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|  | <p align="center">Document name: GEN-2-043 Attachment C-PreeclampsiaScreen™ T1 Instruction Manual</p> | <p align="right">Eurofins Document Reference: 1-D-QM-CF -9059799 NTD Labs SOP ID: GEN-2-043 (Att C) Revision:2</p> |
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Reporting Title: Preeclampsia | T1

Test Definition: PE

Testing Location: Melville, NY

Reporting Location: Melville, NY

Description:

Preeclampsia | T1 includes measuring first trimester maternal serum Placental Growth factor (PIGF), Pregnancy associated plasma protein A (PAPP-A) and alpha-fetoprotein (AFP) and optionally mean arterial pressure (MAP) and uterine artery Doppler pulsitivity index (UtAD-PI). These measurements are compared to median values for a given gestational age and an MoM is calculated for each. The results are entered into a multivariate algorithm that includes nulliparity, previous or family history of PE and chronic hypertension to derive a risk factor for early onset preeclampsia.

Analytical Method(s):

All assays are performed on a PerkinElmer AutoDELFIA instrument.

1. PIGF is measured using a lab-developed solid phase 2-site sandwich fluorometric assay.
2. PAPP-A is measured using a lab-developed solid phase 2-site sandwich fluorometric assay.
3. AFP is measured using a lab-developed solid phase 2-site sandwich fluorometric assay.

Patient preparations:

Counsel patient on prenatal screening for early onset preeclampsia.

Specimen Requirements:

Container/Tube: Red-top Vacutainer® tube or Serum Separator Tube (Red/Grey or Gold Top SST) .

Specimen Volume: 0.5 ml of spun serum or 5 ml of unspun whole blood

Specimen Stability: Serum samples are stable at ambient temperature for 6 days.


Specimen Collection Instructions

See Collection of Serum Specimens from Venipuncture Instruction Manual

Additional Information:

1. Indications for Testing: General population screening of pregnant women
2. Gestational age is determined based on CRL at time of Uterine artery Doppler exam. If uterine artery Doppler exam is not performed, provide a CRL from another ultrasound exam.
3. Special Timing: Draw specimen between 10 weeks 0 days and 13 weeks 6 days.
4. To include Uterine Artery Doppler-PI in the result, the UtAD-PI must be performed when CRL is between 45 and 84 mm.
5. Mean arterial pressure (MAP) must be assessed between 11 weeks 1 day and 13 weeks 6 days. MAP should be obtained in accordance with guidelines of the Fetal Medicine Foundation.
6. The ordering physician should ensure that the ultrasound information has been obtained from a sonographer who is credentialed by and participating in an Uterine artery Doppler quality review program.

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7. If patient is returning at a later date for her ultrasound exam, ultrasound related fields may be left blank. When the patient does return for her ultrasound exam the information may be entered on our portal (<https://ntd.ereports.eurofinsus.com>).
8. Serum specimens are stable at ambient temperature for 6 days
9. Rejection Criteria: hemolysis, lipemia, incorrect tube type

CPT Codes: 1 x 83520,1 x 84163,1 x 82105

Reference Values:

After Screening Risk < 1 in 50 are Within Range
 After Screening Risk ≥ 1 in 50 are Increased Risk

An Interpretive Report will be provided.

Supplemental Report:

No

Testing Algorithm:

Follow up:

1. Increased Risk Results: Recommend immediate follow-up with increased monitoring

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.

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Test Requisition Instructions



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 FB, Sequential Screen I FB, PreeclampsiaScreen™ | T1 or Maternal Fetal Screen™ | 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.

The form is titled "Prenatal Screening Requisition" and includes the following sections:

- Patient Information:** Includes fields for Last Name, First Name, Social Security Number, Date of Birth, Sex, Race, Ethnicity, Height, Weight, Gestational Age, and Pregnancy Status.
- Physician Information:** Includes fields for Ordering Physician, Ordering Physician Signature, Referring Office, Referring Office Phone, and Physician Code.
- Ultrasound Information:** Includes fields for Sonographer, Supervisor, Ultrasound Date, and Ultrasound Number.
- Biophysical Information (per Doppler Screening):** Includes fields for Fetal Growth, Blood Flow, and Cervical Length.
- Billing Information:** Includes fields for Insurance Company, Plan, and Billing Information.
- Specimen Labeling:** Includes fields for Date Drawn and Drawn By.

