Reporting Title: Amniotic Fluid AFP

Test Definition: AFT0001
Testing Location: Melville, NY
Reporting Location: Melville, NY

Description:

If the fetus has an open neural tube defect, AFP is thought to leak directly into the amniotic fluid causing unexpectedly high concentrations of AFP. Other fetal abnormalities such as omphalocele, gastroschisis, congenital renal disease, and esophageal atresia; and other fetal distress situations such as threatened abortion, prematurity, and fetal demise, may also show AFP elevations. The AFP measurement is compared to median values for a given gestational age and a MoM calculated.

Analytical Method(s):

Assay is performed on a PerkinElmer AutoDELFIA instrument.

1. AFP is measured using PerkinElmer's solid phase 2-site sandwich fluorometric assay (product number: PKI B079-201).

Patient preparations:
Prepare patient for amniocentesis in accordance with office procedure.

Specimen Requirements:

Container/Tube: Green Top (Sodium Heparin) Vacutainer® Tube / Transfer tube

Specimen Volume: 1 mL supernatant

Specimen Stability: Amniotic fluid supernatant samples are stable at ambient temperature for 6 days.

Specimen Rejection Criteria: Incorrect tube type

Additional Information:

1. Indications for Testing: Ancillary testing of amniotic fluid for evaluation of Open neural tube defects
2. Special Timing: Draw specimen between 15 weeks, 0 days and 21 weeks 6 days
3. Acetylcholinesterase (AChE) may optionally be ordered in addition to AFP.

CPT Code: 1 x 82105

Reference Values:
AFP MoM < 2 MoM are Within Range
AFP MoM 2-2.49 MoM are Borderline Elevation
AFP MoM ≥ 2.5 MoM are Significant Elevation

An Interpretive Report will be provided.

Supplemental Report:

No

Testing Algorithm:

Reflex Test for Borderline or significantly elevated results: Acetylcholinesterase (CPT Code: 82013,LOINC: 30106-9, Result_ID: 10071)

Consents/Authorizations:

Patient signature on patient authorization/assignment on requisition form is required.

Disclaimer:

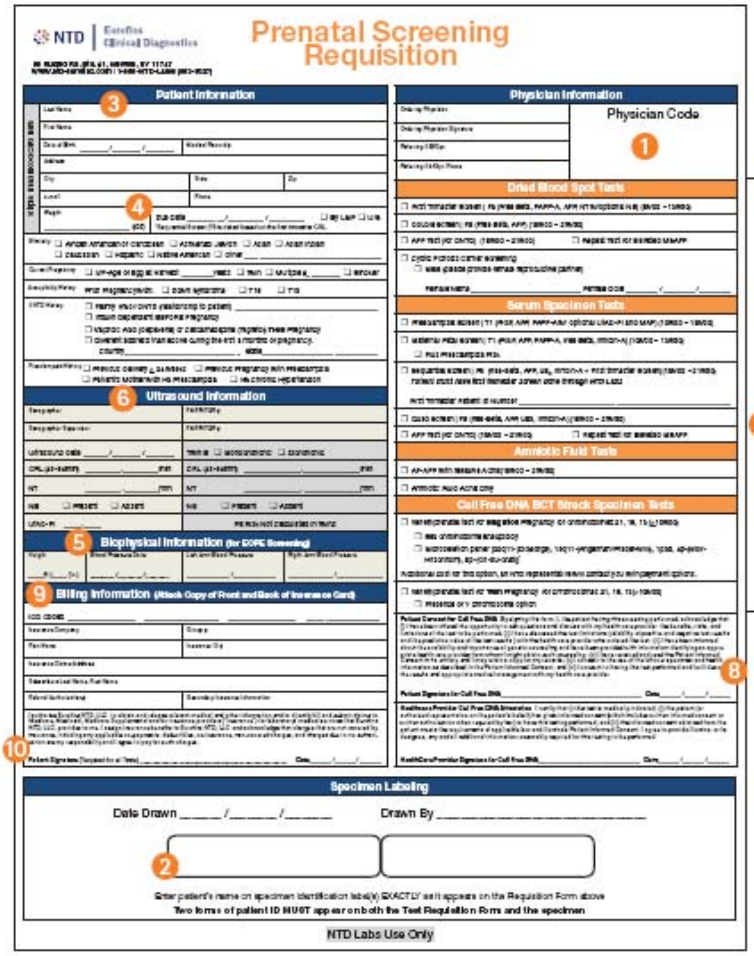
The PerkinElmer AFP assay has been approved by the FDA for testing for Open neural tube defects.

