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Summary of Safety and Effectiveness

April 4, 1996

The following information is provided as a summary of safety and effectiveness information for the DIA SCREEN® Reagent Strip System.

[a] Common Name: Visual Reagent Test Strip for Urinalysis

Trade/Proprietary Name: DIA SCREEN® Reagent Strips, in many different configurations with as many different product codes. DIA SCREEN® is the registered trademark of Dia-Screen Incorporated, a wholly owned subsidiary of Genesis Labs, Inc.

[b] Establishment Registration Number: 2183670

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[c] Contact Person: Bert Walter

[d] Intended Use

The DIA SCREEN® Reagent Strip for Urinalysis is a dip-and-read test strip for semiquantitative urinalysis. DIA SCREEN® Reagent Strips have been developed to allow health care professionals to test semiquantitatively for patient urine levels of specific gravity, ketone, glucose, protein, blood, nitrite, pH, ascorbic acid, bilirubin, and urobilinogen by visual comparison with a color chart.

[e] Product Description

DIA SCREEN® Reagent Strips are plastic strips to which are affixed reagent areas. Several product configurations are included with this submission, but all configurations are limited to one, some or all of the following tests: specific gravity, ketone, glucose, protein, blood, nitrite, pH, ascorbic acid, bilirubin, and urobilinogen.

The reagent test areas on the DIA SCREEN® Reagent Strips are ready to use upon removal from the bottle and the entire reagent strip is disposable after use. The strips are to be read visually, requiring no additional laboratory equipment for testing.

The directions must be followed exactly. Accurate timing is essential to provide optimal results. The reagent strips must be kept in the original bottle containing the desiccant with the cap tightly closed to maintain reagent activity. To obtain optimal results, it is necessary to use fresh, well-mixed, uncentrifuged urine.

Dia-Screen Corporation, a subsidiary of Genesis Labs, Inc., has previously received determinations of substantial equivalence for complete lines of urine reagent strips which have been marketed under the Bioscan (K940043) and DIA SCREEN (K952971) label.

The DIA SCREEN® Reagent Strips will be manufactured by Genesis Labs for distribution by Dia-Screen. The intended use of the strips which are the subject of this new premarket notification is exactly the same as the strips which were reviewed previously (K940043 and K952971).

[f] Substantial Equivalence

The intended use of the strips which are the subject of this new premarket notification is exactly the same as the strips which were reviewed previously (K940043 and K952971).

The design and function of the new DIA SCREEN® Reagent Strips are the same as the design and function of both the Bioscan and DIA SCREEN Reagent Strips which have been previously reviewed under premarket notifications K940043 and K952971.

The DIA SCREEN® Reagent Strips for Urinalysis are substantially equivalent to Ames Multistix 10 SG, Behring Rapignost, Bioscan and Boehringer Mannheim Chemstrip urine test strip systems (90% of all observations are within one color block).

Characteristics of the Ames Multistix 10 SG and Behring Rapignost systems are compared with the DIA SCREEN® system in the following table:

