



New Device Approvals

IMMULITE® AFP and IMMULITE® 2000 AFP - P010007

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: IMMULITE® AFP and IMMULITE® 2000 AFP
Manufacturer: Diagnostic Products Corporation (DPC)
Address: 5700 West 96th Street, Los Angeles, California 90045
Approval Date: November 9, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010007a.pdf>

What is it? This is a laboratory test used to measure the amount of alpha-fetoprotein (AFP) in a pregnant woman's serum (blood) and amniotic fluid (the fluid around the baby) during the 15th to 20th week of pregnancy. It is used with other tests such as ultrasonography or amniography to detect open neural tube defects (NTD) in the fetus (unborn baby).

How does it work? AFP is a substance produced by the unborn baby as it grows. When the neural tube (part of the nervous system) is not properly formed, large amounts of AFP pass into the amniotic fluid and reach the mother's blood. By measuring AFP in the mother's blood and in the amniotic fluid, it is possible to tell whether or not there is a chance that the unborn baby has an open neural tube defect.

When is it used? The AFP blood test should be used between 15th to 22nd weeks after the last menstrual period. The best time is between 16th and 18th weeks.

What will it accomplish? An elevated result indicates that there is a high level of AFP in the blood. This does not always mean that a neural tube defect is present. It means that the mother should have additional tests to see whether or not the unborn baby has a neural tube defect.

When should it not be used? The test should not be used if the mother is carrying multiple babies.

Additional information: Summary of Safety and Effectiveness and labeling will be available at:
<http://www.fda.gov/cdrh/pdf/p010007.html>

Other:

- National Institutes of Health (NIH) MedLine Plus Information on Alpha-Fetoprotein
<http://medlineplus.nlm.nih.gov/medlineplus/ency/article/003573.htm>
- National Institutes of Health (NIH) MedLine Plus Information on Neural Tube Defects
<http://medlineplus.nlm.nih.gov/medlineplus/neuraltubedefects.html>
- National Institutes of Health (NIH) MedLine Plus Information on Spina Bifida
http://www.ninds.nih.gov/health_and_medical/disorders/spina_bifida.htm
- National Institutes of Health (NIH) MedLine Plus Information on Anencephaly
http://www.ninds.nih.gov/health_and_medical/disorders/anencephaly_doc.htm

(Updated 11/28/2001)