510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k081922

B. Purpose for Submission:
Modification to a marketed device

C. Measurand:
17-alpha-Hydroxyprogesterone

D. Type of Test:
Quantitative, time-resolved fluorescent immunoassay based on competition principle

E. Applicant:
Wallac Oy

F. Proprietary and Established Names:
AutoDELFIA® Neonatal 17α-OH-progesterone Kit

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1395 17-Hydroxyprogesterone test system
2. Classification:
   Class I, meets limitations of exemptions 21 CFR § 862.9 (c)(2)
3. Product code:
   JLX, Radioimmunoassay, 17-Hydroxyprogesterone
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   The AutoDELFIA® Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the 1235 AutoDELFIA® automatic immunoassay system.

2. Indication(s) for use:
   See intended use above.

3. Special conditions for use statement(s):
   For Prescription Use Only

4. Special instrument requirements:
   For use with the 1235 AutoDELFIA® automatic immunoassay system

I. Device Description:

The AutoDELFIA Neonatal 17α-OH-progesterone (17-OHP) kit has three package configurations:

Model Number	Reagents for Number of Assays	Description
B024-104	384	Basic 4-plate configuration
B024-112	1152	12-plate configuration (3 x 4 –plate configuration)
B024-01C	1152	12-plate configuration with one additional bottle of 17-OHP Assay Buffer

The kit contains the following components:

Calibrators and controls prepared from washed human blood, with preservative, adjusted to a hematocrit of 50-55%, calibrated using gravimetric methods and spotted onto Whatman 903 specimen collection paper.

The six calibrators contain 17-OHP at the following concentrations (approximate values, ng/mL serum):

A 0 ng/mL	D 25 ng/mL
B 4 ng/mL	E 75 ng/mL
C 10 ng/mL	F 220ng/mL

The three controls contain 17-OHP at the following concentrations (approximate values, ng/mL serum):
C1 (17 ng/mL), C2 (45 ng/mL), and C3 (100 ng/mL).

All human source materials used in the preparation of kit components was tested and found to be non-reactive for the presence of HBsAg, anti-HIV 1 and 2, and HCV by FDA approved methods.

17-OHP Europium tracer, lyophilized
17-OHP Rabbit polyclonal antiserum in Tris-HCl buffer
17-OHP Assay buffer
Microtiter plates coated with goat anti-rabbit antibody

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Wallac Oy AutoDELFIA® Neonatal 17α-OH-progesterone Kit

2. Predicate K number(s):
   k042425

3. Comparison with predicate:

Item	Device	Predicate
Similarities		
Intended Use	For the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper used as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the 1235 AutoDELFIA® automatic immunoassay system.	same
Chemical Principle	Competitive reaction between europium labeled 17-OHP and sample 17-OHP for a limited number of binding sites on 17-OHP specific polyclonal antibodies derived from rabbit	same
Assay Principle	Time-resolved fluoroimmunoassay	same
Instrument	1235 AutoDELFIA® automatic immunoassay system	same
Detection principle	Time-resolved fluorescence	same
Specimen	Filter paper disks with a diameter of approximately 3.2 mm (1/8 inch)	same
Calibrator and Control Matrix	Human blood with a hematocrit of 50-55% and spotted onto filter paper cassettes (Whatman Grade 903)	same
Calibration	Calibrated using gravimetric methods	same
Controls	3 levels (approx. values 17, 45 and 100 ng/mL serum)	same
Assay Buffer	17-OHP Assay Buffer, ready for use	same
Coated Plates	Anti-rabbit IgG Microtitration Strips, 8 x 12 wells coated with anti-rabbit IgG (raised in goat)	same

Item	Device	Predicate
Differences		
Antibodies	Rabbit polyclonal antibodies	Different rabbit polyclonal antibodies
Antibody Cross-Reactions in the Assay	17α-OH pregnenolone sulfate 0.78 % 11-Deoxycortisol 0.62 % 17α-OH pregnenolone 0.83 %	17α-OH pregnenolone sulfate 2.0 % 11-Deoxycortisol 1.82 % 17α-OH pregnenolone 1.20 %

