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

A. 510(k) Number:

k060452

B. Purpose for Submission:

New Device

C. Measurand:

17-alpha-Hydroxyprogesterone

D. Type of Test:

Quantitative, Enzyme Immunoassay

E. Applicant:

Neo-Genesis

F. Proprietary and Established Names:

Accuwell 17-Alpha-Hyderoxyprogesterone Enzyme Immunoassay with Models 6015XX-ECAH

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JLX- Radioimmunoassay, 17-Hydroxyprogesterone	Class I, meets the limitation of exemptions, 21 CFR 862.9 (c), (2)	21 CFR 862.1395, 17-Hydroxy-progesterone test system. 21 CFR 862.9 (c), (2)	75 Clinical chemistry (CH)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

   The Accuwell 17α-Hydroxyprogesterone EIA Kit is designed for the quantitative measurement of 17α-Hydroxyprogesterone (17-OHP) concentrations in neonatal blood samples that have been collected onto Whatman 903® specimen collection paper. The results are used to screen newborns for classical congenital adrenal hyperplasia (CAH).

3. Special conditions for use statement(s):
   For prescription use only

4. Special instrument requirements:

   Microplate reader capable of reading a wavelength of 650 nm

I. Device Description:

The Accuwell 17α-Hydroxyprogesterone EIA Kit contains the following:

- Microplates coated with rabbit anti-17-OHP.
- Enzyme conjugate which contains 17-OHP derivative conjugated to horseradish peroxidase.
- Conjugate diluent which contains tris-buffer, bovine serum and preservatives.
- Wash buffer concentrate which is a concentrated solution of phosphate buffered saline containing a surfactant.
- Color developer which contains 3,3',5,5'-Tetramethylbenzidine in a diluted organic solvent with citrate buffer and hydrogen peroxide.
- Stopping reagent which is a dilute solution of sodium fluoride and a red dye.
- Multi-Analyte standards (0, 10, 25, 50, 100 and 250 ng/mL) serum equivalents. Each card of standards is made from human whole blood, adjusted to a hematocrit of 55% and each level is then spotted onto Whatman 903 specimen collection paper.
- Controls (15, 40 and 90 ng/mL) serum equivalent. Each control card is made from human whole blood, adjusted to a hematocrit of 55% and each level is then spotted onto Whatman specimen collection paper.

Human source material was tested and found negative for HIV 1 and 2, HBV and HCV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Wallac Oy AutoDelfia Neonatal 17α-Hydroxyprogesterone Time-resolved fluoroimmunoassay

2. Predicate 510(k) number(s):

k042425

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for use	Screening for increased levels of 17-OHP in newborns	Screening for increased levels of 17-OHP in newborns
Sample Requirements	Neonatal blood collected on Whatman 903 filter paper	Neonatal blood collected on Whatman 903 filter paper
Specimen	1/8 inch spot punched from a standard collection card of Whatman 903 paper	1/8 inch spot punched from a standard collection card of Whatman 903 paper

Differences		
Item	Device	Predicate
Assay Type	Enzyme-immunoassay	Time-resolved fluoroimmunoassay
Detection Method	Peroxidase which remains bound to micro-wells reacts with peroxide and TMB subsequently converting the TMB from colorless to a blue color which is measured	Europium ions dissociated from the labeled antiserum form highly fluorescent chelates with components of an enhancement solution. Fluorescence in each well is then measured
Standard Range	3.8 to250 ng/mL approximate serum equivalent	Up to 190 ng/mL approximate serum equivalent
Controls	Two levels concentration 14 and 40 ng/mL	Three levels concentration 15, 40 and 90 ng/mL

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

Area of Study	Reference Procedure	Reference Title
Stability Testing	CEN	Stability of In Vitro Diagnostic reagents (13640)
Interference	CLSI/NCCLS EP7-A	Interference Testing in Clinical Chemistry
Method Comparison	CLSI/NCCLS EP9-A	Method Comparison and Bias Estimation using Patient Samples
Precision	CLSI/NCCLS EP5-A	Evaluation of Precision Performance of Quantitative Measurement Methods

