

Ketone: This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.

8. **Substantial Equivalence**:

The KetoChecks for Urinalysis is substantially equivalent to the Bayer Ketostix reagent strips.

Characteristics of the Bayer Ketostix system are compared with the subject KetoChecks system in the following table.

Strip Name **Distributor**	**KetoChecks** Neo Pharm, Inc	**Bayer Ketostix** Bayer
Reagents for:		
Ketone (Acetoacetic acid)	Sodium nitroprusside	Sodium nitroprusside Buffer
Time required to read strips	30 to 120 seconds	15 to 120 seconds
Storage	Between 10-30°C (50°F-86°F). Do Not Store in refrigerator or freezer. Do not expose direct heat, light or Moisture.	Between 15-30°C (59°F-86°F). Do Not Store in refrigerator or freezer. Do not Store in Direct Sunlight.

REAGENTS (Based on dried weight at time of impregnation)

Ketone: 6.0 % w/w sodium nitroprusside, balanced with buffer and nonreactive ingredients.

WARNINGS AND PRECAUTIONS

KetoChecks is for *in vitro* diagnostic use. Do not touch test areas of Urine Reagent Strips.

RECOMMENDED HANDLING PROCEDURES

All unused strips must remain in the original bottles. Transfer to any container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant(s) from bottle. Do not open container until ready to use. Replace cap immediately and tightly after removing reagent strip. Opened bottles should be used within 2 months after first opening.

SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean container according to NCCLS GP16-T guideline and test as soon as possible. Do not centrifuge. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing. The use of urine preservatives is not recommended. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test are. Urine containing glucose may decrease in pH as organisms metabolize the glucose.

Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein test results. The user should determine whether the use of such skin cleanser is warranted.

MATERIALS PROVIDED

1. 1 bottle containing 100 Urine Reagent Strips.
2. A visual color chart for reading results is printed on the bottle.

MATERIALS REQUIRED BUT NOT PROVIDED

1. A timer capable of reading accurately in seconds.
2. It is also recommended that commercial control products be used for quality control checks.

TEST PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap tightly.
2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over (contamination from adjacent reagent pads).
4. Compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results. HOLD STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY.

DRAWINGS

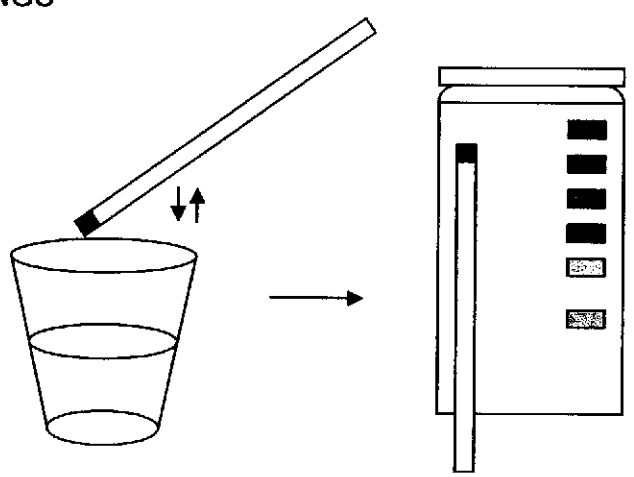

Figure 1. Procedure Illustration

5. Obtain results by direct color chart comparison.

Note: All reagent areas may be read at 30 seconds for screening

positive urine from negative urine. Changes in color after 2 minutes are of no diagnostic value.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new test is performed or whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

Results

Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent normal values; actual values will vary around the nominal value.

LIMITATIONS OF PROCEDURE

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness.

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

Ketone: Color reaction that could be interpreted as "positive" may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.[3]

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of KetoChecks has been determined both in

the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, Urine Reagent Strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATION OF PROCEDURE).

For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to develop their own standards of performance.

Sensitivity:

Ketone: The ketone test area provides semi-quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta-hydroxybutyric acid or acetone. The reagent area detects as little as 5-10 mg/dL acetoacetic acid in urine.

BIBLIOGRAPHY

1. Free, A.H and Free, H.M.: Urinalysis, Critical Discipline of Clinical Science. *CRC Crit. Rev. Clin. Lab. Sci.* 3(4): 481-531; (1972)
2. Yoder, J. Adams, E.C., and Free, A.H.: Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH. *Amer. J. Med Tech.* 31:285; (1965)
3. Tietz, N.W.: Clinical Guide to Laboratory Tests; W.B. Saunders Company, (1976)
4. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry 2nd Ed. 2205; (1994)
5. Shchersten, B. and Fritz, H.: Subnormal Levels of Glucose in Urine. JAMA 201:129-132; (1967)
6. McGarry, J.D.: Lilly Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Dibabetes 28: 517-523 May, (1978)

7. Williamson, D.H.: Physiological Ketoses, or Why Ketone Bodies? Postgrad. Med. J. (June Suppl.): 372-375: (1971).
8. Paterson, P. et al.: Maternal and Fetal Ketone Concentrations in Plasma and Urine. Lancet: 862-865; April 22, (1967)
9. Fraser, J. et al.: Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. Clin. Chem. Acta II: 372-378; (1965)
10. Henry, J.B. et al.: Clinical Diagnosis and Management by Laboratory Methods, 16th Ed. Philiadelphia: Saunders; (1979)

Expected Values

Ketone: Normally, no ketones are present in urines. Detectable levels of ketone may occur in urines during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urines in excessively large amounts before serum ketones are elevated.

9. **Discussion of Clinical Tests Performed**:

KetoChecks versus Bayer Clinical Correlation

Table I. KetoChecks Lot 1 versus Bayer Ketostix Lot 3A04A

	Same Color Block			Within 1 Color Block	
Evaluation One-Lot 1	212/218	97.2%		217/218	99.5%
Evaluation Bayer	254/254	100.0%		254/254	100.0%

Table II. KetoChecks Lot 1 versus KetoChecks Lot 2

	Same Color Block			Within 1 Color Block	
Evaluation One-Lot 1 vs Lot 2	134/138	97.1%		137/138	99.3%

10. **Conclusion**:

For the reasons mentioned above, it may be concluded that Neo Pharm, Inc KetoChecks is substantial equivalence to the commercially available urine analysis strips such as Bayer ketostix and is safe in the hands of lay person.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 6 2004

Mr. Sung H. Pyo
Director of Research and Development
Neo Diagnostics, Inc.
10532 Walker Street, #B
Cypress, CA 90630

Re: k033114
Trade/Device Name: KetoChecks
Regulation Number: 21 CFR 862.1435
Regulation Name: Ketones (nonquantitative) Test System
Regulatory Class: Class I
Product Code: JIN
Dated: March 23, 2004
Received: March 24, 2004

Dear Mr. Pyo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K033114
Device Name: KetoChecks
Indications For Use:

The Neo Diagnostics KetoChecks is intended for the identification of ketones in urine and can be used in the diagnosis of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as Acetoacetic acid) and for monitoring patients on ketogenic diets and patients with diabetes. The test is indicated for use by professionals and for Over the Counter use by lay people.

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033114

Prescription Use ✓ (AND/OR) Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)