	Progesterone 0.37 %	Progesterone 0.47 %
Tracer	17-OHP-Eu tracer stock solution, approximate concentration of 40 nmol/L, lyophilized	17-OHP-Eu tracer stock solution, approximate concentration of 250 nmol/L, lyophilized
Calibrators	6 levels (approx. values 0, 4, 10, 25, 75, and 220 ng/mL serum)	6 levels (approx. values 0, 10, 25, 50, 100 and 250 ng/mL serum)
Analytical Sensitivity / Limit of Blank, Limit of Detection, Limit of Quantitation	Limit of Blank 0.37 ng/mL serum Limit of Detection 0.84 ng/mL serum Limit of Quantitation 1.4 ng/mL serum	Analytical Sensitivity (Limit of Blank) 1.3 ng/mL serum
Precision (Total Variation using a full calibration curve on each plate)	2.12 ng/mL serum CV% 13.0 4.69 ng/mL serum CV% 9.8 7.52 ng/mL serum CV% 14.8 27.0 ng/mL serum CV% 8.3 54.4 ng/mL serum CV% 9.2 109 ng/mL serum CV% 10.8 182 ng/mL serum CV% 9.1	25.9 ng/mL serum CV% 13.2 53.0 ng/mL serum CV% 10.8 114 ng/mL serum CV% 10.9
Precision (Total Variation using one calibration curve for every batch of 4 plates)	2.25 ng/mL serum CV% 14.0 4.89 ng/mL serum CV% 12.0 7.79 ng/mL serum CV% 15.8 27.7 ng/mL serum CV% 9.7 55.7 ng/mL serum CV% 10.5 113 ng/mL serum CV% 12.7 188 ng/mL serum CV% 11.3	25.8 ng/mL serum CV% 14.0 52.9 ng/mL serum CV% 12.4 115 ng/mL serum CV% 11.8
Median Values in Newborn Screening (Study 1)	< 1250 g 20.9 ng/mL serum 1250-2249 g 9.7 ng/mL serum ≥ 2250 g 6.7 ng/mL serum	< 1250 g 35.6 ng/mL serum 1250-2249 g 20.0 ng/mL serum ≥ 2250 g 14.1 ng/mL serum
Median Values in Newborn Screening (Study 2)	< 1250 g 13.3 ng/mL serum 1250-2249 g 12.1 ng/mL serum ≥ 2250 g 7.1 ng/mL serum	< 1250 g 30.2 ng/mL serum 1250-2249 g 23.4 ng/mL serum ≥2250 g 13.7 ng/mL serum

K. Standard/Guidance Document Referenced (if applicable):

Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition (CLSI EP5-A2); Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (CLSI EP6-A); Interference Testing in Clinical Chemistry; Approved Guideline (CLSI EP7-A); Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition (CLSI EP9-A2); Protocols for Determination

of Limits of Detection and Limits of Quantitation; Approved Guideline (CLSI EP17-A).

L. Test Principle:

The AutoDELFIA Neonatal 17α-OH-progesterone (17-OHP) assay is a solid phase, time-resolved fluoroimmunoassay based on the competitive reaction between europium-labeled 17-OHP and sample 17-OHP for a limited amount of binding sites on 17-OHP specific polyclonal antibodies (derived from rabbit). Danazol facilitates the release of 17-OHP from the binding proteins. A second antibody, directed against rabbit IgG, is coated to the solid phase, giving convenient separation of the antibody-bound and free antigen.

Enhancement Solution dissociates europium ions from the labeled antigen into solution where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is then measured. The fluorescence of each sample is inversely proportional to the concentration of 17-OHP in the sample.