Numbered callouts 1-10 are placed on the form to indicate where specific instructions apply. Callout 1 is at the Physician Code field. Callout 2 is at the Date Drawn field. Callout 3 is at the Patient Information section. Callout 4 is at the Gestational Age field. Callout 5 is at the Biophysical Information section. Callout 6 is at the Ultrasound Information section. Callout 7 is at the Test Requests section. Callout 8 is at the Cell Free DNA section. Callout 9 is at the Billing Information section. Callout 10 is at the Patient Signature field.


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

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NTD Prenatal Screening Requisition Form


| NTD Eurofins Clinical Diagnostics | | Prenatal Screening Requisition | |
|---|--|---|--|
| 80 Buland Rd. Suite 1 • Melville, NY • 11747 ntdlabs.com • Phone: 855-754-5221 | | | |
| Physician information | | | |
| Ordering Physician | | Ordering Physician Signature | |
| Referring US/Phys | | Referring US/Phys Phone | |
| | | Physician Code | |
| Patient Information | | | |
| Last Name | | First Name | |
| Address | | City | |
| State | | Zip | |
| Phone | | Date of Birth / / | |
| Due Date / / | | Weight (lb) | |
| *Sequential Screen (F) is dated based on the first trimester CR. | | | |
| Ethnicity | | | |
| <input type="checkbox"/> African American or Caribbean <input type="checkbox"/> Ashkenazi Jewish <input type="checkbox"/> Asian <input type="checkbox"/> Asian Indian <input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Native American <input type="checkbox"/> Other | | | |
| Current Pregnancy (check all that apply) | | | |
| <input type="checkbox"/> IVF - Age of Egg at Harvest _____ yrs. <input type="checkbox"/> Twin <input type="checkbox"/> Multiple # <input type="checkbox"/> Smoker | | | |
| Pregnancy History (check all that apply) | | | |
| <input type="checkbox"/> Prior Pregnancy with Down syndrome <input type="checkbox"/> Prior pregnancy with Trisomy 13 <input type="checkbox"/> Prior Pregnancy with Trisomy 18 | | | |
| <input type="checkbox"/> Family Hx of ONTD (relationship to patient) _____ <input type="checkbox"/> Valproic Acid (Depakene) or Carbamazepine (Tegretol) THIS Pregnancy | | | |
| <input type="checkbox"/> Insulin dependent Before Pregnancy Country _____ State _____ | | | |
| Preeclampsia History (check all that apply) | | | |
| <input type="checkbox"/> Previous Pregnancy with Preeclampsia <input type="checkbox"/> Previous delivery > 24 weeks <input type="checkbox"/> Patient's mother with history of Preeclampsia <input type="checkbox"/> 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 | | Sonographer's supervisor | |
| FMB or NIDP # | | FMB or NIDP # | |
| Ultrasound Date / / | | CRL (43-84mm) _____ mm | |
| | | NT _____ mm | |
| | | NB <input type="checkbox"/> Present <input type="checkbox"/> Absent | |
| | | UtAD-PI (Left) (Right) | |
| Twin B <input type="checkbox"/> Monochorionic <input type="checkbox"/> Dichorionic | | CRL (43-84mm) _____ mm | |
| | | NT _____ mm | |
| | | NB <input type="checkbox"/> Present <input type="checkbox"/> Absent | |
| | | PE Risk Not Calculated in Twins | |
| First Trimester Test Requests | | | |
| <input type="checkbox"/> Maternal Fetal Screen T1 (PIGF, AFP, PAPP-A, free Beta, Inhibin-A, NT w/optional NB) (10w0d - 13w6d) | | Serum - SST (Red/Grey or Gold Top) or Red Top | |
| <input type="checkbox"/> Preeclampsia Screen T1 (PIGF, AFP, PAPP-A w/ optional UtAD and MAP) (10w0d - 13w6d) | | Serum - SST (Red/Grey or Gold Top) or Red Top | |
| <input type="checkbox"/> First Trimester Screen Fβ (Free Beta, PAPP-A, AFP, NT w/optional NB) (9w0d - 13w6d) | | Dried Blood Spot | |
| <input type="checkbox"/> Cystic Fibrosis Carrier Screening | | Dried Blood Spot | |
| <input type="checkbox"/> Male (please provide female reproductive partner) | | | |
| Female Name _____ Female DOB / / | | | |
| Second Trimester Test Requests | | | |
| <input type="checkbox"/> Sequential Screen Fβ (free-Beta, AFP, uEi, Inhibin-A + First trimester Screen) (15w0d - 21w6d) | | Serum - SST (Red/Grey or Gold Top) or Red Top | |
| Patient must have first trimester screen done through NTD Labs First Trimester Patient ID Number _____ | | | |
| <input type="checkbox"/> Quad Screen Fβ (free-Beta, AFP, uE3, Inhibin-A) (15w0d - 21w6d) | | Serum - SST (Red/Grey or Gold Top) or Red Top | |
| <input type="checkbox"/> AFP Test (for ONTD) (15w0d - 21w6d) <input type="checkbox"/> Repeat test for Elevated MSAFP | | Serum - SST (Red/Grey or Gold Top) or Red Top | |
| <input type="checkbox"/> Second Trimester Screen Fβ (Free Beta, AFP) (15w0d - 21w6d) | | Dried Blood Spot | |
| <input type="checkbox"/> AFP Test (for ONTD) (15w0d - 21w6d) <input type="checkbox"/> Repeat test for Elevated MSAFP | | Dried Blood Spot | |
| Amniotic Fluid Specimen Test Requests | | | |
| <input type="checkbox"/> AF-AFP with reflexive AChE (15w0d - 21w6d) | | Amniotic Fluid | |
| <input type="checkbox"/> Amniotic Fluid AChE Only | | Amniotic Fluid | |
| Billing Information (Please Attach a Copy of The Front and Back of the Patient's Insurance Card or Provide Information Below) | | | |
| Insurance Company | | File Name | |
| Subscriber's Last Name, First Name | | Insurance ID# | |
| 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. | | Date / / | |
| Patient Signature (Required for all Tests) | | | |
| Specimen Labeling | | | |
| Date Drawn / / | | Drawn By: _____ | |
| [R4306001 Last Name, First Name] | | [UR4306001 Last Name, First Name] | |
| 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

