Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I 510(k) Number:

K182328

II Applicant:

True Diagnostics, Inc.

III Proprietary and Established Names:

VeriClear Digital Early Result Pregnancy Test

IV Regulatory Information:

Product Code(s)	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 862.1155 - Human Chorionic Gonadotropin (HCG) Test System	CH - Clinical Chemistry

V Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Human Chorionic Gonadotropin (hCG)

C Type of Test:

Qualitative chromatographic immunoassay

VI Intended Use/Indications for Use:

A Intended Use(s):

See Indication for use below.

B Indication(s) for Use:

VeriClear Digital Early Result Pregnancy Test is a rapid chromatographic immunoassay for qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

VeriClear Digital Early Result Pregnancy Test is intended for over-the-counter (OTC) use.

D Special Instrument Requirements:

None

VII Device Description:

A Device Description:

The VeriClear Digital hCG Early Result Pregnancy Test is a qualitative lateral flow immunoassay for the detection of hCG. Each device is provided in a sealed pouch with instructions for use and a desiccant package to control the moisture during storage. The device may be used in midstream or dip mode (with a user-supplied cup) and consists of a plastic housed test stick containing an immunochromatographic strip and electronic and optical components along with a microprocessor and specific algorithms to digitally display test results. The VeriClear Digital Early Result Pregnancy Test is powered by a battery and the test results are displayed on the device's liquid crystal display (LCD) as either "YES+" (for a positive result), "NO-" (for a negative result) or "?" (for an invalid result) on the display.

B Principle of Operation:

The VeriClear Digital hCG Early Result Pregnancy Test is a sandwich immunoassay employing mouse monoclonal antibodies specific for hCG, which are immobilized on the membrane as test line, and goat anti-mouse IgG immobilized on the membrane as control line. After the urine specimen is applied to the device, the hCG present in the specimen will react with a mouse anti-hCG monoclonal antibody conjugate. The conjugate complex migrates along the membrane towards the test and control zones. A digital component integral with the chromatographic strip reads and displays the result of the immunochemical reaction on an LCD (Liquid Crystal Display) screen of the device. The test result is shown on the LCD screen of the device. A "YES+" test result indicates that the pregnancy hormone (hCG) was detected, a "NO-" test result indicates that no hCG was detected, and a "?" result indicates an invalid test.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☐	☒
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:	☒	☐

1. Instrument Name:
   VeriClear Digital Early Result Pregnancy Test

2. Specimen Identification:
   Urine

3. Specimen Sampling and Handling:
   N/A

4. Calibration:
   N/A

5. Quality Control:
   N/A

VIII Substantial Equivalence Information:

A Predicate Device Name(s):
First Response Gold Digital Pregnancy Test

B Predicate 510(k) Number(s):
K123567

C Comparison with Predicate:

Device & Predicate Device(s):	K182328	K123567
General Device Characteristic Similarities		
Intended Use/Indications for Use	Qualitative detection of hCG as an aid in early detection of pregnancy.	Same
Early Detection Claim	Detection of pregnancy as early as 5 days before the expected period or as early as 6	Same

Device & Predicate Device(s):	K182328	K123567
	days before the day of the missed period.	
Test Principle	Lateral flow qualitative immunochromatographic assay with digital display of the result	Same
Sample Matrix	Urine	Same
Traceability	WHO 4th International Standards for hCG	Same
Limit of Detection	10 mIU/mL	Same
Time to Result	3 minutes	Same
General Device Characteristic Differences		
hCG Isoforms Detected	Intact hCG Hyperglycosylated hCG hCG β-subunit	Intact hCG Hyperglycosylated hCG hCG β-subunit hCG β-core fragment
Test Result	Digital readout: result show as YES+ (pregnant), NO- (not pregnant) or ? (invalid)	Yes+ = pregnant No- = not pregnant

IX Standards/Guidance Documents Referenced:

None referenced

X Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A precision study was performed using human urine samples spiked with hCG, traceable to the 4th WHO International Standard to obtain samples with hCG concentrations of 0 mIU/mL, 3 mIU/mL, 5 mIU/mL, 8.5 mIU/mL, 10 mIU/mL, 25 mIU/mL, 50 mIU/mL, and 100 mIU/mL and three lots of VeriClear Digital Early Result Pregnancy Test devices. Each sample was tested using both simulated midstream and dip methods. The tests were performed over the course of 5 consecutive days by 5 different operators. A total of 150 replicates per testing mode (2 replicates/run x 5 operators x 5 days x 3 lots) were obtained for each hCG concentration tested.