The test instructions indicate that there are two different options for calibrating the assay: 1) a calibration curve in duplicate for every batch of up to 4 plates or 2) a full calibration curve in duplicate for each plate.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision of the AutoDELFIA 17-OHP kit was evaluated in the following manner. Seven whole blood specimens were obtained from adults and spiked with 17-OHP at concentrations across the reportable range of the test. The samples were then dispensed onto filter paper and dried at room temperature overnight. The samples were tested over 21 days using three lots of AutoDELFIA kits and three analyzers, for a total of n=216 measurements. The results are summarized below.

Precision data using a full calibration curve in duplicate on each plate:

Sample	Mean 17-OHP Conc. (ng/mL)	Within Plate Variation		Within Lot Variation		Total Variation	
		SD	CV%	SD	CV%	SD	CV%
1	2.12	0.21	9.9	0.25	11.8	0.28	13.0
2	4.69	0.44	9.4	0.46	9.8	0.46	9.8
3	7.52	0.94	12.6	1.07	14.3	1.11	14.8
4	27.0	1.72	6.4	2.21	8.2	2.23	8.3
5	54.4	3.86	7.1	4.97	9.1	5.01	9.2

6	109	7.71	7.1	11.3	10.3	11.8	10.8
7	182	12.3	6.8	15.9	8.7	16.6	9.1

Precision data using one calibration curve in duplicate for every batch of 4 plates:

Sample	**Mean 17-OHP Conc. (ng/mL)**	**Within Plate Variation**		**Within Lot Variation**		**Total Variation**	
		SD	**CV%**	**SD**	**CV%**	**SD**	**CV%**
1	2.25	0.27	11.8	0.30	13.5	0.31	14.0
2	4.89	0.56	11.5	0.58	11.9	0.59	12.0
3	7.79	1.12	14.4	1.19	15.3	1.23	15.8
4	27.7	2.29	8.3	2.66	9.6	2.70	9.7
5	55.7	5.31	9.5	5.84	10.5	5.85	10.5
6	113	10.8	9.1	13.8	12.2	14.7	12.7
7	188	17.1	9.1	21.0	11.2	21.3	11.3

In addition, the kit controls were assayed to determine the precision of the kit. The controls were tested over 21 days using three lots of AutoDELFIA kits and three analyzers, for a total of n=216 measurements. The results are summarized below.

Precision data using a full calibration curve in duplicate on each plate:

Kit control	n	Mean ng/mL	Variation CV %		
			Within Plate	Within Lot	Total
C1	216	15.1	5.4	7.2	7.6
C2	216	41.7	4.7	6.5	6.8
C3	216	89.8	5.0	8.3	8.4

Precision data using one calibration curve in duplicate for every batch of 4 plates:

Kit control	n	Mean ng/mL	Variation CV %		
			Within Plate	Within Lot	Total
C1	216	15.1	8.0	9.1	9.2
C2	216	41.7	7.0	8.0	8.2
C3	216	89.8	8.4	10.6	10.7

b. Linearity/assay reportable range:

The study was performed following the CLSI protocol EP6-A. Whole blood was obtained from six apparently healthy adults. Specimens with low 17-OHP concentration were pooled. A part of the specimen was pooled and spiked to create a sample with high 17-OHP concentration (approximately 250 ng/mL). The high and low pools were mixed in varying proportions to create a dilution series of varying 17-OHP concentrations. Each test sample was spotted on

filter paper in quadruplicate (n=4) and dried overnight. The 17-OHP concentrations of the series of dried blood spot samples were measured with one AutoDELFIA 17-OHP kit lot in a single run in random order.

