

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

A. 510(k) Number:

k102760

B. Purpose for Submission:

New device

C. Measurand:

Human Chorionic Gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Atlas Medical

F. Proprietary and Established Names:

Atlas Home Pregnancy Test (Midstream Format)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCX	Class II	21 CFR § 862.1155, Human Chorionic Gonadotropin (HCG) test system	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Atlas Home Pregnancy Test (Midstream Format) is a home use (OTC) rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in the urine to aid in the early detection of pregnancy.

3. Special conditions for use statement(s):

Atlas Home Pregnancy Test (Midstream Format) is for over-the-counter use.

4. Special instrument requirements:

None

I. Device Description:

The Atlas Home Pregnancy Test consists of a single test strip encased in plastic device housing, with an absorbent tip. The results are generated by immersing the tip in the urine stream for a sufficient amount of time to absorb an adequate sample volume. Each test device consists of a membrane coated with polyclonal anti-hCG antiserum as a test line, mouse anti-hCG antiserum colloidal gold conjugate, and the control line which contains a monoclonal goat anti-mouse antiserum.

J. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
ACON One Step Pregnancy Test Device	k993317

Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate (k993317)
Indications for Use	Same	Qualitative detection of human Chorionic Gonadotropin (hCG) in urine as an aid for early detection of pregnancy.
User	Over-the-Counter Use	Prescription Use
Format	Midstream Method	Cassette
Test Principle	Same	Colloidal Gold Immunoassay (Membrane particle assay)
Detection Limit	Same	25 mIU/mL
Specificity	Same	No interference when tested with FSH, LH and TSH
Test Time	Same	3 minutes
Traceability	Same	WHO 3 rd International Standard
Storage Temperature	36-86°F	59-86°F

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

None were referenced

L. Test Principle:

Atlas Home Pregnancy Test (Midstream Format) is a rapid one-step immuno-chromatographic screening test designed for the detection of human Chorionic

Gonadotropin (hCG) in urine for early detection of pregnancy. The method employs monoclonal-dye conjugate to identify hCG in the test sample.

During testing, the urine sample reacts with the dye conjugate (hCG antibody colloidal gold conjugate) which has been pre-coated on the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action to react with hCG antibody on the membrane and generate a red band. Presence of the red band indicates a positive result, while its absence indicates a negative result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Urine specimens spiked with varying hCG concentrations (1st WHO International Standard-NIBSC code 99/688) were measured in 10 replicates using three different lots. Results were visually interpreted at three minutes after sample application. Based on these results, the sponsor claimed a detection limit of 25 mIU/mL.

hCG concentration (mIU/mL)	Lot 1	Lot 2	Lot 3
0	0 positive 10 negative	0 positive 10 negative	0 positive 10 negative
5	0 positive 10 negative	0 positive 10 negative	0 positive 10 negative
10	0 positive 10 negative	0 positive 10 negative	0 positive 10 negative
15	1 positive 9 negative	1 positive 9 negative	0 positive 10 negative
20	6 positive 4 negative	5 positive 5 negative	5 positive 5 negative
25	10 positive 0 negative	10 positive 0 negative	10 positive 0 negative
100	10 positive 0 negative	10 positive 0 negative	10 positive 0 negative
250	10 positive 0 negative	10 positive 0 negative	10 positive 0 negative

b. *Linearity/assay reportable range:*

Linearity is not applicable since this is a qualitative test.

The test was evaluated for high dose effect. Negative urine samples were spiked with varying hCG concentrations (62,500, 125,000, 250,000, 500,000, 1,000,000 and 2,000,000 IU/mL). All tested concentrations gave a positive result.

Additionally, the sponsor evaluated the effects of the hCG β -core fragment on the performance of the device. A urine sample [20 mIU/mL] was spiked with various concentrations of β -core-fragment hCG (0, 63,000, 125,000, 250,000, 500,000 and 1,000,000 pmol/L). Partial interference was observed at 250,000 pmol/L while higher concentrations (500,000 and 1,000,000 pmol/L) interfered with the performance of the device. The labeling includes a statement that high concentrations of β -core fragment hCG may interfere with the results.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Atlas Home Pregnancy Test (Midstream Format) is calibrated with reference material traceable to WHO 3rd International Standard.

Real-time and accelerated stability testing showed that the devices were stable and detection limit was unchanged for 24 months when stored at 36-86°F.

- d. *Detection limit:*
Please refer to Precision Study Data in Section M1a.

- e. *Analytical specificity:*
To evaluate cross-reactivity, negative and positive urine samples (0 and 25 mIU/mL hCG) were spiked with varying concentrations of other glycoprotein hormones such as LH, FSH and TSH. Each sample was tested in triplicate.