Test Requisition Instructions

NTD | Eurofins Clinical Diagnostics

Prenatal Screening Test Requisition Form Instructions

1. **Account Information** – Please enter Ordering Physician name and Referring Ob/Gyn name and phone number, if applicable. A provider signature is required for patients with Medicaid.
2. **Specimen Labels** – Preprinted with the requisition number. Please enter the patient's last and first name EXACTLY as they appear on the requisition form. Affix label(s) to patient specimen(s). Please complete date drawn and drawn-by fields.
3. **Patient Information** – For all tests, please complete patient weight, ethnicity and current pregnancy information. Complete additional patient history as appropriate for test(s) ordered. *Please note, all patient information requested is used to ensure the most accurate risk assessment possible for your patient.*
4. **Gestational Age** – Complete for tests other than First Trimester Screen I Fβ, Sequential Screen I Fβ, PreeclampsiaScreen℠ I T1 or Maternal Fetal Screen℠ I T1 which require CRL (see section 6).
5. **Biophysical Information** – Complete this section for preeclampsia screening only.
6. **Ultrasound Information** - Please provide sonographer and supervisor names and credentialing numbers. Enter all ultrasound information as appropriate for test(s) ordered.
7. **Test Requests** - Tests are ordered by specimen type. Check all tests that apply and provide appropriate ICD codes.
8. **Cell Free DNA** - BOTH the physician and patient signatures are required.
9. **Billing Information** – Provide photocopy of front and back of insurance card or print the information in the required fields.
10. **Patient Signature** - Required for all tests.



Please call **1-888-NTD-LABS** (683-5227) for further assistance.

Collection of Amniotic Fluid Specimens:

Collect Amniotic Fluids specimens following your standard operating procedure. Centrifuge to remove cells and transfer supernatant to a transfer tube. Send the supernatant for AFP testing.

Special handling needs between time of collection and time received by laboratory

Do not freeze specimens. Label all specimen tubes. Close shipping canisters tightly. Ship specimens within 24 hours via FedEx (priority overnight and Saturday delivery). Transport at room temperature. Refrigerate specimens if delayed before shipping.

Positive Patient Identification and Specimen Labeling

The clinician collecting the specimen is responsible for correctly identifying the patient using two unique patient identifiers that include the patient's complete first and last name, date of birth and/or medical record or hospital number.

Every patient must verbalize his/her name to the clinician, if able to do so by asking "Would you please tell me (or spell) your name and birthdate". It is unacceptable for the clinician to ask the patient to confirm his/her name that was verbalized by the clinician.

The Specimen MUST be labeled with two forms of patient ID that match EXACTLY with the information on the test requisition. The test Requisition has peel off labels preprinted with the Test Requisition Number that may act as one form of ID. Please print the patient's full first and last names on the label exactly as they appear on the requisition and affix to the specimen. Please retain the requisition number in your records and use if inquiring about test results.

