# Reporting Title: Amniotic Fluid AChE

Test Definition: AFT0002
Testing Location: Melville, NY
Reporting Location: Melville, NY

**Description:**
When an ONTD is suspected based upon maternal serum alpha-fetoprotein (AFP) screening results or diagnosed via ultrasound, analysis of AFP and acetylcholinesterase (AChE) in amniotic fluid are useful diagnostic tools. AChE is primarily active in the central nervous system with large amounts of non-specific cholinesterase's found in erythrocytes, skeletal muscle, and fetal serum. Normal amniotic fluid does not contain the specific neurally derived AChE, except in the presence of a fetal ONTD.

**Analytical Method(s):**

Acetylcholinesterase is evaluated using Gel Eletrophoresis.

**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: Suspicion of Open neural tube defect due to elevated Amniotic Fluid AFP or ultrasound findings.
2. Special Timing: None

**CPT Code:** 1 x 82013

**Reference Values:**

Negative (reported as negative [normal] or positive [abnormal] for inhibitable acetylcholinesterase)

An Interpretive Report will be provided.

**Supplemental Report:**
No

**Testing Algorithm:**

Follow up:
It is the experience of this program that amniotic fluids from pregnancies affected with ONTDs produce positive AChE results . Malformations of the abdominal wall of the fetus (gastroschisis or omphalocele)

produce positive AChE in approximately 60% of affected cases. AChE results have been negative in cases of congenital nephrosis. Patients should be counseled accordingly.

**Consents/Authorizations:**

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

Disclaimer:

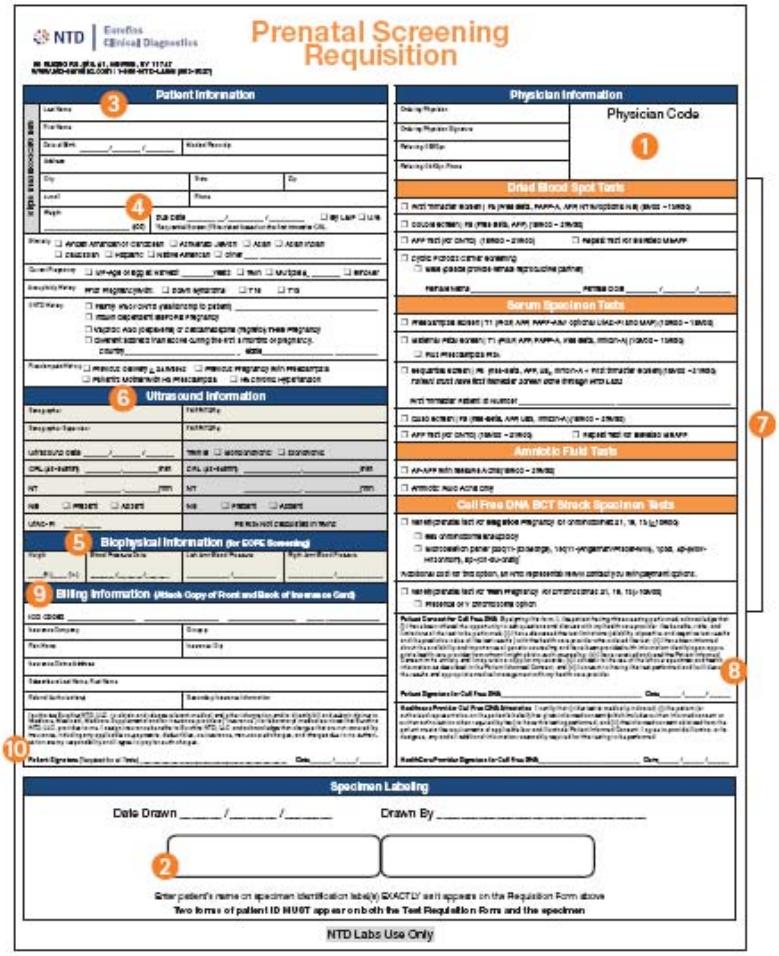
The test was developed and its performance characteristics determined by Eurofins NTD, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration. The methods and performance characteristics have been reviewed and approved by the New York State Department of Health.