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EMR Ask at Order Entry (AOE) Questions:

| Test ID | Question ID | Description | Type | Required |
|---------|-------------|--|-------------|----------|
| PE | NOF | Number of Fetuses <ul style="list-style-type: none"> • 1 • 2 • 3 or more (NT Only) | Answer List | YES |
| PE | SMOKE | Is Patient Smoker <ul style="list-style-type: none"> • No • Yes | Answer List | YES |
| PE | MATWT | Maternal Weight | Plain Text | Yes |
| PE | MWLBSKGS | Units <ul style="list-style-type: none"> • LBS • KGS | Answer List | YES |
| PE | ETHNIC | Ethnicity <ul style="list-style-type: none"> • African American/Caribbean • Asian • Asian Indian • Caucasian • Hispanic • Native American • Other | Answer List | YES |
| PE | USDATE | Ultrasound Date | Plain Text | Yes |
| PE | CRL | CRL | Plain Text | Yes* |
| PE | BPDATE | Blood Pressure Date | Plain Text | No |
| PE | BPLEFT | Blood Pressure Left Arm | Plain Text | No |
| PE | BPRIGHT | Blood Pressure Right Arm | Plain Text | No |
| PE | UTADPI | Uterine Artery Doppler-PI (Mean) | Plain Text | No |
| PE | SONOID | Sonographer Name or MFM/NTQRID | Plain Text | No |
| PE | SSUPER | Sonographer Supervisor (MD) Name or FMF/NTQRID | Plain Text | No |
| PE | HGHT | Maternal Height (Ft.In) | Plain text | Yes |
| PE | PAROUS | Previous Delivery > 24 Weeks <ul style="list-style-type: none"> • No • Yes | Answer List | Yes |
| PE | HXPE | Previous Pregnancy with preeclampsia <ul style="list-style-type: none"> • No • Yes | Answer List | Yes |
| PE | HXPEMO | Patient's Mother with History of Preeclampsia <ul style="list-style-type: none"> • No • Yes | Answer List | Yes |

