510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K193318

B Applicant

Acon Laboratories Inc.

C Proprietary and Established Names

Distinct® Early Detection Pregnancy Test

D 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

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Human chorionic gonadotropin (hCG)

C Type of Test:

Qualitative chromatographic immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Distinct® Early Detection Pregnancy Test is an aid for the early detection of pregnancy intended for home use. The device is a chromatographic immunoassay that performs qualitative detection of human chorionic gonadotropin (hCG) in urine. This test can help determine pregnancy as early as 6 days before the day of the missed period (5 days before the day of the expected period)

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The Distinct® Early Detection Pregnancy Test is a rapid chromatographic immunoassay for in vitro qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. It is for self-testing. The test strip and absorbent tip are assembled in a plastic housing.

B Principle of Operation:

The test strip contains monoclonal anti-hCG antibodies and goat anti-mouse polyclonal antibodies. The test result is shown in the result window and read visually after 3 minutes of urine application.

A blue sign of plus (+) at the test window indicates that hCG has been detected (pregnant). Absence of the plus (+) and only a blue line (-) in the Test Window suggests no hCG has been detected. To serve as a procedural control, a blue line will always appear in the Control Window indicating that proper volume of specimen has been added and membrane wicking has occurred.

V Substantial Equivalence Information:

A Predicate Device Name(s):
First Response Early Result Pregnancy Test

B Predicate 510(k) Number(s):
K123436

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193318	K123436
Device Trade Name	Distinct® Early Detection Pregnancy Test	First Response Early Result Pregnancy Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy	Same
Specimen	Urine	Same
Indications/Intended Users	Over the Counter (OTC)	Same
Test Principle	Lateral Flow Immunoassay	Same
Format	Dip and Midstream	Same
Detection Time	Early detection of pregnancy; 5 days before the expected period (6 days before the day of the missed period)	Same
General Device Characteristic Differences		
Traceability	WHO 5th International Standard for hCG	WHO 4th International Standard for hCG
Read Time	3 to 10 minutes	3 minutes

VI Standards/Guidance Documents Referenced:

CLSI EP07 Interference Testing in Clinical Chemistry.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The sponsor performed a study to evaluate the imprecision of the device with different trained operators using both formats. Thirty negative urine specimens were collected and spiked with WHO 5th International hCG standard to the following concentrations: 3, 6, 8, 10,

12, and 15 mIU/mL. Results were read in duplicate by three operators over five days and the results were read at 3 and 10 minutes using three lots of the device. Results are summarized below:

Dip Method:

hCG levels (mIU/ml)	Result	% Positive
0	Negative 90 Positive 0	0%
3	Negative 90 Positive 0	0%
6	Negative 56 Positive 34	37.8%
8	Negative 28 Positive 62	68.9%
10	Negative 0 Positive 90	100%
12	Negative 0 Positive 90	100%
15	Negative 0 Positive 90	100%

Simulated Urine Stream Method:

hCG levels (mIU/ml)	Result	% Positive
0	Negative 90 Positive 0	0%
3	Negative 90 Positive 0	0%
6	Negative 61 Positive 29	32.2%
8	Negative 17 Positive 73	81.1%
10	Negative 0 Positive 90	100%
12	Negative 0 Positive 90	100%
15	Negative 0 Positive 90	100%

The sponsor also performed a study to evaluate the imprecision of the device using both formats when read by laypersons.

Thirty negative urine specimens were collected and spiked with WHO 5th International hCG standard to the following concentrations: 3, 5, 6, 7.5, 8, 8.5, 10, 12, 15 and 25 mIU/ml. The samples were blinded and randomized prior to being read. A total of 300 lay users performed the test using three lots of the devices; however, the total number of readings was not identical for each concentration, as specified below. Results are summarized below:

Dip Method:

hCG levels (mIU/ml)	Number of results at this concentration	Results	% Positive
0	84	Negative 84 Positive 0	0
3	81	Negative 81 Positive 0	0
5	81	Negative 70 Positive 11	14
6	81	Negative 50 Positive 31	38
7.5	81	Negative 38 Positive 43	53
8	81	Negative 25 Positive 56	69
8.5	81	Negative 20 Positive 61	75
10	81	Negative 0 Positive 81	100
12	81	Negative 0 Positive 81	100
15	84	Negative 0 Positive 84	100
25	84	Negative 0 Positive 84	100