L. Test Principle:

The samples can be processed with two different methods; (1) a 1/8 inch disc from each blood spot is placed directly into designated wells of the coated microplate with an overnight incubation, (2) An elution is done using an 1/8 inch disc from each blood spot which is placed in the designated well of an uncoated microplate and saline is added to elute the blood from the dried blood spot. A portion of the eluate is then transferred into a designated well of the coated microplate with an overnight incubation or for 3 hours.

The Accuwell 17α-hydroxyprogesterone immunoassay (EIA) is based on the competition principle. An unknown amount of antigen present in the sample and a fixed amount of enzyme labeled antigen compete for the binding sites of the antibodies coated onto the wells. After incubation the wells are washed to stop the competition reaction and the color developer is added. The color development is terminated by the addition of the stopping reagent and the absorbance measured at 650 nm and is inversely proportional to the amount of the antigen in the sample. Results of samples can be determined directly using the standard curve.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision was assessed using three neonatal dried bloodspots prepared by the Centers for Disease Control and Prevention Neonatal Screening Quality Control Program. Samples were prepared using three different assay procedures: Over night Eluate (ON Eluate), Three hour Eluate (3 Hr Eluate) and Over Night Direct (ON Direct). Each of these samples was assayed in duplicate once a day for 20 days. Results are presented in the table below:

	ON Eluate			3 Hr Eluate			ON Direct		
Sample ID	CDC 451	CDC 452	CDC 453	CDC 451	CDC 452	CDC 453	CDC 451	CDC 452	CDC 453

	Number	40	40	40	40	40	40	40	40	40
	Mean	28.2	56.1	108.1	26.2	53.0	104.6	29.5	57.9	108.6
	SD	3.0	4.9	12.3	3.4	4.1	11.9	4.2	5.8	13.2
	%CV	10.7	8.8	11.4	12.9	7.7	11.3	14.1	10.0	12.2
Within-Run SD	Sr	1.0	2.1	2.9	1.9	2.2	5.4	1.5	4.4	11.7
Between-Day SD	Sdd	2.9	4.5	12.1	2.9	3.4	10.7	3.9	3.9	6.2
Within Device SD	ST	3.1	5.0	12.5	3.4	4.1	12.0	4.2	5.8	13.3
Daily Mean Standard Error	B	3.0	4.8	12.3	3.1	3.8	11.4	4.1	5.0	10.4

b. *Linearity/assay reportable range:*

The linearity of the Accuwell 17-OHP measurement was demonstrated by spiking four serum samples with purified analyte to concentrations of 3.8, 10, 25 and 300 ng/mL. Samples were inter-diluted to make a total of twelve levels with a range between 3.8 - 300 ng/mL. Each sample was combined with lysed, commercially obtained, human, red blood cells to obtain an equivalent hematocrit of 55%. The samples were the spotted onto filter paper and dried. Each sample was tested in quadruplicate for each assay procedure and the average recovery was calculated and plotted against the targeted recoveries. Linear regression of comparison data yielded the following relationship:

ON Eluate - $y = 1.0083x-1.3865$ $r = 0.9998$

3 Hr Eluate - $y = 1.1015x – 4.7189$ $r = 0.997$

ON Direct - $y = 1.1146x-4.9283$ $r = 0.997$

The reportable range for the Accuwell 17-OHP measurements is 3.8-250 ng/mL

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The standards and controls are prepared using commercially available human serum stripped of the analyte then purified 17-OHP analyte is added gravimetrically to various concentrations. Each serum concentration is then mixed with lysed red blood cells to a hematocrit concentration equivalent to 55%. The blood mixtures are then spotted onto filter paper in ½ inch circles. The spotted cards are randomly selected throughout the lot and the

concentrations tested. Each new lot of cards is tested against a standard curve prepared from the previously approved lots.

