510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K234152

B Applicant

Aceso Laboratories, Inc.

C Proprietary and Established Names

ACESO Early 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:

ACESO Early Pregnancy Test is intended for the 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.

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This device is intended for home-use only.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

The device is intended for home-use only and not intended for clinical-care settings.

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

The ACESO Early Pregnancy Test consists of a single test strip assembled in a plastic housing, with an absorbent tip and is designed to be tested in dip or instream mode. The test is packaged sealed with a desiccant and instructions for use. The result is displayed within the test window by two distinct colored lines, one control line and one test line.

B Principle of Operation:

The ACESO Early Pregnancy Test is a qualitative, lateral flow immunoassay used for in vitro qualitative detection of human chorionic gonadotropin (hCG) in urine. When the absorbent end is exposed to 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 membrane, which is coated with goat anti-hCG polyclonal antibody. During the test, hCG in the urine specimen reacts with the dye conjugate and forms a complex. The complex migrates along the membrane to the hCG antibody line (T) and remains captured in the T line. The test

result is shown in the test window and read visually between 3 and 10 minutes of urine application. A red colored band develops in the T line, indicating a positive result. If there is no hCG or levels are below the cut-off in the urine, there is no red band in the test zone, indicating a negative result. The Control line should develop in the control zone regardless of the test result. Absence of a control line, even in the presence of a colored T line, indicates an invalid test result.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Wondfo One Step HCG Urine Pregnancy Test Strip, Wondfo One Step HCG Urine Pregnancy Test Cassette, Wondfo One Step HCG Urine Pregnancy Test Midstream

B Predicate 510(k) Number(s):

K150022

C Comparison with Predicate(s):

Device & Predicate Device(s):	K234152	K150022
Device Trade Name	ACESO Early Pregnancy Test	Wondfo One Step HCG Urine Pregnancy Test Strip, Wondfo One Step HCG Urine Pregnancy Test Cassette, Wondfo One Step HCG Urine Pregnancy Test Midstream
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy.	Same
Early Detection Claim	Pregnancy can be detected 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	Same
Specimen	Urine	Same
Methodology	Chromatographic immunoassay	Same
Claimed Analytical Sensitivity	10 mIU/mL	Same
Results	Qualitative	Same

Target User	Over the Counter use	Same
General Device Characteristic Differences		
Time to Result	3-10 minutes	5 minutes
Traceability	World Health Organization (WHO) 5th International Standard (IS)	World Health Organization (WHO) 4th International Standard (IS)

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 negative female urine samples spiked with hCG (traceable to the 5th WHO IS) to obtain samples with hCG concentrations of 0, 3, 5, 8, 10, 15, 25 and 50 mIU/mL. Each sample was tested in replicates of 10 using 3 lots of the ACESO Early Pregnancy Test. Testing was performed using both instream and dip sampling methods by 3 operators at 1 site over 5 days, for a total of 150 replicates per sampling method per hCG concentration. The tables below summarize the precision data for both instream and dip testing.

ACESO Early Pregnancy Test (instream sampling method)

hCG concentration (mIU/mL)	Lot 1	Lot 2	Lot 3	Total result		% Negative	% Positive
				-	+		
0	50-/0+	50-/0+	50-/0+	150	0	100%	0%
3	50-/0+	50-/0+	50-/0+	150	0	100%	0%
5	24-/26+	23-/27+	27-/23+	74	76	49.3%	50.7%
8	3-/47+	2-/48+	2-/48+	7	143	4.7%	95.3%
10	0-/50+	0-/50+	0-/50+	0	150	0%	100%
15	0-/50+	0-/50+	0-/50+	0	150	0%	100%
25	0-/50+	0-/50+	0-/50+	0	150	0%	100%
50	0-/50+	0-/50+	0-/50+	0	150	0%	100%