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| | | | | |
|----|--------|--|-------------|-----|
| PE | HXCHHY | Chronic Hypertension <ul style="list-style-type: none"> • No • Yes | Answer List | Yes |
|----|--------|--|-------------|-----|

EMR Result Codes:

| Data Type | Code | LOINC | Name | Contains Result | Comments |
|-----------|--------|---------|-------------------------------------|-----------------|---|
| CE | RSKTBL | | Risk Table | No | Included if disorders are available |
| ST | EOPE | | Early Onset Preeclampsia | Yes | Risk result information contained in NTEs |
| CE | PRF | | Prior Risk Factors | Yes | Included if data is available (contained in NTEs) |
| CE | SM | | Serum Markers | No | Included if any Serum markers are available |
| CE | PIGF | | PIGF | Yes | Measurements contained in NTEs |
| CE | PAPPA | 32046-5 | PAPP-A | Yes | Measurements contained in NTEs |
| CE | AFP | 19176-7 | AFP | Yes | Measurements contained in NTEs |
| CE | PM | | Physical Markers | No | Included if any physical markers are available |
| CE | MAP | | Mean Arterial Pressure (MAP) | Yes | Measurements contained in NTEs |
| CE | UTADPI | | Uterine Artery Doppler PI (UtAD-PI) | Yes | Measurements contained in NTEs |
| CE | DGD | | Demographic Data | Yes | Included if demographic 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

Preeclampsia Screen™ | T1 Report

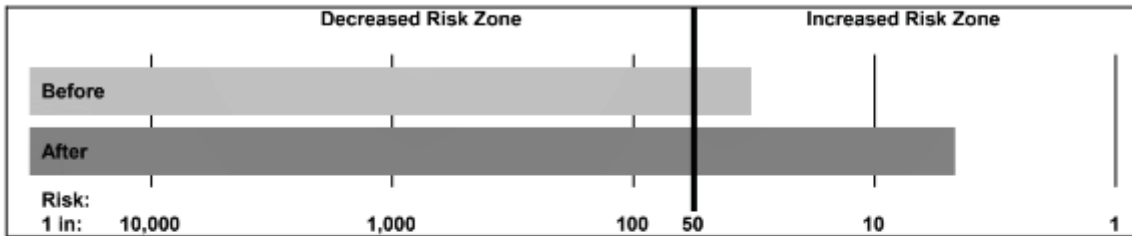
| | | |
|--|------------------------------|--|
| <p>Physician ID #: 24328 Physician Tel #: (000) 000-0000 OB SPECIALISTS 100 ANYWHERE ST MELVILLE, NY 11747</p> | <p>EXAMPLE REPORT</p> | <p>Patient Name: PESCREEN, INCREASEDRISK Patient ID #: 17PE0008888 Client ID #: 1234567 Date of Birth: 01/01/88 (age at EDC: 29) CRL (mm): 53.1 Multi. Preg: No Smoker: No Sonographer: SONOPERSON Sono Supervisor: SONODOCTOR</p> <p>U/S Date: 03/09/17 GA @ U/S: 11w6d Draw Date: 03/09/17 GA @ Draw: 11w6d (CRL) MAP Date: 03/09/17 GA @ MAP: 11w6d Date Received: 03/10/17 Report Date: 03/21/17</p> |
|--|------------------------------|--|

Interpretation: INCREASED RISK FOR EARLY ONSET PREECLAMPSIA

| Prior Risk Factors | | Serum Markers | | | | | |
|-----------------------------|-------------------|-------------------------------------|------------|-----|------|------------|-----|
| Ethnicity | Afr. Amer./Carib. | PIGF | 20.2 pg/ml | MoM | 0.78 | Percentile | 30 |
| Previous delivery >24 weeks | Yes | PAPP-A | 520 mU/l | | 0.29 | | 2.5 |
| Fam Hx Preeclampsia | No | AFP | 26.23 U/ml | | 1.92 | | 90 |
| Previous Preeclampsia | Yes | Physical Markers | | | | | |
| Chronic Hypertension | No | Mean Arterial Pressure (MAP) | 92 mm Hg | MoM | 1.08 | Percentile | 80 |
| Weight | 152 lbs | Uterine Artery Doppler PI (UIAD-PI) | 2.1 | | 1.23 | | 70 |
| Height | 5' 2" | | | | | | |
| BMI | 27.8 | | | | | | |

| Risk Table | Cut-Off | Risk Before Screening | Risk After Screening | Result |
|--------------------------|---------|-----------------------|----------------------|-----------------------|
| Early Onset Preeclampsia | 1 in 50 | 1 in 26 | 1 in <5 | INCREASED RISK |


