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510(k) Summary

AUG - 7 2008

Introduction 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 k071649

Submitter	**Name**	Wallac Oy
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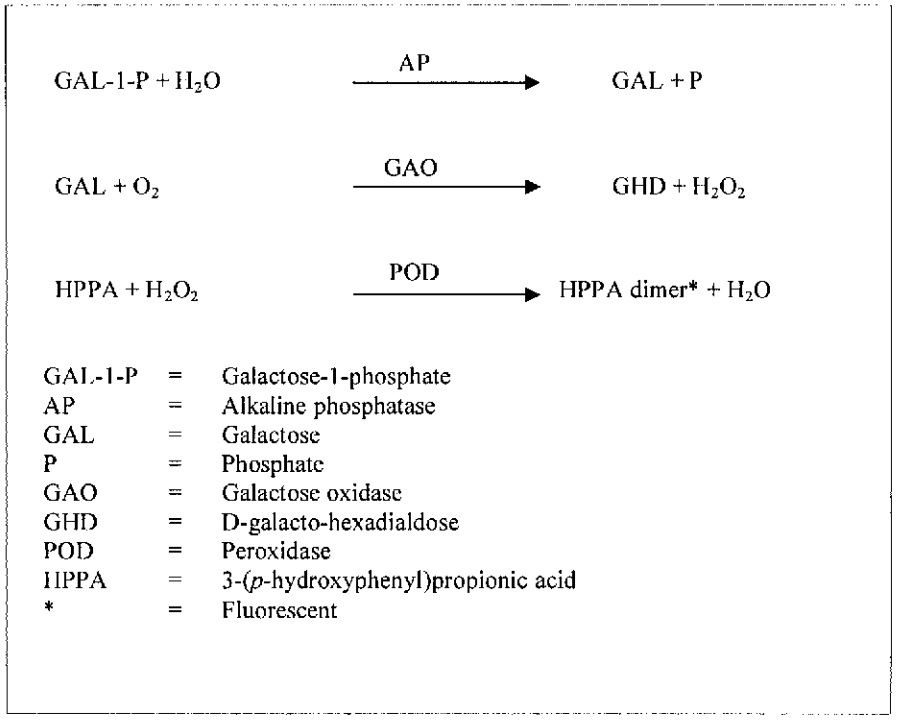
	Contact Person	Helena Lundström Registration Manager
	Date of Preparation	July 31, 2008
Device name	**Trade Name**	Neonatal Total Galactose Kit
	Common Name	Enzymatic Methods, galactose
	Classification Name	Galactose Test System (21 CFR 862.1310) Class I
	Product Code	JIA
Predicate device	BioRad Quantase™ Neonatal Total Galactose Screening Assay (k990654)	
Description of the device	The Neonatal Total Galactose kit makes use of a fluorescent galactose oxidase method. The assay measures total galactose, i.e. both galactose and galactose-1-phosphate. The following schematic summarizes the reactions that occur during the test procedure:	



The fluorescence can be measured using an excitation central wavelength of 340 nm (or 320 nm) and emission central wavelength of 405 nm. The fluorescence of each sample is proportional to the concentration of galactose in the sample.

Intended use

The Neonatal Total Galactose kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia.

Substantial Equivalence

The Neonatal Total Galactose kit is substantially equivalent to the BioRad Quantase™ Neonatal Total Galactose Screening Assay (k990654).

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Device Comparison The following table compares the Neonatal Total Galactose kit with the predicate device.