ACESO Early Pregnancy Test (dip sampling method)

hCG concentration (mIU/mL)	Lot 1	Lot 2	Lot 3	Total result		% Negative	% Positive
				-	+		
0	50-/0+	50-/0+	50-/0+	150	0	100%	0%
3	50-/0+	50-/0+	50-/0+	150	0	100%	0%
5	26-/24+	24-/26+	26-/24+	76	74	50.7%	49.3%
8	2-/48+	1-/49+	2-/48+	5	145	3.3%	96.7%
10	0-/50+	0-/50+	0-/50+	0	150	0%	100%
15	0-/50+	0-/50+	0-/50+	0	150	0%	100%
25	0-/50+	0-/50+	0-/50+	0	150	0%	100%
50	0-/50+	0-/50+	0-/50+	0	150	0%	100%

In addition to the testing summarized above, an additional precision study was performed using negative female urine samples spiked with hCG (traceable to the 5th WHO IS) to obtain samples with hCG concentration of 4 mIU/mL. Samples were tested in replicates of 50 using 3 lots of the test and testing was performed using both instream and dip sampling methods by 3 operators at 1 site on 1 day, for a total of 150 replicates per sampling method. The tables below summarize the precision data for both instream and dip testing.

ACESO Early Pregnancy Test (dip and instream sampling method at 4 mIU/mL)

	Lot 1	Lot 2	Lot 3	Total result		% Negative	% Positive
				-	+		
Instream sampling method	48-/2+	49-/1+	48-/2+	145	5	96.7%	3.3%
Dip sampling method	49-/1+	49-/1+	48-/2+	146	4	97.3%	2.7%

Because the device detects low levels of hCG that could be found in some non-pregnant women, the sponsor included a limitation in the labeling (see Section III.C. above).

2. Linearity:

Linearity is not applicable since this is a qualitative device.

3. Analytical Specificity/Interference:

Interference from Endogenous and Exogenous Substances

To evaluate potential interference, a urine pool from non-pregnant healthy females was used to prepare samples with hCG concentrations of 0, 3 and 10 mIU/mL, which were then spiked with potentially interfering exogenous and endogenous substances at the concentrations listed in the table below. Samples were tested in replicates of 3 by 3 operators using 3 lots of the candidate device. No interference was observed at the concentrations shown in the table below:

Substance	Highest concentration tested that demonstrated no interference
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic acid	20 mg/dL
Glucose	2 mg/dL
Hemoglobin	20 mg/dL
Tetracycline	20 mg/dL
Ampicllin	20 mg/dL
Albumin	20 mg/dL
Beta hydroxybutyrate	2000 mg/dL
Ephedrine	20 mg/dL
Phenylpropanololamine	20 mg/dL
Phenothiazine	20 mg/dL
EDTA	80 mg/dL
Salicyclic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Codeine	6 ug/dL
Ethanol	1.0%
Bilirubin	2 mg/dL
Pregnanediol	1500ug/dL
Thiophene	20 mg/dL
Ketone	20 mg/dL

Cross-Reactivity of structurally-related compounds

To evaluate cross-reactivity, urine samples were spiked to hCG concentrations of 3 mIU/mL and 10mIU/mL and then spiked with the following potential cross reactants: follicle-stimulating hormone (FSH), luteinizing hormone (LH), and thyroid-stimulating hormone (TSH). Samples were tested in replicates of 3 by 3 operators using 3 lots of candidate device. The results demonstrated no cross-reactivity from potential cross-reactants up to 1000 mIU/mL LH, 1000 mIU/mL FSH, 1 mIU/mL TSH in either samples at the claimed cutoff (10 mIU/mL) or below the claimed cutoff (3 mIU/mL).

Effects of hCG β-core (hCGβcf) fragment:

Interference testing was performed to evaluate whether high levels of β-core (hCGβcf) fragment interfere with device performance. Negative urine samples (0 mIU/mL) and negative samples spiked with hCG levels of 3 mIU/mL, 10 mIU/mL, and 20,000 mIU/mL hCG were then spiked with hCGβcf at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000 pmol/L and 500,000 pmol/L. Samples were tested in replicates of 5 by 3 operators using 3 lots of the candidate device. The results show that the performance of the candidate device is not affected by hCGβcf concentrations up to 500,000 pmol/L.

