Reporting Title: Quad Screen | FB

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

Description:

The 4-marker screen includes alpha-fetoprotein (AFP), free Beta human chorionic gonadotropin (fbhCG), unconjugated estriol (uE3) and inhibin A. Analyte values are compared to median values at a given gestational age and multiple of the median (MoM) results obtained. The MoM results are used in a multivariate algorithm that includes the mother's age to derive risk factors for Down syndrome and trisomy 18. The screen for ONTD's uses the AFP MoM only.

Analytical Method(s):

All assays are 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).
2. Free Beta hCG is measured using a lab-developed solid phase 2-site sandwich fluorometric assay.
3. UE3 is measured using PerkinElmer's solid phase competition fluorometric assay (product number: PKI B083-CO1).
4. Inhibin A is measured using PerkinElmer's solid phase 2-site sandwich fluorometric assay (product number: PKI B064-112).

Patient preparations:
Counsel patient on prenatal screening for aneuploidy and open neural tube defects.

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 Rejection Criteria: hemolysis, lipemia, incorrect tube type

Specimen Collection Instructions

See Blood Specimen Collection from Venipuncture Instruction Manual

Additional Information:

1. Indications for Testing: General population screening of pregnant women
2. GA at draw date is calculated by EDC or by Ultrasound. If data is entered for both methods, gestational age will be calculated based on Ultrasound. This comment relates to Ask on Entry questions (EDC, EDCUS, GAUS and USDATE).

3. Special Timing: Draw blood between 15 weeks, 0 days and 21 weeks, 6 days.
4. Do not draw blood after performing amniocentesis, as that may lead to an artificially increased serum alpha-fetoprotein level and unreliable results.

CPT Code: 1 x 82105, 1 x 84704, 1 x 82677, 1 x 86336

Reference Values:

Down syndrome:
After Screening Risk < 1 in 300 are Within Range
After Screening Risk ≥ 1 in 300 are Increased Risk

Trisomy 18

After Screening Risk < 1 in 150 are Within Range
After Screening Risk ≥ 1 in 150 are Increased Risk

Total ONTDs/VWD
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:

Follow up testing:
1. Increased Risk Results for Down syndrome or Trisomy 18 and GA<19 weeks: Genetic counseling and offer amniocentesis for diagnostic confirmation or noninvasive prenatal testing (NIPT).
2. Increased Risk Results for Down syndrome or Trisomy 18 and GA>=19 weeks: Genetic Counseling and offer of amniocentesis.
3. MSAFP Borderline Elevation and GA<19 weeks: Repeat blood or serum.
4. MSAFP Borderline Elevation and GA>=19 weeks: Genetic Counseling, Ultrasound and offer of amniocentesis.
5. MSAFP Significant Elevation: Genetic Counseling, Ultrasound and offer of amniocentesis.

Consents/Authorizations:

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

Disclaimer:

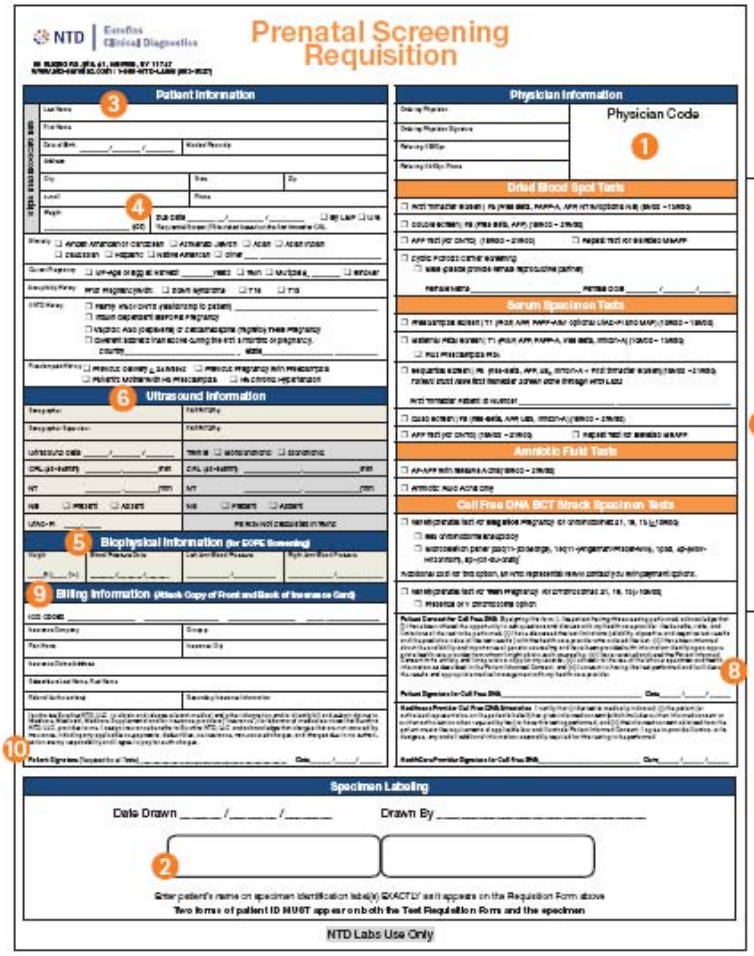
The test was developed and its performance characteristics determined by Eurofins NTD, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration. The methods and performance characteristics have been reviewed and approved by the New York State Department of Health.