	Predicate Device	**New Device**
Device characteristics	**BioRad Quantase Total Galactose Screening Assay**	**PerkinElmer Neonatal Total Galactose Kit**
Device Similarities		
Intended use	The Quantase™ Neonatal Total Galactose Screening Assay is intended for use as a screening method for measuring the total D(+)galactose concentrations in newborn blood spot specimens.	The kit is intended for the quantitative determination of total galactose (galactose and galacatose-1-phosphate) concentrations in blood specimens dried on filter paper as aid in screening newborns for galactosemia.
Technology	Enzymatic assay	The same
Kit content	Calibrators/Standards, Controls and Enzymatic Reagents	The same, plus Assay Plates
Specimen type	Newborn dried blood spot specimens	The same
Interpretation of results	Standard curve	The same
Calibrator format	Dried blood spots	The same
Number of Controls	Two	The same
Control format	Dried blood spots	The same
Device Differences		
Methodology	Colorimetric end point method	Prompt Fluorescence
Instrumentation	Plate reader	Victor$_2$™ D Fluorometer or equivalent
Calibrators/standards: Number of levels	Five (Four standard levels + Standard 0 which is plain white paper)	Six (six calibrator levels)
Analytical sensitivity	0.60 mg/dL	1.3 mg/dL
Linearity	0.6 to 55 mg/dL	1.3 to 56 mg/dL
Measuring Range	0.6 to 50 mg/ mL	1.3 to 40 mg/ mL
Expected values	Mean total galactose concentration 1.05 mg/dL (n=462) measured with a punch size of 3/16" .	Median total galactose concentration, 1.7 mg/dL (n=2109) measured with a punch size of 1/8".

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<table>
<tr>
<td>Specificity/Recovery</td>
<td>Mean recovery of D(+) galactose in the presense of 100mg/dL of the following sugars and D(+)galactose metabolites was 95.07% (S:D: 7.49%).
D-(+)-Gucose
α-Lactose
D(-)Fructose
Sucrose
Maltose
D(+)Mannose
D-Mannitol
Galactitol
D-Galacturonic Acid
D-Glucuronic Acid
D(-)Ribose</td>
<td>Mean recovery of galactose in the presence of galactose, galactose-1-phosphate or galactose + galactose-1-phosphate was 79 – 81 %.</td>
</tr>
<tr>
<td>Interference</td>
<td>No interference observed with known antibiotics, non-antibiotics and metabolites</td>
<td>No interference with glucose, mannose, fructose, ascorbate, bilirubin, hemoglobin, protein BSA and acetaminophen. Glutathione (60 mg/dL) and lipemic samples (0.25 -1 g/dL) interfere with the assay.</td>
</tr>
<tr>
<td>Precision</td>
<td>Intra-assay (1/8 punch size)
<table>
<tr><th>Mean D(+) Galactose conc.(mg/dL)</th><th>% CV</th><th>n</th></tr>
<tr><td>1.06</td><td>13.99</td><td>20</td></tr>
<tr><td>6.81</td><td>10.02</td><td>20</td></tr>
<tr><td>14.23</td><td>6.67</td><td>20</td></tr>
<tr><td>33.96</td><td>3.94</td><td>20</td></tr>
</table>
Total Assay (1/8 punch size)
<table>
<tr><th>Mean D(+) Galactose conc.(mg/dL)</th><th>% CV</th><th>n</th></tr>
<tr><td>1.43</td><td>17.42</td><td>39</td></tr>
<tr><td>6.97</td><td>6.27</td><td>40</td></tr>
<tr><td>14.53</td><td>7.43</td><td>40</td></tr>
<tr><td>33.58</td><td>8.53</td><td>40</td></tr>
</table>
</td>
<td>Intra-assay and total variation
<table>
<tr><th>Mean Galactose conc.(mg/dL)</th><th>Intra-assay (%CV)</th><th>Total variation (%CV)</th><th>n</th></tr>
<tr><td>7.1</td><td>6.6</td><td>12.3</td><td>143</td></tr>
<tr><td>13.8</td><td>6.5</td><td>10.8</td><td>144</td></tr>
<tr><td>20.2</td><td>5.3</td><td>8.6</td><td>144</td></tr>
</table>
<table>
<tr><th>Mean Galactose conc.(mg/dL)</th><th>Intra-assay (%CV)</th><th>Total within lot variation (%CV)</th><th>n</th></tr>
<tr><td>3.5</td><td>7.8</td><td>12.7</td><td>80</td></tr>
<tr><td>11</td><td>7.2</td><td>11.8</td><td>80</td></tr>
<tr><td>23</td><td>6.0</td><td>8.4</td><td>80</td></tr>
<tr><td>36</td><td>5.2</td><td>8.6</td><td>80</td></tr>
</table>
</td>
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Method Comparison