Effects of urine pH:
A study was performed to evaluate the effects of pH on device performance. Negative urine samples (0 mIU/mL) and negative samples spiked with hCG to levels of 3 mIU/mL and 10 mIU/mL were adjusted to have pH values of 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0. The hCG samples with the different pH levels were test in 3 replicates by 3 operators using 3 lots of the device. The results demonstrated that changes in pH ranging from 4.0 to 9.0 do not interfere with either positive or negative results from the device.

Effects of urine specific gravity:
A study was performed to evaluate the effects of urine specific gravity on device performance. Negative urine samples (0 mIU/mL) and negative samples spiked with hCG levels of 3 mIU/mL and 10 mIU/mL were adjusted to specific gravities of 1.000, 1.009, 1.015, 1.017, 1.020, 1.022, 1.028, and 1.035. Samples were tested in 3 replicates by 3 different operators using 3 lots of the device. The results demonstrated that changes in specific gravity ranging from 1.000 to 1.035 do not interfere with either positive or negative results from the device.

Effects of hook effect study:
Negative urine samples were spiked with hCG at concentrations of 6,250, 12,500, 25,000, 50,000, 100,000, 200,000, and 500,000 mIU/mL. Three lots of the device were tested by 3 different operators. The results demonstrated that no hook effect was observed at hCG concentration up to 500,000 mIU/mL.

4. Assay Reportable Range:

   Not applicable.

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

   Traceability
   The ACESO Early Pregnancy Test is calibrated against the World Health Organization (WHO) International Standard (IS) 5th Edition, NIBSC code 07/364.

6. Detection Limit:

   A detection limit study was performed using negative human urine samples spiked with hCG (traceable to the WHO 5th IS) to obtain concentrations of 0, 3, 5, 8, 10, 15, 25, and 50 mIU/mL hCG. Samples were tested in both dip and instream sampling methods in replicates of 20 by 3 different operators using 3 lots of the device. Each operator tested one lot of the device.

ACESO Early Pregnancy Test (instream sampling method)

hCG concentration (mIU/mL)	Lot 1	Lot 2	Lot 3	% Positive
0	20-/ 0+	20-/0+	20-/0+	0%
3	20-/0+	20-/0+	20-/0+	0%
5	10-/10+	9-/11+	10-/10+	51.7%
8	1-/20+	0-/20+	2-/18+	95.0%
10	0-/20+	0-/20+	0-/20+	100.0%
15	0-/20+	0-/20+	0-/20+	100.0%
25	0-/20+	0-/20+	0-/20+	100.0%
50	0-/20+	0-/20+	0-/20+	100.0%

ACESO Early Pregnancy Test (dip sampling method)

hCG concentration (mIU/mL)	Lot 1	Lot 2	Lot 3	% Positive
0	20-/ 0+	20-/0+	20-/0+	0%
3	20-/0+	20-/0+	20-/0+	0%
5	11-/9+	10-/10+	10-/10+	48.3%
8	1-/19+	1-/19+	0-/20+	96.7%
10	0-/20+	0-/20+	0-/20+	100.0%
15	0-/20+	0-/20+	0-/20+	100.0%
25	0-/20+	0-/20+	0-/20+	100.0%
50	0-/20+	0-/20+	0-/20+	100.0%

The claimed sensitivity or cut-off of the ACESO Early Pregnancy Test is 10mIU/mL. See also Section VII.A.1. above for additional precision/reproducibility information.

7. Assay Cut-Off:

The device claimed cutoff is 10 mIU/mL hCG. See Detection Limit (Section VII.A.6.) and Precision/Reproducibility (Section VII.A.1.) sections above.