The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial regression. The third order model fit the data better than the linear model. However, for dilution points greater than 4 ng/mL, the maximum observed difference (%) between the models was 7 %. For concentrations ≤ 4 ng/mL, the observed absolute difference between the models was 0.19 ng/mL. The results are summarized below:

Dilution	**Linear model Predicted 17-OHP (ng/mL serum)**	**Third Order model Predicted 17-OHP (ng/mL serum)**	**Absolute difference between models (ng/mL serum)**	**Relative difference between models (%)**
0	0.53	0.60	0.07	*
0.003	1.37	1.40	0.04	*
0.004	1.53	1.56	0.03	*
0.005	1.78	1.80	0.02	*
0.01	3.03	3.01	-0.03	*
0.02	5.53	5.42	-0.11	-2.0
0.07	19.1	18.7	-0.32	-1.7
0.2	50.5	51.0	0.43	0.9
0.4	101	104	3.20	3.2
0.6	151	155	4.48	3.0
0.8	201	201	0.39	0.2
0.9	226	221	-4.88	-2.2
1	251	238	-13.0	-5.2

The value of the highest kit calibrator may vary slightly but does not exceed 220 ng/mL. The package insert states that samples with values above the highest calibrator are not considered accurate but are highly indicative of CAH. The reportable range is from 1.4 to 220 ng/mL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* There is no international reference preparation or reference method for 17-OHP. The AutoDELFIA Neonatal 17-OHP kits are traceable to commercially available purified 17-OHP.

Six calibrators and three controls are supplied with the kit as dried blood spots on Whatman 903 filter paper. They are prepared from human blood with a hematocrit value of 50-55% and purified 17-OHP. They are calibrated using gravimetric methods.

Real-time stability including shelf-life, transport, and in-use stability studies for the entire kit were performed, including the controls and calibrators.

Additionally, accelerated stability studies were also performed separately for the kit calibrators and controls. The study protocols and statistically calculated acceptance limits were reviewed and found to be acceptable.

d. *Detection limit:*
The sponsor states that the Limit of Blank (LoB) study was performed in accordance with the recommendations of CLSI document EP-17. The LoB was calculated from data using three kit lots over six testing days and a total of 108 measurements of blank (analyte free) dried blood spot samples on filter paper. Calibrators and controls were tested in quadruplicate and duplicate respectively for each assay. Since the assay does not report values less than zero, the LoB was estimated non-parametrically, as CLSI EP-17 advises, as the 95th percentile of the measurements. The limit of blank was observed to be 0.37 ng/mL.

To estimate the Limit of Detection (LoD) and the Limit of Quantitation (LoQ), five low level samples (dried blood spot samples on filter paper) were prepared from heparinized whole blood. These samples were analyzed using the predicate method. Repeated measurements (n = 108) were carried out using the proposed device with each sample. Statistical analysis yielded a limit of detection of 0.84 ng/mL and a limit of quantitation of 1.4 ng/mL.

The package insert states that values below 1.4 ng/mL should be reported as "<1.4 ng/mL."

e. *Analytical specificity:*
Interference from various compounds was evaluated at 17-OHP concentrations of approximately 25 and 70 ng/mL. The potential interferant was added to whole blood specimens containing 17-OHP, spotted onto filter paper, dried, and tested. Specimens without added interferant were also tested (control). The sponsor used a two sample t-test at the 95% confidence interval to evaluate the significance of any difference seen between test and control samples.

Compound	**Concentration added to samples**
Bilirubin (conjugated)	20 mg/dL
Bilirubin (unconjugated)	20 mg/dL
Hemoglobin	0.5 g/dL
Triglycerides (Intralipid)	3000 mg/dL

Analysis of the data showed that conjugated and unconjugated bilirubin, hemoglobin and triglycerides (Intralipid) at the tested levels did not interfere with the assay.

Compounds whose structures are similar to 17-OHP were evaluated for potential cross-reactivity using a published method. The lists of compounds tested and results are summarized below:

Substance	**Cross reactivity %**
21-Deoxycortisol	0.91
17α-OH pregnenolone	0.83
17α-OH pregnenolone sulfate	0.78
11-Deoxycortisol	0.62
Progesterone	0.37
Deoxycorticosterone	0.02
16α-OH progesterone	<0.01
17α-OH pregnenolone glucuronide	<0.01
Pregnenolone	<0.01
16α-OH pregnenolone	<0.01
20α-Dihydroprogesterone	<0.01
Prednisone	<0.01
Prednisolone	<0.01
Dexamethasone	<0.01
Cortisol	<0.01
5β-Dihydrocortisol	<0.01
Cortisone	<0.01
5β-Dihydrocortisone	<0.01
Testosterone	<0.01
Dehydroisoandrosterone	<0.01
Dehydroisoandrosterone sulfate	<0.01
Spironolactone	<0.01
17β-Estradiol	<0.01
Estriol	<0.01

f. Assay cut-off:
Not applicable.