The stability of the standards and controls were determined by studies that support the expiration date of 12 months.

d. Detection limit:

The limit of the blank was determined by calculating 2 SD from the mean of n=26 sample aliquots (zero standard) in one run on a single day using each of the three assay procedures. The analytical sensitivity was estimated to be 2.2 ng/mL for the Over night Eluate, 1.5 ng/mL 3 Hour Eluate and 2.3 ng/mL Over Night Direct.

e. Analytical specificity:

Studies were performed to assess common or known substances that could interfere with the method. Hemoglobin up to 1200 mg/dL, bilirubin, conjugated and unconjugated up to 300 mg/dL, and lipids up to 1875 mg/dL caused no detectable interference.

Cross-reactivity was assessed by testing compounds whose structures could potentially cause interference. The lists of compounds tested are listed below:

Substance	Cross Reactivity	Substance	Cross Reactivity
21-Desoxycortisol	2.4 %	Cholesterol	<0.01 %
16α-Hydroxyprogestrone	1.2 %	Corticosterone	<0.01 %
11-Desoxycortisol	0.6 %	Cortisol Glucuronide	<0.01 %
Progesterone	0.5 %	Cortisone	<0.01 %
5-Pregnen-3β,17-Diol-20-one 3 sulfate	0.2 %	Cortisone 21-Sulphate Sodium Salt	<0.01 %
Cortisol	0.06 %	Dehydroisoandrosterone	<0.01 %
Desoxycorticosterone	0.06 %	Dehydroepiandrosterone Sodium Sulphate	<0.01 %
1-Dehydrotestosterone	<0.01 %	Dexamethasone	<0.01 %
5β-Dihydrocortisol	<0.01 %	Estriol	<0.01 %
5β-Dihydrocortisone	<0.01 %	Estrone	<0.01 %
6β-Hydroxycortisol	<0.01 %	Prednisolone	<0.01 %
11-Dehydrocorticosterone	<0.01 %	Prednisone	<0.01 %
16α-Hydroxypregnenolone	<0.01 %	Pregnenolone	<0.01 %
17α-Estradiol	<0.01 %	Pregnenolone Sulphate, Sodium Salt	<0.01 %
17α-Hydroxypregnenolone	<0.01 %	Spironolactone	<0.01 %
17β-Estradiol	<0.01 %	Testosterone	<0.01 %
20α-Hydroxyprogesterone	<0.01 %	Tetrahydrocortisol	<0.01 %
Aldosterone	<0.01 %	Tetrahydrocorisone	<0.01 %

Studies were pe

f. *Assay cut-off:*

See expected values below.

2. <u>Comparison studies:</u>

a. *Method comparison with predicate device:*
A retrospective study was conducted to compare the results obtained with the Accuwell 17-OHP EIA to those obtained by a currently marketed neonatal 17-OHP screening device. Test samples were submitted to the study as blinded neonatal dried blood spots collected in sequence under

routine screening conditions from a U.S. department of public health laboratory. Original screening results for each sample using the predicate test kit were also obtained from the submitting laboratory for method comparison.

A summary of results of the method comparisons are provided in Tables 9 – 20, below. (Samples interpreted below as "Follow-Up" were not confirmed as positive for CAH.)

Table 9: Predicate vs. Accuwell O/N Direct

Values at the 99th, 97.5th, and 95th Percentiles for a Population of Babies **≥2500 gm and 0-1 Days** of Age at Sample Collection

		99th Percentile					97.5th Percentile					95th Percentile			
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 27.5	≥ 27.5	Totals:	**Predicate**		< 25.8	≥ 25.8	Totals:	**Predicate**		< 21.8	≥ 21.8	Totals:
Normal	< 43.8 N=130	114	**16**	130	Normal	< 43.8 N=130	112	**18**	130	Normal	< 43.8 N=130	100	**30**	130
Follow-Up	≥ 43.8 N = 3	**0**	3	3	Follow-Up	≥ 43.8 N = 3	**0**	3	3	Follow-Up	≥ 43.8 N = 3	**0**	3	3
	Totals:	114	19	133		Totals:	112	21	133		Totals:	100	33	133

