

FEB 1 2000

44.

510(K) Notification

Diagnostics Chemicals Limited

Product Cat. No. 790-01, 790-15



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## 20.0 510(k) SMDA SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K 994035

**Prepared:** November 22, 1999

**Summiteer:** Diagnostic Chemicals Limited

**Address:** West Royalty Industrial Park  
Charlottetown  
P.E.I., C0A 1B0  
Canada  
(902) 566-1396

**Contact:** Karen Callbeck

**Device:** Trade Name: ImmunoDip™ Urinary Albumin Screen  
Common Name: Test for microalbuminuria

**Classification:** Division of Clinical Laboratory Devices  
Panel- Clinical Chemistry  
Classification Code- 75 JIR (Urinary Protein or Albumin)

**Predicate Devices:** DCLare™ ImmunoDip™ stick for Microalbuminuria (Diagnostic Chemicals Limited- K972337), Microalbumin Assay/Array® Analyzer (Beckman Instruments Inc.- K922273), N-Assay TIA Microalbumin (Crestat Diagnostics/Kamiya Biomedical Company- K934146), BeSure Plus OneStep Ovulation Prediction test (Syntron Bioresearch, Inc, K983113), One Step Ovulation Predictor (Selfcare, Inc.-K991386) MiniClinic Ovulation Predictor (Vanguard Biomedical- K960233), and Clearplan Easy Ovulation Test (Whitehall Labs- K981271).

### Device Description:

ImmunoDip™ Urinary Albumin Screen is an immunochromatographic test strip which is encased in a plastic housing. The ImmunoDip™ Urinary Albumin Screen is placed into a urine sample for at least three minutes and is then removed and read. Results are determined by visually comparing the relative color intensity of two blue bands to obtain a semi-quantitative result of Negative ( $\leq 18$  mg/L) or Positive ( $>18$  mg/L).



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**Intended Use:**

The ImmunoDip™ Urinary Albumin Screen tests for the presence of elevated levels of albumin in urine. Elevated urinary albumin is also known as microalbuminuria. Elevated albumin is an early sign of possible kidney damage. Detection of elevated urinary albumin can aid in the early detection and monitoring of the course of incipient nephropathy in diabetics and hypertensive patients. For *IN VITRO* diagnostic use.

**Technological Characteristics:**

ImmunoDip™ Urinary Albumin Screen is an immunochromatographic test strip containing monoclonal mouse antibodies against human serum albumin bound to colored latex beads. Human albumin is fixed in a band at the bottom half of the testing region. Goat anti-mouse antibodies are fixed in a band at the top half of the testing region. The dipstick is encased in an open-ended plastic housing.

When the dipstick is placed into a urine sample cup, the urine sample migrates up the test strip. Albumin present in the urine binds with blue colored latex beads present in the strip. Both beads and albumin are carried up the device by capillary action. At low levels of albumin, the great majority of blue beads are bound at the lower band containing human albumin. At higher levels of albumin, many of the beads pass through the lower band and are bound at the upper band. Levels of albumin above the decision level value of 18 mg/L will produce color on the upper band which is darker than the lower band. By observing the appearance of the two lines, the user can semi-quantitatively determine the urine microalbumin concentration as either Negative ( $\leq 18$  mg/L), or Positive ( $> 18$  mg/L).

**Assessment of Performance:**

The performance characteristics on the ImmunoDip™ Urinary Albumin Screen were evaluated in precision studies to determine the within-day, between-day, within-run and between-run precision. Physician Office Laboratory (POL) studies were carried out in which the performance of trained laboratory technicians was compared against that of POL users. Clinical studies which compared results obtained with the Urinary Albumin Screen against three existing urinary albumin assay methods were also carried out.

In an internal 20 day precision study utilizing two levels of albumin in urine, 100% agreement was obtained between two operators and two additional observers in all instances of within-day, between-day, within-run and between-run testing.

In the POL studies, professional and POL users participated in the evaluations of six proficiency samples over a clinically relevant range of concentrations (4.5 mg/L, 9.0 mg/L, 15 mg/L, 22 mg/L, 36 mg/L and 72 mg/L). The POL results showed an overall agreement with expected results of 91% (range of 89%- 94%). This was not significantly different from the results obtained with trained laboratory personnel who reported overall agreement of 95% (range 93% - 97%).



The majority of deviations from expected results were observed at the two sampling levels nearest the 18 mg/L level that separate the positive and negative results. Excluding the 15 and 22 mg/L samples, both groups exceeded 98% accuracy. No significant differences were observed within-run (15 replicates), between-runs (5 different days), or between sites (3 POL sites). Results demonstrated that lay users can obtain results equivalent to those obtained by trained laboratory workers.

