

Early Screen® Summary

- Earliest, safest, most accurate screening with highest detection, lowest screen positives, and highest yield of any screening test.
- Early Screen® NT/freeBeta/PAPP-A detects 91% of DS and 97% of T-18/13 with <2.4% screen positive rate.
- NT/NB/freeBeta/PAPP-A detect 97% of DS and T-18/13 at 5% screen positives.
- Documented accurate TWIN screening: 80% DR with 7.2% SPR vs. 10.4% SPR with NT alone.
- Earliest, safest, most accurate detection of ~40% of heart defects, many other anomalies and perinatal risks.
- Strongly preferred in all patient surveys.
- Coverage by the majority of insurance providers. Contact us for current list.
- Free Supplies & Transport.
- Call GeneCare or visit www.genecare.com for Official FMF NT/NB/TF, 11-13 Week Scan, Hands-On Training Courses.

GeneCare Medical Genetics Center
201 Sage Road, Suite 300
Chapel Hill, NC 27514
(800) 277-4363 • info@genecare.com

GENECARE™
Medical Genetics Center
201 Sage Road, Suite 300, Chapel Hill, NC 27514
(800) 277-4363 • info@genecare.com

Early Screen®
DETECTS OVER:
90% of Down Syndrome
and
40% of Cardiac Anomalies

PROVIDER INFORMATION

Early Screen® First Trimester™ Prenatal Screening

Nuchal Translucency, Nasal Bone
freeBeta, PAPP-A with
11-13week Ultrasound Exam



*“Earliest, Safest and Most Accurate
One Step Prenatal Screening Test”*

*Official FMF Pregnancy Management
NT/NB/TF Hands-On Training Courses*

800-277-4363
www.genecare.com

GENECARE™
Medical Genetics Center

What is Early Screen®?

Ultrasound providers with operator-specific Nuchal Translucency (NT), Nasal Bone (NB), and Tricuspid Flow (TF) Practical Certificates combine these ultrasound assessments with dried blood **freeBeta-hCG and PAPP-A** placental proteins analysis at 11 to 13 weeks 6 days. Patient-specific risks are provided for Down syndrome (DS), Trisomy 18 (T-18), and Trisomy 13 (T-13). Screening reports are called, faxed, web portal, and/or mailed to your office. Genetic counseling, CVS and amniocentesis are available to patients for diagnostic testing.

Early Screen and the 11-13 Week Ultrasound Exam also detects many other chromosome abnormalities, about 40% of fetal heart defects, many other anomalies, and perinatal risk.

NT/freeBeta/PAPP-A is the only First Trimester™ Screen recognized by ACOG, ACMG, NICHD (2004) and is Standard of Care.

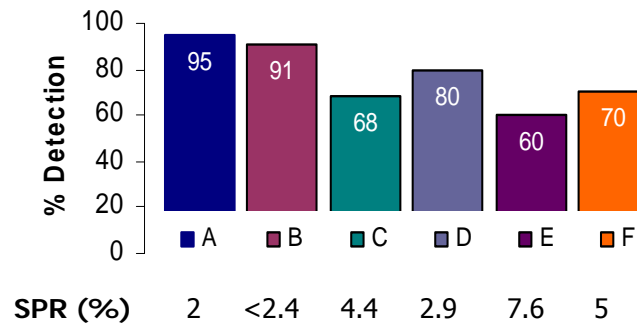
Physicians specifically order GeneCare's Early Screen, not a general first trimester screen. GeneCare uses the FMF database to provide the most extensive risk assessments for all patients.

EARLY SCREEN®

FMF NT/NB/TF/dried blood freeBeta PAPP-A for DS, T-13/18 risk for singletons, twins, triplets, quadruplets, diabetics, and patients of all ages

The international FMF literature has conclusively documented FMF Standard **Nasal Bone assessment increases DS detection to 95% with 2% Screen Positive Rate (SPR) and is an acceptable medical procedure.**

Down Syndrome Detection



A: NT/NB/freeBeta/PAPP-A (11w0d - 13w6d)
B: NT/freeBeta/PAPP-A (11w0d - 13w6d)
C: freeBeta/PAPP-A (09w0d - 13w6d)
D: AFP/freeBeta (13w4d - 22w3d)
E: Triple (15w0d - 20w6d)
F: Quad (15w0d - 20w6d)

- **EARLY SCREEN®** exceeds triple, quad, hCG, contingent, sequential and integrated DS and T-18 detection rates (DR) at lower SPR and provides T-13, twin, multiples, and diabetic risk assessments.
- **Early Screen® significantly reduces DS screen positives** to less than 2.5% for more accurate and safer screening than any other screening protocol (Cicero, Prenatal Diagn., 2003).
- **Early Screen® reassures over 97% of low risk patients @ 11-13wks**, reduces unnecessary anxiety, decreases unnecessary diagnostic CVSs and amniocenteses, and saves time and cost.
- **Early Screen®** is strongly preferred by surveyed patients in all 8 studies. Early testing provides patient privacy, reduces anxiety and makes screening safer.

- **The YIELD (PPV)** for Down Syndrome, Trisomy 18/13 is 1 identified case out of 17 CVSs or amniocenteses performed, more than 3 TIMES that of triple (1/80) or quad screening!
- Early Screen® is 35% more cost effective than triple screen (Obstet. Gynecol., 2002) and is more cost effective than hCG, quad, sequential and integrated screens.
- All studies have conclusively shown freeBeta is very effective (2.7 MOM), but hCG (1.2 MOM) is not effective.
- No study shows a benefit of hCG, sequential or integrated screening over dried blood EARLY SCREEN.
- GeneCare provides genetic counseling, ultrasound, CVS, amniocentesis and continuing education.

Follow-Up Tests

- NT ≥ 3.5mm, Low PAPP-A, and Low freeBeta are each associated with increased perinatal risk, therefore, combine every NT/NB with freeBeta/PAPP-A to obtain each of these risk assessments.
- Increased Risk Tests should NOT be repeated.
- Give patients who receive Within Normative Range results The Next Step pamphlet. Offer either AFP Only screen or targeted fetal ultrasound.
- Offer patients with an NT ≥3.5mm and normal karyotype a fetal targeted ultrasound and echocardiogram ≥20 weeks to detect many other NT associated anomalies and about 40% of heart defects.

(800) 277-4363
www.genecare.com