

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

A. 510(k) Number:

k071100

B. Purpose for Submission:

New device

C. Measurand:

pH

D. Type of Test:

Qualitative

E. Applicant:

Common Sense Ltd.

F. Proprietary and Established Names:

Amniscreen™ Home Detection Liner Kit

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1550

2. Classification:

Class I; meets limitations of exemptions 21CFR 862.9(c)(9)

3. Product code:

CEN: Dye-Indicator, pH (Urinary, Non-Quant.)

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indication(s) for use below.

2. Indication(s) for use:

The Amniscreen™ Home Detection Liner Kit is intended to detect possible leakage of amniotic fluid when vaginal wetness is experienced during pregnancy by indicating pH level. pH levels greater than 5.2 produce a blue-green color. Patients are instructed to report or show test results to their healthcare provider for interpretation and medical care.

3. Special conditions for use statement(s):

The device is intended for prescription home use. In the labeling, a limitation is provided, stating that AmniScreen can only detect a difference in pH levels and should be used only as indicated according to the test procedure. In addition, users are instructed not to use the test if it has been less than 12 hours since they have had sexual intercourse, used a vaginal douche, or used any other vaginal products, if they have had any recent vaginal bleeding or spotting, and while sweating (e.g., during or immediately after exercise). Users are also instructed to alert the healthcare provider if they have been diagnosed with a vaginal infection within the last three days, are being treated with an antibiotic, or are on a diet that may alter vaginal pH, as these may interfere with test results.

4. Special instrument requirements:

None are required.

I. Device Description:

The AmniScreen™ Home Detection Liner Kit contains a Testing Panty-Liner (TPL) and a Drying Tray (DT). The TPL is comprised of a regular panty-liner with a detachable indicator strip, covered with two layers of one-way perforated film. The DT is a plastic tray to use for drying the TPL strip after discharge collection and before reading the test results. The TPL is supplied in a sealed envelope.

The AmniScreen™ kit is supplied as a 3 TPL/3 DT kit or a 20 TPL/20 DT kit.

The test is basically performed by wearing the TPL (for up to 12 hours or until wetness is sensed), removing the indicator strip and observing for color change, and, if needed, allowing it to dry in the DT for 30 minutes and observing for color change again.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Amniotest™

2. Predicate K number(s):

k914419

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	To detect possible leakage of amniotic fluid by indicating pH level	Same

Differences		
Item	Device	Predicate
Intended Use Setting	Home	Clinical site
Sample collection device	Panty-liner	Swab collected by healthcare professional
Duration of test	Up to 12 hours	15 seconds

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

None referenced

L. Test Principle:

The test uses a dye-indicator strip that changes color when in contact with fluids at pH levels greater than or equal to 5.2.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

To confirm the repeatability of the AmniScreen™ Home Detection Liner around the claimed cutoff, duplicate samples of three different batches were used to test two simulated discharges around the intended cutoff of 5.2. After

the samples were added to the panty liner, the strip was removed and allowed to dry for 10 minutes before reading the results. The results were as follows:

Solution	Sample 1	Sample 2	Sample 3
pH = 5.0	Stained	Stained	Stained
pH = 4.5	No stain	No stain	No stain

b. Linearity/assay reportable range:

Not applicable

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

Shelf life studies were performed on three different lots in real time at room temperature (about 25°C) and under accelerated conditions (at 50°C). The products passed the lab tests (visual observation, chemical testing, and leaching). Data from both studies supported the calculated shelf life of 4 years.

d. Detection limit:

The detection limit is a pH of ≥ 5.2 . See precision/reproducibility above.

A study was conducted to check the possibility that any sample of amniotic fluid will cause a non-reversible blue stain when in contact with the AmniScreen™ strip. Given that amniotic fluids may vary in pH level between 6.9 and 7.5 units and urea concentrations up to 4 mM, different solutions with pH levels between 6.5 and 8.0 units and different ammonium ions concentrations spanning between 4 mM and 175 mM were used in the study. The solutions were dripped on the AmniScreen™ device and after 30 minutes, the strip was removed from the panty liner and allowed to dry. The results showed that solutions with pH levels of 6.8 or greater and ammonium ions concentrations of up to 5 mM produced a blue color that was still visible 2 hours later.

e. Analytical specificity:

Urine with pH levels of 7.0 and above can interfere with the test.

In the labeling, users are instructed not to use the test if it has been less than 12 hours since they have had sexual intercourse, used a vaginal douche, or used any other vaginal products, if they have had any recent vaginal bleeding or spotting, and while sweating (e.g., during or immediately after exercise). Users are also instructed to alert the healthcare provider if they have been diagnosed with a vaginal infection within the last three days, are being treated

with an antibiotic, or are on a diet that may alter vaginal pH, as these may interfere with test results.

f. Assay cut-off:

See Precision/Reproducibility above.

