May 15, 2019

True Diagnostics, Inc.
% Jinjie Hu, Principle Consultant
Axteria BioMed Consulting Inc.
8040 Cobble Creek Circle
Potomac, MD 20854

Re: k182328
Trade/Device Name: VeriClear™ Digital Early Result Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: April 5, 2019
Received: April 5, 2019

Dear Jinjie Hu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182328

Device Name
VeriClear Digital Early Result Pregnancy Test

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

SUBMITTER:

True Diagnostics, Inc.
2782 Loker Ave. West
Carlsbad, CA 92010

Contact person:

Jinjie Hu,
Axteria BioMed Consulting Inc.
8040 Cobble Creek Circle
Potomac, MD 20854
Tel: 1-(301)814-4985
Email: jinjiehu@axteriabiomed.com

Date prepared: May 13, 2019

Purpose of Submission: To obtain a substantial equivalence for the VeriClear™ Digital Early Result Pregnancy Test

510(k) Number:
K182328

A. Purpose for Submission:
New Device

B. Measure:
Human Chorionic Gonadotropin (hCG)

C. Type of Test:
Qualitative chromatographic immunoassay

D. Applicant:
True Diagnostics, Inc. U.S.A

E. Proprietary and Established Names:
VeriClear™ Digital Early Result Pregnancy Test

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1155 Human Chorionic Gonadotropin (hCG) test System

2. Classification:
   Class II

3. Product Code:
   LCX: hCG, Over the Counter

4. Panel:
   Chemistry (75)

G. Intended Use:

1. Intended use(s):
   See Indication for use below.

2. 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.

3. Special condition for use statement(s):
   This device is intended for over-the-counter (OTC) use.

4. Special instrument requirements:
   None

H. Device Description:

The VeriClear™ hCG Early Result Pregnancy Test utilize the identical immunochemical principles for the detection of hCG in the urine as in K172257. It is a device intended for use by the lay user in the early detection of pregnancy by way of a series of immunochromatographic assay using colloidal gold as a direct label. The subject 510(k) device differs in which it provides a digital display of the test result for the consumer to read in place of the colored lines of the above referenced analog device. The VeriClear™ Digital Early Result Pregnancy Test device incorporates electronic and optical components along with a microprocessor and specific algorithms into the plastic housing. VeriClear™ Digital Early Result Pregnancy Test is capable of correctly determining and interpreting the test results correctly, and shows the results as “YES+” (Pregnancy), “NO-” (Non-pregnancy) or “?” (Error) on a display. The VeriClear™ Digital Early Result Pregnancy Test is powered by battery and the testing results will be displayed on the screen until the battery is used up.

All components are integrated and unitized into the plastic housing.

I. Substantial Equivalence Information:

1. Predicate device name(s):

   Church & Dwight Co., FIRST RESPONSE GOLD DIGITAL PREGNANCY TEST

2. Predicate K number(s):

K123567

3. Comparison with predicate

Feature	**Proposed Device** **Pending**	**Predicate Device** **K123567**
Similarities		
Intended Use	Qualitative detection of hCG for an aid in early detection of pregnancy.	Same
Target User	Over-the-counter	Same
Test Principle	Lateral flow qualitative immunochromatographic assay with digital display for the result	Same
Electronic components	Microprocessor with specific circuitry and algorithms; LCD read out with batteries as power source	Same
Early detection claim	Detection of pregnancy as early as 5 days before the expected period or as early as 6 days before the day of the missed period.	Same
Sample Matrix	Urine	Same
Traceability	WHO 4th International Standards for hCG	Same
Analytical Sensitivity	10 mIU/ml	Same
Time to Result	3 minutes	Same
Sample Application	Stream and Dipping Methods	Same
Sampling Time	5 seconds in urine stream 5 seconds in cup (Dipping)	Same
Device Format	Single Use	Same
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 Read Out, result show as Yes, No or Invalid	Visual read, result show control line, test line

J. Standard/Guidance Document referenced (if applicable):

None referenced ◦

K. Test Principle:

The VeriClear™ Digital Early Result Pregnancy Test uses the same test principle as used in the analog counterpart device – VeriClear™ hCG Early Result Pregnancy Test (K172257). The VeriClear™ Digital Early Result Pregnancy Test detects the presence of hCG in a urine sample of a pregnant woman by way of a series of immunochemical reactions via component reagents striped onto a chromatographic strip in a plastic housing.

A digital component integrated with the test strip reads and displays the result of the immunochemical reaction on an LCD (Liquid Crystal Display) screen of the device.