Simulated Urine Stream Method:

hCG levels (mIU/ml)	Number of results at this concentration	Result	% Positive
0	84	Negative 84 Positive 0	0
3	81	Negative 81 Positive 0	0
5	81	Negative 68 Positive 13	16
6	81	Negative 52 Positive 29	36
7.5	81	Negative 41 Positive 40	49
8	81	Negative 26 Positive 55	68
8.5	81	Negative 22 Positive 59	73
10	81	Negative 0 Positive 81	100
12	81	Negative 0 Positive 81	100
15	84	Negative 0 Positive 84	100
25	84	Negative 0 Positive 84	100

2. Linearity:

   Not Applicable. This is a qualitative test.

3. Analytical Specificity/Interference:

   Cross-Reactivity

   The sponsor performed a study to evaluate potential cross-reactivity from LH, FSH and TSH with the candidate device by measuring hCG in samples with various concentrations of hCG, LH, FSH and TSH as specified in the table below.

Solution	Concentrations
1	0 mIU/mL and 1000 mIU/mL FSH
2	0 mIU/mL and 1000 mIU/mL LH
3	0 mIU/mL and 1000 μIU/mL TSH
4	3 mIU/mL hCG and 1000 mIU/mL FSH
5	3 mIU/mL hCG and 1000 mIU/mL LH
6	3 mIU/mL hCG and 1000 μIU/mL TSH
7	10 mIU/mL hCG and 1000 mIU/mL FSH
8	10 mIU/mL hCG and 1000 mIU/mL LH
9	10 mIU/mL hCG and 1000 μIU/mL TSH

The prepared samples were tested with the candidate device in triplicate using three lots and the results were read at 3 and 10 minutes. All results at 0 and 3 mIU/mL were negative and all results at 10 mIU/mL were positive.

Interfering Substances

The sponsor performed a study to evaluate potential interference from common exogenous and endogenous compounds. Negative urine was spiked with potentially interfering substances and hCG standard solution to the concentrations listed in the table below.

Spiked samples were tested in triplicate using one lot of the candidate device. There were no deviations from the expected positive or negative results. Results are summarized below.

Endogenous Substances

Analyte	Concentration Tested	Results at 0 mIU/mL hCG	Results at 3 mIU/mL hCG	Results at 10 mIU/mL hCG
Bilirubin	50 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Hemoglobin	1000 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Albumin	2000 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Glucose	2000 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Urea	2000 mg/ dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Uric acid	150 mg/ dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Oxalic acid	50 mg/ dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Creatinine	250 mg/ dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Sodium nitrite	10 mg/ dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos

Exogenous Substances

Analyte	Concentration Tested	Results at 0 mIU/mL hCG	Results at 3 mIU/mL hCG	Results at 10 mIU/mL hCG
Acetaminophen	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Ascorbic Acid	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Caffeine	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Gentisic Acid	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Salicylic Acid	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Acetylsalicylic	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Ethanol	1.0 %	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Tetracycline	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Theophylline	20 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
Ibuprofen	50 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos
EDTA	80 mg/dL	3 neg / 0 pos	3 neg / 0 pos	0 neg / 3 pos

Effects of Urine pH

The sponsor performed a study to evaluate the effect of urine pH on the results. A negative urine pool was split and separately adjusted in pH increments of 1.0 from pH 4.0 to 9.0. Aliquots of each pH adjusted urine sample were then spiked with hCG to concentrations of 3 and 10 mIU/mL and read at 3 and 10 minutes. There were no deviations from the expected positive or negative results.

Specific Gravity

The sponsor performed a study to evaluate the effect of urine specific gravity on the results. A negative urine pool was split and adjusted with sodium chloride or purified water to produce samples with a specific gravity ranging from 1.003 – 1.035. Aliquots of each specific gravity adjusted urine sample were then spiked with hCG to concentrations of 3 and 10 mIU/mL and read at 3 and 10 minutes. There were no deviations from the expected positive or negative results.

