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

A. 510(k) Number:

k112101

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 hCG Pregnancy Serum/Urine Cassette Test

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

The Polymed Therapeutics Fastep™ hCG Pregnancy Serum/Urine Cassette Tests is a rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in serum or urine specimen to aid in the early detection of pregnancy. For professional use only.

3. Special conditions for use statement(s):

The Polymed Therapeutics Fastep™ hCG Pregnancy Serum/Urine Cassette Test is intended for prescription use (clinical laboratory, Point of Care (POC) and physician's office laboratory (POL) use).

The test kits are for health care professionals use including professionals at physician's office labs (POLs) and Point-of-care sites (POC).

4. Special instrument requirements:

None, this device is a visually-read, single-use device

I. Device Description:

The Fastep™ hCG Pegnancy Serum/Urine Test is a rapid test to detect the presence of hCG in serum or urine specimens in a qualitative format as an aid in the early detection of pregnancy. The test is available in a cassette format.

Devices are packaged one device per pouch and should be used immediately after opening.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Teco Diagnostics One-Step Urine/Serum Combo Pregnancy Test

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

k964461

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy. For POLs settings.	Same
Specimen type	Urine or serum	Same

Similarities		
Item	Device	Predicate
Test Principle	Lateral flow sandwich Immunochromatographic assay	Same
Detection reagent	Colloidal Gold	Same
Read time	Serum: 5 minutes Urine: 3 minutes	Same
Specificity	Negative at: hFSH: 1000mIU/mL hTSH: 1000 uIU/mL	Same

Differences		
Item	Device	Predicate
Cutoff	20 mIU/ml	25 mIU/ml
Specificity	No effect from: hLH: 300 mIU/ml	No effect from: hLH: 500 mIU/ml

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

Not applicable

L. Test Principle:

The Polymed Therapeutics Fastep™ hCG Pregnancy Serum/Urine Cassette Tests is aqualitative, lateral flow sandwich immunochromatographic assay for the detection of human chorionic gonadotropin (hCG) in serum and urine. The membrane is pre-coated with monoclonal anti-hCG antibodies on the test band region and anti-mouse antibodies in the control band region. During testing, the sample reacts with the dye conjugate (mouse anti-hCG antibody-colloidal gold conjugate) which has been pre-coated on the test strip. The mixture them migrates upward on the membrane chromatographically by capillary action to react with anti-hCG antibodies on the membrane and generate a colored line. 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. The absence of the test line in the "T" region indicates a negative result. Two colored lines should be observed in the viewing window at the "C" and "T" regions in order to indicate a positive result. No line in the "C" region will indicate that the test is invalid and needs to be repeated.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A Point of Care (POC) study was conducted to evaluate the reproducibility of the

device by the intended operators. The study was conducted at 3 healthcare POC sites by 9 healthcare professionals (HCPs) (3 operators per site). 3 different lots (one lot per site) were used for the study. The reproducibility of the device was evaluated by testing negative urine and serum samples spiked with hCG, traceable to WHO International 4th Standard, (0 mIU/ml, 10 mIU/ml, 15 mIU/ml, 20mIU/ml, 40mIU/ml and 100mIU/ml). All samples were blinded to the HCPs. Each concentration level was tested 5 times a day for 5 consecutive days. The results are summarized below:

Urine:

hCG levels (mIU/ml)	Total No. Tested	% Agreement	Site 1		Site 2		Site 3		Total Results	
			(+)	(-)	(+)	(-)	(+)	(-)	(+)	(-)
0	225	100	0	75	0	75	0	75	0	225
10	225	100	0	75	0	75	0	75	0	225
15	225	100	0	75	0	75	0	75	0	225
20	225	96.9	71	4	74	1	73	2	218	7
40	225	100	75	0	75	0	75	0	225	0
100	225	100	75	0	75	0	75	0	225	0

Serum:

hCG levels (mIU/ml)	Total No. Tested	No. Tested per site	Site 1		Site 2		Site 3		Total Results	
			(+)	(-)	(+)	(-)	(+)	(-)	(+)	(-)
0	225	100	0	75	0	75	0	75	0	225
10	225	100	0	75	0	75	0	75	0	225
15	225	100	0	75	0	75	0	75	0	225
20	225	96.9	72	3	73	2	73	2	218	7
40	225	100	75	0	75	0	75	0	225	0
100	225	100	75	0	75	0	75	0	225	0

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

A high dose hook effect study was performed by spiking high levels of hCG concentrations 0-1,000,000 mIU/ml (0, 10, 20, 100, 62,500, 125,000, 250,000, 500,000 and 1,000,000) into negative urine and serum samples and evaluating the test result lines. A positive result was observed up to 1,000,000 mIU/ml. Therefore no hook effect was observed for urine/serum samples with hCG concentrations up to 1,000,000 mIU/ml.

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

The Polymed Therapeutics Fastep™ hCG Pregnancy Serum/Urine Cassette and Dipstick Test is standardized to the WHO Fourth International Standard 75/589

A shelf-life stability test of the device was performed in real-time and the results showed that the device is stable for 24 months when stored at 2-8˚C or room temperature (up to 30˚C). This is a single use device and labeling states that test should be performed immediately after opening pouch.

d. Detection limit:

The sensitivity of the device was tested by spiking pooled male urine and serum with varying concentrations (0, 10, 12.5, 15.0, 17.5, 20, 24, 30.0, 35.0, 40, and 100 mIU/mL) of hCG traceable to WHO International 4th Standard . Three separate lots of the device were tested in house using randomization methods. Results are summarized below.