2. Comparison studies:

a. Method comparison with predicate device:

See other clinical supportive data.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

See other clinical supportive data.

b. Clinical specificity:

See other clinical supportive data.

c. Other clinical supportive data (when a. and b. are not applicable):

A feasibility study with 108 women between 20 and 42 weeks gestation arriving at the hospital to give birth or routine examination was conducted using the AmniScreen liner for 1-6 hours. In this study, the gestation age for three groups was delineated as follows: 89.4 % at 36-42 weeks, 5.8 % at 26-35 weeks and 4.8% at 20-25 weeks. Five patients were excluded due to protocol deviations. The detection of amniotic fluid leakage was made by either finding obvious pooled amniotic fluid in the posterior fornix or in the absence of obvious fluid, detection of Ferning and positive nitrazine paper test. Among the 103 valid cases, there were 8 false positive results and no false negative results with the AmniScreen liner.

A clinical study was conducted to demonstrate that the AmniScreen™ can indicate whether wetness sensed by pregnant women may be caused by amniotic fluid leakage.

Three hundred thirty-nine (339) pregnant participants arriving at three different hospital test sites sensing unexplained wetness were enrolled in the

clinical study. The participants were between 17 and 42 weeks gestation, with the average at 37.2 weeks (standard deviation of 3.9), and had an average age of 27.5 years.

The clinician provided each subject with a single AmniScreen™ and explained the proper use and handling of AmniScreen™ and how to read the result. The subjects had to use the AmniScreen™ up to 12 hours or until they noticed any wetness, allow the strip to dry for 30 minutes, and record any occurrence of color change on the form. The clinician also independently interpreted and recorded the test result.

A second healthcare provider who was blinded to the previous results determined the clinical diagnosis from the following three methods: pooling test, ferning test, and pH test by nitrazine paper. A positive pooling test or positive result in both the pH test and the ferning test was defined as a positive standard clinical diagnosis.

Ten (10) participants were found to have violated the exclusion criteria. An additional 20 cases were dropped from the intent-to-treat cohort, as they did not complete the required tests to obtain a final clinical diagnosis. Therefore, 309 women's results were included in the data analysis.

The sensitivity of the test, or the percentage of true positive amniotic fluid leaks, was calculated. One hundred and fifty-four (154) of the 161 patients diagnosed as having amniotic fluid leakage observed the presence of a blue-green stain on a yellow background, demonstrating in 95.65% sensitivity.

The specificity of the test, or the percentage of true negative results, was also calculated. One hundred and twenty-five (125) of the 148 patients with a negative clinical diagnosis observed the absence of a blue-green stain on a yellow background, demonstrating 84.46% specificity.

The overall agreement, the percentage of time the patient-read results and the clinician-read results of the AmniScreen™ tests match, was found to be 97.4%.

At the end of the study, the women were asked to complete a questionnaire. Almost all of the women thought the blue-green stain on the strip was clear or very clear to distinguish and the result possibilities in the labeling were clear to very clear. Only 2 women felt uncomfortable using the panty liner. All others experienced no discomfort, were quite comfortable, or were indifferent. Although the majority of women correctly recorded their result as positive or negative, about 50% seemed unsure as to whether their wetness was caused by amniotic fluid or urine leakage. Similarly, for those who responded to the question about what it meant when the color change faded and disappeared, about one-third were split between amniotic fluid leakage and urine leakage,

and two-thirds responded that they didn't know. The labeling was revised to clarify the results section.

A secondary objective of the clinical study was to show that AmniScreen™ has similar levels of performance in detecting amniotic fluid as pH paper. The clinician-read pH paper results were compared to the final clinical diagnosis. The sensitivity of the pH paper was found to be 91.21%, and the specificity was found to be 89.58%.

A small study was conducted to evaluate 2nd trimester stain stability. Amniotic fluid from 49 patients between 18-23 weeks gestation was added to two AmniScreen™ devices (2 per patient) and observed for color change. Results were recorded in increments from 0 minutes up to 12 hours. One hundred percent (100%) of the samples had blue color stains on the yellow strip within the first 5 minutes and remained stable through the 12-hour follow-up.

A small study was conducted to evaluate 3rd trimester stain stability. Patients arriving at the delivery room were asked to use the AmniScreen™ device until they felt a wetness sensation. When the participants finished using the device, the study coordinator recorded the occurrence of color change every 15 minutes during a 4 hour period and after 7 days. For all 17 cases, the AmniScreen™ positive color results were visible when the strip was removed, after 4 hours, and after 7 days.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values are based on literature. It is stated in the labeling that amniotic fluid normally has pH levels of 6.7 or greater.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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