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

A. 510(k) Number:

k132834

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Polymed Therapeutics, Inc.

F. Proprietary and Established Names:

Fastep S10 hCG Serum/Urine Combo Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JHI	Class II	21 CFR 862.1155, Human Chorionic Gonadotropin (HCG) test system	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:
   The Fastep S10 hCG Serum/Urine Combo Test is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or

serum specimens. This kit is intended for use as an aid in early detection of pregnancy.

This product is only intended for prescription use in clinical laboratories and is not intended for point-of-care use settings.

3. Special conditions for use statement(s):

For prescription use only in clinical laboratories

4. Special instrument requirements:
Not applicable,

I. Device Description:

The Fastep S10 hCG Serum/Urine Combo Test measures the presence of the hormone Human Chorionic Gonadotropin (hCG) in human urine or serum to aid in the early detection of pregnancy. The test devices are in two different formats: Strip and Cassette. Results are read visually by the end user. For a positive result, a colored line appears in the test and control regions of the device. For a negative result, a colored line appears in the control region, but no colored line appears in the test region of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
QuickVue One-Step hCG Combo Test

2. Predicate 510(k) number(s):
k020801

3. Comparison with predicate:

Similarities

Item	Candidate Device: Fastep S10 hCG Serum/Urine Combo Test (k132834)	Predicate: QuickVue One-Step hCG Combo Test (k020801)
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy.	Same
Specimen	Urine or serum	Same
Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Detection reagent	Colloidal gold	Same
Read time	Serum: 5 minutes Urine: 3 minutes	Same

Cut-Off Values	10 mIU/mL for serum and 20 mIU/mL for urine	Same
Configurations	Strip and cassette	Same

Differences

	Candidate Device: Fastep S10 hCG Serum/Urine Combo Test (k132834)	Predicate: QuickVue One-Step hCG Combo Test (k020801)
Intended Population	For prescription use in clinical laboratories only	For prescription use in point of care sites

K. Standard/Guidance Document Referenced (if applicable):
None referenced

L. Test Principle:

The Fastep S10 hCG Serum/Urine Combo Test is a lateral flow chromatographic immunoassay. When the absorbent end of the test is immersed into a serum or urine sample, the sample is absorbed into the device by capillary action and mixes with the antibody-dye conjugate (mouse anti-beta hCG monoclonal antibody), flowing across the pre-coated (goat anti hCG polyclonal antibody) membrane. At analyte concentrations above the target cut off, it produces a colored test line that indicates a positive result. When analyte concentrations are below the cutoff, no colored band shows in the test region, indicating a negative result.

One colored line appears in the control region "C" regardless of the presence of hCG. The presence of this colored line in the "C" region serves as verification for sufficient volume and proper flow and as a control for the reagents. No line in the "C" region indicates that the test is invalid.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Negative serum and urine specimens were spiked with varying hCG (commercially available and traceable to the 4th WHO international Standard) concentrations. The spiked samples were measured in 10 replicates using 3 different lots for each format. Tests were performed by three different operators for each lot in 2 runs per day for 5 days. Results are shown in the following tables:

Serum Strip format

hCG Concentration (mIU/mL)	Overall % agreement	Lot 1		Lot 2		Lot 3	
		-	+	-	+	-	+
0	100%	30	0	30	0	30	0
2	100%	30	0	30	0	30	0
4	100%	30	0	30	0	30	0
6	100%	30	0	30	0	30	0
8	91%	28	2	27	3	27	3
9	71%	23	7	20	10	21	9
10	97%	1	29	2	28	0	30
12	100%	0	30	0	30	0	30
14	100%	0	30	0	30	0	30
16	100%	0	30	0	30	0	30
18	100%	0	30	0	30	0	30
20	100%	0	30	0	30	0	30
50	100%	0	30	0	30	0	30
100	100%	0	30	0	30	0	30
150	100%	0	30	0	30	0	30

