

LABORATORY COLLECTION MANUAL	DOCUMENTATION FOR AFP TETRA MATERNAL SCREENING TEST
Effective Date: 6/2004	Page 1 of 2

I. PURPOSE OF TESTING:

The AFP Tetra Test is done to screen for open neural tube defects and certain chromosome disorders, such as Down syndrome and Trisomy 18, early in pregnancy. This test may lead to the detection of ABOUT 80% of fetuses with open spina bifida; 90% anencephaly; 75-80% Down syndrome; and trisomy 18, 60%.

- A. Neural tube defects (such as spina bifida and anencephaly) occur when the spine and brain do not develop completely. Down syndrome and Trisomy 18 results from the presence of an extra chromosome (numbers 21 and 18, respectively) and cause both mental and physical abnormalities.
- B. Some open neural tube defects and those covered with skin may not be detected. Most OTHER birth defects and mental retardation are NOT detectable by the test.

II. TIMING OF TEST:

Because this test is based partially on calculations derived from gestational age, etc., it is absolutely necessary that the test be done **BETWEEN 15-21 WEEKS GESTATION**. The test will not be calculated otherwise. Optimal age is **BETWEEN 16-18 WEEKS GESTATION**. **SPECIMEN MUST BE COLLECTED PRIOR TO AMNIOCENTESIS**.

III. NECESSARY DOCUMENTATION FROM PHYSICIAN'S OFFICE:

Because the test is based partially on calculations again there is required information that must be sent with the patient specimen in order for the specimen to be processed. The following information must accompany the specimen:

- ❖ Patient's name
- ❖ Patient's Date of Birth
- ❖ Estimated Date of Delivery
- ❖ Gestational age in a 1-2 digit whole number in weeks.
- ❖ How gestational age was determined? LMP, EDD, ultrasound?)
- ❖ Date the patient was stated gestational age
- ❖ Last menstrual period: month/day/year.
- ❖ Weight: 2-3 digit whole number
- ❖ Race of patient
- ❖ Is patient an Insulin-Dependent Diabetic?
- ❖ Is this a multiple pregnancy: how many fetuses?
- ❖ Is there a history of Neural Tube Defects in patient's family? Who was affected: (include parents, siblings, offspring, aunts, uncles, cousins, and grandparents.)
- ❖ Is this a first or a repeat specimen?

For the calculation of the gestational age, please use the date of the last menstrual period, the physical exam, or the ultrasound. **THE ESTIMATED DATE OF DELIVERY** will override other information in the calculation of this test.

IV. TESTS INCLUDED:

- ❖ Dimeric Inhibin A (DIA)
- ❖ Human chorionic gonadotropin (hCG)
- ❖ Alpha-fetoprotein
- ❖ Unconjugated estriol (uE3)

LABORATORY COLLECTION MANUAL	DOCUMENTATION FOR AFP TETRA MATERNAL SCREENING TEST
Effective Date: 6/2004	Page 2 of 2

V. LIMITATIONS OF TEST, WHAT IF THE TEST IS ABNORMAL?

If the screening result is abnormal it DOES NOT necessarily mean that the baby has a birth defect, but rather that the risk is higher than average.

- A. Abnormal screening results are often caused by:
 - Incorrect pregnancy dating. If a basic ultrasound shows a different gestational age, the screening results will be recalculated and may lead to a different interpretation.
 - Previously unidentified twins. A basic ultrasound will show this, too, and again a recalculation will be done.
- B. The following might be recommended:
 - A more detailed ultrasound
 - An amniocentesis, which can be tested for the same defects.

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APPROVED BY: Martin F. Belli, M.D. DATE: 6-2004

See original policy in the Laboratory for all documented annual reviews.

Reference:

- 1 LabCorp Comprehensive List of Procedures, AFP Serum Tetra Profile p. 113, 2003