2. Comparison studies:
   a. Method comparison with predicate device:

   Studies were performed to compare the performance of the proposed device to the predicate device in two routine screening laboratories (study 1 and study

2) by measuring the 17-OHP concentration in a total of 2175 and 1826 infants (study 1 and study 2, respectively). The specimens were routine and retrospective CAH-screen negative specimens. The results were analyzed and classified according to the birth weights of the infants. The results are summarized in the tables below:

Note: According to the sponsor, the measurements obtained with the proposed device are lower than those obtained with the predicate device because the revised kit contains a more specific polyclonal anti-17-OHP antiserum which demonstrates lower cross-reactivity and less non-specific binding.

Study 1: descriptive statistics, proposed device

Birth weigh (g)	n	17-OHP (ng/mL serum)		Percentile (ng/mL serum)	
		Mean	Median	90^{th}	95^{th}
< 1250	362	28.2	20.9	56.7	73.6
1250–2249	498	15.0	9.7	33.5	40.8
≥ 2250	1315	8.3	6.7	14.3	20.9

Study 1: descriptive statistics, predicate device

Birth weigh (g)	n	17-OHP (ng/mL serum)		Percentile (ng/mL serum)	
		Mean	Median	90^{th}	95^{th}
< 1250	362	57.7	35.6	135	178
1250–2249	498	32.1	20.0	76.9	98.4
≥ 2250	1315	18.2	14.1	31.5	49.0

Study 2: descriptive statistics, proposed device

Birth weigh (g)	n	17-OHP (ng/mL serum)		Percentile (ng/mL serum)	
		Mean	Median	90^{th}	95^{th}
< 1250	168	26.7	13.3	59.5	95.0
1250–2249	372	21.0	12.1	54.3	68.6
≥ 2250	1286	9.4	7.1	16.1	28.3

Study 2: descriptive statistics, predicate device

Birth weigh (g)	n	17-OHP (ng/mL serum)		Percentile (ng/mL serum)	
		Mean	Median	90^{th}	95^{th}
< 1250	168	54.6	30.2	125	202
1250–2249	372	46.3	23.4	137	167
≥ 2250	1286	19.4	13.7	32.9	66.5

Screening Performance (Screening results and true diagnosis of the proposed device):

Using the data from non-CAH samples, the cut-offs were determined by calculating the 17-OHP concentrations corresponding to the 90th and 95th population percentiles in both studies. The results for the screening performance of the proposed device including retrospective CAH diagnosed screening specimens are summarized in the tables below:

Study 1: In total, 17 confirmed CAH case samples were assayed in this study. All of them were retrospective samples.

Study 1: < 1250 g weight category, 90th percentile-based cut-off.

Proposed Cut-off 56.7 ng/mL	Predicate Cut-off 135 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	31	1	30
+	-	7	0	7
-	+	7	0	7
-	-	319	**1***	318
Total		364	2	362

Study 1: < 1250 g weight category, 95th percentile-based cut-off.

Proposed Cut-off 73.6 ng/mL	Predicate Cut-off 178 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	13	1	12
+	-	7	0	7
-	+	7	0	7
-	-	337	**1***	336
Total		364	2	362

*** In this case, the mother had CAH. Treatment for CAH includes lifetime daily medication, prednisone or dexamethasone. Because the specimen was taken during the first day of life, the mother's treatment would have impacted the 17-OHP test result of the infant.**

Study 1: 1250-2249g weight category, 90th percentile-based cut-off.

