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

Prenatal Screening Test Requisition Form Instructions

1. **Account Information** – Please enter ordering physician name and referring physician name and phone number, if applicable. A provider signature is required for patients with Medicaid.

2. **Specimen Labels** – Preprint 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 | FS, Sequential Screen | SS, Preeclampsia Screen™ | TS or Maternal Fetal Screen™ | T1 which require CHD (see section 3).

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.

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Effective date: May 18, 2018

During the actual use of this form, cover page need not be printed.
Collection of Amniotic Fluid Specimens:

Collect Amniotic Fluid 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

### Prenatal Screening Requisition

#### Physician Information
- **Last Name:** [Blank]
- **First Name:** [Blank]
- **Address:** [Blank]
- **City:** [Blank]
- **State:** [Blank]
- **Zip Code:** [Blank]
- **Date of Birth:** [Blank]
- **Medical Record #:** [Blank]
- **Physician Code:** [Blank]

#### Patient Information
- **Last Name:** [Blank]
- **First Name:** [Blank]
- **Date of Birth:** [Blank]
- **Gender:** [Blank]
- **Race:** [Blank]
- **Ethnicity:** [Blank]
- **Marital Status:** [Blank]
- **Age at Harvest:** [Blank]
- **Twin:** [Blank]
- **Multiple:** [Blank]
- **Smoker:** [Blank]
- **Pre-Implantation Diagnosis:** [Blank]
- **Pre-Implantation Pregnancy:** [Blank]
- **Previous Prenatal Screen:** [Blank]
- **Previous Delivery:** [Blank]
- **Patient’s Mother’s History:** [Blank]
- **Previous Pregnancy:** [Blank]
- **History of Chronic Hypertension:** [Blank]

#### Biophysical Information
- **Height:** [Blank]
- **Weight:** [Blank]
- **BMI:** [Blank]
- **Gestational Age:** [Blank]
- **Abnormal Body Measurement:** [Blank]
- **Abnormal Blood Pressure:** [Blank]
- **Antihypertensive Medication:** [Blank]

#### Ultrasound Information
- **Weeks of Gestation:** [Blank]
- **Feet:** [Blank]
- **Inches:** [Blank]
- **Antihypertensive Medication:** [Blank]
- **Abnormal Body Measurement:** [Blank]
- **Abnormal Blood Pressure:** [Blank]
- **Antihypertensive Medication:** [Blank]

#### First Trimester Test Requests
- **Maternal Risk Screen:** [Blank]
- **PAPP-A:** [Blank]
- **Free Beta hCG:** [Blank]
- **Free Beta hCG:** [Blank]
- **Nuchal Translucency:** [Blank]

#### Second Trimester Test Requests
- **Sequential Screening:** [Blank]
- **AFP:** [Blank]
- **Quad Screen:** [Blank]
- **AFL:** [Blank]
- **Maternal Risk Screen:** [Blank]
- **PAPP-A:** [Blank]
- **Free Beta hCG:** [Blank]

#### Amniotic Fluid Specimen Test Requests
- **AFL:** [Blank]
- **AFL:** [Blank]
- **AFL:** [Blank]

#### Billing Information
- **Name:** [Blank]
- **Address:** [Blank]
- **City:** [Blank]
- **State:** [Blank]
- **Zip Code:** [Blank]

#### Specimen Labeling
- **Date Drawn:** [Blank]
- **Drawn By:** [Blank]
### EMR Ask at Order Entry (AOE) Questions:

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<th>Question ID</th>
<th>Description</th>
<th>Type</th>
<th>Required</th>
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<tr>
<td>SECTRIACHE</td>
<td>HXNTD</td>
<td>Family History of ONTD&lt;br&gt;• None&lt;br&gt;• Prev Child&lt;br&gt;• Patient’s Sister’s Child&lt;br&gt;• Patient’s Brother’s Child&lt;br&gt;• Patient’s Sister&lt;br&gt;• Patient’s Brother&lt;br&gt;• Patient’s Aunt&lt;br&gt;• Patient’s Uncle&lt;br&gt;• Partner’s Prev Child&lt;br&gt;• Partner’s Brother</td>
<td>Answer List</td>
<td>YES</td>
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<tr>
<td>SECTRIACHE</td>
<td>NOF</td>
<td>Number of Fetuses&lt;br&gt;• 1&lt;br&gt;• 2</td>
<td>Answer List</td>
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<td>SECTRIACHE</td>
<td>EDD</td>
<td>Due Date</td>
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<td>SECTRIACHE</td>
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<td>GA at U/S (Weeks.Days)</td>
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### EMR Result Codes:

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<td>2nd Trimester</td>
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<td>Acetylcholinesterase</td>
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<td>Measurements contained in NTEs</td>
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<tr>
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<td>Notification</td>
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<td>Included for Unsatisfactory Specimens Only</td>
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Example Report

Ache Only Report

Patient Name: ACHI, ONLY
Client ID #: 17AF1101172
Physician ID #: 24123
Physician Tel #: (020) 000-0000

Physician Name: OB SPECIALISTS
100 ANYWHERE ST.
MELVILLE, NY 11747

2nd Trimester

<table>
<thead>
<tr>
<th>Marker/Analyte</th>
<th>Value</th>
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<tbody>
<tr>
<td>Acetylcholinesterase</td>
<td>Negative</td>
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</tbody>
</table>

Open Neural Tube Defect NOT suspected.

Comments:
- It is the experience of this program that amniotic fluids from pregnancies affected with ONTDs produce positive ACHI results. Malformations of the abdominal wall of the fetus (gastroschisis or omphalocele) produce positive ACHI in approximately 50% of affected cases. ACHI results have been negative in cases of congenital nephrosis.

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Physician Information Brochure

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