The performance of ImmunoDip™ Urinary Albumin Screen on clinical urine samples was compared against that of two predicate methods; the semi-quantitative DCLare™ ImmunoDip™ Stick for Microalbuminuria (K972337) and full quantitative urinary albumin testing using the Beckman Array (K922273) and the Kamiya (Crestat) Microalbumin Assay (K934146). Specificity ranged from 95-97%. Sensitivity was 95% against both methodologies. Efficiency ranged from 95-97%. These results indicate that the ImmunoDip™ Urinary Albumin Screen gives performance which is substantially equivalent to that of existing methods for urinary albumin measurement.

**CONCLUSION:**

The ImmunoDip™ Urinary Albumin Screen provides a convenient method for screening for microalbuminuria. Studies indicate that use of the device by POL users provides results which are comparable to the results obtained by trained laboratory personnel. The ImmunoDip Urinary Albumin Screen provides results which are comparable to other methods currently used in clinical laboratories and physicians office laboratories..



DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 1 2000

Food and Drug Administration  
2098 Gaither Road  
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Ms. Karen Callbeck, R.T., B.Sc.  
Regulatory Affairs Coordinator, Diagnostic Division  
Diagnostics Chemicals Limited  
16 McCarville Street  
Charlottetown,  
PE, C1E 2A6  
CANADA

Re: K994035  
Trade Name: ImmunoDip Urinary Albumin Screen  
Regulatory Class: I reserved  
Product Code: JIR  
Dated: November 29, 1999  
Received: November 29, 1999

Dear Ms. Callbeck:

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.

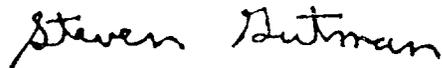
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S'.

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

## INDICATIONS FOR USE

510(k) Number (if known): K994035

Device Name: ImmunoDip Urinary Albumin Screen

### Indications for Use:

There are several kidney disease conditions that can produce high levels of albumin in urine (1). Determining albumin in the urine at the low levels measured by this test is helpful for early detection and treatment of patients at risk for renal (kidney) disease. Low but elevated urinary albumin levels, or microalbuminuria, refers to a level of the human protein albumin in urine above about 18 mg/L. Levels above 18 mg/L are not normally found in healthy individuals. These low but significant levels are not detectable with older dipstick assays. The ImmunoDip™ Urinary Albumin Screen classifies samples as positive or negative based on their being above or below a level of 18 mg/L.

Conditions in which elevated levels of albumin in urine may be present include: Type 1 and Type 2 diabetes (2-8); hypertension (9, 10); and renal disease found in pregnancy (11). There are other less common causes as well. Diabetes is the largest single cause. One study found 45% of the insulin-dependent diabetics develop serious kidney disease (3). Testing for elevated levels of albumin in urine helps to identify those diabetics who are prone to kidney disease. Scientific studies indicate that proper control of blood glucose (blood sugar) levels and blood pressure help slow or prevent kidney damage (1,9).

### References:

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2. Viberti, G. C., Pickup J. C., Jarrett, R. J., Keen, H. *N Engl J Med* 1979; 300: 638-41. Effect of control of blood glucose on urinary excretion of albumin and  $\beta_2$ -microglobulin in insulin-dependent diabetes.
3. Mogensen, C. E. & Christensen, C. K. *N Engl J Med* 1984; 311: 89-93. Predicting diabetic nephropathy in insulin-dependent patients.
4. Mogensen, C. E. *N Engl J Med* 1984; 310: 356-360. Microalbuminuria predicts clinical proteinuria and early mortality in maturity-onset diabetes.
5. Deckert, T., Feldt-Rasmussen, B., Borch-Johnsen, K., Jensen, T. & Kofoed-Enevoldsen, A. *Diabetologia* 1989; 32: 219-226. Albuminuria reflects widespread vascular damage. The Steno hypothesis.
6. Waller, K. V., Ward, K. M., Mahan, J. D. & Wismatt, D. K. *Clin Chem* 1989; 35: 755-765. Current concepts in proteinuria.
7. Mattock, M. B., Keen, H., Viberti, G. C., El-Gohari, M. R., Murrells, T. J., Scott, G. S., Wing, J. R. & Jackson, P. G. *Diabetologia* 1988; 31: 82-87. Coronary heart disease and urinary excretion rate in Type 2 (non-insulin-dependent) diabetic patients.
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9. Mathiesen, E. R., Romm, B., Jensen, T., Storm, B. & Deckert, T. *Diabetes* 1990; 39: 245-249. Relationship between blood pressure and urinary albumin excretion in development of microalbuminuria.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Bernhardt for M.J. Cooper  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K994035

Prescription Use   
(Per 21 CFR 801.109)

OR

Over the Counter Use