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

A. 510(k) Number:

k180771

B. Purpose for Submission:

Modification of a previously cleared device to include a dip mode testing format.

C. Measurand:

Human chorionic gonadotrophin (hCG)

D. Type of Test:

Qualitative

E. Applicant:

Acro Biotech, Inc.

F. Proprietary and Established Names:

ACRO HCG Pregnancy Rapid Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155 - Human chorionic gonadotropin (hCG) test system

2. Classification:

   Class II

3. Product code:

   LCX

4. Panel:

   Chemistry 75

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The ACRO hCG Pregnancy Rapid Test is for use by the over the counter consumers for the visual qualitative detection of Human Chorionic Gonadotropin (hCG) in urine. It is to be used in either dip mode or midstream mode for the early detection of pregnancy.

3. Special conditions for use statement(s):

   The device is intended for over-the-counter use.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

The ACRO HCG Pregnancy Rapid Test is designed to be tested in midstream mode and dip mode. The ACRO HCG Pregnancy Rapid Test consists of a single test strip encased in plastic device housing, with or without an additional absorbent tip. Each device includes one device, sealed in a foil-pouch with a desiccant pack, a urine cup and a package insert. The test utilizes a combination of antibodies to selectively detect elevated levels of hCG in urine.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACRO HCG Pregnancy Rapid Test

2. Predicate 510(k) number(s):

   k172512

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy	Same
Cutoff	25 mIU/ml	Same
Test Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Detection reagent	Colloidal gold	Same
Traceability	WHO 4th International Standard	Same
Storage Temperature	35 - 86°F (2 – 30 ^{o}C)	Same
Read time	3 to 10 minutes	Same

Differences		
Item	Device	Predicate
Sampling format(s)	Mid-stream and Dip modes, with or without absorbent tip	Mid-stream mode, with or without absorbent tip

K. Standard/Guidance Document Referenced (if applicable):

ISO 14971:2007, Medical Devices - Application of risk management to medical devices

L. Test Principle:

The ACRO HCG Pregnancy Rapid Test is a lateral flow sandwich immunochromatographic assay. The device utilizes a combination of antibodies to hCG: one labeled with a chromophore dye that is impregnated into the sample pad and the second, which is printed as a line onto the test zone of the test strip. The device also has a second antibody printed onto the test zone of the test strip that serves as a procedural control to indicate that a sufficient volume of urine migrated up the test strip during sample testing. During the procedure, the absorbent end of the device is immersed into a urine sample. The specimen migrates via capillary action along the membrane to react with the antibody-dye conjugate, and hCG within the sample forms a complex with the antibody-dye conjugate. The hCG-antibody-dye conjugate complex continues to migrate along the membrane to the test region, where it is captured on the test line by a second anti-hCG antibody, and excess anti-hCG antibody-dye conjugate (without bound hCG) migrates to the control line where it is captured by antibodies to the anti-hCG antibody. A visible control line indicates that the sample successfully migrated into the test zone. A specimen with hCG below the cutoff should produce no test line in the test zone (demarcated a “T” on the device), and one control line in the test zone (demarcated as “C” on

the device). A specimen with hCG above the cutoff should produce both a test line and a control line in the test zone. An invalid result produces either no lines on the device (i.e. no test or control lines) or one test line in the test zone (i.e. a test line but no control line).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A precision study was performed using hCG negative human urine samples spiked with hCG (traceable to the WHO 4th international standard) to create samples with hCG concentrations of 0 mIU/mL, 12.5 mIU/mL, 20 mIU/mL, 25 mIU/mL, 40 mIU/mL and 100 mIU/mL. These samples were tested by laboratory professionals to evaluate within run, between run and between operator precision. Six operators, using three lots of ACRO HCG Pregnancy Rapid Test for five consecutive days performed the testing. Testing was performed in-house by dip mode method, and the results are summarized in the table below. Precision performance in mid-stream mode was previously reviewed in k172512.

Dip-mode results summary:

hCG (mIU/mL)	Total no. tested	% agreement	Lot 1		Lot 2		Lot 3		Total Results	
			+	-	+	-	+	-	+	-
0	75	100	0	25	0	25	0	25	0	75
12.5	75	100	0	25	0	25	0	25	0	75
20	75	62.7	9	16	10	15	9	16	28	47
25	75	100	25	0	25	0	25	0	75	0
40	75	100	25	0	25	0	25	0	75	0
100	75	100	25	0	25	0	25	0	75	0

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The test is calibrated against reference material traceable to WHO 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 in the predicate k172512.

d. Detection limit:

See section M.1.a., above.

e. Analytical specificity:

To evaluate the potential for interference by certain endogenous or exogenous compounds, each potentially interfering substance was prepared by spiking the substance to the desired concentration into an hCG negative specimen and a positive specimen containing 25 mIU/mL hCG. Each sample was tested in three replicates using 3 lots of the candidate device. No interference was observed from the endogenous or exogenous compounds tested at the concentrations noted in the table below, for either negative or positive hCG urine samples, when tested using the candidate device in the dip mode. Analytical specificity was demonstrated for the mid-stream mode in k172512.