Early Onset Preeclampsia Risk



Recommendations:

- Immediate follow-up with increased monitoring.

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

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

CAUTION: This 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. These results do not eliminate the possibility that this pregnancy may be associated with birth defects or pregnancy complications including preeclampsia, pre-term delivery and low birth weight. This report contains Protected Health Information. The recipient shall not disclose this information unless required to provide appropriate medical care without the permission of the patient. The multiple of the median and risk results provided in this report are dependent on the accuracy of the demographic and ultrasound information provided. The ordering physician should ensure that the ultrasound information has been obtained from a sonographer who is credentialed by and participating in a uterine artery Doppler quality review program such as FMF. Eurofins NTD, LLC assumes no responsibility for ensuring that the ultrasound information has been obtained by a properly credentialed sonographer, including verification or updates to credentialing status.

This report was generated on: 03/21/2017 01:53:20 PM

Physician Information Brochure

Early Onset Preeclampsia

Earlier Insight Means More Opportunity



Early Onset Preeclampsia: One of the Remaining Great Challenges in Obstetrics¹

Early onset preeclampsia (EOPE) is defined as preeclampsia resulting in the delivery of the fetus before 34 weeks' gestation. EOPE contributes more to the morbidity and mortality of pregnant mothers and babies than the more frequent, late onset form.²⁻⁴ **EOPE is a more commonly occurring condition than Down syndrome.**

**1 in
200**

Early onset preeclampsia
pregnancies^{12,13}

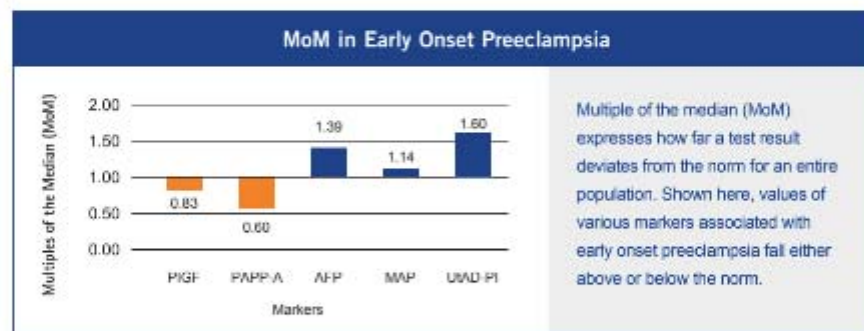
**1 in
700**

Down syndrome (trisomy 21)
live births¹⁴

Early risk assessment of EOPE allows a valuable window of opportunity for education, increased monitoring and prophylactic intervention, including low-dose aspirin, to significantly decrease the severity and/or incidence of the disease.⁵⁻¹¹ To date, there has been no reliable way to detect early onset preeclampsia, particularly for patients experiencing their first pregnancy. Until now.

PreeclampsiaScreenSM | T1: Earlier Insight Means More Opportunity

PreeclampsiaScreenSM | T1 is a first-of-its-kind serum screening test that analyzes three biochemical markers in the mother's blood: PAPP-A (pregnancy-associated plasma protein-A), PIGF (placental growth factor) and AFP (alpha fetoprotein). Together, these three biochemical markers can contribute to accurate prediction of risk for early onset preeclampsia in the first-trimester.^{16,17,18-21}



*MAP = mean arterial pressure; UtAD-PI = uterine artery Doppler pulsatility index.

