

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

A. 510(k) Number:

K030849

B. Analyte:

Placental alpha-1 Microglobulin

C. Type of Test:

Qualitative

D. Applicant:

N-Dia, Inc.

E. Proprietary and Established Names:

AmniSure™ Fetal Membranes Rupture Test/AmniSure™ ROM (Rupture Of fetal Membranes) Test

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1550; 21 CFR 862.1660
2. Classification:
I
3. Product Code:
NQM; JJX
4. Panel:
75

G. Intended Use:

1. Intended use(s):
The AmniSure ROM (Rupture Of fetal Membranes) Test is a rapid, non-instrumented, qualitative immunochromatographic test for the *in vitro* detection of amniotic fluid in vaginal secretions of pregnant women. AmniSure detects PAMG-1 protein marker of the amniotic fluid in vaginal secretions. The test is for use by health care professionals to aid in the detection of ROM in pregnant women at > 34 weeks gestation when patients report signs, symptoms or complaints suggestive of ROM.

The Human freeze-dried PAMG-1 (amniotic fluid protein control) is an assayed quality control material for the *in vitro* qualitative testing (positive control) intended to monitor the performance of the AmniSure ROM Test.

2. Indication(s) for use:
The AmniSure one-step Fetal Membranes Rupture Test is a rapid, non-instrumented qualitative immunochromatographic test for the *in vitro* detection of amniotic fluid in vaginal secretion of pregnant women. AmniSure detects PAMG-1 protein marker of the amniotic fluid in vaginal secretions. The test is for use by health care professionals to aid in the detection of rupture of membranes (ROM) in pregnant women at > 34 weeks gestation when patients report signs, symptoms or complaints suggestive of ROM.

3. Special condition for use statement(s):
This device is for near patient testing (point of care) use.
4. Special instrument Requirements:
Not applicable

H. Device Description:

The AmniSure product is supplied in a package containing 25 test kits. Each test kit consists of a sterile Dacron swab (applicator) for sampling, plastic vial with solvent for extracting the sample from the swab, and a foil pouch. The foil pouch contains a test strip (dipstick) and a packet of desiccant.

The test strip (dipstick) is a standard lateral flow device. The test strip contains colloidal gold labeled mouse monoclonal antibodies, immobilized mouse monoclonal antibodies (test region), and rabbit anti-mouse anti-immunoglobulin antibodies (control region).

The Human PAMG-1 (amniotic fluid protein control) is a native protein purified from the amniotic fluid. It is lyophilized from buffered saline solution, pH 7.2. The control consists of one vial containing 10 µg of the freeze-dried PAMG-1 protein (10 ng/mL PAMG-1 after reconstitution).

I. 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	Aid in detecting rupture of amniotic membrane in pregnant women	Aid in detecting rupture of amniotic membrane in pregnant women
Differences		
Item	Device	Predicate
Analyte	Placental alpha-1 microglobulin (PAMG-1)	pH
Principle	Immunochromatographic assay	Colorimetric assay

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

None referenced

K. Test Principle:

The test principle is lateral flow immunochromatography.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

Not applicable

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

The control is native protein purified from the amniotic fluid (purity of > 92% as observed on SDS-PAGE).

d. Detection limit:

AmniSure detects 5-7 ng/mL of PAMG-1. The sensitivity was set by a factor of 20 above the background level of PAMG-1.

To validate the sensitivity, four PAMG-1 concentrations (1 ng/mL, 5 ng/mL, 10 ng/mL, and 20,000 ng/mL) were tested on twenty-six (26) kits. All samples at 5 ng/mL and higher produced positive results, and all 1 ng/mL samples produced negative results.

e. Analytical specificity:

Vaginal infections, sperm, and urine were found to not interfere with the test. PAMG-1 concentration in vaginal exudates during infections (20 samples) did not exceed 3 ng/mL, and all samples gave negative results on the AmniSure. PAMG-1 in ten (10) sperm samples did not exceed 4 ng/mL, and all samples gave negative results on the AmniSure. Urine samples obtained from pregnant women at 25-40 weeks gestation gave negative results when tested on the AmniSure.

Additionally, no cross reactivity was observed with alpha-2-microglobulin, human chorionic gonadotropin, trophoblastic beta-1-glycoprotein, human placental lactogen, alpha fetoprotein, human serum albumin, and some IGFBP proteins.

f. Assay cut-off:

See Detection limit above.

2. Comparison studies:

a. Method comparison with predicate device:

The clinical performance of AmniSure was determined by one study involving two sites. Patients between 34-41 weeks of gestation, without active vaginal bleeding from any source and placenta previa, were evaluated by clinical assessment control and the AmniSure device. The clinical assessment control was considered positive if two out of three tests (nitrazine, ferning, and pooling) were positive. Statistical analysis is available on 159 women with the positive and negative agreements between AmniSure and the control as follows:

Positive agreement = 97.2% (69/71), 95% CI = (90.2%, 99.7%)

Negative agreement = 97.6% (81/83), 95% CI = (91.6%, 99.7%)

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:
The expected values were determined in literature studies and from research performed by the sponsor. Concentration of PAMG-1 concentration in cervical and vaginal secretions of pregnant women without complications was measured and ranged from 0.05 to 0.22 ng/mL. PAMG-1 concentrations in the amniotic fluid fall into 2,000-25,000 ng/mL range.

M. Conclusion:

The AmniSure™ Fetal Membranes Rupture Test is similar to the predicate device in intended use (i.e., detection of rupture of membranes in pregnant women). The devices differ in technological characteristics; however, the methodology of the AmniSure device is well-established and raises no concerns with safety or effectiveness. Furthermore, the AmniSure™ device was found to be in > 97% agreement with the standard clinical procedures used to detect rupture of membranes. Therefore, I recommend a substantial equivalence determination for the AmniSure™ Fetal Membranes Rupture Test.