K132834

510(k) SUMMARY

JAN - 9 2014

1. Date: December 20, 2013
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4. Device Name: Fastep S10 hCG Serum/Urine Combo Test
   Classification: Class II

Product Code	CFR #	Panel
JHI	862.1155, Human chorionic gonadotropin (HCG) test system	Clinical Chemistry

5. Predicate Devices:
   K020801, QuickVue One-Step hCG Combo test
   Quidel Corporation
6. Intended 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.
7. Device Description
   Fastep S10 hCG Serum/Urine Combo Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine or serum for the early detection of pregnancy. During pregnancy, HCG is produced by the placenta shortly after the embryo attaches to the uterine lining. The test devices are in two different formats: Strip, Cassette.
8. Substantial Equivalence Information
   A summary comparison of features of the Fastep S10 hCG Serum/Urine Combo Test and the predicate device is provided in the following table.

Item	Device	Predicate
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy. For prescription use in clinical laboratories, not for POC	Same except that the predicate can be used for POC use settings.

	use.	
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
Usage	For prescription use	Same
Cut-Off Values	10 mIU/mL for serum and 20 mIU/mL for urine	Same
Configurations	Strip and cassette	Same
Storage	4 – 30°C	15 - 30°C
Reading Control Window	1 window for result reading and control reading	2 windows: Small Control Window and Large Read Result Window
Read Result Window	No preprinted line on membrane	Pre-printed horizontal blue line on membrane
Positive result	2 colored red/pinkish horizontal lines in control and test regions	Pink and blue plus sign in large Window, along with a blue line in small Window
Negative result	1 colored line in control region only	Blue horizontal line in Large Window, along with a blue line in small Window

9. Test Principle

It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a 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 concentration above the target cut off, it produces a colored test line that indicates a positive result. When analyte concentration is below the cutoff, no colored band shows in the test region, indicating a negative result. No line in the "C" region indicates that the test is invalid.

10. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility/Cut-Off Value

Negative serum 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)	Lot 1 HCG1203004		Lot 2 HCG1204001		Lot 3 HCG1204023		Overall Agreement
	# of negative	# of positive	# of negative	# of positive	# of negative	# of positive	
0	30	0	30	0	30	0	100%
2	30	0	30	0	30	0	100%
4	30	0	30	0	30	0	100%
6	30	0	30	0	30	0	100%
8	28	2	27	3	27	3	91%
9	23	7	20	10	21	9	71%
10	1	29	2	28	0	30	97%
12	0	30	0	30	0	30	100%
14	0	30	0	30	0	30	100%
16	0	30	0	30	0	30	100%
18	0	30	0	30	0	30	100%
20	0	30	0	30	0	30	100%
50	0	30	0	30	0	30	100%
100	0	30	0	30	0	30	100%
150	0	30	0	30	0	30	100%

Serum Cassette format

hCG Concentration (mIU/mL)	Lot 1 HCG1212025		Lot 2 HCG1305011		Lot 3 HCG1306024		Overall Agreement
	# of negative	# of positive	# of negative	# of positive	# of negative	# of positive	
0	30	0	30	0	30	0	100%
2	30	0	30	0	30	0	100%
4	30	0	30	0	30	0	100%
6	30	0	30	0	30	0	100%
8	27	3	28	2	26	4	90%
9	24	6	21	9	22	8	74%
10	1	29	1	29	2	28	96%
12	0	30	0	30	0	30	100%
14	0	30	0	30	0	30	100%
16	0	30	0	30	0	30	100%
18	0	30	0	30	0	30	100%
20	0	30	0	30	0	30	100%
50	0	30	0	30	0	30	100%
100	0	30	0	30	0	30	100%
150	0	30	0	30	0	30	100%

Negative 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.