The test is performed by placing the absorbent collection tip into the urine stream for 5 seconds, or alternatively, by fully immersing the collection tip in a urine sample collected in a urine cup for 5 seconds. After urine is applied to The VeriClear™ Digital Early Result Pregnancy Test, the clock symbol starts blinking in about 30 seconds, which indicates the test has already started. The test result is shown on the LCD screen within 3 minutes. A "YES+" test result indicates the pregnancy hormone (hCG) was detected (Pregnant) and "NO-" test result indicates that no hCG was detected (Not pregnant).

L. Performance Characteristics (if/when applicable):

The sensitivity, precision, specificity, interference, method comparison, clinical early detection, clinical specificity and storage stability studies were tested and verified with the proposed devices**.** Software validation and reader reliable was performed specifically to ensure the performance of VeriClear™ Digital hCG Reader electronic read-out result**.** The VeriClear™ Digital hCG Reader meets the safety and EMC requirements of IEC/EN61010-1: 2001, IEC/EN61010-2-101: 2002, EN61326; 2006 and IEC61000-4-2.

A lay user study was conducted to evaluate two application methods (stream and dipping) and the easiness of use by following the instructions. The results demonstrate that the instruction manual of VeriClear™ Digital Early Result Pregnancy Test is understandable and clear enough for lay user, and the devices are easy to operate by following the instruction.

1. <u>Analytical performance:</u>

a. 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.

A within-lot precision test was performed using one lot of the VeriClear™ Digital Early Result Pregnancy Test. The test was performed in one day by a single operator. A total of 20 replicates for each level of standard (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) were obtained.

An inter-lot precision test was performed using three different lots of VeriClear™ Digital Early Result Pregnancy Test devices. The tests were performed over a course of five consecutive days by five different operators. On each day, and with each lot, each operator performed 2 replicates per run for each level of standard (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) using both simulated stream and dipping methods. A total of 150 replicate data points were obtained using all three lots.

Within-Lot Reproducibility of VeriClear™ Digital Early Result Pregnancy Test Device

HCG Standards (mIU/ml)	Total # of Test	VeriClear™ Digital Early Result Pregnancy Test Device Lot 1					
		Simulated Stream			Dipping		
		Negative	Positive	P/Total	Negative	Positive	P/Total
0	20	10	0	0/10	10	0	0/10
3.0	20	10	0	0/10	10	0	0/10
5.0	20	10	0	0/10	10	0	0/10
8.5	20	3	7	7/10	3	7	7/10
10	20	0	10	10/10	0	10	10/10
25	20	0	10	10/10	0	10	10/10
50	20	0	10	10/10	0	10	10/10
100	20	0	10	10/10	0	10	10/10

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

HCG Standards (mIU/ml)	Total # of Test	VeriClear™ Digital Early Result Pregnancy Test Device (Simulated Stream Method)								
		Observed Results Lot 1			Observed Results Lot 2			Observed Results Lot 3		
		P (+)	N (-)	P/Total	P (+)	N (-)	P/Total	P (+)	N (-)	P/Total
0	150	0	50	0/50	0	50	0/50	0	50	0/50

3.0	150	0	50	0/50	0	50	0/50	0	50	0/50
5.0	150	0	50	0/50	0	50	0/50	0	50	0/50
8.5	150	35	15	35/50	34	16	34/50	35	15	35/50
10	150	50	0	50/50	50	0	50/50	50	0	50/50
25	150	50	0	50/50	50	0	50/50	50	0	50/50
50	150	50	0	50/50	50	0	50/50	50	0	50/50
100	150	50	0	50/50	50	0	50/50	50	0	50/50

Inter-Lot Reproducibility of VeriClear™ Digital Early Result Pregnancy Test Device (Dipping Method)

HCG Standards (mIU/ml)	**Total # of Test**	**VeriClear™ Digital Early Result Pregnancy Test Device (Dip Method)**								
		Observed Results Lot 1			**Observed Results Lot 2**			**Observed Results Lot 3**		
		P (+)	N (-)	P/Total	P (+)	N (-)	P/Total	P (+)	N (-)	P/Total
0	150	0	50	0/50	0	50	0/50	0	50	0/50
3.0	150	0	50	0/50	0	50	0/50	0	50	0/50
5.0	150	0	50	0/50	0	50	0/50	0	50	0/50
8.5	150	34	16	34/50	35	15	35/50	34	16	34/50
10	150	50	0	50/50	15	0	50/50	50	0	50/50
25	150	50	0	50/50	15	0	50/50	50	0	50/50
50	150	50	0	50/50	15	0	50/50	50	0	50/50
100	150	50	0	50/50	15	0	50/50	50	0	50/50