Spiked Compound	Negative Urine (0 mIU/mL hCG)	Positive Urine (25 mIU/mL hCG)
LH [300 mIU/mL]	Negative	Positive
FSH [1000 mIU/mL]	Negative	Positive
TSH [1000 mIU/mL]	Negative	Positive

To evaluate potential interference from certain exogenous compounds, male urine samples containing 0 and 25 mIU/mL hCG were visually interpreted at three and ten minutes after sample application.

Interferant	3 minutes		10 minutes	
	0 mIU/mL hCG	25 mIU/mL hCG	0 mIU/mL hCG	25 mIU/mL hCG
Acetaminophen [20 mg/dL]	-	+	-	+
Acetoacetic Acid [2000 mg/dL]	-	+	-	+
Ascorbic Acid [20 mg/dL]	-	+	-	+
B-hydroxybutyrate [2000 mg/dL]	-	+	-	+
Caffeine [20 mg/dL]	-	+	-	+
Ephedrine [20 mg/dL]	-	+	-	+
Gentisic Acid [20 mg/dL]	-	+	-	+
Phenylpropanolamine [20 mg/dL]	-	+	-	+
Salicylic Acid [20 mg/dL]	-	+	-	+
Phenothiazine [20 mg/dL]	-	+	-	+
EDTA [80 mg/dL]	-	+	-	+

Acetylsalicylic Acid [20 mg/dL]	-	+	-	+
Benzoylcegonine [10 mg/dL]	-	+	-	+
Cannabinol [10 mg/dL]	-	+	-	+
Codeine [6 µg/dL]	-	+	-	+
Methadone [6 µg/dL]	-	+	-	+
Ethanol [1.0%]	-	+	-	+
Methanol [10%]	-	+	-	+
Albumin [2000 mg/dL]	-	+	-	+
Glucose [2000 mg/dL]	-	+	-	+
Bilirubin [2 mg/dL]	-	+	-	+
Atropine [20 mg/dL]	-	+	-	+
Estriol-17-beta [1400 µg/dL]	-	+	-	+
Hemoglobin [500 mg/dL]	-	+	-	+
Pregnanediol [1500 µg/dL]	-	+	-	+

To evaluate potential interference from changes in pH, negative and positive urine samples (spiked with 0 and 25 mIU/mL hCG, respectively) were tested at pH values ranging from 4 to 9. The results were visually interpreted at three minutes after sample application.

pH	0 mIU/mL hCG	25 mIU/mL hCG
4	-	+
5	-	+
6	-	+
7	-	+
8	-	+
9	-	+

To evaluate potential interference from specific gravity change, negative and positive urine samples (spiked with 5 and 25 mIU/mL hCG, respectively) were tested at specific gravity values ranging from 1.000 to 1.035 g/mL. The sponsor claimed that changes of urine specific gravity did not interfere with test results.

Specific Gravity (g/mL)	5 mIU/mL hCG	25 mIU/mL hCG
1.000	-	+
1.010	-	+
1.015	-	+
1.025	-	+
1.035	-	+

f. Assay cut-off:

The detection limit for a positive test using the Atlas Home Pregnancy Test (Midstream Format) is 25 mIU/mL.

2. Comparison studies:

a. *Method comparison with predicate device:*

Two method comparison studies were performed to determine the performance characteristics of the proposed device. Samples for both studies were collected from women at early stage of pregnancy (less than 5 weeks) and women suspecting that they were pregnant. In the first study, one hundred subjects (58 pregnant and 42 non-pregnant women, aged 18 to 45 years) performed a midstream self test. Additionally, the hundred subjects collected a urine sample and it was tested on the proposed and the predicate device (ACON Midstream Pregnancy Test; k983090) by laboratory professionals. The results are presented in the table below.

New device (lay users)	Predicate (professional users)	
	Positive	Negative
Positive	58	0
Negative	0	42

For the second method comparison study, fifty one subjects performed a midstream self test (two subjects had an invalid result due to insufficient sample volume) using the proposed device according to the package insert written in English and then collected a urine sample for testing by a laboratory professional. The collected urine samples were split and tested on the proposed and the predicate device (ACON One Step Pregnancy Test Device; k993317) by laboratory professionals. The results are presented in the table below.

New device (lay users)	Predicate (professional users)	
	Positive	Negative
Positive	29	0
Negative	0	20

A lay user reproducibility study was also performed to evaluate whether lay users could correctly observe the test line at the claimed cutoff. Forty female lay user subjects (18 to 45 years) evaluated their own urine sample as well as a supplied spiked control urine sample near the cutoff concentration. All subjects were able to read the result of their own sample as well as the control sample near the cutoff.