The Accuwell 17-OHP EIA (ON Direct) results for this population were: mean =16.5 ng/mL, with a range of 3.7 to 85.6 ng/mL; while the predicate kit yielded: mean =22.6 ng/mL, with a range of 10.1 to 86.0 ng/mL

The correlation was found to be: y (Predicate) = 0.970 (Accuwell ON Direct) + 6.569, R = 0.9570

Table 10: Predicate vs. Accuwell O/N Eluate

Values at the 99th, 97.5th, and 95th, Percentiles for a

		99th Percentile					97.5th Percentile					95th Percentile			
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 23.9	≥ 23.9	Totals:	**Predicate**		< 22.3	≥ 22.3	Totals:	**Predicate**		< 20.2	≥ 20.2	Totals:
Normal	< 43.8 N=130	106	**24**	130	Normal	< 43.8 N=130	103	**27**	130	Normal	< 43.8 N=130	101	**29**	130
Follow-Up	≥ 43.8 N = 3	**0**	3	3	Follow-Up	≥ 43.8 N = 3	**0**	3	3	Follow-Up	≥ 43.8 N = 3	**0**	3	3
	Totals:	106	27	133		Totals:	103	30	133		Totals:	101	32	133

Population of Babies **≥2500 gm and 0-1 Days** of Age at Sample Collection

The Accuwell 17-OHP EIA (ON Eluate) results for this population were: mean =16.7 ng/mL, with a range of 5.3 to 65.6 ng/mL; while the predicate kit yielded: mean =22.6 ng/mL, with a range of 10.1 to 86.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.049 (Accuwell ON Direct) + 5.066, R =

0.9257

Table 11: Predicate vs. Accuwell 3 Hour Eluate
Values at the 99th, 97.5th, and 95th Percentiles for a
Population of Babies **≥2500 gm and 0-1 Days** of Age at Sample Collection

		99th Percentile					97.5th Percentile					95th Perce	
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up			**Accuwell**	Normal	Follow up
Predicate		< 23.0	≥ 23.0	Totals:	**Predicate**		< 21.7	≥ 21.7	Totals:	**Predicate**		< 19.8	≥ 19.8
Normal	< 43.8 N=130	104	**26**	130	Normal	< 43.8 N=130	103	**27**	130	Normal	< 43.8 N=130	99	**31**
Follow-Up	≥ 43.8 N = 3	**0**	3	3	Follow-Up	≥ 43.8 N = 3	**0**	3	3	Follow-Up	≥ 43.8 N = 3	**0**	3
	Totals:	104	29	133		Totals:	103	30	133		Totals:	99	34

The Accuwell 17-OHP EIA (3Hr Eluate) results for this population were: mean =17.3 ng/mL, with a range of 5.1 to 71.1 ng/mL; while the predicate kit yielded: mean =22.6 ng/mL, with a range of 10.1 to 86.0 ng/mL.

The correlation was found to be: y (Predicate) = 0.998 (Accuwell ON Direct) + 5.410, R = 0.9291

Table 12: Predicate vs. Accuwell O/N Direct
Values at the 95th Percentile for a
Population of Babies **≥2500 gm and 2-3 Days** of Age at Sample Collection

		95th Percentile		
	Accuwell	Normal	Follow-up	
Predicate		< 18.5	≥ 18.5	Totals:
Normal	< 29.2 N=118	113	**5**	118
Follow-Up	≥ 29.2 N = 15	**0**	15	15
	Totals:	113	20	133

The Accuwell 17-OHP EIA (ON Direct) results for this population were: mean =11.3 ng/mL, with a range of 3.4 to 81.1 ng/mL; while the predicate kit yielded: mean =16.2 ng/mL, with a range of 6.9 to 81.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.045 (Accuwell ON Direct) + 4.392, R = 0.9785