Precision Study Result Summary- Operators

hCG level (mIU/ml)	**Operator 1**	**Operator 2**	**Operator 3**	**Operator 4**	**Operator 5**	**Over all % Positive**
0	0/60	0/60	0/60	0/60	0/60	0 %
3	0/60	0/60	0/60	0/60	0/60	0 %
5	0/60	0/60	0/60	0/60	0/60	0 %
8.5	42/60	42/60	42/60	40/60	41/60	69%
10	60/60	60/60	60/60	60/60	60/60	100%
25	60/60	60/60	60/60	60/60	60/60	100%
50	60/60	60/60	60/60	60/60	60/60	100%
100	60/60	60/60	60/60	60/60	60/60	100%

b. Linearity/assay reportable range:

Not applicable. This is a qualitative device.

c. High dose hook effect study:

Negative urine samples were spiked with hCG stock solution to a final concentration up to 450,000 mIU/ml, and then tested in 2 replicate per lot using two lots of devices. The results demonstrated that no hook effect was observed at hCG concentrations up to 450,000 mIU/ml.

d. Traceability:

The tests are calibrated against the WHO 4th International Standards for hCG.

e. Stability:

Testing protocol and acceptance criteria used to support the shelf life were reviewed and found to be acceptable. The sponsor claimed a 24-month shelf life of the devices stored in the sealed foil pouches at 39-86 ºF (4-30 ºC).

f. Detection limits (sensitivity):

An analytical sensitivity study was performed using negative human urine samples spiked with hCG traceable to the WHO 4th international standard for hCG to obtain final concentrations of 0, 3.0, 5.0, 7.0, 7.5,8.5, 9.0, 10, 12.5, 15 and 25 mIU/ml.

A total of 45 replicate (3 operators x 3 days x 5 replicates per run) data points were obtained for each lot at each level of hCG sample being tested, using both dipping and simulated stream methods.

The results are summarized in the following table.

hCG Standards Conc. (mIU/ml)	**# of positive result /# of total test**			**% Positive**
	Lot 1 Stream	**Lot 2 Dipping**	**Lot 3 Dipping**	
0	0/15	0/15	0/15	0 %
3.0	0/15	0/15	0/15	0 %
5.0	0/15	0/15	0/15	0 %
7.0	3/15	3/15	3/15	20 %
7.5	8/15	8/15	8/15	53.3 %
8.5	10/15	10/15	11/15	68.9 %
9.0	15/15	14/15	14/15	95.6 %
10.0	15/15	15/15	15/15	100 %
12.5	15/15	15/15	15/15	100 %
15.0	15/15	15/15	15/15	100 %

25.0	15/15	15/15	15/15	100 %

The results demonstrate that the analytical sensitivity of the VeriClear™ Digital Early Result Pregnancy Test (the lowest concentration yielding 100 % positive results) is 10 mIU/ml.

g. Analytical specificity

Structure non-related compounds

To evaluate potential interference from certain exogenous compounds, each interfering substance was prepared at 100X concentration bulk and spiked into negative urine and positive urine samples (containing 10mIU/ml hCG). Each spiked urine sample was mixed and to make sure a homogeneous solution before testing. Each sample was tested using 2 different lots of the testing kits.

Each sample was tested in 5 replicate per lot using two lots of devices. No interference effect was observed at the concentration tested.

The results are demonstrated below.

Interferent	**Concentration at which no significant interference was observed**
Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Human serum Albumin	2000 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 %
Salicylic Acid	20 mg/dL

Structure-related compounds:

Negative and positive urine contain 10 mIU/ml hCG were spiked with various concentrations of the following potential cross reactants: hLH, hFSH, and hTSH. The samples were tested by two operators using two lots of the test kits. No cross reactivity was observed at the concentrations tested below.

Reactant	**Concentration at which no significant interference was observed**
hLH	1000 mIU/ml
hFSH	1000 mIU/ml
hTSH	1000 µIU/ml

Effect of urine pH

Effects of urine pH were performed by adjusting urine pool to a pH range from 4 to 9 in 1 pH unit increment. The samples with spiked hCG concentrations or non-spiked hCG of different pH unit were tested by using VeriClear™ Digital Early Result Pregnancy Test Device. The results demonstrate that varying ranges of pH (from 4 to 9) does not interfere with the performance of the test.

Effect of urine specific gravity:

Effect of specific gravity of urine was determined by using across the specific gravity hCG-free urine samples of normal (1.030) to low (1.003). Each urine sample was spiked with hCG stock solution to a final concentration of 10 mIU/ml. The VeriClear™ Digital Early Result Pregnancy Test devices were tested in duplicate using the two negative and spiked urine samples. The results demonstrated that specific gravity ranges from 1.003 to 1.030 did not affect the expected results or accuracy of the result.

Effect of hCG β-core fragment:

Both hCG free and hCG standard samples (5 mIU/ml, 10 mIU/ml, 25 mIU/ml, 20,000 mIU/ml) 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. All the interference tests have been performed on two lots of VeriClear™ Digital Early Result Pregnancy Test devices. All devices yielded correct results with hCG β-core fragment concentration up to 408,000 pmol/L.

h. Assay cutoff

See detection limits section.

