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

## I Background Information:

### A 510(k) Number

K232715

### B Applicant

ACON Laboratories, Inc.

### C Proprietary and Established Names

Distinct® Digital 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® Digital Pregnancy Test is an over-the-counter chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. It is intended for use as an aid for the early detection of pregnancy. This test can help determine if you are pregnant as early as 6 days before the day of the missed period (5 days before the day of your expected period).

### C Special Conditions for Use Statement(s):
OTC - Over The Counter

### D Special Instrument Requirements:

None.

## IV Device/System Characteristics:

### A Device Description:

The Distinct® Digital Pregnancy Test is a qualitative lateral flow immunoassay for the detection of hCG. The test contains anti-hCG antibodies conjugated with colored particles and anti-hCG antibodies coated on the membrane. Each device is provided in a sealed pouch with instructions for use. The device consists of a plastic-housed test stick containing an immunochromatographic strip and electronic and optical components along with a microprogrammed control unit and specific algorithms to digitally display test results. The result is displayed to the user in the test window as “PREGNANT” or “NOT PREGNANT”.

### B Principle of Operation:

The Distinct® Digital Pregnancy Test is an immunoassay employing monoclonal antibodies that detect hCG in urine. If hCG is present in the urine sample, it is bound by a conjugated monoclonal antibody in the optical detection system. After the application of urine, the test result is shown in the result window and is read visually after 3 minutes. The optical detection system utilizes two red light emitting diodes (LEDs) as light sources and a photo sensor to confirm the presence of the sample fluid in the test line zone and determine the color change in the test line zone. The device provides the result on the LCD display as either "Pregnant" or "Not Pregnant," or displays an error symbol “ ?” if sample volume is insufficient, or if an operation error occurs.

## V 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(s):**

| **Device & Predicate Device(s):** | K232715 | K123567 |
|---|---|---|
| Device Trade Name | Distinct® Digital Pregnancy Test | FIRST RESPONSE Gold Digital Pregnancy Test |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | Qualitative detection of hCG to aid in the early detection of pregnancy | Same |
| Early Detection Claim | Pregnancy can be detected as early as six days before the day of the missed period (five days before the day of the expected period) | Same |
| Intended use environment | Over-the-counter | Same |
| Specimen | Urine | Same |
| Time to Result | 3 minutes | Same |
| hCG Sensitivity | 10 mIU/ml | Same |
| **General Device Characteristic Differences** | | |
| Traceability | World Health Organization (WHO) 5$^{th}$ International Standard for hCG | World Health Organization (WHO) 4$^{th}$ International Standard for hCG |

## VI Standards/Guidance Documents Referenced:

None referenced.

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

A precision study was performed using a pooled female human negative urine sample spiked with hCG to obtain samples with hCG concentrations of 0, 3, 4, 5, 6, 8, 10, 12, and 15 mIU/mL. Each sample was tested using three lots of the Distinct® Digital Pregnancy Test in both simulated midstream and dip sampling methods. The tests were performed over the

course of 5 days, 2 runs per day, in replicates of 5, by 3 different operators. A total of 150 replicates were performed per sampling method per hCG concentration. The sensitivity was determined to be 10 mIU/mL hCG.

Simulated midstream method:

| hCG concentration (mIU/mL) | Operator/ Lot#1 | Operator/ Lot#2 | Operator/ Lot#3 | Summary | % Positive |
|---|---|---|---|---|---|
| | # positive/total | | | | |
| 0 | 0/50 | 0/50 | 0/50 | 0/150 | 0% |
| 3 | 0/50 | 0/50 | 0/50 | 0/150 | 0% |
| 4 | 0/50 | 0/50 | 0/50 | 0/150 | 0% |
| 5 | 3/50 | 2/50 | 4/50 | 9/150 | 6.0% |
| 6 | 18/50 | 20/50 | 18/50 | 56/150 | 37.3% |
| 8 | 38/50 | 43/50 | 41/50 | 122/150 | 81.3% |
| 10 | 50/50 | 50/50 | 50/50 | 150/150 | 100% |
| 12 | 50/50 | 50/50 | 50/50 | 150/150 | 100% |
| 15 | 50/50 | 50/50 | 50/50 | 150/150 | 100% |