High Dose Hook Effect Study

The sponsor performed a study to evaluate whether very high concentrations of hCG could produce a hook effect with the candidate device. Samples were prepared by spiking a negative urine pool with hCG to concentrations of 500, 1,000, 10,000, 100,000, 500,000 and 1,000,000 mIU/mL. Sample were tested in triplicate using three lots of the device. All concentrations of hCG with all three lots produced the expected positive results and no hook effect was observed.

4. Assay Reportable Range:

Not applicable. This is a qualitative test.

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

Traceability:

The test is calibrated against the WHO 5th International Standard (IS) for Chorionic Gonadotrophin (hCG).

Stability:

The shelf life of the Distinct® Early Detection Pregnancy Test were verified by accelerated, open pouch and on-going real-time stability studies. From the results of the study, it was concluded that Distinct® Early Detection Pregnancy Test is stable at 55℃ for 10 weeks and 45℃ for 22 weeks which support the shelf life up to 24 months at 2 – 30° C (36 – 86° F).

6. Detection Limit:

See section VII.A.1 above.

7. Assay Cut-Off:

The claimed cutoff of the assay is 10 mIU/mL. See section VII.A.1 above for performance around the cutoff.

B Comparison Studies:

1. Method Comparison with Predicate Device:

The sponsor performed a combined lay user and method comparison study to evaluate the accuracy of the candidate device. A total of 205 volunteer participants (lay users) were recruited at three clinical sites with 68 or 69 participants at each clinical site. Laypersons tested their own urine samples using the Distinct® Early Pregnancy Test followed the directions in the package insert. Approximately half of the subjects used the dip method and half used the midstream method. Trained laboratory professionals then tested the same urine samples using the candidate device and the predicate device. The samples were blind labeled before being given to the laboratory professionals for testing. Three lots of the candidate device were used in the study and the results are summarized below:

Candidate device (layperson) vs. predicate device (professional)

Urine stream Method		Predicate (Professional)		
		Pos	Neg	Total
Candidate (Layperson)	Pos	51	0	51
	Neg	0	51	51
	Total	51	51	102

Urine Dipping Method		Predicate (Professional)		
		Pos	Neg	Total
Candidate (Layperson)	Pos	52	0	52
	Neg	0	51	51
	Total	52	51	103

Candidate device (professional) vs. predicate device (professional)

Urine stream Method		Predicate (Professional)		
		Pos	Neg	Total
Candidate (Professional)	Pos	51	0	51
	Neg	0	51	51
	Total	51	51	102

Urine Dipping Method		Predicate (Professional)		
		Pos	Neg	Total
Candidate (Professional)	Pos	52	0	52
	Neg	0	51	51
	Total	52	51	103

After testing, subjects were asked to complete a questionnaire to collect feedback on the test including ease of use, clarity and readability of the package insert. All of the participants reported that the test instructions were easy to follow and that it was easy to read the test results.

2. Matrix Comparison:

Not applicable. The device is intended for use with urine samples only.

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable.

2. Clinical Specificity:

Specificity Study to Determine False-Positive Results Rate

A study was performed to determine the incidence of positive test results using the candidate device among non-pregnant women in three age groups: 18-40, 41-45, and 55 and older. A

total of 300 subjects provided samples with 100 for each age group. Three lots of the candidate device were used for this study. No positive results were observed for any of the age groups.

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

Detection of hCG in Early Pregnancy Clinical Samples

Urine from 65 non-pregnant women expecting to become pregnant were collected daily starting 8 days prior to their expected period through the date of their expected menstrual period (EMP), as well as the 6th or 7th day after their EMP. Each patient collected her own urine and sent the sample to a clinical site where they were tested by a laboratory professional. Three lots of the candidate device were used and the pregnancy status was confirmed by ultrasound or a quantitative blood hCG result.

Time Point	Number of Positive	Number of Negative	% Positive
EMP +6 or 7 days	65	0	100.0%
EMP	65	0	100.0%
EMP-1 day	65	0	100.0%
EMP-2 days	65	0	100.0%
EMP-3 days	63	2	96.9%
EMP-4 days	61	4	93.8%
EMP-5 days	49	16	75.4%
EMP-6 days	32	33	49.2%
EMP-7 days	13	51	20.3%
EMP-8 days	6	54	10.0%

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

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

IX Conclusion:

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