## 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.

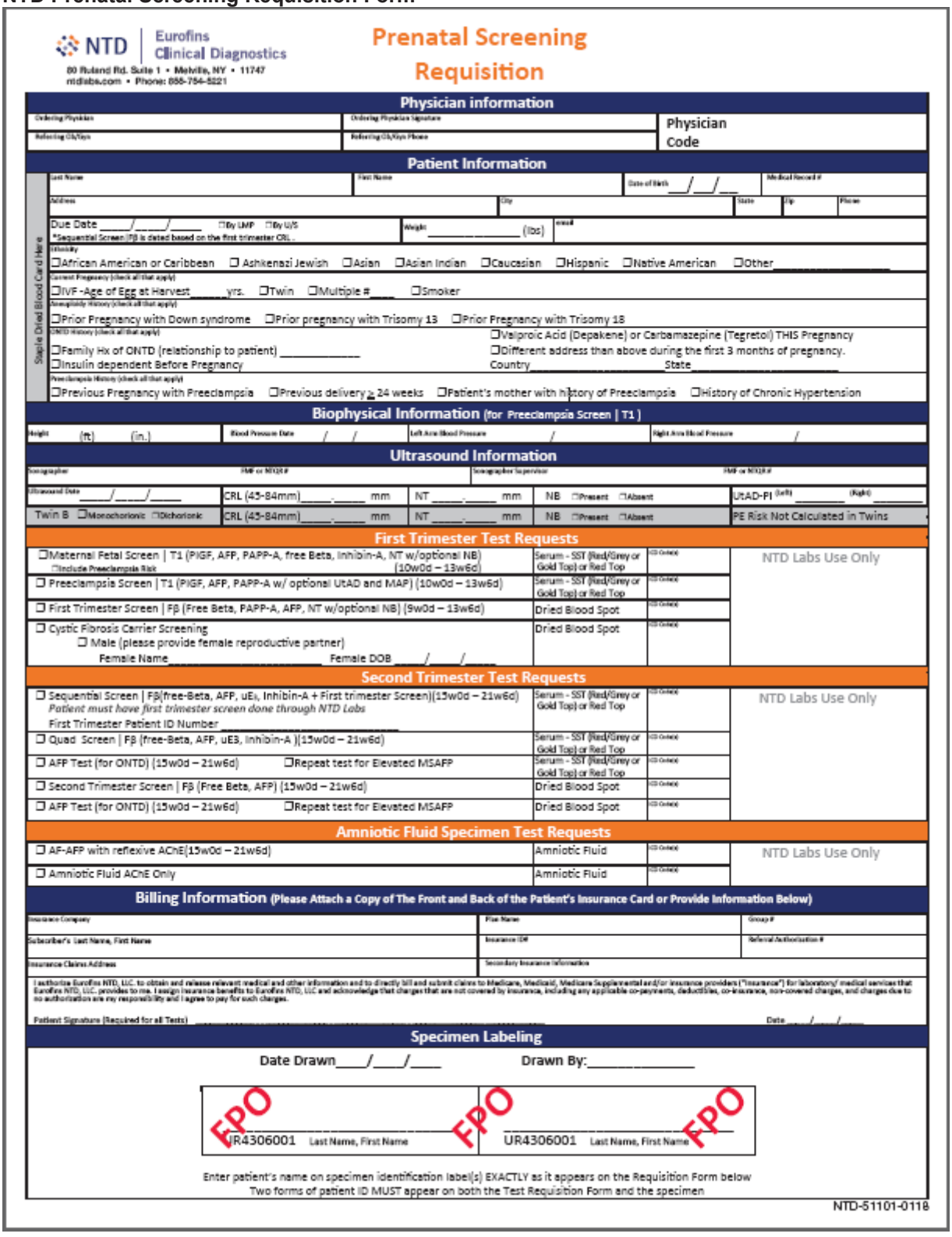
If using your own specimen labels please include two unique patient identifiers that include the patient's complete first and last name, date of birth and/or medical record or hospital number and/or the test requisition number. All information must match exactly on the test requisition form.