Serum Cassette format

hCG Concentration (mIU/mL)	Overall % agreement	Lot 1		Lot 2		Lot 3	
		-	+	-	+	-	+
0	100%	30	0	30	0	30	0
2	100%	30	0	30	0	30	0
4	100%	30	0	30	0	30	0
6	100%	30	0	30	0	30	0
8	90%	27	3	28	2	26	4
9	74%	24	6	21	9	22	8
10	96%	1	29	1	29	2	28
12	100%	0	30	0	30	0	30
14	100%	0	30	0	30	0	30
16	100%	0	30	0	30	0	30
18	100%	0	30	0	30	0	30

20	100%	0	30	0	30	0	30
50	100%	0	30	0	30	0	30
100	100%	0	30	0	30	0	30
150	100%	0	30	0	30	0	30

Urine Strip format

hCG Concentration (mIU/mL)	Overall % agreement	Lot 1		Lot 2		Lot 3	
		-	+	-	-	+	-
0	100%	30	0	30	0	30	0
5	100%	30	0	30	0	30	0
10	100%	30	0	30	0	30	0
12	100%	30	0	30	0	30	0
14	100%	30	0	30	0	30	0
16	88%	25	5	28	2	26	4
18	66%	21	9	19	11	19	11
20	96%	1	29	2	28	1	29
22	100%	0	30	0	30	0	30
25	100%	0	30	0	30	0	30
30	100%	0	30	0	30	0	30
35	100%	0	30	0	30	0	30
50	100%	0	30	0	30	0	30
75	100%	0	30	0	30	0	30
100	100%	0	30	0	30	0	30
250	100%	0	30	0	30	0	30

Urine Casette format

hCG Concentration (mIU/mL)	Overall % agreement	Lot 1		Lot 2		Lot 3	
		-	+	-	-	+	-
0	100%	30	0	30	0	30	0
5	100%	30	0	30	0	30	0
10	100%	30	0	30	0	30	0
12	100%	30	0	30	0	30	0
14	100%	30	0	30	0	30	0
16	80%	24	6	26	4	22	8

18	57%	19	11	17	13	15	15
20	98%	1	29	0	30	1	29
22	100%	0	30	0	30	0	30
25	100%	0	30	0	30	0	30
30	100%	0	30	0	30	0	30
35	100%	0	30	0	30	0	30
50	100%	0	30	0	30	0	30
75	100%	0	30	0	30	0	30
100	100%	0	30	0	30	0	30
250	100%	0	30	0	30	0	30

b. Linearity/assay reportable range:

Not applicable. This is a qualitative test.

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

This test is calibrated with reference material traceable to the World Health Organization (WHO) 4th International Standard for Chorionic Gonadotropin (75/589).

The stability testing protocol and acceptance criteria used to support the shelf life were reviewed and found to be acceptable. The sponsor claims a 24-month shelf life for the test when stored at 39-86ºF (4-30ºC).

d. Detection limit

See section M.1.a above. The sponsor claims that the cut-off values of serum and urine are 10 mIU/mL and 20 mIU/mL hCG, respectively.

e. Analytical specificity:

A cross-reactivity study was performed by adding known amounts of LH, FSH and TSH to negative and positive samples using three different lots by three operators. Results are shown in the following table:

Negative Sample Spiked with	Operator A	Operator	Operator C
LH (300mIU/mL)	—	—	—
FSH (1000mIU/mL)	—	—	—
TSH (1000µIU/mL)	—	—	—

Positive Sample Spiked with	Operator A	Operator	Operator C
LH (300mIU/mL)	+	+	+
FSH (1000mIU/mL)	+	+	+
TSH (1000μIU/mL)	+	+	+

No cross-reactivity was observed for either urine or serum samples at the concentrations that were tested for LH, FSH and TSH.

To evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked into both hCG free and hCG positive samples. Each spiked sample was mixed for 5 minutes to ensure a homogeneous solution before testing. Each sample was tested using 3 different lots of the testing kit. The sponsor states that none of the following substances at the stated concentrations interfere with the assay.

