510(k) Summary

JUN 11 2010

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

The assigned 510 (k) number is **K100101**

Date: June 10, 2010

Submitted by:

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Trade Name:

GSP Neonatal GALT kit (3303-001U)

Common Name:
Regulation:

GSP Neonatal GALT kit (21 CFR 862.1315)

Classification Name:
Product Code:

Galactose-1-phosphate uridyl transferase test system (KQP)

Predicate device:

Neonatal GALT (formerly Isolab Galactose-1-Phosphate Uridyl Tranferase test) (K950803)

Device Description:

The GSP™ Neonatal GALT assay is an adaptation of the quantitative enzymatic assay of Beutler and Baluda. The fluorescence is measured with the GSP Instrument using an excitation wavelength of 355 nm and an emission wavelength of 460 nm. The GSP Neonatal GALT assay uses prompt fluorescence technology.

Intended Use:

This kit (*GSP™ Neonatal GALT*) is intended for the quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity in blood specimens dried on filter paper as an aid in screening newborns for classical galactosemia caused by GALT deficiency using the GSP™ instrument.

Device Comparison:

Comparison of the GSP Neonatal GALT device with its predicate.

GSP Neonatal GALT Test System		
Characteristics	**Proposed Device**	**Neonatal GALT (K950803)**
Intended Use/Indications for Use	This kit (GSP Neonatal GALT) is intended for the quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity in blood specimens dried on filter paper as an aid in screening newborns for classical galactosemia caused by GALT deficiency using the GSP™ instrument. The GSP instrument and GSP chemistries are for professional use only.	This kit (Neonatal GALT) is intended for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity in blood specimens dried on filter paper as an aid in screening newborns for classical galactosemia caused by GALT deficiency
Intended User	Same	Adequately trained laboratory personnel performing newborn screening
Instrument Platform	GSP instrument	1420 Victor D series fluorometer
Test Mode	Same	Batch mode
Detection Technology	Same	Prompt fluorescence
Sample Type	Same	Dried blood spots.
Plate Capacity	26 plates	1 plate
Reagents	Individually bar-coded reagents	No bar-coded reagents
User Interface	GSP software –MicroSoft Windows Vista embedded - touch screen	Wallac 1420 D software running on MicroSoft Windows XP Professional
Instrument Components	Instrument (consists of plate manipulator and modules). External PC Barcode reader.	Instrument Printer Computer
Calibrators	Same	Six levels of GALT calibrators
Source	Same	Sheep blood with GALT, phosphoglucomutase, glucose-6-phosphate dehydrogenase and dithiothreitol with ProClin 300 as preservative.
Matrix	Filter paper cassettes (Whatman no.903)	Filter paper sheets (Whatman no. 903)
Concentrations	A 1 U/dL B 3 U/ dL C 6 U/ dL D 9 U/ dL E 15 U/ dL F 25 U/ dL	A 1.8 U/g Hb B 5 U/g Hb C 8 U/g Hb D 11 U/g Hb E 14 U/g Hb F 18 U/g Hb

Controls	Same	Two levels of GALT controls
Source	Human and sheep blood with ProClin 300 as preservative	Sheep blood with GALT, phosphoglucomutase, glucose-6-phosphate dehydrogenase and dithiothreitol with ProClin 300 as preservative.
Matrix	Filter paper cassettes (Whatman no.903)	Filter paper sheets (Whatman no. 903)
Concentrations	Approx. values: Low 4 U/dL High 13 U/dL	Approx. values: Normal 12.7 U/g Hb Abnormal 2.1 U/g Hb
Substrate Reagent Ingredients	Same	Contains beta-nicotinamide adenine dinucleotide phosphate,uridine 5'-diphosphoglucose, galactose-1-phosphate, and dithiothreitol
Reconstitution Buffer	Ready-for-use buffer contains magnesium sulfate, ethylenediaminetetraacetic acid, tris aminomethane, Triton X-100, and ProClin 300 as preservative.	Ready-for-use buffer contains magnesium sulphate, ethylenediaminetetraacetic acid, tri aminomethane, and ProClin 300 as preservative.
MicroPlates	Clear uncoated, sold separately	Black uncoated
Detection	Same	Defined by analyte specific protocol
Calculation	GSP Workstation software, X-axis LIN, Y-axis LIN; fitting algorithm linear regression	The system incorporates programs for data reduction, and the results obtained as printouts of calibration curves, unknown activities etc.
Incubation Detail	20 min + 2 hours, 37°C	3 hours, 37°C and 60min, RT
Testing Integrity Controls	Floating Disk Control – detects floating sample disks in the wells before measuring GALT activity Elution Control - detects missing sample disks in the wells after measuring GALT activity	Not available

Performance Characteristics

Precision:

Precision was determined in accordance with NCCLS (CLSI) document EP5-A2.