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/Kiys | Referring Clk/Kiys 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: FβI 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 | NMF or NT/CF # | Sonographer Supervisor | NMF or NT/CF #
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 | 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 | |
| ☐ First Trimester Screen \| Fβ (Free Beta, PAPP-A, AFP, NT w/optional NB) (9w0d – 13w6d) | Dried Blood Spot | CD Order | |
| ☐ Cystic Fibrosis Carrier Screening ☐ Male (please provide female reproductive partner) Female Name_____ Female DOB ____/____/____ | Dried Blood Spot | CD Order | |

**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 | 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 | |
| ☐ AFP Test (for ONTD) (15w0d – 21w6d) ☐Repeat test for Elevated MSAFP | Serum - SST (Red/Grey or Gold Top) or Red Top | CD Order | |
| ☐ Second Trimester Screen \| Fβ (Free Beta, AFP) (15w0d – 21w6d) | Dried Blood Spot | CD Order | |
| ☐ AFP Test (for ONTD) (15w0d – 21w6d) ☐Repeat test for Elevated MSAFP | Dried Blood Spot | CD Order | |

**Amniotic Fluid Specimen Test Requests**

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

**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 |
|---|---|---|---|---|
| SECTRIACHE | HXNTD | Family History of ONTD<br>• None<br>• Prev Child<br>• Patient's Sister's Child<br>• Patient's Brother's Child<br>• Patient's Sister<br>• Patient's Brother<br>• Patient's Aunt<br>• Patient's Uncle<br>• Partner's Prev Child<br>• Partner's Brother | Answer List | YES |
| SECTRIACHE | NOF | Number of Fetuses<br>• 1<br>• 2 | Answer List | YES |
| SECTRIACHE | EDD | Due Date | Plain Text | NO |
| SECTRIACHE | GAUS | GA at U/S (Weeks.Days) | Plain Text | NO |
| SECTRIACHE | USDATE | U/S Date | Plain Text | NO |

**EMR Result Codes:**

| Data Type | Code | LOINC | Name | Contains Result | Comments |
|---|---|---|---|---|---|
| CE | MKRANA | | Markers/Analytes | No | Included if any 1T markers are available |
| CE | 2T | | 2nd Trimester | No | |
| 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

### Ache Only Report



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

| | |
|---|---|
| Patient Name: | ACHE, ONLY |
| Client ID #: | |
| Patient ID #: | 17AF1101172 |
| Date of Birth: | 10/08/88 |
| Age at EDC: | 29 |
| Mat. Weight: | |
| Ethnicity: | Afr. Amer./Carib. |
| Prev Chrom Hx: | None |
| Multi. Preg: | No |
| EDC: | 02/25/18 |

2nd Trimester data

| | |
|---|---|
| Insulin Rx: | Yes |
| Fam Hx ONTD: | No |
| State: | NY |
| Draw Date: | 10/31/17 |
| GA @ Draw: | 23w2d |
| GA by: | EDC By U/S |
| Date Received: | 11/01/17 |
| Report Date: | 11/03/17 |

2nd Trimester

| Marker/Analyte | Value |
|---|---|
| Acetylcholinesterase | Negative |

Open Neural Tube Defect NOT suspected.

Comments:

- It is the experience of this program that amniotic fluids from pregnancies affected with ONTDs produce positive AChE results. Malformations of the abdominal wall of the fetus (gastroschisis or omphalocele) produce positive AChE in approximately 60% of affected cases. AChE results have been negative in cases of congenital nephrosis.

*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: 11/03/2017 04:13:48 PM

Page 1 of 1

ISO

## Physician Information Brochure

N/A

**Patient Information Brochure**
N/A