B Comparison Studies:

1. Method Comparison with Predicate Device:
Urine samples were collected from a total of 100 women with ages ranging from 20 to 45 years. All women were tested to determine their pregnancy status. Samples were masked and randomized by people who labeled the samples but did not participate in the testing. All women included in the study were less than five weeks pregnant. A total of 100 samples and three lots were tested for each format (dip, instream). Of the 100 women, 53 women tested positive. The results are summarized below.

ACESO Early Pregnancy Test (Dip sampling method)

	Predicate Device	Positive	Negative	Total
Candidate Device	Positive	53	0	53
	Negative	0	47	47
Total		53	47	100

ACESO Early Pregnancy Test (Instream sampling method)

	Predicate Device	Positive	Negative	Total
Candidate Device	Positive	53	0	53
	Negative	0	47	47
Total		53	47	100

2. Matrix Comparison:

Not applicable. The devices are 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:
A total of 650 urine samples from day -8 to day +1 relative to the day of their expected menstrual period (EMP) were collected from 65 different women between the ages of 21-40 years. Each sample was tested using both dip and instream sampling methods across 3 lots of the device. The early pregnancy detection results are summarized in the tables below:

ACESO Early Pregnancy Test (dip sampling method)

Days Relative to EMP	Total (n)	Positive (n)	% Positive
-8	65	6	9.2
-7	65	16	24.6
-6	65	31	47.7
-5	65	50	76.9
-4	65	63	96.9
-3	65	65	100.0
-2	65	65	100.0
-1	65	65	100.0
0	65	65	100.0
+1	65	65	100.0

ACESO Early Pregnancy Test (instream sampling method)

Days Relative to EMP	Total (n)	Positive (n)	% Positive
-8	65	6	9.2
-7	65	16	24.6
-6	65	31	47.7
-5	65	50	76.9
-4	65	63	96.9
-3	65	65	100.0
-2	65	65	100.0
-1	65	65	100.0
0	65	65	100.0
+1	65	65	100.0

Lay User Study

A lay-user study was performed with a total of 100 lay users with varying educational and occupational backgrounds with an age range of 21-45 years old. Lay users tested their own urine specimen. Fifty-five (55) lay users tested using the instream sampling method and 45 lay users tested using the dip sampling method. Each subject also provided a sample for professional testing. Lay user results compared to clinical pregnancy status and professional user results are shown below. The data demonstrated 100% agreement between lay-user and professional results.

ACESO Early Pregnancy Test (dip and instream method)		Professional Result		Total
		Positive	Negative	
Lay User Result	Positive	53	0	53
	Negative	0	47	47
Total		53	47	100

Ease of use of the device was also assessed and demonstrated that users found the test easy to perform and that all of the lay persons carried out the test correctly.

Lay user spiked sample study:

In a separate study, a total of 100 lay users (58 using dip method) and (42 using instream method) each tested four urine samples spiked with 3, 5, 8, and 10mIU/mL hCG. Samples were blinded and the order of testing was randomized. Professionals also conducted testing with the spiked urine samples. A comparison of lay user and professional results for each urine sample and sampling method is shown below.

Lay Person vs Professional Results

# Samples	hCG Concentration (mIU/mL)	Lay User Result		Professional Result		Percent Agreement
		# Positive	# Negative	# Positive	# Negative	
100	3	0	100	0	100	100%
100	5	48	52	51	49	97%
100	8	96	4	95	5	99%
100	10	100	0	100	0	100

Testing of Non-Pregnant Women:
Urine samples from 100 non-pregnant women were tested from each of the following three cohorts: pre-menopausal (ages 18~40 years old), peri-menopausal (41~55 years old) and post-menopausal (>55 years old). Three lots of the device were used and the lay user performed their own tests using both dip and instream sampling methods. Results of the study are shown in the table below.

Cohort	Test Result			
	Dip sampling method	%Positive	Instream sampling method	% Positive
Pre-menopausal (18-40 yrs)	0+/50-	0	0+/50-	0
Peri-menopausal (41-55 yrs)	0+/50-	0	0+/50-	0
Menopausal (>55 yrs)	0+/50-	0	0+/50-	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.