Test Requisition Instructions

NTD | Eurofins Clinical Diagnostics

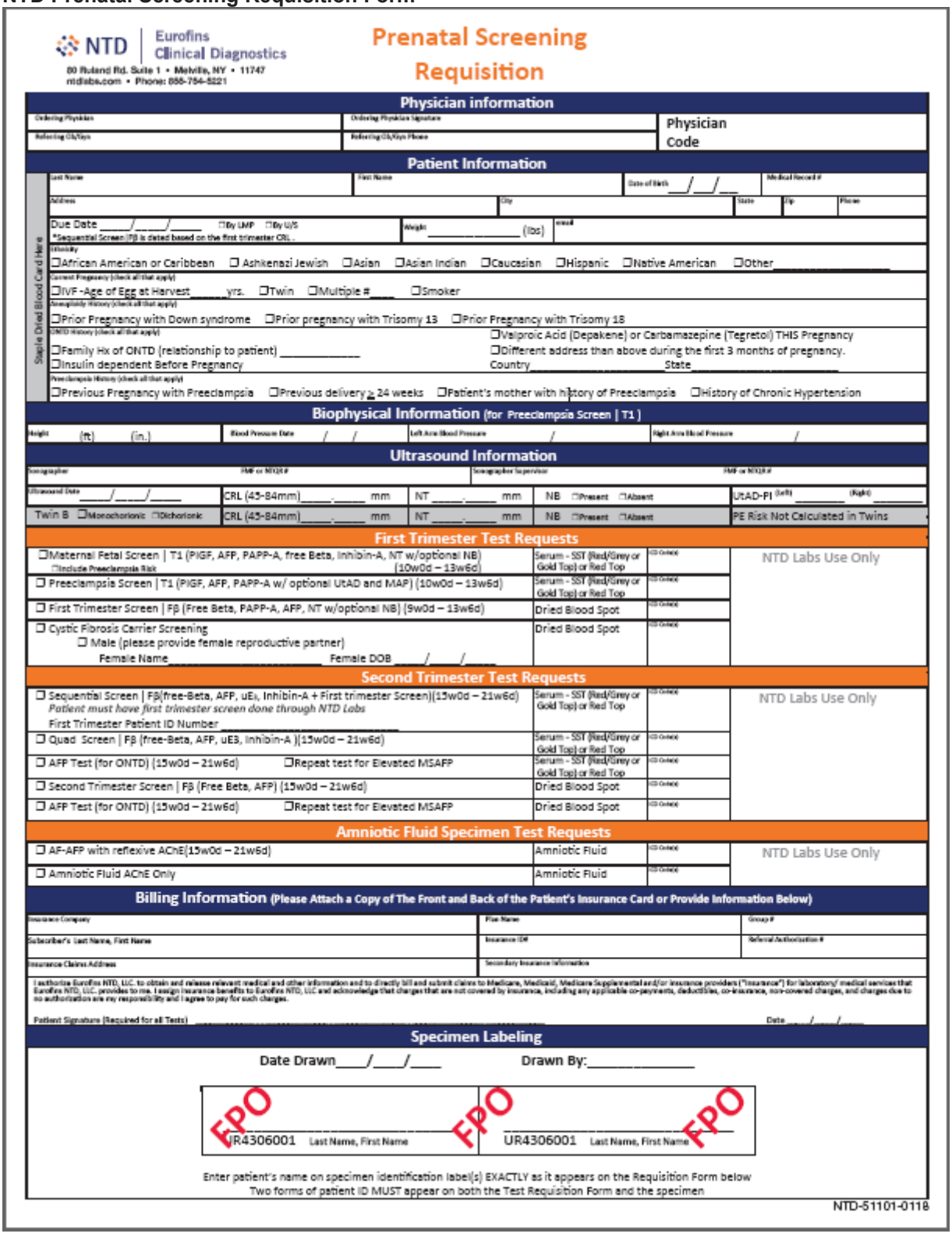
Prenatal Screening Test Requisition Form Instructions

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℠ | 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.