Inter-Lot Reproducibility of VeriClear Digital Early Result Pregnancy Test Device (Simulated MidStream Method):

hCG Level (mIU/mL)	Total # of Tests	VeriClear Digital Early Result Pregnancy Test Device (Simulated Midstream Mode)								
		Observed Results Lot 1			Observed Results Lot 2			Observed Results Lot 3		
		P (+)	N (-)	% Positive	P (+)	N (-)	% Positive	P (+)	N (-)	% Positive
0.0	150	0	50	0%	0	50	0%	0	50	0%
3.0	150	0	50	0%	0	50	0%	0	50	0%
5.0	150	0	50	0%	0	50	0%	0	50	0%
8.5	150	35	15	70%	34	16	68%	35	15	70%
10.0	150	50	0	100%	50	0	100%	50	0	100%
25.0	150	50	0	100%	50	0	100%	50	0	100%
50.0	150	50	0	100%	50	0	100%	50	0	100%
100.0	150	50	0	100%	50	0	100%	50	0	100%

Inter-Lot Reproducibility of VeriClear Digital Early Result Pregnancy Test Device (Dip Method):

hCG Standards (mIU/mL)	Total # of Test	VeriClear Digital Early Result Pregnancy Test Device (Dip Mode)								
		Observed Results Lot 1			Observed Results Lot 2			Observed Results Lot 3		
		P (+)	N (-)	% Positive	P (+)	N (-)	% Positive	P (+)	N (-)	% Positive
0.0	150	0	50	0%	0	50	0%	0	50	0%
3.0	150	0	50	0%	0	50	0%	0	50	0%
5.0	150	0	50	0%	0	50	0%	0	50	0%
8.5	150	34	16	68%	35	15	70%	34	16	68%
10.0	150	50	0	100%	15	0	100%	50	0	100%
25.0	150	50	0	100%	15	0	100%	50	0	100%
50.0	150	50	0	100%	15	0	100%	50	0	100%
100.0	150	50	0	100%	15	0	100%	50	0	100%

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

Structurally non-related compounds

Negative urine samples and positive urine samples (containing 10 mIU/mL hCG) were spiked with potentially interfering exogenous and endogenous substances, and then

tested using 2 lots of the candidate device. No interference effect was observed at the concentrations tested, as reported in the below table.

Substance	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Human serum Albumin	2000 mg/dL
Hemoglobin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Cortisol	200 ng/dL
EDTA	80 mg/dL
Phenylpropanolamine	20 mg/dL
Ephedrine	20 mg/dL
Gentisic acid	20 mg/dL
Glucose	2000 mg/dL
Tetracycline	20 mg/dL
Uric acid	10 mg/dL
Bilirubin	20 mg/dL
Ethanol	0.1 %
Ethanol	1 %
Salicylic Acid	20 mg/dL

Cross reactivity of structurally-related compounds:

Negative urine samples and positive (10 mIU/mL hCG) urine samples were spiked with hLH, hFSH, and hTSH, and tested using two lots of devices. No cross reactivity was observed at the concentrations tested, as reported in the below table.

Substance	Concentration
hLH	1000 mIU/mL
hFSH	1000 mIU/mL
hTSH	1000 µIU/mL

Effect of urine pH and Specific Gravity:

Negative urine samples and positive (10 mIU/mL hCG) urine samples were adjusted to pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 and then tested using the candidate device. The positive and negative hCG results were not affected by urine pH ranges between 4.0 and 9.0.

Negative urine samples and positive (10 mIU/mL hCG) urine samples were adjusted to Specific Gravity values of 1.003, 1.005, 1.010, 1.015, 1.020 and 1.030 and then tested using the candidate device. The positive and negative hCG results were not affected by urine Specific Gravity ranges between 1.003 and 1.030.

Effect of hCG β-core fragment:

Negative urine samples (0 and 5 mIU/mL hCG) and positive urine samples (10, 25 and 20,000 mIU/mL hCG) were spiked with hCG β-core fragment at concentrations of 51,000 pmol/L, 102,000 pmol/L, 204,000 pmol/L and 408,000 pmol/L and tested using 2 lots of the candidate device. All samples yielded correct results with hCG β-core fragment concentrations up to 408,000 pmol/L.

High dose hook effect study:

Negative urine samples were spiked with hCG at concentrations up to 450,000 mIU/mL, and tested in 2 replicates per lot using two lots of devices for each format. The results demonstrated that no hook effect was observed at hCG concentrations up to 450,000 mIU/mL.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The VeriClear Digital Early Result Pregnancy Test is traceable to the World Health Organization 4th International Standard for hCG.

   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 of the devices stored in the sealed foil pouches at 39-86 ºF (4-30 ºC).

6. Detection Limit:

   See section IX.A.1.

7. Assay Cut-Off:

   See section IX.A.1.