Strip Name Distributor Reagents for:	**This 510 (k)** **DIA SCREEN®** DIA SCREEN®	**Previous 510 (k)** **DIA SCREEN®** DIA SCREEN®	**Ames Multistix 10 SG** Ames	**Rapignost** Behring
Specific Gravity	Bromthymol blue Detergent	NA	Bromthymol blue Poly (methyl vinyl-ether maleic anhydride	NA
Ketone	Sodium nitroprusside	Sodium nitroprusside	Sodium nitroprusside Buffer	Sodium nitroprusside Glycine Buffer
Glucose	Glucose oxidase Peroxidase Potassium iodide	Glucose oxidase Peroxidase Potassium iodide	Glucose oxidase Peroxidase Potassium iodide Buffer	Glucose oxidase Peroxidase Tolidine hydrochloride Buffer
Protein	Tetrabromphenol blue Citric acid	Tetrabromphenol blue Citric acid	Tetrabromphenol blue Buffer	Tetrabromphenol blue Buffer
Blood	2,5 Dimethylhexane-2,5-dihydroperoxide 3,3',5,5'-Tetramethylbenzidine	NA	Diisopropylbenzene-dihydroperoxide 3,3',5,5'-Tetramethylbenzidine	Cumene hydroperoxide Tetramethylbenzidine dihydrochloride Buffer
Nitrite	Hydroxy(3)-1,2,3-tetrahydrobenzo-(h)quinoline p-Arsanilic acid	NA	p-Arsanilic acid 1,2,3,4-Tetrahydro-benzo(h)quinoline-3-ol Buffer	4-Arsanilic acid N-(Naphthyl)-ethylenediammonium Dihydrochloride Buffer
pH	Bromthymol blue Methyl red	NA	Bromthymol blue Methyl red	Bromthymol blue Cresol red Methyl red
Ascorbic Acid	Phosphomolybdic acid			2,6-Dichloro-phenol-indophenol Buffer salts

Strip Name Distributor Reagents for:	**This 510 (k)** **DIA SCREEN®** DIA SCREEN®	**Previous 510 (k)** **DIA SCREEN®** DIA SCREEN®	**Ames Multistix 10 SG** Ames	**Rapignost** Behring
Bilirubin	2,4 Dichlorobenzene-diazonium salt	NA	2,4-Dichloroaniline-diazonium salt Buffer	2,4-Dichlorobenzene-diazonium salt Buffer
Urobilinogen	Dimethylaminobenzaldehyde	NA	Diethylaminobenzaldehyde	Fluorodiazoniumtetra-fluoroborate Buffer

	This 510 (k)	Previous 510 (k)		
Strip Name	**DIA SCREEN®**	**DIA SCREEN**	**N - Multistix**	**Rapignost**
Distributor	DIA SCREEN®	DIA SCREEN	Ames	Behring
Packaged with Desiccant	Yes	Yes	Yes	Yes
Control Available	Yes	Yes	Yes	Yes
Time required to read strips	30 to 60 seconds	60 seconds	30 to 60 seconds	60 seconds
Storage	Between 15 - 30 °C (59°-86° F). Do Not Store in refrigerator or freezer. Do not expose to moisture, heat or light.	Between 15 - 30 °C (59°-86° F). Do Not Store in refrigerator or freezer. Do not expose to moisture, heat or light	Between 15°- 30° C (59°-86° F) Do Not Store in Direct Sunlight	Between 15 - 30° C (59°- 86° F). Do Not Store in refrigerator or freezer. Do not expose to moisture, heat or light.
510 (k)	This submission	K952971	------	------
Expected Values:				
Specific Gravity	Random urines vary from 1.001-1.035. Twenty-four hour urines from normal adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022	NA	Random urines vary from 1.001-1.035. Twenty-four hour urines from normal adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022	NA
Ketone	Should not be detected in normal urine.	Should not be detected in normal urine.	Normal specimens yield negative results.	Should not be detected in normal urine
Glucose	None found in normal urine. Concentrations of 100 mg/dL may be considered abnormal.	None found in normal urine. Concentrations of 100 mg/dL may be considered abnormal.	None found in normal urine. Concentration of 100 mg/dL may be considered abnormal.	None found in normal urine. Concentrations of 100 mg/dL may be considered abnormal.