The variation of the GSP Neonatal GALT assay was determined using dried blood spot samples and controls, 3 kit lots, and 3 GSP instruments. The study was performed over 25 days in 27 runs each consisting of 2 plates with 4 replicates per sample. The analysis of variance approach was used to calculate the following:

Precision data using a full calibration curve on each plate:

RESULTS								
Sample	n	Mean GALT activity (U/dL)	Within run variation		Within lot variation		Total variation	
			SD	CV%	SD	CV%	SD	CV%
S1	209*	2.5	0.3	10.3	0.4	14.3	0.4	15.9
S2	216	3.1	0.3	8.6	0.4	12.6	0.4	13.1
S3	206*	3.9	0.2	6.1	0.3	8.3	0.3	8.6
S4	216	5.3	0.3	5.7	0.5	9.0	0.5	9.2
S5	216	7.1	0.3	3.8	0.5	7.4	0.5	7.6
S6	216	13.1	0.9	6.7	1.2	8.9	1.2	9.1
S7	216	18.3	0.6	3.1	0.9	5.1	1.0	5.4
S8	216	22.5	0.7	3.0	1.1	4.9	1.2	5.2

* Some results have been excluded because of technical errors.

Precision data using one calibration curve valid for 24 h.

RESULTS								
Sample	n	Mean GALT activity (U/dL)	Within run variation		Within lot variation		Total variation	
			SD	CV%	SD	CV%	SD	CV%
S1	209*	2.4	0.3	12.8	0.3	14.3	0.4	15.7
S2	216	3.0	0.4	12.2	0.4	13.3	0.4	13.6
S3	206*	3.9	0.3	7.6	0.3	8.8	0.3	9.0
S4	216	5.3	0.4	7.9	0.5	9.6	0.5	9.8
S5	216	7.0	0.4	5.7	0.6	7.9	0.6	8.3
S6	216	13.0	1.0	7.4	1.2	9.0	1.2	9.5
S7	216	18.2	0.7	3.8	1.0	5.5	1.1	6.0
S8	216	22.4	0.8	3.4	1.2	5.3	1.3	5.8

* Some results have been excluded because of technical errors.

Linearity:

Linearity was determined in accordance with NCCLS document EP6-A.

For GALT activities over 4 U/dL, the maximum observed difference (%) between the linear and 3rd order regression models is -2.6 %. For activities ≤ 4 U/dL, the maximum observed absolute difference between the models is 0.07 U/dL.

For GSP Neonatal GALT, the method has been demonstrated to be linear throughout the measuring range, from extends from 2.5 U/dL to 25 U/dL.

Detection Limit:

The limits of blank, detection and quantitation were determined in accordance with NCCL document EP17-A.

The Limit of Blank (LoB) for GSP Neonatal GALT kit is 1.6 U/dL, defined as the 95th percentile of a distribution of blank (GALT deficient) samples (n=83). The Limit of Detection (LoD) is 2.5 U/dL based on 351 determinations of five low level samples. The Limit of Quantitation (LoQ) is 2.5 U/dL, defined as the lowest activity with a total CV equal or less than 20% (n=209).

Analytical Specificity:

The GSP Neonatal GALT kit was evaluated for interference in accordance with CLSI document EP7-A2.

Whole blood with three different GALT activities (approximately 3, 6 and 12 U/dL) were enriched above the endogenous levels with possible interfering substances as presented below.

Icteric (unconjugated bilirubin (≤ 40 mg/dL blood), conjugated bilirubin (≤ 40 mg/dL blood)) and lipemic (Intralipid ≤ 1000 mg/dL blood) samples did not interfere with the assay. Ascorbic acid (≤ 3 mg/dL blood) and galactose (≤ 50 mg/dL blood) did not interfere with the assay at tested concentrations.

Glutathione did not interfere up to concentration of 18.8, 37.5 and 56.3 mg/dL blood at sample GALT activities of 3, 6 and 12 U/dL, respectively. Glutathione concentrations above these levels caused a decrease of up to 63% in GALT activity.

Galactose-1-phosphate (GAL-1-P) had no effect on the low GALT activity sample (3 U/dL), while a GAL-1-P concentration of 12.5 mg/dL blood interfered with the result of the samples with GALT activities 6 and 12 U/dL. The measured GALT result decreased up to 37%.

Total protein (HSA) had no effect on the high (12 U/dL) activity sample. HSA did not interfere up to added concentration of 3000 mg/dL blood, which is approximately two times higher than the normal endogenous concentration of normal neonates, at sample GALT activities 3 and 6 U/dL. Added HSA concentrations above this level caused an increase up to 30% in GALT activity.

The effect of hematocrit was tested by adjusting the amount of red blood cells with plasma on three whole blood samples with different GALT activities (approximately <1, 6, and 15 U/dL), and testing the blood samples for GALT activity according to CLSI document EP7-A2. The results are shown below.