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

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 | Weight _____ (lbs) | email
*Sequential Screen: FB is dated based on the first trimester CRL.

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(U)D # | Sonographer Supervisor | NMF or NT(U)D #

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
SECTRIQUAD	MATWT	Maternal Weight	Plain Text	YES
SECTRIQUAD	MWLBSKGS	Units • LBS • KGS	Answer List	YES
SECTRIQUAD	ETHNIC	Ethnicity • African American/Caribbean • Asian • Asian Indian • Caucasian • Hispanic • Native American • Other	Answer List	YES
SECTRIQUAD	HXCHROM	Previous History of Chromosome Abnormality • None • Trisomy 21 • Trisomy 18 • Trisomy 13 • Trisomy 21 and 18 • Trisomy 21 and 13 • Trisomy 21, 18, 13	Answer List	YES
SECTRIQUAD	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
SECTRIQUAD	IVFAGE	IVF-Age of Egg (years)	Plain Text	NO
SECTRIQUAD	NOF	Number of Fetuses • 1 • 2	Answer List	YES
SECTRIQUAD	SMOKE	Is Patient a Smoker • No • Yes	Answer List	YES
SECTRIQUAD	VALPRO	Valproic Acid or carbamazepine used	Answer	YES

		during preg • No • Yes	List	
SECTRIQUAD	IDDM	Insulin dependent diabetic Prior to pregnancy • No • Yes	Answer List	YES
SECTRIQUAD	EDD	EDD	Plain Text	NO
SECTRIQUAD	EDDUS	EDD Confirmed by U/S • No • Yes	Answer List	NO
SECTRIQUAD	GAUS	GA at U/S (Weeks.Days)	Plain Text	NO
SECTRIQUAD	USDATE	U/S Date	Plain Text	NO
SECTRIQUAD	CO3MO	Address-Country(If different 1st 3 mos. of preg)	Plain Text	NO
SECTRIQUAD	ST3MO	Address-State(If different 1st 3 mos. Of preg)	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	DOWNS	59462-2	Down Syndrome	Yes	Risk result information contained in NTEs
ST	T18	59462-2	Trisomy 18	Yes	Risk result information contained in NTEs
ST	TONTD	59462-2	Total ONTDs/VWD	Yes	Risk result information contained in NTEs
ST	DOWNS-B	59462-2	Down Syndrome Twin B	Yes	Displayed for twin B, Risk result information contained in NTEs
ST	T18-B	59462-2	Trisomy 18 Twin B	Yes	Displayed for twin B, Risk result information contained in NTEs
ST	TONTD-B	59462-2	Total ONTDs/VWD Twin B	Yes	Risk result information contained in NTEs
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	FBHCGV2	25373-2	Free Beta hCG	Yes	Measurements contained in NTEs
CE	UE3	15064-9	uE3	Yes	Measurements contained in NTEs
CE	INH	23883-2	Inhibin-A	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	REC-B		Recommendations Twin B	Yes	Displayed for twin B, Only displayed if recommendations are available
CE	COM	55107-7	Comments	Yes	Only displayed if comments are available
CE	COM-B	55107-7	Comments Twin B	Yes	Displayed for twin B, Only displayed if comments are available
CE	FTR		Footer	Yes	Only displayed if footer is available
CE	FTR-B		Footer Twin B	Yes	Displayed for twin B, Only displayed if footer is available
CE	NOT		Notification	Yes	Included for Unsatisfactory Specimens Only
CE	NOT-B		Notification Twin B	Yes	Included for Unsatisfactory Specimens Only, Displayed for twin B