Urine Strip format

hCG Concentration (mIU/mL)	Lot 1 HCG1203004		Lot 2 HCG1204001		Lot 3 HCG1204023		Overall Agreement
	# of negative	# of positive	# of negative	# of positive	# of negative	# of positive	
0	30	0	30	0	30	0	100%
5	30	0	30	0	30	0	100%
10	30	0	30	0	30	0	100%
12	30	0	30	0	30	0	100%
14	30	0	30	0	30	0	100%
16	25	5	28	2	26	4	88%
18	21	9	19	11	19	11	66%
20	1	29	2	28	1	29	96%
22	0	30	0	30	0	30	100%
25	0	30	0	30	0	30	100%
30	0	30	0	30	0	30	100%
35	0	30	0	30	0	30	100%
50	0	30	0	30	0	30	100%
75	0	30	0	30	0	30	100%
100	0	30	0	30	0	30	100%
250	0	30	0	30	0	30	100%

Urine Cassette format

hCG Concentration (mIU/mL)	Lot 1 HCG1212025		Lot 2 HCG1305011		Lot 3 HCG1306024		Overall Agreement
	# of negative	# of positive	# of negative	# of positive	# of negative	# of positive	
0	30	0	30	0	30	0	100%
5	30	0	30	0	30	0	100%
10	30	0	30	0	30	0	100%
12	30	0	30	0	30	0	100%
14	30	0	30	0	30	0	100%
16	24	6	26	4	22	8	80%
18	19	11	17	13	15	15	57%
20	1	29	0	30	1	29	98%
22	0	30	0	30	0	30	100%
25	0	30	0	30	0	30	100%
30	0	30	0	30	0	30	100%
35	0	30	0	30	0	30	100%
50	0	30	0	30	0	30	100%
75	0	30	0	30	0	30	100%
100	0	30	0	30	0	30	100%

250	0	30	0	30	0	30	100%

Cut-off values of 10 mIU/mL for serum and 20 mIU/mL for urine are established.

b. Stability

Stable at 4-30°C for 24 months based on the accelerated stability study at 50°C and real time stability determination at both 4°C and 30°C.

c. Specificity / Cross Reactivity

High Dose Effect

Negative urine (serum) samples were spiked with varying high hCG concentrations. The spiked samples were tested by 3 different lots and 3 different operators. No hook effect was observed at these concentrations. Typical results are shown in the following table.

hCG Concentration (mIU/mL)	**Operator A**	**Operator B**	**Operator C**
62500	+	+	+
125000	+	+	+
250000	+	+	+
500000	+	+	+
1000000	+	+	+
2000000	+	+	+

Effects of hCG β-core fragment

Serum samples with 0mIU/mL hCG and 10mIU/mL hCG were spiked with varying concentrations of β-core fragment hCG. These samples were tested by 3 different lots and 3 different operators. No difference was observed for different lots and different operators. Interference was observed at concentrations of 500 pmol/L and above for hCG free serum samples, and no interference was observed for serum samples spiked with 10mIU/mL hCG. The same results were observed for urine samples with 0mIU/mL hCG and 20mIU/mL hCG.

β-core fragment hCG (pmol/L)	Sample with 0mIU/mL hCG	Serum Sample with 10mIU/mL hCG	Urine Sample with 20mIU/mL hCG
0	–	+	+
10	–	+	+
20	–	+	+
50	–	+	+
100	–	+	+
200	–	+	+
500	+	+	+
1000	+	+	+
2000	+	+	+
5000	+	+	+
10000	+	+	+
20000	+	+	+
65000	+	+	+
100000	+	+	+
500000	+	+	+
1X10e6	+	+	+

2X10e6	+	+	+

Effects of glycoprotein LH, FSH and TSH

Negative and positive samples (0 and 20 mIU/mL hCG for urine, and 0 and 10 mIU/mL hCG for serum) were spiked with various concentrations of other glycoprotein hormones such as LH, FSH, and TSH. Samples were tested using three different lots by three operators. Typical results are shown in the following table.

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

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

d. Interference

To evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked in both hCG free and hCG positive (10mIU/mL for serum, 20mIU/mL for urine) samples. Each spiked urine 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. Results are shown in the following table.