The PerkinElmer Neonatal Total Galactose kit (y) was compared with the BioRad Quantase™ Neonatal Total Galactose Screening Assay (k990654). using routine newborn screening dried blood spot specimens in the range of 72 µmol/L to 1970 µmol/L (1.3–35.5 mg/dL) (determined with the PerkinElmer kit). The correlation was found to be:

$$y = 0.65x + 1.73, \quad r = 0.87 \quad (n = 842)$$

The total galactose cut-off values by percentile for both the PerkinElmer Neonatal Total Galactose kit and the predicate were determined by analyzing 2109 routine newborn screening dried blood spot specimens representing an US population. The results are shown in the table below:

Total galactose cut-off values by percentile				
	PerkinElmer kit		Predicate	
	µmol/L	mg/dL	µmol/L	mg/dL
Median	94	1.7	33	0.6
95th percentile	283	5.1	233	4.2
97.5th percentile	355	6.4	316	5.7
99th percentile	461	8.3	521	9.4
99.5th percentile	549	9.9	678	12.2

The screening summaries using the 95th and 99th percentiles are presented in the tables below. The samples used in the study, representing an US population, included 2116 newborn dried blood samples (2109 routine screening specimens and seven restrospective specimens of which three were diagnosed true positives for galactosemia).

In the tables below the screening positives (+) are samples ≥ cut-off and the screening negatives (-) are samples < cut-off.

Screening summary using the 95th percentile				
Predicate	PerkinElmer kit	Total	Diagnosed galactosemia	No diagnosed galactosemia
+	+	73	3	70
+	-	41	0	41
-	+	46	0	46
-	-	1956	0	1956
Total		2116	3	2113

Screening summary using the 95th percentile		Predicate		
		+	-	Total
PerkinElmer kit	+	73	46	119
	-	41	1956	1997
	Total	114	2002	2116

When the 95th percentile was used as a cut-off for both methods, the positive percent agreement was 64% (73/114) and the overall percent agreement was 95.9% ((73+1956)/2116).

Screening summary using the 99th percentile				
Predicate	PerkinElmer kit	Total subjects	Diagnosed galactosemia	No diagnosed galactosemia
+	+	21	3	18
+	-	8	0	8
-	+	9	0	9
-	-	2078	0	2078
Total		2116	3	2113

Screening summary using the 99th percentile		Predicate		
		+	-	Total
PerkinElmer kit	+	21	9	30
	-	8	2078	2086
	Total	29	2087	2116

When the 99th percentile was used as a cut-off for both methods, the positive percent agreement was 72.4% (21/29) and the overall percent agreement was 99.2% ((21+2078)/2116).

The total galactose concentrations of the three true galactosemia specimens used in the study were as shown in the table below:

Total Galactose concentrations of true positive specimens		
Specimen no.	PerkinElmer kit (mg/dL)	Commercially available kit (mg/dL)
1	16.6	23.9
2	12.1	14.6
3	22.2	39.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Wallac Oy
c/o Ms. Helena Lundstrom
Regulatory Affairs Manager
Mustionkatu 6, PO Box 10
Turku 20750, Finland

AUG - 7 2008

Re: k071649
Trade/Device Name: Neonatal Total Galactose Kit
Regulation Number: 21 CFR 862.1310
Regulation Name: Galactose Test System
Regulatory Class: Class I
Product Code: JIA
Dated: July 21, 2008
Received: July 24, 2008

Dear Ms. Lundstrom:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

Indication for Use

510(k) Number (if known): k071649

Device Name: Neonatal Total Galactose Kit

Indication For Use:

This kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF 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)__k071649____