8. Accuracy (Instrument):

   See section IX.B.1

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Urine samples were collected from 366 women for pregnancy testing. Of the 366 women, 215 were suspected to be pregnant. Patient samples were randomly collected at various time throughout the day. Ages of these women ranged from 19 to 41 years. All samples were masked and randomized prior to testing, and were tested by professionals using the candidate device (VeriClear Digital Early Result Pregnancy Test; in simulated midstream mode and in dip mode) and the predicate (First Response Digital Early Result Pregnancy Test; in dip mode). The results are summarized in the table below.

	Predicate Device			
Candidate Device (Simulated Midstream Mode)		**Positive**	**Negative**	**Total**
	Positive	215	0	215
	Negative	0	151	151
	Total	215	151	366

	Predicate Device			
Candidate Device (Dip Mode)		**Positive**	**Negative**	**Total**
	Positive	215	0	215
	Negative	0	151	151
	Total	215	151	366

2. Matrix Comparison:

   Not Applicable. The device is intended for urine samples only.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Detection of hCG in Early Pregnancy Clinical Samples

A total of 616 urine samples were collected from 56 different women (25 - 43 years old) who planned to become pregnant. The women were followed throughout their conception cycles with urine collected from day -9 to day +1 of their expected period. The VeriClear Digital Early Result Pregnancy Test device detected hCG in 69% of samples from five days before the expected menstrual period and 100% of samples from one day before the expected menstrual period. The early pregnancy detection results are summarized below:

Day in cycle relative to EMP	hCG Positive Ratio (%)		Overall Pregnancy Detection Rate (%)
	Simulated Midstream Mode	Dip Mode	
-9 days	0%	0%	0%
-8 days	0%	0%	0%
-7 days	12%	12%	12%
-6 days	41%	41%	41%
-5 days	69%	69%	69%
-4 days	94%	94%	94%
-3 days	98%	98%	98%
-2 days	98%	98%	98%
-1 days	100%	100%	100%
0 days	100%	100%	100%
+1 days	100%	100%	100%

E Lay User Study

A lay user study was performed at an intended use site with a total of 216 women with diverse educational and professional backgrounds, ages 18 years and older. 108 lay users tested the simulated midstream method and 108 lay users tested the dip method of the device. Lay users were only provided with the package insert prior to performing the study. Lay user results compared to professional user results are listed below.

Pregnancy Result	Lay user vs. Professional user	
	Simulated Midstream Mode	Dip Mode
Pregnant	9/9 (100%)	7/7 (100%)
Non-pregnant	99/99 (100%)	101/101 (100%)
Total	108/108 (100%)	108/108 (100%)

Besides testing their own urine samples, lay users also tested 4 spiked urine samples around the cut-off level, at concentrations of 3.0, 7.0, 8.5 and 10 mIU/mL hCG. A total of 216 samples were tested by using the VeriClear Digital Early Result Pregnancy Test at each hCG level. Among the 216 devices tested at each hCG level, 108 were tested via the simulated midstream mode, while the other 108 were tested via the dip mode. Lay user results compared to professional user results are listed below.

hCG level mIU/mL	Lay user vs. Professional user					
	Simulate Midstream Mode			Dip Mode		
	Positive Results		Percentage of Agreement	Positive Results		Percentage of Agreement
	Lay user	Professional user		Lay user	Professional user	
3.0	0	0	100%	0	0	100%
7.5	52	52	100%	56	56	100%
8.5	77	77	100%	73	73	100%
10.0	108	108	100%	108	108	100%

All the lay users participated in the study were given a questionnaire to rate how well they understand the instruction in the package insert. A Flesch-Kincaid reading analysis was performed on the OTC package insert and the score demonstrated a reading Grade Level of 7.9. The result of the questionnaire reflected that the consumers found the test easy to use and that they did not have trouble understanding the labeling or interpreting results.

F Specificity Study to Determine False-Positive Result Rate

A study was performed to determine the incidence of false positive test results from VeriClear Digital Early Result Pregnancy Test among non-pregnant women in three age groups: 15–41 years of age (pre-menopausal), 42–55 years of age (peri-menopausal) and >55 year of age (post- menopausal). A total of 320 subjects provided urine samples including 100 from pre-menopausal patients, 111 from peri-menopausal patients, and 109 from post-menopausal patients. All 320 urine samples were tested with three lots of VeriClear Digital Early Result Pregnancy Test devices. No positive results were observed in any of the age groups.

G Clinical Cut-Off:

Not applicable.

H Expected Values/Reference Range:

Not applicable.

I Other Supportive Instrument Performance Characteristics Data:

Not applicable.

XI Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

XII Conclusion:

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