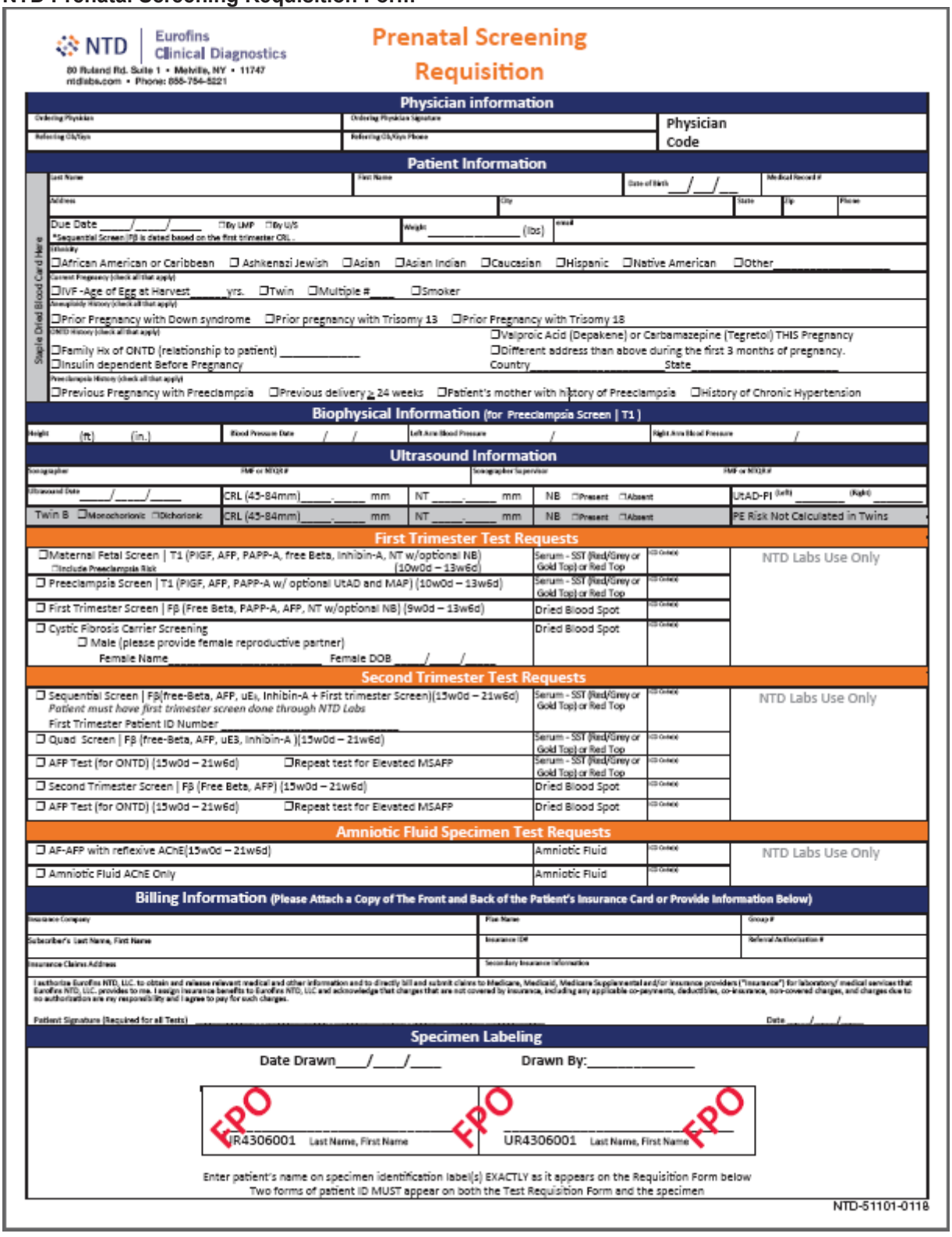
If using your own specimen labels please include two unique patient identifiers that include the patient's complete first and last name, date of birth and/or medical record or hospital number and/or the test requisition number. All information must match exactly on the test requisition form.

Enter the name of the person drawing the specimen on the test requisition to allow for traceability

Safe disposal of materials used in collection

Use only an approved disposal container for syringes and needles used in collection of specimens. Do not throw needles or syringes into the garbage, recycling containers, the toilet, plastic milk jugs, bleach bottles, or soda bottles. NTD cannot accept biohazardous materials and is not affiliated with any licensed medical waste haulers. If necessary please contact a regional hospital to direct you to an appropriate medical waste removal expert.

NTD Prenatal Screening Requisition Form



NTD Eurofins Clinical Diagnostics
80 Roland Rd. Suite 1 • Melville, NY • 11747
ntdlabs.com • Phone: 888-784-5221

Prenatal Screening Requisition

Physician information

Ordering Physician | Ordering Physician Signature | Physician Code
Referring Clk/Kiosk | Referring Clk/Kiosk Phone

Patient Information

Staple Dried Blood Card Here

Last Name | First Name | Date of Birth ___/___/___ | Medical Record #
Address | City | State | Zip | Phone
Due Date ____/____/____ ☐By LMP ☐By U/S
*Sequential Screen: If β is dated based on the first trimester CRL.
Weight _____ (lbs) | email
Ethnicity
☐African American or Caribbean ☐ Ashkenazi Jewish ☐Asian ☐Asian Indian ☐Caucasian ☐Hispanic ☐Native American ☐Other _____
Current Pregnancy (check all that apply)
☐IVF -Age of Egg at Harvest_____yrs. ☐Twin ☐Multiple #____ ☐Smoker
Aneuploidy History (check all that apply)
☐Prior Pregnancy with Down syndrome ☐Prior pregnancy with Trisomy 13 ☐Prior Pregnancy with Trisomy 18
ONTD History (check all that apply)
☐Family Hx of ONTD (relationship to patient) _____
☐Insulin dependent Before Pregnancy
☐Valproic Acid (Depakene) or Carbamazepine (Tegretol) THIS Pregnancy
☐Different address than above during the first 3 months of pregnancy.
Country_____State_____
Preeclampsia History (check all that apply)
☐Previous Pregnancy with Preeclampsia ☐Previous delivery ≥ 24 weeks ☐Patient's mother with history of Preeclampsia ☐History of Chronic Hypertension