Example Report

NTD Eurofins Clinical Diagnostics

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

Quad Screen | Fß Report

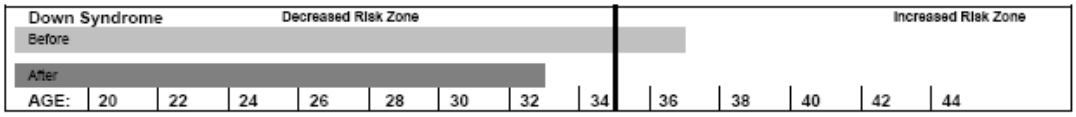
Patient Name:	QUAD, TEST		
Client ID #:			
Patient ID #:	18SE4773102	2nd Trimester data	
Date of Birth:	03/11/81	Insulin Rx:	No
Age at EDC:	37	Fam Hx ONTD:	No
Mat. Weight:	160 lbs	State:	NY
Ethnicity:	Caucasian	Draw Date:	03/11/18
Prev Chrom Hx:	None	GA @ Draw:	15w4d
Multi. Preg:	No	GA by:	EDC By U/S
Smoker:	No	Date Received:	03/13/18
EDC:	08/29/18	Report Date:	03/15/18

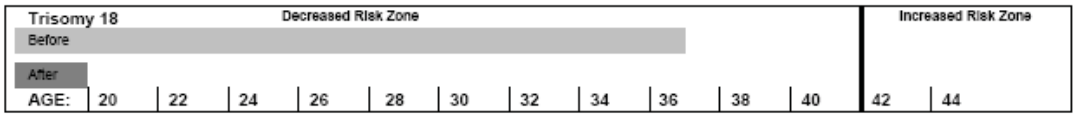
Physician ID #: 24328
Physician Tel #: (000) 000-0000
OB SPECIALISTS
100 ANYWHERE ST
MELVILLE, NY 11747

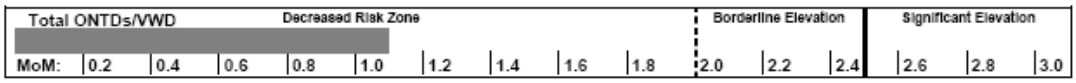
2nd Trimester

Marker/Analyte	Value	MoM	%ile
AFP	28.48 (IU/ml)	1.11	60
Free Beta hCG	17.04 (ng/ml)	1.67	70
uE3	3.025 (nmol/L)	1.03	50
Inhibin-A	353.03 (pg/ml)	1.80	90

Risk Table	Cut-Off	Risk Before Screening	Risk After Screening	Result
Down Syndrome	1 in 300	1 in 191	1 in 438	WITHIN RANGE
Trisomy 18	1 in 150	1 in 556	1 in 18,570	WITHIN RANGE
Total ONTDs/VWD	2 MoM	1 in 588	1 in 18,360	WITHIN RANGE
Open Spina Bifida	--	1 in 2,000	1 in 28,911	---
Anencephaly	--	1 in 1,429	1 in 92,568	---
Ventral Wall Defect	--	1 in 2,000	1 in 110,217	---







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

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

CAUTION: 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. These results do not eliminate the possibility that this pregnancy may be associated with birth defects including open neural tube defects, ventral wall defects, Down syndrome, trisomy 18, 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. **Any recommendations or comments on specific analytes are provided as a courtesy to the ordering physician and do not constitute medical advice.**

