

# AmnioStat-FLM®-PG



## AmnioStat-FLM®-PG (Fetal Lung Maturity)

Catalog Number 91030-006

The ability to determine antenatal pulmonary maturity is of great importance in the timing of delivery for pregnancies in high risk categories, such as diabetes mellitus, Rh immunization, toxemia, premature rupture of the membrane, premature labor, uncertain gestational age, intrauterine growth retardation, and repeat cesarean section.

AmnioStat-FLM®-PG is a rapid, qualitative, slide agglutination assay for phosphatidylglycerol (PG) in amniotic fluid. Analysis of amniotic fluid for PG is widely accepted as a reliable method for determining fetal lung maturity. The presence of PG indicates fetal lung maturity and freedom from developing Respiratory Distress Syndrome (RDS) upon delivery.

In clinical studies in which AmnioStat-FLM-PG was compared to the analysis of PG using TLC, the two tests were concordant in 87% to 95% of the cases. In the over six hundred specimens analyzed in six different studies, a high positive AmnioStat-FLM-PG reaction was not associated with a single neonate with RDS. Please see the product insert for technical references.

### Features and Benefits

- Simple: Slide Agglutination Method
- Sensitive: 0.5 µg/mL PG
- Fast: Stat testing capability around the clock, with results in 15 minutes.
- Flexible: Amniocentesis or vaginal pool samples may be assayed.
- Unique: Unlike other tests for fetal lung maturity, results are unaffected by moderate blood or meconium contamination of amniotic fluid samples.
- Convenient: Easy-to-use kit include all reagents and controls to assay 6 patients.
- Reliable: Worldwide clinical use since 1982.

### Equipment Required

#### Rotators

- 60 RPM fixed speed (110V, 60 Hz US)
- 60 RPM fixed speed (220V, 60 Hz Int'l)

*Quality* defines the beginning and the end of product manufacture at Irvine Scientific. It begins with stringent supplier qualification standards and confirmation of incoming raw materials. Quality objectives and standards direct the detail of our manufacturing processes and protocols. In-process testing and confirmation ensures quality through each product's manufacture and endstage testing confirms that a product can be released into finished goods inventory. Quality of process at Irvine Scientific delivers confidence in performance and outcomes for our customers.

For In Vitro Diagnostic Use. Always refer to product insert for complete instructions for use. For more information on all of our Prenatal/Cytogenetic Products, please visit our website at [www.irvinesci.com](http://www.irvinesci.com) and click "Prenatal". For more technical information, please call us at 1 (800) 437 5706 or 1 (949) 261 7800.

EC REP MPE  
Schutweg 13 A  
5145 NP Waalwijk, The Netherlands



CATALOG #91030 Rev.2

### United States Headquarters

Irvine Scientific  
2511 Daimler Street, Santa Ana, CA 92705  
USA  
Phone: 1 (949) 261-7800  
Toll Free: 1 (800) 437-5706  
Fax: 1 (949) 261-6522  
[www.irvinesci.com](http://www.irvinesci.com)

### European Headquarters

Irvine Scientific  
Unit 31, Newtown Business Center, Block D  
Newtownmountkenedy  
County Wicklow  
Ireland  
Phone: +353 1 281 99 20  
Fax: +353 1 281 99 28



**IrvineScientific®**