Strip Name Distributor **Expected values:**	**This 510 (k)** **DIA SCREEN®** DIA SCREEN®	**Previous 510 (k)** **DIA SCREEN®** DIA SCREEN®	**Ames Multistix 10 SG** Ames	**Rapignost** Behring
Protein	Normal specimens ordinarily contain some protein (0-4 mg/dL). Persistent results of trace or higher indicate significant proteinuria.	Normal specimens ordinarily contain some protein (0-4 mg/dL). Persistent results of trace or higher indicate significant proteinuria.	Normal specimens ordinarily contain some protein (0-4 mg/dL). A color matching any "+" block indicates significant proteinuria	Normal specimens ordinarily contain some protein (0-4 mg/dL). Persistent results of 30 mg/dL or higher indicate significant proteinuria
Blood	The practical detection limit of this test is 5 to 10 erythrocytes per microliter of urine	NA	The significance of the trace reaction may vary among patients. Clinical judgment is required	The practical detection limit of this test is 5 to 10 erythrocytes per microliter of urine
Nitrite	Any degree of pink color after 30 seconds indicates clinically significant bacteria	NA	Normally, no nitrite is detectable in urine	Concentrations between .05 and 0.1 mg/dL produce a pink color, indicating significant bacteria
pH	Normal urine has a pH of 6 and urine pH values generally range from 5 to 8	NA	Both the normal and abnormal pH range is from 5 to 9 pH units	Normal urine has a pH of 6 and urine pH values generally range from 5 to 9
Ascorbic Acid	Urinary excretion of ascorbic acid can result from the intake of vitamin C	NA	NA	Any color change after 60 seconds indicates a positive result
Bilirubin	No bilirubin is detectable in urine of healthy persons	NA	Normally, no bilirubin is detectable in healthy persons	No bilirubin is detectable in urine of healthy persons
Urobilinogen	Normal range is 0.1 to 1.0 mg/dL	NA	Normal range is 0.1 to 1.0 Ehrlich units per 100 mL	Normal range is 0.5 to 1.0 mg/dL

Clinical Laboratory Evaluation of DIA SCREEN® Strips

The DIA SCREEN® Reagent Strip for Urinalysis is a dip-and-read test strip intended for use as an in-vitro diagnostic aid using urine specimens. DIA SCREEN® Reagent Strips have been developed to allow health care professionals to semiquantitatively determine levels of specific gravity, ketone, glucose, protein, blood, nitrite, pH, ascorbic acid, bilirubin, and urobilinogen in patient urine by visual comparison with a color chart of each concentration range. No additional reagents or laboratory equipment are required. These reagent strips are packaged in a plastic vial containing a desiccant. The test strips must be maintained tightly capped in the plastic vial to assure reagent activity. The directions-for-use must be followed exactly.

An independent laboratory evaluation of the new DIA SCREEN® Reagent Strips for Urinalysis was conducted under the direction of Nancy Brunzel, C.L.S., M.T., at the University of Minnesota Department of Medical Technology. The purpose of the laboratory evaluation was to establish the performance of the DIA SCREEN® Reagent Strip for Urinalysis when compared to "510 (k) approved" marketed urinalysis strip systems.

The study consisted of comparing the performance of two (2) manufactured lots of DIA SCREEN® Reagent Strips with one (1) lot of a marketed product (Ames Multistix 10 SG and Behring Rapignost).

Fresh urine samples were obtained at the medical facility. The comparison strips, Ames Multistix 10 SG and Behring Rapignost strips, and abnormal urine controls were furnished by Dia-Screen. When data between the two products did not agree within one color block, an alternate procedure (see table below) was used to test the sample.

Analyte	Confirmation Test	Manufacturer
Specific Gravity	Refractometer	NA
Ketone	Acetest	Ames
Glucose	Chemstrip Reagent Strip	Boehringer Mannheim
Protein	SSA	NA
Blood	Microscopic Evaluation	NA
Nitrite	Microscopic Evaluation	NA
pH	pH Meter	NA
Ascorbic Acid	Urispec Reagent Strip	Henry Schein
Bilirubin	Ictotest	Ames
Urobilinogen	Chemstrip Reagent Strip	Boehringer Mannheim

Fresh, well-mixed, and uncentrifuged urine from a mixed patient population was reacted with the DIA SCREEN® Reagent Strips and the results were read by visual comparison with the DIA SCREEN® color chart. Results of these readings were compared to results measured by Multistix 10 SG and Rapignost Strips.