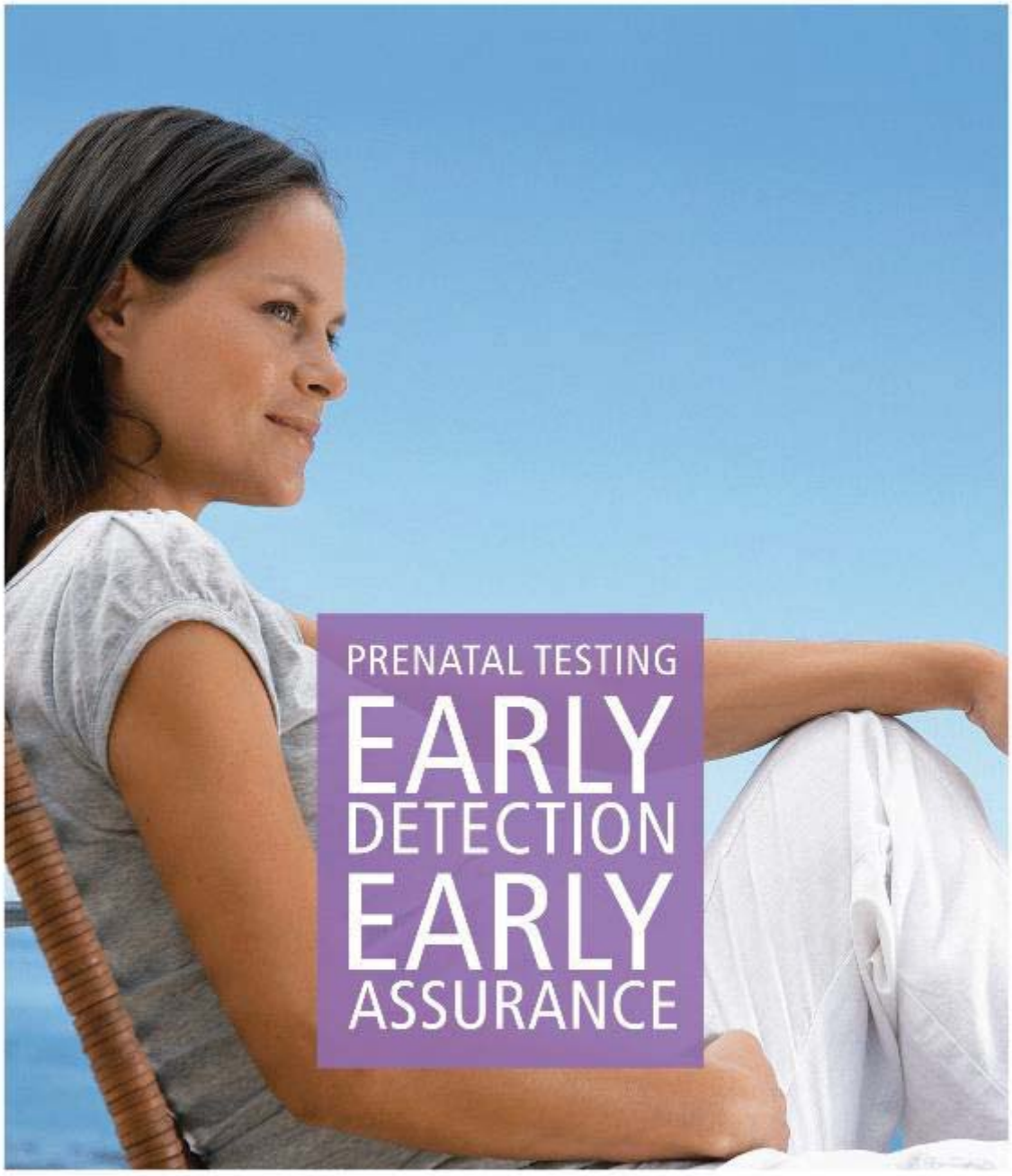
This report was generated on: 03/15/2018 04:01:48 PM

Page 1 of 1

ISO

During the actual use of this form, cover page need not be printed.

Physician Information Brochure



Prenatal Testing for Aneuploidy and ONTDs

NTD Labs
a Eurofins company

NTD LABS: A LEADER IN PRENATAL TESTING FOR MORE THAN 30 YEARS

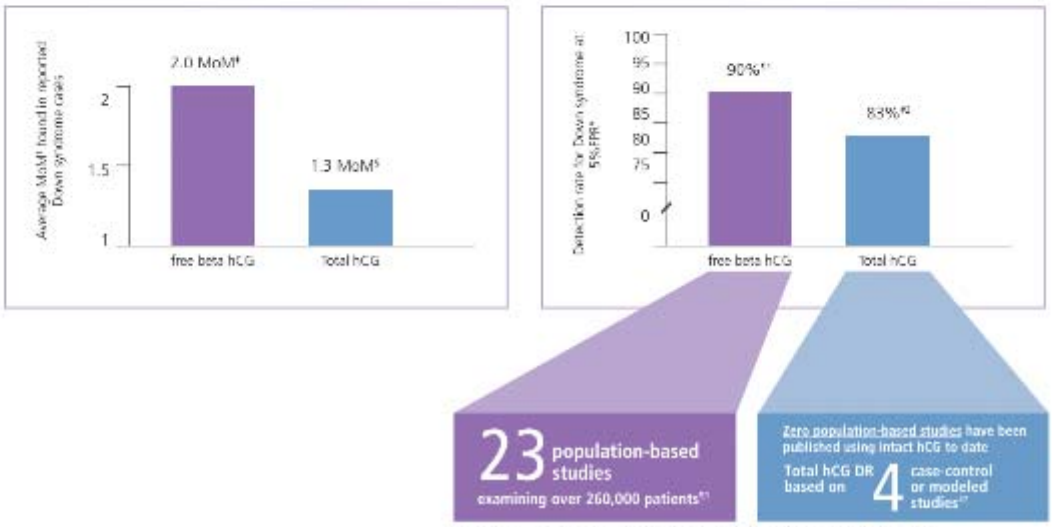
Only NTD Labs offers all of the following:

