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

A. 510(k) Number:

k061549

B. Purpose for Submission:

Modified device

C. Measurand:

Phosphatidylglycerol

D. Type of Test:

Semi-quantitative

E. Applicant:

Irvine Scientific Sales Co., Inc.

F. Proprietary and Established Names:

AmnioStat-FLM-PG

G. Regulatory Information:

1. <u>Regulation section:</u>

   21 CFR 862.1455 – Lecithin/sphingomyelin ratio in amniotic fluid test system

2. <u>Classification:</u>

   Class II

3. <u>Product code:</u>

   JHG – Chromatographic separation, lecithin/sphingomyelin ratio

4. <u>Panel:</u>

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

    AmnioStat®-FLM-PG is an immunologic semi-quantitative agglutination test, based on the use of two quantified positive controls, and is intended for determining the presence of phosphatidylglycerol (PG) in human amniotic fluid to determine fetal lung maturity.

2. Indication(s) for use:

    The AminoStat-FLM-PG Kit is intended to be used for the immunological detection of phosphatidylglycerol (PG) in amniotic fluid to determine fetal lung maturity of the fetus collected from transabdominal or vaginal pool samples.

3. Special conditions for use statement(s):

    This device is for prescription use.

4. Special instrument requirements:

    None required

I. Device Description:

The AmnioStat-FLM-PG Kit includes the following materials:

*   Agglutination Cards- 1 card per test: Cardboard with laminate.
*   Negative Control- 1 Vial with Yellow cap and label: Contains no PG in Buffer with 0.02% sodium azide.
*   Low-Positive Control- 1 Vial with Orange cap and label: Contains 0.5μg egg phosphatidylglycerol/mL phosphate buffer/lecithin matrix with 0.02% sodium azide.
*   High-Positive Control- 1 Vial with Red cap and label: Contains 2.0μg egg phosphatidylglycerol/mL phosphate buffer/lecithin matrix with 0.02% sodium azide.
*   Reagent A- 1 Vial with Green cap and label: Contains optimized concentrations of lecithin (avian egg yolk) and cholesterol (ovine wool), and Sudan Black B in ethanol.
*   Reagent B- 1 Vial per test with Blue cap and label: Contains rabbit anti-phosphatidylglycerol IgG fraction in phosphate buffer with 0.02% sodium azide.
*   Buffer Solution- 1 Bottle with Black cap and white label: Phosphate dilution buffer with 0.02% sodium azide.

AmnioStat-FLM-PG is supplied in a twelve (12) patient and six (6) patient test kit.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   AmnioStat-FLM

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

   k822150

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Determining the presence of phosphatidylglycerol in human amniotic fluid at concentrations indicative of fetal lung maturity	Same
Principle	Imuunological agglutination	Same

Differences		
Item	Device	Predicate
Components	Disposable agglutination card and use of Sudan Black B in one reagent to distinguish and differentiate kit controls	Glass slide and use of mirror to distinguish and differentiate kit controls

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

None referenced

L. Test Principle:

AmnioStat-FLM-PG is an immunological agglutination test.

M. Performance Characteristics (if/when applicable):

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

The AmnioStat-FLM-PG test kit produces reproducible results for the three (3) kit controls. As prescribed in the Assay Protocol for the Preparation of Lipid Particles, ten (10) separate "negative", "low positive", and "high positive" PG Controls were prepared and separately reacted with Reagent B. In each of the ten (10) tests performed, the "negative" controls gave no agglutination, the "low positive" controls gave agglutination patterns that were less than the "high positive" control, and the "high positive" controls gave agglutination reactions at least three (3) times higher than the "low positive" controls (as judged by visual inspection and scoring).

b. *Linearity/assay reportable range:*

Not applicable

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

See k822150.

d. *Detection limit:*

See Assay cut-off below.

e. *Analytical specificity:*

See k822150.

f. *Assay cut-off:*

AmnioStat-FLM-PG produces a "high positive" result with specimens containing PG at a concentration of approximately 2 μg/mL or greater. A "low positive" result is obtained with specimens containing PG at approximately 0.5 μg/mL. A "negative" result is obtained when PG is absent, or present at concentrations below 0.5 μg/mL.

2. Comparison studies:

a. *Method comparison with predicate device:*

The AmnioStat-FLM-PG test kit was compared to the AmnioStat-FLM test kit. The test results are shown in the **Table 1** below:

TABLE 1

LBC # Samples ( )	AmnioStat-FLM			AmnioStat-FLM-PG		
	Neg	Low Pos	High Pos	Neg	Low Pos	High Pos
Immature (12)	TND*	TND	TND	12		
Borderline (9)	7	2		6	1	1
Mature (12)	1	1	10	1	3	8

*TND = test not done. In addition to the test kit comparison, the test facility also performed a Lamellar Body Count (LBC). If the LBC is less than 30,000 the AmnioStat-FLM test is not performed.

The AmnioStat-FLM-PG test kit was also compared to another commercially available test kit. The test results are shown in **Table 2** below:

TABLE 2

LBC # Samples ( )	Abbott TDX-FLM*	AmnioStat-FLM-PG		
		Neg	Low Pos	High Pos
Immature (3)	5	3		
Borderline (1)		1		
Mature (4)	3	1		3

*The cut off values for scoring fetal lung maturity indices are: immature = < 36 mg/g, borderline = 36-54 mg/g, and mature = > 54 mg/g. Out of the eight (8) amniotic fluid samples tested by the commercially available method, five (5) amniotic fluid samples had results equating to "immature" and three (3) amniotic fluid samples had results equating to "mature."

b. *Matrix comparison:*

Summaries of the three published clinical studies were provided to support use of both transabdominal amniocentesis samples and vaginal pool samples.

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):

      Clinical testing was performed using the AmnioStat-FLM-PG test kit and the Lamellar Body Count (LBC) at two (2) independent laboratories and involved a total of seventy-three (73) patient transabdominal amniocentesis samples. The test results obtained from the comparison study yielded no false positive test results and demonstrated that the AmnioStat-FLM-PG test kit performs in accordance with the intended use of the product.

      In clinical studies in which AmnioStat-FLM-PG was compared to the analysis of PG using TLC, the two tests were found to be concordant in $\geq 87\%$ of the cases.

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   The reference range is based on literature.

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.