Interferents	Concentration	Interferents	Concentration
Acetaminophen	20mg/dL	Methanol	10%
Acetoacetic Acid	2000mg/dL	Albumin	2000mg/dL
Asorbic Acid	20mg/dL	Glucose	2000mg/dL
B-hydroxybutyrate	2000mg/dL	Bilirubin	2mg/dL
Caffeine	20mg/dL	Atropine	20mg/dL
Ephedrine	20mg/dL	Estriol-17-beta	1400ug/dL
Gentisic Acid	20mg/dL	Hemoglobin	500mg/dL
Phenylpropanolamine	20mg/dL	Pregnanediol	1500ug/dL
Salicylic Acid	20mg/dL	Thiophene	20mg/dl
Phenothiazine	20mg/dL	Ampicillin	20mg/dl
EDTA	80mg/dL	Tetracycline	20mg/dl
Acetylsalicylic Acid	20mg/dL	Ketone	20mg/dl
Benzoylecgonine	10mg/dL	Codeine	6ug/dL
Cannabinol	10mg/dL	Ethanol	1.00%

A pH study was performed to evaluate the device. Results demonstrate that urine and serum samples with pH 4.0 – 9.0, do not affect the results.

A specific gravity study was performed to evaluate the device. Results demonstrate that urine samples are not affected when the specific gravity range is from 1.00 to 1.035.

Interference studies to hCG β-core fragment were also performed in samples containing intact hCG in the presence of β-core fragment at concentrations of 1.0 x 10^6 picomoles. The results indicate that high levels of hCG β -core fragment (≥ 500 pmol /L) can lead to a positive results for hCG-free samples (in both serum and urine

formats). No false negative results were identified for the sample with 1.0 x 10^6 picomoles of beta core.

A high dose hook effect study was performed by spiking high levels of hCG concentrations 62,500-2,000,000 mIU/mL (62,500, 125,000, 250,000, 500,000, 1,000,000 and 2,000,000) into negative urine and serum samples and evaluating the test result lines. No hook effect was observed up to 2,000,000 mIU/mL hCG.

f. Assay cut-off:

See section M.1.a above. The sponsor claims that the cut-off values of serum and urine are 10 mIU/mL and 20 mIU/mL hCG, respectively.

2. Comparison studies:

a. Method comparison with predicate device:
A method comparison study was performed, comparing the results obtained from the Fastep S10 hCG Serum/Urine Combo Test to the results from the predicate device. 100 urine and 100 serum samples were collected from 100 women (about half of whom were less than 5 weeks pregnant). All samples were randomly masked prior to analysis. Samples were tested by three different health professionals with the candidate device (using three different lots) and the predicate device. Testing was performed according to the labeling. The results are shown in the tables below.
*All discrepant results were from samples from women subjects who were early in pregnancy (less than 5 weeks pregnant based on day of last menstrual period) or were from samples with hCG concentrations around the cut-off of the device.

Summary Results for Urine Strip

		Predicate Device	
		+	-
New Device	+	47	0
	-	2*	51

Summary Results for Urine Cassette

		Predicate Device	
		+	-
New Device	+	48	0
	-	1*	51

Summary Results for Serum Strip

		Predicate Device	
		+	-
New Device	+	48	0
	-	1*	51

Summary Results for Serum Cassette Predicate Device

	Cleared device	+	-
New Device	+	48	0
	-	1*	51

b. Matrix comparaison:

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):
Not applicable.

4. Clinical cut-off:
Not applicable.

5. Expected values/Reference range:
The labeling states "hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200IU/mL about 2-3 months after the last menstrual period. The Fastep S10 hCG Serum/Urine Combo Test Device (Urine/Serum) has a cut-off level of 10mIU/ml in serum and 20mIU/ml in urine. Reportedly, a level of 10-25 mIU/mL or more, is present 7-10 days after conception. Patients suspected to be pregnant but showing negative test results should be re-tested with first morning specimens obtained 48-72 hours later."

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.