Biophysical Information (for Preeclampsia Screen | T1)

Height (ft) (in.) | Blood Pressure Date ___/___/___ | Left Arm Blood Pressure ___/___ | Right Arm Blood Pressure ___/___

Ultrasound Information

Sonographer | NMP or NT(CP)# | Sonographer Supervisor | NMP or NT(CP)#
Ultrasound Date ____/____/____ | CRL (45-84mm)____.____ mm | NT ____.____ mm | NB ☐Present ☐Absent | UtAD-PI (Left) _____ (Right) _____
Twin B ☐Monochorionic ☐Dichorionic | CRL (45-84mm)____.____ mm | NT ____.____ mm | NB ☐Present ☐Absent | PE Risk Not Calculated in Twins

First Trimester Test Requests

☐Maternal Fetal Screen | T1 (PlGF, AFP, PAPP-A, free Beta, Inhibin-A, NT w/optional NB) (10w0d – 13w6d) ☐Include Preeclampsia Risk	Serum - SST (Red/Grey or Gold Top) or Red Top	CD Order(s)	NTD Labs Use Only
☐ Preeclampsia Screen | T1 (PlGF, AFP, PAPP-A w/ optional UtAD and MAP) (10w0d – 13w6d)	Serum - SST (Red/Grey or Gold Top) or Red Top	CD Order(s)	
☐ First Trimester Screen | Fβ (Free Beta, PAPP-A, AFP, NT w/optional NB) (9w0d – 13w6d)	Dried Blood Spot	CD Order(s)	
☐ Cystic Fibrosis Carrier Screening ☐ Male (please provide female reproductive partner) Female Name_____ Female DOB ____/____/____	Dried Blood Spot	CD Order(s)	

Second Trimester Test Requests

☐ Sequential Screen | Fβ(free-Beta, AFP, uE3, Inhibin-A + First trimester Screen)(15w0d – 21w6d) *Patient must have first trimester screen done through NTD Labs* First Trimester Patient ID Number _____	Serum - SST (Red/Grey or Gold Top) or Red Top	CD Order(s)	NTD Labs Use Only
☐ Quad Screen | Fβ (free-Beta, AFP, uE3, Inhibin-A)(15w0d – 21w6d)	Serum - SST (Red/Grey or Gold Top) or Red Top	CD Order(s)	
☐ AFP Test (for ONTD) (15w0d – 21w6d) ☐Repeat test for Elevated MSAFP	Serum - SST (Red/Grey or Gold Top) or Red Top	CD Order(s)	
☐ Second Trimester Screen | Fβ (Free Beta, AFP) (15w0d – 21w6d)	Dried Blood Spot	CD Order(s)	
☐ AFP Test (for ONTD) (15w0d – 21w6d) ☐Repeat test for Elevated MSAFP	Dried Blood Spot	CD Order(s)	

Amniotic Fluid Specimen Test Requests

☐ AF-AFP with reflexive AChE(15w0d – 21w6d)	Amniotic Fluid	CD Order(s)	NTD Labs Use Only
☐ Amniotic Fluid AChE Only	Amniotic Fluid	CD Order(s)	

Billing Information (Please Attach a Copy of The Front and Back of the Patient's Insurance Card or Provide Information Below)

Insurance Company | Plan Name | Group #
Subscriber's Last Name, First Name | Insurance ID# | Referral Authorization #
Insurance Claims Address | Secondary Insurance Information

I authorize Eurofins NTD, LLC. to obtain and release relevant medical and other information and to directly bill and submit claims to Medicare, Medicaid, Medicare Supplemental and/or insurance providers ("Insurance") for laboratory/ medical services that Eurofins NTD, LLC. provides to me. I assign insurance benefits to Eurofins NTD, LLC and acknowledge that charges that are not covered by insurance, including any applicable co-payments, deductibles, co-insurance, non-covered charges, and charges due to no authorization are my responsibility and I agree to pay for such charges.