Analyte	Concentration
Acetaminophen	20 mg/dL
Acetoacetic acid	2000 mg/dL
Ascorbic Acid	20 mg/dL
Atrophine	20 mg/dL
Acetosalicyclic acid	20 mg/dL
Albumin	2000 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Codeine	10 mg/dL
Ephedrine	20 mg/dL
EDTA	80 mg/dL
Ethanol	1%
Gentisic Acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	1 mg/dL
Methadone	10 mg/dL
Methanol	10%
Phenylpropanolamine	20
Phenothiazine	20
Estriol-17-beta	1.4
Pregnanediol	1.5
Salicylic acid	20

Hook effect study:

To determine if the ACRO HCG Pregnancy Rapid Test has a hook effect due to high levels of hCG, hCG negative urine samples were spiked with varying hCG concentrations 10 IU/mL, 100 IU/mL, 500 IU/mL, 1000IU/mL). These samples were evaluated in dip mode with 3 lots of ACRO HCG Pregnancy Rapid Test device in

triplicates per sample. No hCG hook effect was observed at hCG levels up to 1,000 IU/mL. Absence of hook was demonstrated for the mid-stream mode in k172512.

Effects of hCG β-core fragment:

To evaluate the effect of hCG β-core fragment, an hCG negative urine sample and a urine sample with 25 mIU/ml hCG were spiked with hCG β-core fragment to yield samples with concentrations of 100 pmol/L, 150 pmol/L, 200 pmol/L, 250 pmol/L, 300 pmol/L, 500 pmol/L, 5,000 pmol/L, 50,000 pmol/L and 500,000 pmol/L. These samples were tested in dip mode using six lots of the candidate device in triplicates per lot in dip mode format. Positive results were observed with hCG β-core fragment concentrations greater than 200 pmol/L. No hook effect was observed at concentrations of hCG β-core fragment up to 500000 pmol/L.

Cross-Reactivity:

To evaluate cross-reactivity for the candidate device in dip mode, hCG negative and hCG positive urine samples (25 mIU/mL hCG) were spiked with various concentrations of glycoprotein hormones LH, hFSH, TSH. These samples were evaluated with 3 lots of ACRO HCG Pregnancy Rapid Test device in three replicates per sample. The results demonstrate that there is no interference at 500 mIU/mL LH, 1000 mIU/mL hFSH, 1000 mIU/mL TSH in either negative or positive urine samples. Cross-reactivity performance was demonstrated for the mid-stream mode in k172512.

pH interference study:

To evaluate potential interference for the candidate device in dip mode from changes in urine pH, urine samples containing 0 mIU/mL, and 25 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9 in duplicates. The results indicated that changes in pH range of 4~9 do not interfere with either positive or negative results from the device. Performance across various pH values was demonstrated for the mid-stream mode in k172512.

Specific Gravity interference study:

To evaluate potential interference from changes in specific gravity for the candidate device in dip mode, urine samples containing 0 mIU/mL and 25 mIU/mL of hCG were tested in duplicates using one lot of ACRO HCG Pregnancy Rapid Test, at specific gravity values ranging from 1.010, 1.022, 1.030, 1.027, 1.028, 1.008, 1.026,1.021,1.008, 1.013,1.016, 1.018, 1.014 and 1.015. The results indicated that changes in specific gravity do not interfere with either positive or negative results from the device. Performance across various specific gravity values was demonstrated for the mid-stream mode in k172512.

f. Assay cut-off:

See Section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

A lay user study was performed with 175 lay users including 113 pregnant and 62 non-pregnant female subjects. Each subject tested her own urine sample using dip mode testing method on the candidate device following instructions on the package insert. The same sample was tested by a professional using the same lay user samples, who performed testing on the candidate device and on the predicate device in dip mode testing method. Lay user performance was demonstrated for the mid-stream mode in k172512.

Summary of results is presented in the table below:

Results in dip-mode by professional (candidate device) vs. (predicate device)

		Predicate Device		Total
		Positive	Negative	
Candidate Device	Positive	113	1	114
	Negative	0	61	61
	Total	113	62	175

Results in dip-mode lay user (candidate device) vs. professional (candidate device)

Dip Mode		Candidate Device (POC)		Total
		Positive	Negative	
Candidate Device (Lay user)	Positive	113	1	114
	Negative	0	61	61
	Total	113	62	175

b. Matrix comparison:

Not Applicable.

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

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