All 3 lots combined (Urine samples):

Urine Controls**hCG Levels (mIU/ml)**	**Number Tested**	**Number of Negative**	**Number of Positive**	**% Negative**	**% Positive**
0	75	75	0	100	0
10.0	75	75	0	100	0
12.5	75	69	6	92.0	8.0
15.0	75	36	39	48.0	52.0
17.5	75	6	69	8.0	92.0
20.0	75	0	75	0	100
24.0	75	0	75	0	100
30.0	75	0	75	0	100
35.0	75	0	75	0	100
40.0	75	0	75	0	100
100.0	75	0	75	0	100

All 3 lots combined (Serum samples):

hCG Levels (mIU/ml)	**Number Tested**	**Number of Negative**	**Number of Positive**	**% Negative**	**% Positive**
0	75	75	0	100	0
10.0	75	75	0	100	0
12.5	75	64	11	85.3	14.7
15.0	75	37	38	49.3	50.7
17.5	75	7	68	9.3	90.7
20.0	75	0	75	0	100
24.0	75	0	75	0	100
30.0	75	0	75	0	100
35.0	75	0	75	0	100
40.0	75	0	75	0	100
100.0	75	0	75	0	100

The sponsor claims a cutoff for positive as 20mIU/mL.

e. Analytical specificity:

i.) A cross-reactivity study was performed by adding known amounts of LH, FSH and TSH to pooled negative urine and serum samples. Samples were tested in duplicate. Samples were tested at 0 and 20 mIU/ml of hCG. The cross-reactivity results are shown below:

Urine hCG:

Concentration (IU/ml)	HCG 0 mIU/ml		HCG 20 mIU/ml	
	Result 1	Result 2	Result 1	Result 2
LH 300 mIU/mL	(-)	(-)	(+)	(+)
FSH 1000 mIU/mL	(-)	(-)	(+)	(+)
TSH 1000 μIU/ml	(-)	(-)	(+)	(+)

Serum hCG

Concentration (IU/ml)	HCG 0 mIU/ml		HCG 20 mIU/ml	
	Result 1	Result 2	Result 1	Result 2
LH 300 mIU/mL	(-)	(-)	(+)	(+)
FSH 1000 mIU/mL	(-)	(-)	(+)	(+)
TSH 1000 μIU/ml	(-)	(-)	(+)	(+)

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

ii.) An interference study was performed by adding known amounts of potential interfering substances to urine and serum samples that contain 0 and 20, mIU/mL of hCG. The sponsor states that none of the following substances at the stated concentrations interfere with the assay.

Urine Samples:

Interfering substance	Concentration
Acetaminophen	20 mg/dl
Acetylsalicylic Acid	20 mg/dl
Albumin	2000 mg/dl
Ascorbic Acid	20 mg/dl
Atropine	20 mg/dl
Bilirubin	2 mg/dl
Caffeine	20 mg/dl
EDTA	80 mg/dl
Ethanol	1%
Gentensic Acid	20 mg/dl
Glucose	2 g/dl
Hemoglobin	1 mg/dl
Methanol	1%
Salicylic Acid	20 mg/dl

Serum Samples:

Interfering substance	Concentration
Acetaminophen	20 mg/dl
Acetylsalicylic Acid	20 mg/dl
Albumin	2000 mg/dl
Ascorbic Acid	20 mg/dl
Atropine	20 mg/dl
Bilirubin	40 mg/dl
Caffeine	20 mg/dl
EDTA	80 mg/dl
Ethanol	1%
Gentensic Acid	20 mg/dl
Glucose	2 g/dl
Hemoglobin	125 mg/dl
Methanol	1%
Salicylic Acid	20 mg/dl
Triglyceride	1200 mg/dl

iii.) A pH study was performed to evaluate the device and the sponsor concluded that urine and serum samples with pH 3.0 – 8.5 would not affect the results.

iv.) A specific gravity study was performed to evaluate the device and the sponsor concluded that the performance of Fastep hCG Serum/Urine Pregnancy test at negative and cutoff points are not affected when the specific gravity range of urine specimens is at 1.00 to 1.03.

v.) Interference studies to β-core hCG were also performed; the results indicate there was no interference with β-core hCG up to 8.53 pmol/L

f. Assay cut-off:

See 1.d. above

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed comparing the Fastep™ cassette panel to the Teco One-Step Combo Card Test (predicate device). Testing was conducted by one HCP at 4 POC sites. 19-46 individuals per site were enrolled in the study (N=145). The samples were collected from women who fit the following categories: childbearing age, suspected pregnant women, (e.g. within days of missing the expected menses), women early in pregnancy, (e.g. within the first 30 days of pregnancy), and the first trimester of pregnancy. All samples were masked prior to analysis. Testing was performed according to the labeling.

Urine:

	Teco One-Step Combo Card Test (predicate kit)			
		+	-	Total
Fastep™ Cassette Panel	+	59	0	59
	-	0	86	86
	Total	59	86	145

Serum:

	Teco One-Step Combo Card Test(Predicate Kit)			
		+	-	Total
Fastep™ Cassette Panel	+	58	0	58
	-	1	86	87
	Total	59	86	145

b. Matrix comparison:

This test is only applicable to urine or serum samples. Performance with both of these matrices is described in the performance sections above.

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 “Negative results are expected in healthy non-pregnant women” The amount of hCG will vary greatly with gestational age and between individuals.”

The telephone number of the distributor has been provided in the labeling for technical assistance.

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.