Dip method:

| hCG concentration (mIU/mL) | Operator/ Lot#1 | Operator/ Lot#2 | Operator/ Lot#3 | Summary | % Positive |
|---|---|---|---|---|---|
| | # positive/total | | | | |
| 0 | 0/50 | 0/50 | 0/50 | 0/150 | 0% |
| 3 | 0/50 | 0/50 | 0/50 | 0/150 | 0% |
| 4 | 0/50 | 0/50 | 0/50 | 0/150 | 0% |
| 5 | 2/50 | 1/50 | 4/50 | 7/150 | 4.7% |
| 6 | 15/50 | 16/50 | 17/50 | 48/150 | 32.0% |
| 8 | 44/50 | 32/50 | 40/50 | 116/150 | 77.3% |
| 10 | 50/50 | 50/50 | 50/50 | 150/150 | 100% |
| 12 | 50/50 | 50/50 | 50/50 | 150/150 | 100% |
| 15 | 50/50 | 50/50 | 50/50 | 150/150 | 100% |

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

Urine specimens from non-pregnant females were pooled and used to prepare samples with hCG concentrations of 3 mIU/mL and 10 mIU/mL that were then spiked with the potentially interfering exogenous and endogenous substances listed below. Control samples containing no test substance were also tested to compare to the test samples. No interference effect was observed at the tested concentrations shown in the table below.

| Substance tested | Highest concentration tested that demonstrated no interference |
|---|---|
| Acetaminophen | 20 mg/dL |
| Acetylsalicylic Acid | 65 mg/dL |
| Acetone | 2 mL/dL |
| Albumin | 6000 mg/dL |
| Ampicillin | 10 mg/dL |
| Ascorbic Acid | 20 mg/dL |
| Atropine | 1 mg/dL |
| Bilirubin | 50 mg/dL |
| Caffeine | 20 mg/dL |
| Creatinine | 250 mg/dL |
| EDTA | 80 mg/dL |
| Ethanol | 1% v/v |
| Estriol | 1 mg/dL |
| Gentisic Acid | 20 mg/dL |
| Glucose | 2000 mg/dL |
| Hemoglobin | 2000 mg/dL |
| Ibuprofen | 50 mg/dL |
| Oxalic acid | 50 mg/dL |
| Phenothiazine | 10 mg/dL |
| Phenylpropanolamine | 10 mg/dL |
| Salicylic Acid | 60 mg/dL |
| Sodium nitrite | 10 mg/dL |
| Tetracycline | 20 mg/dL |
| Theophylline | 20 mg/dL |
| Urea | 2000 mg/dL |
| Uric acid | 150 mg/dL |

Cross-Reactivity of similar compounds

To evaluate cross-reactivity, negative urine samples and urine samples containing hCG concentrations of 3 mIU/mL and 10mIU/mL were spiked with the following potential cross reactants:1000 mIU/mL follicle-stimulating hormone (FSH), 1000 mIU/mL luteinizing hormone (LH), or 1 mIU/mL thyroid-stimulating hormone (TSH). Samples were tested in replicates of 3 using 3 lots of the candidate device. No cross-reactivity was observed at the tested concentrations.

Effect of urine pH and Specific Gravity

A study was performed to evaluate the effects of pH on device performance. Negative human urine samples and urine samples containing 3 mIU/mL and 10 mIU/mL hCG were adjusted to pH values from 4.0 to 9.0 and tested using the candidate device. The results demonstrated that samples within the pH range of 4.0 to 9.0 do not interfere with either positive or negative results from the device.

A study was performed to evaluate the effects of urine specific gravity on device performance. Negative human urine samples and urine samples containing 3 mIU/ml and 10 mIU/mL hCG were adjusted to specific gravity values from 1.000 to 1.035 and tested using

the candidate device. The results demonstrated that samples within the specific gravity range of 1.000 to 1.035 do not interfere with either positive or negative results from the device.

High dose hook effect
Negative pooled human urine spiked up to 1,000,000 mIU/mL hCG were tested in replicates of 3 using 3 lots of the candidate device. No hook effect was observed at concentrations of up to 1,000,000 mIU/mL hCG.

Effect of hCG β-core fragment
Urine samples containing 3 mIU/mL and 10 mIU/mL hCG spiked with hCG β-core fragment at a concentration 1,000,000 pmol/L were tested in replicates of 2 using 3 lots of the candidate device. The results demonstrated that the candidate device is not affected by concentrations of hCG β-core fragment up to 1,000,000 pmol/L.

4. Assay Reportable Range:

   Not applicable.

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

   The Distinct Digital Pregnancy Test is calibrated against the World Health Organization's 5th International Standard for human chorionic gonadotropin (NIBSC code 07/364).

6. Detection Limit:

   The detection limit was determined in the precision study (see Section VII.A.1. above).

7. Assay Cut-Off:

   The device cutoff is 10 mIU/mL hCG. See Precision/Reproducibility (Section VII.A.1.) sections above.