Table 13: Predicate vs. Accuwell O/N Eluate

Values at the 95th Percentile for a

Population of Babies ≥**2500 gm and 2-3 Days** of Age at Sample Collection

		95th Percentile		
	Accuwell	Normal	Follow-up	
Predicate		< 18.7	≥ 18.7	Totals:
Normal	< 29.2 N=118	114	**4**	118
Follow-Up	≥ 29.2 N = 15	**0**	15	15
	Totals:	114	19	133

The Accuwell 17-OHP EIA (ON Eluate) results for this population were: mean =12.2 ng/mL, with a range of 3.4 to 67.5 ng/mL; while the predicate kit yielded: mean =16.2 ng/mL, with a range of 6.9 to 81.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.156 (Accuwell ON Eluate) + 2.030, R = 0.9729

Table 14: Predicate vs. Accuwell 3 Hour Eluate

Values at the 95th Percentile for a

Population of Babies ≥**2500 gm and 2-3 Days** of Age at Sample Collection

		95th Percentile		
	Accuwell	Normal	Follow-up	
Predicate		< 17.7	≥ 17.7	Totals:
Normal	< 29.2 N=118	115	**3**	118
Follow-Up	≥ 29.2 N = 15	**0**	15	15
	Totals:	115	18	133

The Accuwell 17-OHP EIA (3Hr Eluate) results for this population were: mean =12.8 ng/mL, with a range of 4.5 to 69.6 ng/mL; while the predicate kit yielded: mean =16.2 ng/mL, with a range of 6.9 to 81.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.150 (Accuwell ON Direct) + 1.495, R = 0.9691

Table 15: Predicate vs. Accuwell O/N Direct
Values at the 97.5th and 95th Percentiles for a Population of **Babies ≥2500 gm and ≥ 4 Days** of Age at Sample Collection

97.5th Percentile					95th Percentile				
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 14.8	≥ 14.8	Totals:	**Predicate**		< 11.5	≥ 11.5	Totals:
Normal	< 21.9 N=192	181	**11**	192	Normal	< 21.9 N=192	170	**22**	192
Follow-Up	≥ 21.9 N = 5	**0**	5	5	Follow-Up	≥ 21.9 N = 5	**0**	5	5
	Totals:	181	16	197		Totals:	170	27	197

The Accuwell 17-OHP EIA (ON Direct) results for this population were: mean =7.3 ng/mL, with a range of 2.2 to 22.6 ng/mL; while the predicate kit yielded: mean =9.5 ng/mL, with a range of 2.7 to 31.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.090 (Accuwell ON Direct) + 1.565, R = 0.9538

Table 16: Predicate vs. Accuwell O/N Eluate
Values at the 97.5th and 95th Percentiles for a Population of Babies **≥2500 gm and ≥ 4 Days** of Age at Sample Collection

97.5th Percentile					95th Percentile				
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 15.2	≥ 15.2	Totals:	**Predicate**		< 13.6	≥ 13.6	Totals:
Normal	< 21.9 N=192	181	**11**	192	Normal	< 21.9 N=192	178	**14**	192
Follow-Up	≥ 21.9 N = 5	**1**	4	5	Follow-Up	≥ 21.9 N = 5	**0**	5	5
	Totals:	182	15	197		Totals:	178	19	197

The Accuwell 17-OHP EIA (ON Eluate) results for this population were: mean =7.8 ng/mL, with a range of 1.4 to 26.5 ng/mL; while the predicate kit yielded: mean =9.5 ng/mL, with a range of 2.7 to 31.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.070 (Accuwell ON Eluate) + 1.172, R = 0.9142

Table 17: Predicate vs. Accuwell 3 Hour Eluate

Values at the 97.5th and 95th Percentiles for a
Population of **Babies ≥2500 gm and ≥ 4 Days** of Age at Sample Collection