A summary of the data obtained from the clinical evaluation described above is provided in the following tables (pages 9 and 10):

DIA SCREEN versus Ames and Rapignost Clinical Correlation

Tables I and II present the percentage of responses for the indicated lots of the DIA SCREEN and Ames and Rapignost Reagent Strips that are within the same color block and that are within plus or minus one color block. Table III presents a similar analysis for the two lots of the DIA SCREEN Reagent Strips.

Table I. DIA SCREEN Lot 00226A versus Ames Lot D397095 and Rapignost Lot 633962A

	Same Color Block		Within 1 Color Block	
Specific Gravity	24/58	41.4%	53/58	91.4%
Ketone	52/58	89.6%	58/58	100%
Glucose	46/58	79.3%	58/58	100%
Protein	41/57	71.9%	57/57	100%
Blood	45/58	77.6%	53/58	91.4%
Nitrite	56/57	98.2%	57/57	100%
pH	23/58	39.6%	58/58	100%
Ascorbic Acid	46/57	80.7%	56/57	98.2%
Bilirubin (lot 0306A)	44/48	91.7%	46/48	95.8%
Urobilinogen	49/54	90.7%	50/54	92.6%

Table II. DIA SCREEN Lot 00226B versus Ames Lot D397095 and Rapignost Lot 633962A

	Same Color Block		Within 1 Color Block	
Specific Gravity	25/58	43.1%	52/58	89.6%
Ketone	51/58	87.9%	58/58	100%
Glucose	49/58	84.5%	58/58	100%
Protein	43/57	75.4%	57/57	100%
Blood	46/58	79.3%	53/58	91.4%
Nitrite	56/57	98.2%	57/57	100%
pH	27/58	46.5%	58/58	100%
Ascorbic Acid	49/57	86.0%	57/57	100%
Bilirubin (lot 0306B)	44/48	91.7%	46/48	95.8%
Urobilinogen	49/54	90.7%	50/54	92.6%

Table III. DIA SCREEN Lot 00226A versus DIA SCREEN Lot 00226B

	Same Color Block		Within 1 Color Block	
Specific Gravity	54/58	93.1%	58/58	100%
Ketone	57/58	98.3%	58/58	100%
Glucose	55/58	94.8%	58/58	100%
Protein	55/57	96.5%	57/57	100%
Blood	57/58	98.3%	58/58	100%
Nitrite	57/57	100%	57/57	100%
pH	52/58	89.6%	58/58	100%
Ascorbic Acid	54/57	94.7%	56/57	98.2%
Bilirubin (lots 0306A/B)	48/48	100%	48/48	100%
Urobilinogen	54/54	100%	54/54	100%

DIA SCREEN versus Ames and Rapignost Clinical Correlation

Adjusted to use confirmatory test results for discrepant results.

Tables IV and V present the percentage of responses of the DIA SCREEN strip within one color block of the Ames and Rapignost Test Strips or the confirmatory test method when discrepancies of greater than one color block arose. 96.5% agreement within one color block was obtained for all analytes.

Table IV. DIA SCREEN Lot 00226A versus Ames Lot D397095 and Rapignost Lot 633962A

	Within 1 Color Block	
Specific Gravity	55/58	96.5%
Ketone	58/58	100%
Glucose	58/58	100%
Protein	57/57	100%
Blood	57/58	98.3%
Nitrite	57/57	100%
pH	58/58	100%
Ascorbic Acid	56/57	98.2%
Bilirubin (lot 0306A)	48/48	100%
Urobilinogen	54/54	100%

Table V. DIA SCREEN Lot 00226B versus Ames Lot D397095 and Rapignost Lot 633962A

	Within 1 Color Block	
Specific Gravity	55/58	96.5%
Ketone	58/58	100%
Glucose	58/58	100%
Protein	57/57	100%
Blood	57/58	98.3%
Nitrite	57/57	100%
pH	58/58	100%
Ascorbic Acid	57/57	100%
Bilirubin (lot 0306B)	48/48	100%
Urobilinogen	54/54	100%