Earlier Insight with PreeclampsiaScreenSM | T1

| | Biochemistry + History + MAP + UtAD-PI |
|------------------------------------|--|
| Markers | PIGF, PAPP-A, AFP, MAP, UtAD-PI |
| Gestational age (ultrasound dated) | 11 weeks, 1 day–13 weeks, 6 days |
| Detection rate at 5% FPR* | 91% |
| Requirements | 5 ml maternal serum in SST tube or red top tube, MAP and UtAD-PI measurement |

*False positive rates are representative of a general screening population. Rates may vary depending on history. Risk cutoff in each case is 1 in 50.

Early Preeclampsia Screening Improves Clinical Focus

| In 2,000 pregnancies, 10 cases of EOPE are expected ^{12,13,22} | |
|---|---------------------|
| Screening | Detected EOPE Cases |
| No screening | |
| Maternal history | |
| Biochemistry | |
| Biochemistry + MAP | |
| Biochemistry + MAP + UtAD-PI | |

PreeclampsiaScreenSM | T1 enables accurate risk assessment of early onset preeclampsia, allowing for earlier detection, intervention and management of the pregnancy.

Research Supports Earlier Intervention

Research has shown that a combination of maternal factors and biomarkers can provide effective first-trimester screening of EOPE. Additionally, for decades, the use of low-dose aspirin for the prevention of preeclampsia has been an important research question, and more than 50 trials have been conducted around the world to assess its effect.²³ Still more research is being conducted, with further insights to come.

Prediction and Prevention of Early Onset Preeclampsia:

The Impact of Aspirin after First-Trimester Screening

The Park study includes a prospective analysis of two consecutive cohorts of patients screened for EOPE using history, MAP, UtAD-PI and PAPP-A between 11 and 13 weeks. The screening algorithm detected 92% of EOPE (10% FPR), while aspirin given to patients screened as high risk for EOPE reduced the disease prevalence by 90%.²⁴

| | Observational | | Interventional | | |
|-------------------|------------------------------|----------------|------------------------------|----------------|-----------------------------|
| Patients | 3,066 | | 2,717 | | Sequential Cohorts |
| Testing | MAP UtAD PAPP-A Demographics | | MAP UtAD PAPP-A Demographics | | Same Screening Algorithm |
| Screening Results | 2,760 Screen (-) | 300 Screen (+) | 2,453 Screen (-) | 264 Screen (+) | 9.7-9.9% FPR |
| Treatments | | | | LDA | <16 Weeks |
| Outcomes | 1 EOPE | 11 EOPE | 0 EOPE | 1 EOPE | 90% Reduction in Prevalence |
| | 92% Detection | | | | |

Risk Factors for Preeclampsia

- Having high blood pressure before becoming pregnant
- High blood pressure or preeclampsia in previous pregnancies
- Having a mother or sister who had preeclampsia
- In vitro fertilization
- First pregnancy
- Pregnancy with more than one baby
- Maternal age younger than 20 or older than 40 years
- Certain health conditions, such as diabetes, kidney disease, rheumatoid arthritis or lupus
- Obesity
- African-American or Caribbean descent

Having one or more of these risk factors does not mean that a patient will develop preeclampsia, but it may point to the need for early screening to help further evaluate and assess risk.

About NTD Labs

For more than 30 years, NTD Labs has pioneered the research and development of prenatal screening protocols for CNTDs, Down syndrome, trisomy 18 and trisomy 13. Today, NTD Labs serves universities, medical centers, hospitals, laboratories, obstetricians and maternal fetal medicine specialists worldwide—providing risk assessment services that help healthcare professionals and patients make more informed decisions.

For more information about PreeclampsiaScreen™ | T1, please contact your NTD Labs Genetics Account Executive, call us at **1-888-NTDLABS** (683-5227) or visit www.ntdlabs.com/preeclampsia

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Patient Information Brochure

PreeclampsiaScreen™ | T1

Early Onset Preeclampsia
Earlier Insight Means
More Opportunity



What is early onset preeclampsia?

Early onset preeclampsia is defined as preeclampsia that results in the delivery of the baby before 34 weeks gestation. It can be more severe than the later, more common form of preeclampsia and can even be life-threatening in rare cases.

When babies are born earlier than expected, they usually spend time in the neonatal intensive care unit (NICU) and, in some cases, may face possible lifelong disabilities. Early onset preeclampsia can also put mothers at future risk for cardiovascular disease.