		97.5th Percentile					95th Percentile		
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 15.6	≥ 15.6	Totals:	**Predicate**		< 14.1	≥ 14.1	Totals:
Normal	< 21.9 N=192	176	**16**	192	Normal	< 21.9 N=192	174	**18**	192
Follow-Up	≥ 21.9 N = 5	**0**	5	5	Follow-Up	≥ 21.9 N = 5	**0**	5	5
	Totals:	176	21	197		Totals:	174	23	197

The Accuwell 17-OHP EIA (3Hr Eluate) results for this population were: mean =8.3 ng/mL, with a range of 2.2 to 28.4 ng/mL; while the predicate kit yielded: mean =9.5 ng/mL, with a range of 2.7 to 31.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.024 (Accuwell 3Hr Eluate) + 1.081, R = 0.9350

Table 18: Predicate vs. Accuwell O/N Direct

Values at the 99th and 97.5th Percentiles for a
Population of Babies **1400 - 2500 gm and 1-6 Days** of Age at Sample Collection

		99th (100th) Percentile					97.5th Percentile		
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 46.0	≥ 46.0	Totals:	**Predicate**		< 43.9	≥ 43.9	Totals:
Normal	< 45.1 N=28	28	**0**	28	Normal	< 40.3 N=26	26	**0**	26
Follow-Up	≥ 45.1 N = 2	**1**	1	2	Follow-Up	≥ 40.3 N = 4	**3**	1	4
	Totals:	29	1	30		Totals:	29	1	30

The Accuwell 17-OHP EIA (ON Direct) results for this population were: mean =19.3 ng/mL, with a range of 6.5 to 47.8 ng/mL; while the predicate kit yielded: mean =25.5 ng/mL, with a range of 9.0 to 65.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.22 (Accuwell ON Direct) + 1.971, R = 0.9556

Table 19: Predicate vs. Accuwell O/N Eluate
Values at the 99th and 97.5th Percentiles for a
Population of Babies **1400 - 2500 gm and 1-6 Days** of Age at Sample Collection

		99th (100th) Percentile					97.5th Percentile		
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 31.7	≥ 31.7	Totals:	**Predicate**		< 28.4	≥ 28.4	Totals:
Normal	< 45.1 N=28	24	**4**	28	Normal	< 40.3 N=26	23	**3**	26
Follow-Up	≥ 45.1 N = 2	**1**	1	2	Follow-Up	≥ 40.3 N = 4	**1**	3	4
	Totals:	25	5	30		Totals:	24	6	30

The Accuwell 17-OHP EIA (ON Eluate) results for this population were: mean =19.2 ng/mL, with a range of 6.7 to 40.2 ng/mL; while the predicate kit yielded: mean =25.5 ng/mL, with a range of 9.0 to 65.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.234 (Accuwell ON Direct) + 1.812, R = 0.8770

Table 20: Predicate vs. Accuwell 3Hr Eluate
Values at the 99th and 97.5th Percentiles for a
Population of Babies **1400 - 2500 gm and 1-6 Days** of Age at Sample Collection

		99th (100th) Percentile					97.5th Percentile		
	Accuwell	Normal	Follow-up			**Accuwell**	Normal	Follow-up	
Predicate		< 33.3	≥ 33.3	Totals:	**Predicate**		< 27.7	≥ 27.7	Totals:
Normal	< 45.1 N=28	26	**2**	28	Normal	< 40.3 N=26	23	**3**	26
Follow-Up	≥ 45.1 N = 2	**1**	1	2	Follow-Up	≥ 40.3 N = 4	**2**	2	4
	Totals:	27	3	30		Totals:	25	5	30

The Accuwell 17-OHP EIA (3Hr Eluate) results for this population were: mean =19.3 ng/mL, with a range of 6.6 to 39.2 ng/mL; while the predicate kit yielded: mean =25.5 ng/mL, with a range of 9.0 to 65.0 ng/mL.