- The highest detection rate available in a first trimester biochemical screen with the superior free beta hCG protocol[1,2]
- Instant risk assessment (IRA)—provides same day, in-office results as early as 11 weeks, 1 day gestation
- Optional nasal bone assessment to increase first trimester Down syndrome detection rate to 98%[3,4]
- Separate twin reports
- Report flags option available offering more insight into potential adverse pregnancy outcomes, such as:
  - fetal loss
  - preterm birth
  - congenital adrenal hypoplasia
  - low birth weight
  - stillbirth
  - steroid sulfatase deficiency
  - preeclampsia
  - placenta accreta
  - Smith-Lemli-Opitz syndrome
- The first screening test in the U.S. to detect risk of early onset preeclampsia
- Rapid turnaround for screening tests: 1-2 days from sample receipt

Highest detection rate for Down syndrome in a biochemical screen

Scientific evidence demonstrates that free beta hCG* is consistently and significantly elevated in Down syndrome cases.[5] One of the cornerstones of NTD's prenatal screening is the measurement of this important biomarker to provide the most sensitive screening results possible at the earliest point during pregnancy.

Free beta hCG, a subunit of total hCG, is the most accurate biomarker for Down syndrome detection showing significantly higher deviation from normal pregnancy levels in Down syndrome cases, compared with total hCG levels.[6]



Free beta hCG delivers the highest first trimester detection rates (DRs) for Down syndrome.[1,2]

Largest body of evidence

23 population-based studies, including 2 NIH studies, validate free beta hCG as the superior biomarker**

	Author	Journal	Year	No. of Patients	No. of DS Cases	No. Detected	DR	FPR
1	Krantz	Obstetrics & Gynecology	2000	5721	38	30	91%	5.0%
2	Tsui	Journal of Formosan Medical Association	2001	1506	2	2	100%	4.7%
3	Nicolaides	European Journal of Human Genetics	2001	1602	5	4	80%	8.2%
4	Schaefer	Prenatal Diagnosis	2002	4939	14	12	86%	5.0%
5	Wagner (BUN Study)	The New England Journal of Medicine	2003	8205	61	52	85%	4.4%
6	Borrell	Prenatal Diagnosis	2004	2773	8	7	88%	3.3%
7	Sherbanee	Prenatal Diagnosis	2004	4989	15	14	93%	5.9%
8	Scott	Australian and New Zealand Journal of Obstetrics and Gynaecology	2004	1985	5	5	100%	7.2%
9	Hadlow	BJOG: An International Journal of Obstetrics and Gynaecology	2005	10,436	32	29	91%	3.6%
10	Nicolaides	Ultrasound in Obstetrics and Gynecology	2005	75,602	325	301	93%	5.2%
11	Wiedemann	Ultrasound in Obstetrics and Gynecology	2005	6452	11	10	91%	2.1%
12	Malone (FASTER Study)	The New England Journal of Medicine	2005	38,167	117	109	86%	5.6%
13	Perni	American Journal of Obstetrics & Gynecology	2006	4600	22	20	91%	5.0%
14	Spiegel	Fetal Diagnosis and Therapy	2006	2196	8	7	88%	4.0%
15	O'Leary	Obstetrics & Gynecology	2006	22,280	80	68	83%	3.7%
16	Krakowski	Ultraschall in der Medizin	2007	3840	26	23	88%	6.0%
17	Leung	Ultrasound in Obstetrics and Gynecology	2007	2943	13	13	100%	5.1%
18	Valinen	American Journal of Obstetrics & Gynecology	2007	4705	24	21	88%	4.9%
19	Jacobs	BJOG: An International Journal of Obstetrics and Gynaecology	2007	15,249	60	55	92%	5.6%
20	Hsu	Fetal Diagnosis and Therapy	2008	1801	9	8	89%	5.6%
21	Kirkegaard	Prenatal Diagnosis	2008	10,340	97	87	90%	3.8%
22	Lumgens	Fetal Diagnosis and Therapy	2008	19,738	100	96	96%	3.8%
23	Schielke	European Journal of Obstetrics & Gynecology and Reproductive Biology	2009	10,616	59	52	88%	4.4%
Totals and averages††				260,241	1115	988	90%	5%