The results demonstrate that the analytical sensitivity of the VeriClear™ Digital Early

Result Pregnancy Test (the lowest concentration yielding 100 % positive results) is 10 mIU/ml.

2. Comparison studies:

a. Method comparison with predicate device:

Urine samples were collected from 366 women at physician offices for pregnancy testing and 215 of them were suspected to be pregnant. All samples were randomly collected at various time throughout the day. Ages of these women ranged from 19 to 41 years. Samples were masked and randomized by people who did not participate in the testing. All samples were tested by two different health care professionals. Each person tested with two different lots of device at same time. One lot was used by for simulated stream method; another lot was used for dipping method.

The results are summarized in the table below.

	First Response Digital Early Result Pregnancy Test			
VeriClear™ Digital Early Result Pregnancy Test (Simulated Stream Method)		Positive	Negative	Total
	Positive	215	0	215
	Negative	0	151	151
	Total	215	151	366

	First Response Digital Early Result Pregnancy Test			
VeriClear™ Digital Early Result Pregnancy Test (Dipping Method)		Positive	Negative	Total
	Positive	215	0	215
	Negative	0	151	151
	Total	215	151	366

b. Matrix comparison:
Not Applicable. The device is intended for urine samples only.

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):

4. Detection of hCG in Early Pregnancy Clinical Samples

A total of 616 urine samples were collected from 56 different women of 25 to 43 years old, who planned to become pregnant. These 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 positive 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 Stream	Dipping	
-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%

5. Lay User Study

The purpose of this study is to demonstrate that the intended users is able to safely and correctly perform the VeriClear™ Digital Early Result Pregnancy Test using their own urine and with the provided hCG control according to the Instruction for Use. A total of 109 female subjects with diverse educational and professional backgrounds and ages (between 18 to 63 years old) participated in the study. Lay users were only provided with the package insert prior to performing the study.

The comparison results between lay user and professional user are listed below:

Pregnancy Result	Lay user vs. Professional user	
	Simulated Stream	Dipping
Pregnant	9/9 (100%)	9/9 (100%)
Non-pregnant	100/100 (100%)	100/100 (100%)
Total	109/109 (100%)	109 /109(100%)

Besides testing their own urine samples, lay users also tested 4 blind hCG urine samples at hCG concentrations of 3.0 mIU/ml, 7.5 mIU/ml, 8.5 mIU/ml and 10 mIU/ml. A total of 109 samples were tested by using the VeriClear™ Digital Early Result Pregnancy Test at hCG each level. Among the 109 devices tested at each hCG level, 50 of them were tested in simulated stream method, while 59 were tested in dipping method. The test results

collected by lay user using VeriClear™ Digital Early Result Pregnancy Test device were also interpreted by the professional.

The results are summarized below:

hCG mIU/ml	Lay user vs. Professional user					
	Simulate Stream Method			Dipping Method		
	Positive Results		Percentage of Agreement	Positive Results		Percentage of Agreement
	Lay user	Professional user		Lay user	Professional user	
3	0	0	100%	0	0	100%
7.5	24	24	100%	28	28	100%
8.5	35	35	100%	41	41	100%
10	50	50	100%	59	59	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 to determine if the package insert content is appropriate for a reading Grade level of 5.5. The result of the questionnaire reflects that the consumers found the test easy to use and they did not have trouble understanding the labeling or interpreting results.

6. 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 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 pre-menopausal patients, 111 peri-menopausal patients, and 109 post-menopausal patients. All 320 urine samples were tested with three lots of VeriClear™ Digital Early Result Pregnancy Test devices and quantitatively analyzed for hCG level of each subject with Microwell Quantitative hCG test. Positive test results on VeriClear™ Digital Early Result Pregnancy Test device or hCG levels > 5.00 mIU/ml measured by Microwell Quantitative hCG test were referred to clinical confirmation of pregnancy. The results are summarized in table below:

Age Group	Urine specimens (n)	VeriClear™ Digital Early Result Pregnancy Test	Microwell Elisa Quantitative hCG Test	
		Positive Ratio (%)	Approx. Mean Concentration	Concentration Range
Pre-menopausal (15–41 years)	100	0/100 (0%)	1.04 mIU/ml	0.00–2.50 mIU/ml

Peri-menopausal (42–55 years)	111	0/100 (0%)	1.16 mIU/ml	0.45–2.00 mIU/ml
Post-menopausal (>55 years)	109	0/100 (0%)	1.11 mIU/ml	0.57–2.26 mIU/ml

7. Clinical Cut-off

Not applicable

8. Expected value/ Reference Range:

Not applicable