Proposed Cut-off 33.5 ng/mL	Predicate Cut-off 76.9 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	38	1	37
+	-	16	1	15
-	+	13	0	13
-	-	433	0	433
Total		500	2	498

Study 1: 1250 - 2249g weight category, 95th percentile-based cut-off.

Proposed Cut-off 40.8 ng/mL	Predicate Cut-off 98.4 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	17	0	17
+	-	10	2	8
-	+	8	0	8
-	-	465	0	465
Total		500	2	498

Study 1: ≥ 2250 g weight category, 90th percentile-based cut-off.

Proposed Cut-off 14.3 ng/mL	Predicate Cut-off 31.5 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	119	13	106
+	-	28	0	28
-	+	26	0	26
-	-	1155	0	1155
Total		1328	13	1315

Study 1: ≥ 2250 g weight category, 95th percentile-based cut-off.

Proposed Cut-off 20.9 ng/mL	Predicate Cut-off 49.0 ng/mL	Total subjects	Diagnosed CAH	No diagnosed CAH
+	+	60	11	49
+	-	19	2	17
-	+	18	0	18
-	-	1231	0	1231
Total		1328	13	1315

Study 2: In total, 13 confirmed CAH case samples were assayed in this study. All of them were retrospective samples.

Study 2: < 1250 g weight category, 90th percentile-based cut-off.

Proposed Cut-off 59.5 ng/mL	Predicate Cut-off 125 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	15	0	15
+	-	2	0	2
-	+	2	0	2
-	-	149	0	149
Total		168	0	168

Study 2: < 1250 g weight category, 95th percentile-based cut-off.

Proposed Cut-off 95.0 ng/mL	Predicate Cut-off 202 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	5	0	5
+	-	4	0	4
-	+	4	0	4
-	-	155	0	155
Total		168	0	168

Study 2: 1250 - 2249g weight category, 90th percentile-based cut-off.

Proposed Cut-off 54.3 ng/mL	Predicate Cut-off 137 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	30	0	30
+	-	8	0	8
-	+	8	0	8
-	-	326	0	326
Total		372	0	372

Study 2: 1250 - 2249g weight category, 95th percentile-based cut-off.

Proposed Cut-off 68.6 ng/mL	Predicate Cut-off 167 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	11	0	11
+	-	8	0	8
-	+	8	0	8
-	-	345	0	345
Total		372	0	372

Study 2: ≥ 2250 g weight category, 90th percentile-based cut-off.

Proposed Cut-off 16.1 ng/mL	Predicate Cut-off 32.9 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	121	13	108
+	-	21	0	21
-	+	21	0	21
-	-	1136	0	1136
Total		1299	13	1286

Study 2: ≥ 2250 g weight category, 95th percentile-based cut-off.

Proposed Cut-off 28.3 ng/mL	Predicate Cut-off 66.5 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	68	12	56
+	-	9	0	9
-	+	10	0	10
-	-	1212	**1***	1211
Total		1299	13	1286

*** Using percentiles higher than the 90th percentile as the assay's cut-off resulted in one false negative result out of the 13 clinically confirmed CAH samples assayed. Laboratories should take this into consideration when setting their screening cut-offs**.

b. Matrix comparison:
Not applicable. The device should only be used with neonatal whole blood from heel prick.

3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable.

   b. Clinical specificity:
   Not applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):
   Not applicable.

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   According to the sponsor, the measurements obtained with the proposed device are lower than those obtained with the predicate device because the revised kit contains a more specific polyclonal anti-17-OHP antiserum which demonstrates lower cross-reactivity and less non-specific binding.

   The package insert includes precautionary language that each laboratory should establish their own reference range and cut-off values and that cut-offs from another 17-OHP screening test should not be used.

   The package insert also includes the following precautionary language "Using percentiles higher than the 90th percentile as the assay's cut-off resulted in one false negative result out of the 13 clinically confirmed CAH samples assayed. Laboratories should take this into consideration when setting their screening cut-offs".

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.