Interferents	3 minutes for urine (5 minutes for serum)						10 minutes					
	0mIU/mL hCG			Positive hCG			0mIU/mL hCG			Positive hCG		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
Acetaminophen (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Acetoacetic Acid (2000mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Asorbic Acid (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
B-hydroxybutyrate (2000mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Caffeine (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Ephedrine (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Gentisic Acid (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Phenylpropanolamine(20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Salicylic Acid (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Phenothiazine (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
EDTA (80mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Acetylsalicylic Acid (20mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Benzoylecgonine (10mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Cannabinol (10mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Codeine (6ug/dL)	–	–	–	+	+	+	–	–	–	+	+	+
Ethanol (1.0%)	–	–	–	+	+	+	–	–	–	+	+	+
Methanol (10%)	–	–	–	+	+	+	–	–	–	+	+	+
Albumin (2000mg/dL)	–	–	–	+	+	+	–	–	–	+	+	+

Glucose (2000mg/dL)	−	−	−	+	+	+	−	−	−	+	+	+
Bilirubin (2mg/dL)	−	−	−	+	+	+	−	−	−	+	+	+
Atropine (20mg/dL)	−	−	−	+	+	+	−	−	−	+	+	+
Estriol-17-beta (1400ug/dL)	−	−	−	+	+	+	−	−	−	+	+	+
Hemoglobin (500mg/dL)	−	−	−	+	+	+	−	−	−	+	+	+
Pregnanediol (1500ug/dL)	−	−	−	+	+	+	−	−	−	+	+	+
Thiophene (20mg/dl)	−	−	−	+	+	+	−	−	−	+	+	+
Ampicillin (20mg/dl)	−	−	−	+	+	+	−	−	−	+	+	+
Tetracycline(20mg/dl)	−	−	−	+	+	+	−	−	−	+	+	+
Ketone(20mg/dl)	−	−	−	+	+	+	−	−	−	+	+	+

All data show that there is no interference for the listed compounds at the stated concentrations.

e. Effect of Urine Specified Gravity and Urine pH

Negative and positive urine samples containing 0 and 20 mIU/mL hCG were tested at pH values from 4 to 9 using 3 different lots by 3 different operators. Typical results are shown in the following table.

pH	0 mIU/mL hCG			20mIU/mL hCG		
	Operator A	Operator B	Operator C	Operator A	Operator B	Operator C
4	−	−	−	+	+	+
5	−	−	−	+	+	+
6	−	−	−	+	+	+
7	−	−	−	+	+	+
8	−	−	−	+	+	+
9	−	−	−	+	+	+

Negative and positive urine samples containing 5 and 20 mIU/mL hCG were tested at density values ranging from 1.000 to1.035 using 3 different lots by 3 different operators. Typical results are shown in the following table.

Specific Gravity (g/mL)	5 mIU/mL hCG			20mIU/mL hCG		
	Operator A	Operator B	Operator C	Operator A	Operator B	Operator C
1.000	−	−	−	+	+	+
1.010	−	−	−	+	+	+
1.015	−	−	−	+	+	+
1.025	−	−	−	+	+	+
1.035	−	−	−	+	+	+

Data show that there is no interference from pH and specific gravity of tested urine samples.

2. Comparison Studies

A method comparison study was performed, comparing the results obtained from the Fastep S10 hCG Serum/Urine Combo Test to the results from predicate devices (QVUE). 100 each urine or serum samples were collected from 100 women (about half of them were pregnant, early stage at less than 5 weeks). Samples were randomly collected at various times throughout the day. Ages ranged from 20 to 49 years. The samples were

blind labeled. Samples were tested by three different health professionals with the proposed and the predicate devices. Each person could only perform tests for one device format. For example, a person who tested the strips could not test the cassettes. Each person tested three different lots of the device and one predicate device at the same time, but not sequentially. Typical results are shown in the following tables.

Summary Results for Urine Strip

	Cleared device	+	-
New Device	+	**47**	**0**
	-	**2**	**51**

Summary Results for Urine Cassette

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

Summary Results for Serum Strip

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

Summary Results for Serum Cassette

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

The study result shows that over 95% agreements for positive samples, and 100% agreement for negative samples.

3. Clinical Studies

   Not applicable

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that Fastep S10 hCG Serum/Urine Combo Test is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2014

POLYMED THERAPEUTICS, INC
C/O J.J XIA
LSI INTERNATIONAL
12828 DOE LANE
GAITHERSBURG MD 20878

Re: K132834
Trade/Device Name: Fastep S10 HCG Serum/Urine Combo Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: JHI
Dated: November 18, 2013
Received: November 20, 2013

Dear Mr. Xia:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k132834

Device Name: Fastep S10 hCG Serum/Urine Combo Test

Indications 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.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (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 Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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