Patient Signature (Required for all Tests) _____ Date ____/____/____

Specimen Labeling

Date Drawn____/____/____ Drawn By:_____

FPO UR4306001 Last Name, First Name | FPO UR4306001 Last Name, First Name FPO

Enter patient's name on specimen identification label(s) EXACTLY as it appears on the Requisition Form below
Two forms of patient ID MUST appear on both the Test Requisition Form and the specimen

NTD-51101-0118

EMR Ask at Order Entry (AOE) Questions:

Test ID	Question ID	Description	Type	Required
SECTRIAFAFP	HXNTD	Family History of ONTD • None • Prev Child • Patient's Sister's Child • Patient's Brother's Child • Patient's Sister • Patient's Brother • Patient's Aunt • Patient's Uncle • Partner's Prev Child • Partner's Brother	Answer List	YES
SECTRIAFAFP	NOF	Number of Fetuses • 1 • 2	Answer List	YES
SECTRIAFAFP	EDD	Due Date	Plain Text	NO
SECTRIAFAFP	GAUS	GA at U/S (Weeks.Days)	Plain Text	NO
SECTRIAFAFP	USDATE	U/S Date	Plain Text	NO

EMR Result Codes:

Data Type	Code	LOINC	Name	Contains Result	Comments
CE	RSKTBL		Risk Table	No	Included if disorders are available
ST	AFAFP		AFP	Yes	Included if disorders are available
CE	MKRANA		Markers/Analytes	No	Included if any 1T markers are available
CE	2T		2nd Trimester	No	
CE	AFP2	19176-7	AFP	Yes	Measurements contained in NTEs
CE	ACHE	30106-9	Acetylcholinesterase	Yes	Measurements contained in NTEs
CE	DGD		Demographic Data	Yes	Included if demographic data is available (contained in NTEs)
CE	2TD		2nd Trimester Data	Yes	Included if test-specific data is available (contained in NTEs)
CE	REC		Recommendations	Yes	Only displayed if recommendations are available
CE	COM	55107-7	Comments	Yes	Only displayed if comments are available
CE	FTR		Footer	Yes	Only displayed if footer is available
CE	NOT		Notification	Yes	Included for Unsatisfactory Specimens Only

Example Report

NTD | Eurofins Clinical Diagnostics

80 Ruland Rd, Suite 1 • Melville, NY • 11747 • (631) 425-0800 • Fax (631) 425-0864 • ntdreporting@eurofins.com

Amniotic Fluid AFP Report

Physician ID #: 24328
Physician Tel #: (000) 000-0000
OB SPECIALISTS
100 ANYWHERE ST
MELVILLE, NY 11747

Patient Name: AFAFP, TEST
Client ID #:
Patient ID #: 17AF1221171
Date of Birth: 01/01/88
Age at EDC: 30
Mat. Weight: 155 lbs
Ethnicity: Afr. Amer./Carib.
Prev Chrom Hx: None
Multi. Preg: No

2nd Trimester data
Insulin Rx: No
Fam Hx ONTD: No
State: NY
Draw Date: 12/20/17
GA @ Draw: 16w5d
GA by: U/S
Date Received: 12/21/17
Report Date: 12/22/17

2nd Trimester

Marker/Analyte	Value	MoM
AFP	4224.21 (IU/ml)	0.41

Amniotic Fluid AFP Interpretation: **WITHIN RANGE**

Amniotic Fluid AFP Reference Range:
Within Range: <2.00 MoM
Borderline Elevation: 2.00-2.49 MoM
Significant Elevation: >2.50 MoM

Open Neural Tube Defect NOT suspected.

Jonathan B. Carmichael, Ph.D
Laboratory Director,
Eurofins NTD, LLC

Terrence W. Hallahan, Ph.D
Laboratory Director,
Eurofins NTD, LLC

CAUTION: These results do not eliminate the possibility that this pregnancy may be associated with birth defects including open neural tube defects, ventral wall defects, or other disorders not detectable by this screening test. This report contains Protected Health Information. The recipient shall not disclose this information without the permission of the patient unless required to provide appropriate medical care.

This report was generated on: 12/22/2017 04:11:55 PM

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ISO

Physician Information Brochure
N/A

Patient Information Brochure
N/A