Effect of hematocrit

Hematocrit % (approximate value)	Sample 1		Sample 2		Sample 3	
	n	U/dL	n	U/dL	n	U/dL
35	12	0.99	12	7.3	12	13.2
44	12	0.37	11	6.5	12	14.9
53	12	0.00	12	5.6	10	15.4
62	11	0.00	12	5.0	12	15.6
70	12	0.00	11	4.6	12	15.2

Samples with low GALT activity might get slightly elevated or lowered results from the GSP Neonatal GALT assay due to differences in the hematocrit level. GALT activity is in the red blood cells and hence the GALT activity varies based on hematocrit level. However, hemoglobin is known to absorb part of the excitation and emission light. In samples with normal GALT activity the change in hematocrit is compensated with the hemoglobin effect. In samples with low GALT activity there is not enough GALT activity to overcome the quenching effect of hemoglobin and thus the samples with low GALT activity and low hematocrit may result in elevated results and samples with low GALT activity and high hematocrit may result in lower results.

The differences in hematocrit level have no effect on the screening classification of samples with no GALT activity (classical galactosemia).

Comparison Studies:

The 3303-001U GSP Neonatal GALT kit was compared to the NG-1100/4100 Neonatal GALT kit in a routine screening laboratory by measuring the GALT activity in a total of 2205 infants. The specimens were routine (n = 2146) and retrospective low GALT activity (n = 33) screening specimens. A comparison of the routine screening samples is provided in the table below.

Method	n	Range	Mean	Median	0.5th percentile	1.0st percentile	1.5th percentile
GSP 3303-001U (U/dL)	2146	2.5–25*	15.5	15.6	5.5	6.7	7.5
NG-1100/4100 (U/g Hb)	2146	3.0–18	10.2	10.2	5.1	5.7	6.1

* Samples that resulted in values below 2.5 U/dL were reported as "<2.5 U/dL" and samples that resulted in values above 25 U/dL were reported as ">25 U/dL".

Screening Performance
Cut-off values based on the 0.5th, 1.0st, and 1.5th percentiles were used for both methods.

Samples that resulted in values below 2.5 U/dL were reported as"<2.5 U/dL" and considered screen positive for classical galactosemia. Samples that resulted in values above 25 U/dL were reported as">25 U/dL" and considered screen negative for classical galactosemia.

Please note that the cut-off values used in this section only apply to this study. If the measured median GALT activity of routine samples is lower than the values given in this section, a higher percentile should be used to determine the cut-off (see sections "SPECIMEN COLLECTION AND HANDLING" and "EXPECTED VALUES AND INTERPRETATION OF RESULTS").

Screening performance using the 0.5th percentile

Neonatal GALT kit	NG-1100/4100		
GSP 3303-001U	Test Positive	Test Negative	Total
Test Positive	39*	5	44
Test Negative	3	2132	2135
Total	42	2137	2179

* Includes all 33 retrospective low GALT activity screening specimens

Overall percent agreement = (39 + 2132) / (2179)*100% = 99.6% (CI 99.3%–99.9%)
Positive percent agreement = (39 / 42)*100% = 92.9% (CI 83.9%–100%)
Negative percent agreement = (2132 / 2137)*100% = 99.8% (CI 99.5%–100%)

Screening performance using the 1.0st percentile.

Neonatal GALT kit	NG-1100/4100		
GSP 3303-001U	Test Positive	Test Negative	Total
Test Positive	45*	8	53
Test Negative	8	2118	2126
Total	53	2126	2179

* Includes all 33 retrospective low GALT activity screening specimens

Overall percent agreement = (45 + 2118) / (2179)*100% = 99.3% (CI 98.9%–99.7%)
Positive percent agreement = (45 / 53)*100% = 84. 9% (CI 74.3%–95.5%)
Negative percent agreement = (2118 / 2126)*100% = 99.6% (CI 99.3%–99.9%)

Screening performance using the 1.5th percentile.

Neonatal GALT kit	NG-1100/4100		
GSP 3303-001U	**Test Positive**	**Test Negative**	**Total**
Test Positive	51*	14	65
Test Negative	10	2104	2114
Total	61	2118	2179

* Includes all 33 retrospective low GALT activity screening specimens

Overall percent agreement = (51 + 2104) / (2179)*100% = 98.9% (CI 98.4%–99.4%)
Positive percent agreement = (51 / 61)*100% = 83.6% (CI 73.5%–93.7%)
Negative percent agreement = (2104 / 2118)*100% = 99.3% (CI 99.0%–99.7%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
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PerkinElmer, Inc.
c/o Ms. Kay A. Taylor
Director, Regulatory and Clinical Affairs
8275 Carloway Road
Indianapolis, IN 46236

JUN 11 2010

Re: k100101
Trade/Device Name: GSP Neonatal GALT kit
Regulation Number: 21 CFR § 862.1315
Regulation Name: Galactose-1-phosphate uridyl transferase test system
Regulatory Class: Class II
Product Code: KQP
Dated: April 28, 2010
Received: April 30, 2010

Dear Ms. Taylor:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
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 Form

510(k) Number (if known): **K100101**

Device Name: **GSP Neonatal GALT**

Indications for Use:

The GSP Neonatal GALT kit is intended for the quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity in blood specimens dried on filter paper as an aid in screening newborns for classical galactosemia caused by GALT deficiency using the GSP™ instrument.

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

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100101