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

   A lay user study was performed with a total of 202 women aged 18 to 45 (pregnant and not pregnant) with diverse educational and professional backgrounds at 3 clinical sites. Lay users in this study tested their own samples using the candidate device (Distinct® Digital Pregnancy Test; in dip method and midstream method). Urine samples from the lay users were collected and masked prior to testing by trained technicians using the predicate device (First Response Digital Pregnancy Test; in dip method). Lay user results were compared to results obtained from trained technicians testing the same urine samples using the predicate device. The results are summarized below.

Midstream method:

| Layperson, Candidate Device (Midstream method) | | Technician Results, Predicate device (dip method) | | |
|---|---|---|---|---|
| | | Pregnant | Not pregnant | Total |
| Candidate device | Pregnant | 68 | 0 | 68 |
| | Not pregnant | 0 | 34 | 34 |
| | Total | 68 | 34 | 102 |

Dip method:

| Layperson, Candidate Device (Dip method) | | Technician Results, Predicate device (dip method) | | |
|---|---|---|---|---|
| | | Pregnant | Not pregnant | Total |
| Candidate device | Pregnant | 66 | 0 | 66 |
| | Not pregnant | 0 | 34 | 34 |
| | Total | 66 | 34 | 100 |

There was 100% agreement between candidate device and predicate device.

Each subject performed the testing following the package insert instructions without any assistance. Ease of use of the candidate device was assessed through a questionnaire that was completed at the end of the study. The questionnaire results indicated that lay users found the test easy to use, the results clear and easy to read and the instructions for use easy to understand.

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):

Detection of hCG in Early Pregnancy Clinical Samples
Urine samples from days 0 to -8 relative to the day of the expected menstrual period (EMP) were collected from 62 different women aged 18 to 45 years from the intended use population. Each sample was tested using both dip and simulated midstream methods of sampling across 3 lots of devices. The early pregnancy detection results are summarized in table below.

| Days relative to missed period | Sample (n) per sampling method | Dip method | | Stimulated midstream method | |
|---|---|---|---|---|---|
| | | Pregnant (n) | Pregnant (%) | Pregnant (n) | Pregnant (%) |
| -8 | 60 | 4 | 6.7 | 4 | 6.7 |
| -7 | 62 | 9 | 14.5 | 9 | 14.5 |
| -6 | 62 | 27 | 43.5 | 27 | 43.5 |
| -5 | 62 | 45 | 72.6 | 45 | 72.6 |
| -4 | 62 | 55 | 88.7 | 55 | 88.7 |
| -3 | 62 | 58 | 93.5 | 58 | 93.5 |
| -2 | 62 | 62 | 100.0 | 62 | 100.0 |
| -1 | 62 | 62 | 100.0 | 62 | 100.0 |
| 0 | 62 | 62 | 100.0 | 62 | 100.0 |

Non-pregnant urine sample analysis

A study was performed to determine the incidence of positive results in urine from females not suspected to be pregnant with the candidate device. A total of 300 urine samples from 100 pre-menopausal women (ages 18-40), 100 peri-menopausal women (ages 41-55), and 100 postmenopausal women (>55) were tested with 3 lots of the device, according to package insert instructions by a trained technician. The results of this study are presented below:

Summary of Specificity Testing (Midstream and Dip Method)

| Cohort (Years old) | # of Samples | Positive Results (%) |
|---|---|---|
| Pre-menopausal women (18-40) | 100 | 0/100 (0%) |
| Peri-menopausal women (41-55) | 101 | 0/101 (0%) |
| Postmenopausal women (>55) | 99 | 1/99 (1%)* |

*One lay person had a positive result.

The labeling includes the following mitigation for risk of false positives results: “If you are in, or approaching, menopause you may obtain a false pregnant result even though you are not pregnant.”

Lay user spiked sample study

A second study lay user study was conducted with a total of 300 women (150 lay users using dip method and 150 lay users using simulated midstream method) testing samples spiked with 0, 3, 5, 6, 7.5, 8, 8.5, 10, 12 and 15 mIU/mL hCG using 3 lots of the device. Results for each urine sample and sampling method are summarized below.

| hCG level (mIU/mL) | Simulated midstream | Dip method |
|---|---|---|
| | % Positive | % Positive |
| 0 | 0% | 0% |
| 3 | 0% | 0% |
| 5 | 6.7% | 8.9% |
| 6 | 40% | 33.3% |
| 7.5 | 62.2% | 55.6% |
| 8 | 75.6% | 77.8% |
| 8.5 | 82.2% | 77.8% |
| 10 | 100% | 100% |
| 12 | 100% | 100% |
| 15 | 100% | 100% |

**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.