Although there is no cure for preeclampsia, medical research suggests that some steps may be taken during pregnancy to prevent it, delay its onset or lessen its symptoms. These may include increased monitoring and prophylactic intervention, including low-dose aspirin.

Preeclampsia: Earlier Insight Is Better

Early onset preeclampsia is a potentially serious condition that occurs in approximately 1 in every 200 pregnancies. It's important to assess your risk for early onset preeclampsia as early as possible in your pregnancy so that if you are at risk, steps may be taken to protect your health and the health of your baby.

What is preeclampsia?

Preeclampsia is a sudden increase in blood pressure and protein in the urine after the 20th week of pregnancy, or in the absence of protein in the urine, any of the following:

- Thrombocytopenia (platelet counts < 100,000/microliter)
- Renal insufficiency
- Impaired liver function
- Pulmonary edema
- Cerebral or visual symptoms

Preeclampsia can lead to eclampsia, or convulsions, posing serious health implications for mother and baby. Symptoms of preeclampsia may include:

- High blood pressure (≥ 140/90 mmHg)
- Swelling in the face, hands and feet (although swollen feet are common during pregnancy)
- Weight gain of more than five pounds in a week
- Other problems such as headache, blurred vision, abdominal pain and nausea

Who's at risk for preeclampsia?

Preeclampsia affects about 5%-7% of all pregnancies. While the early onset form of preeclampsia is not as common as the late onset form, early onset preeclampsia contributes more to the morbidity and mortality of pregnant mothers and babies.¹⁻⁵ Occurring in upward of 1 in 200 pregnancies,^{6*} early onset preeclampsia is a more commonly occurring condition than Down syndrome.^{6*}

Risk factors for preeclampsia include:

- Having high blood pressure before becoming pregnant
- High blood pressure or preeclampsia in previous pregnancies
- Having a mother or sister who had preeclampsia
- In vitro fertilization
- First pregnancy
- Pregnancy with more than one baby
- Maternal age younger than 20 or older than 40 years
- Certain health conditions, such as diabetes, kidney disease, rheumatoid arthritis or lupus
- Obesity
- African-American or Caribbean descent

Having one or more of these risk factors does not mean that you will develop preeclampsia, but it may point to the need for early screening to help further evaluate and refine your risk.



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First-trimester preeclampsia screening can help your doctor assess your risk profile earlier and more accurately than by using your history alone. The sooner you know, the more opportunity there is to prevent early onset preeclampsia or delay its onset.

What does the test involve?
 PreeclampsiaScreen™ | T1 can be ordered at the same time as other first-trimester screening tests (such as screening for Down syndrome) and requires only a simple blood draw. Your doctor may also choose to order additional measurements, including MAP or UAD-PI, which may involve a visit to an ultrasound center.

The earlier you know, the earlier you and your doctor can take steps to prevent or delay the onset of preeclampsia.

A first-trimester test can help.
 PreeclampsiaScreen™ | T1 is an advanced blood test that helps determine your risk for early onset preeclampsia. It measures the presence of three biological "markers" of preeclampsia in the mother's blood: PAPP-A (pregnancy-associated plasma protein-A), AFP (alpha fetoprotein) and PIGF (placental growth factor). When detected at certain levels, these markers can indicate a higher risk of early onset preeclampsia.

Your medical history and demographic information (e.g. height, weight, ethnicity and smoking status) are also needed to provide an accurate risk assessment for early onset preeclampsia. Your doctor may also include these additional biophysical measurements:

- Mean arterial pressure (MAP) involves taking exact blood pressure measurements from both arms
- Uterine artery Doppler pulsatility index (UAD-PI) is a special type of sonogram (ultrasound) that measures the blood flow between you and your baby



The earlier you know, the better.
 Determining your risk for early onset preeclampsia during your first-trimester can help protect your health and the health of your baby. The earlier you know, the earlier you and your doctor can take steps to prevent or delay the onset of preeclampsia. Your doctor can help you decide what is best for you and your pregnancy.



Learn more about early onset preeclampsia. Speak with your doctor or contact us at **1-888-NTD-LABS (683-5227)** or visit www.ntdlabs.com/preeclampsia.

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