ACOG‡‡ recommends prenatal aneuploidy screening be offered to ALL pregnant women, regardless of age[7]

According to the American College of Medical Genetics (ACMG):[8]

- Free beta hCG is a discriminatory Down syndrome screening marker before 11 weeks' gestation, but hCG is not
- Free beta hCG is univariately a more discriminatory Down syndrome screening marker than hCG between 11 and 13 weeks' gestation
- The best time for Down syndrome screening is at 11 completed weeks' gestation, as clinical sensitivity and specificity are reduced by 13 completed weeks' gestation

ACMG Technical Standards & Guidelines for Prenatal Screening. 2010

The protocol used at NTD Labs is similar to that of the Perni study, with the addition of AFP. The addition of AFP enables our lab to achieve a

~93%[4,6] Detection Rate | 5%[4,6] False Positive

for Down Syndrome

† Human chorionic gonadotropin
‡ Multiple of the median
§ Average based on an analysis of 17 published studies that included 2[illegible] screened Down syndrome cases
‖ Average based on an analysis of 17 published studies that included 4[illegible] screened cases
¶ See previous

†† Calculated by NTD Labs from an average of 23 published studies. Full list of references can be found at http://www.ntdlabs.com/references.
‡‡ Full list of references can be found at http://www.ntdlabs.com/references.
‖‖ American Congress of Obstetricians and Gynecologists

NTD Labs is the proven leader in prenatal screening

The pioneering efforts of NTD Labs have resulted in the most sensitive biochemical screening results possible at the earliest point during pregnancy.

Test Name	FirstTrimesterScreen | FB	Integrated Risk Assessment	Nasal Bone	SequentialScreen | FB	QuadScreen | FB	AFPTest (w. comb)
Advantage	High accuracy, early results	Early, instant results in office	The highest available detection rate in the 1st trimester	The highest available detection rate, including the 2nd trimester	For patients who present too late for 1st trimester screening	For all patients who need screening for ONTDs
Down syndrome DR	93%[1] (80% for twins[5])	93%[1,6]	96%[4,6] (89% for twins[5])	96%[1,6] (96% with NB[4])	79%[1,7]	NA
Down syndrome FPR	5%[1,6] (7% for twins[5])	5%[1,6]	2%[4,7] (3% for twins[5])	5.8%[1,6] (2.9% with NB[4])	5%[1,7]	NA
Trisomy 13/18 DR	95%[1,6]	95%[1,6]	95%[1,6]	95%[1,6]	79% (T18 only)[1,6]	NA
Trisomy 13/18 FPR	0.3%[1,6]	0.3%[1,6]	0.3%[1,6]	0.3%[1,6]	0.3% (T18 only)[1,6]	NA
Spina bifida DR	NA	NA	NA	90%[1,6]	90%[1,6]	90%[1,6]
Anencephaly DR	NA	NA	NA	98%[1,6]	98%[1,6]	98%[1,6]
Markers	free beta hCG, PAPP-A, AFP, NT	free beta hCG, PAPP-A, AFP, NT	free beta hCG, PAPP-A, AFP, NT, nasal bone (NB) absent/present	1. free beta hCG, PAPP-A, AFP, NT, (NB) 2. AFP, free beta hCG, unconjugated estriol, inhibin-A	AFP, free beta hCG, unconjugated estriol, inhibin-A	AFP
Timing	11 weeks, 1 day–13 weeks, 6 days	**blood sample** 9 weeks, 0 days–13 weeks, 6 days **NT scan** 11 weeks, 1 day–11 weeks, 6 days	11 weeks, 1 day–13 weeks, 6 days	11 weeks, 1 day–13 weeks, 6 days and 15 weeks, 0 day–21 weeks, 6 days	15 weeks, 0 days–21 weeks, 6 days	15 weeks, 0 days–21 weeks, 6 days
Diagnostic options	CVS,* amniocentesis	CVS, amniocentesis	CVS, amniocentesis	CVS, amniocentesis	Amniocentesis	Amniocentesis

*Chorionic villus sampling.

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