The correlation was found to be: y (Predicate) = 1.174 (Accuwell 3Hr Eluate) + 2.795, R = 0.8421

b. Matrix comparison:

Not applicable.

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):

   See the method comparison study above and the expected values below.

4. Clinical cut-off:

   See expected values below.

5. Expected values/Reference range:
   In a separate study of 444 infants whose samples were collected for testing at 1-3days of age and whose birth weights were ≥ 2500 gm, 17-OHP concentrations were measured using each of the Accuwell 17-OHP methods. Samples were collected on S&S filter paper no. 903 and stored for up to 7 months prior to Accuwell testing. Based on the results obtained, the sponsor provides the following guidelines in the labeling for samples taken at 1-3 days of age from babies with birth weights ≥ 2500 gm. The data show the cut-off values at which re-testing or other follow-up should be considered.

Accuwell Expected Values at the 95th, 97.5th and 99th Percentiles for a Population of Babies ≥2500 gm and 1-3 Days of Age at Sample Collection

Accuwell O/N Direct		**17-OHP (ng/mL serum)**		
		Percentiles		
Age (days)	n	95th	97.5th	99th
1-3	444	20.8	25.0	27.8

Accuwell O/N Eluate		**17-OHP (ng/mL serum)**		
		Percentiles		
Age (days)	n	95th	97.5th	99th
1-3	444	19.1	21.7	23.9

Accuwell 3 hr Eluate		17-OHP (ng/mL serum)		
		Percentiles		
Age (days)	n	95th	97.5th	99th
1-3	444	19.3	21.5	24.3

In the same study, a small sample (n = 91) of infants with birth weights < 2500 gm were tested using the Accuwell 17-OHP assay methods. The study showed the following:

Accuwell Expected Values at the 95th, 97.5th and 99th Percentiles for a Population of Babies <2500 gm and 1-3 Days of Age at Sample Collection

Accuwell O/N Direct		17-OHP (ng/mL serum)		
		Percentiles		
Age (days)	N	95th	97.5th	99th
1-3	91	33.9	43.9	46.4

Accuwell O/N Eluate		17-OHP (ng/mL serum)		
		Percentiles		
Age (days)	n	95th	97.5th	99th
1-3	91	25.7	31.7	40.9

Accuwell 3 Hr Eluate		17-OHP (ng/mL serum)		
		Percentiles		
Age (days)	n	95th	97.5th	99th
1-3	91	26.3	32.5	40.5

In a study of 391 infants whose samples were collected for testing at ≥ 4 days of age and whose birth weights were ≥ 2500 gm, 17-OHP concentrations were measured using each of the Accuwell 17-OHP methods. Samples were collected on S&S filter paper no. 903 and stored for up to 7 months prior to Accuwell testing. Based on the results obtained, the following guidelines can be given for samples taken at ≥ 4 days of age from babies with birth weights ≥ 2500 gm. The data show the cut-off values at which re-testing or other follow-up should be considered.

Accuwell Expected Values at the 95th, 97.5th and 99th Percentiles for a Population of Babies ≥2500 gm and 1-3 Days of Age at Sample Collection

Accuwell O/N Direct		17-OHP (ng/mL serum)		
		Percentiles		
Age (days)	n	95th	97.5th	99th
≥ 4	391	11.5	14.8	21.1

Accuwell O/N Eluate		17-OHP (ng/mL serum)		
		Percentiles		
Age (days)	n	95th	97.5th	99th
≥ 4	391	13.6	15.2	19.5

Accuwell 3 hr Eluate		17-OHP (ng/mL serum)		
		Percentiles		
Age (days)	n	95th	97.5th	99th
≥ 4	391	14.1	15.6	19.4

The values shown here should be used only as a guideline, and were calculated based on a specific population of samples as defined by the manufacturer. The sponsor recommends in the labeling that each laboratory should establish its own cut-off values for 17-OHP in its own population.

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.