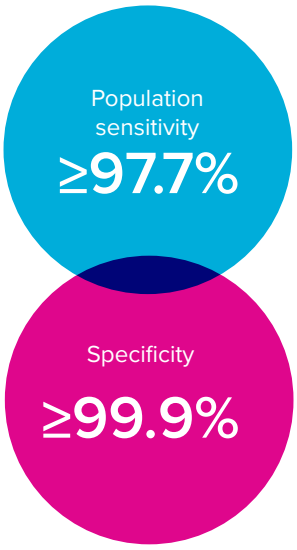
MaterniT® GENOME

CLINICAL UPDATE
COMMERCIAL EXPERIENCE n=10,272

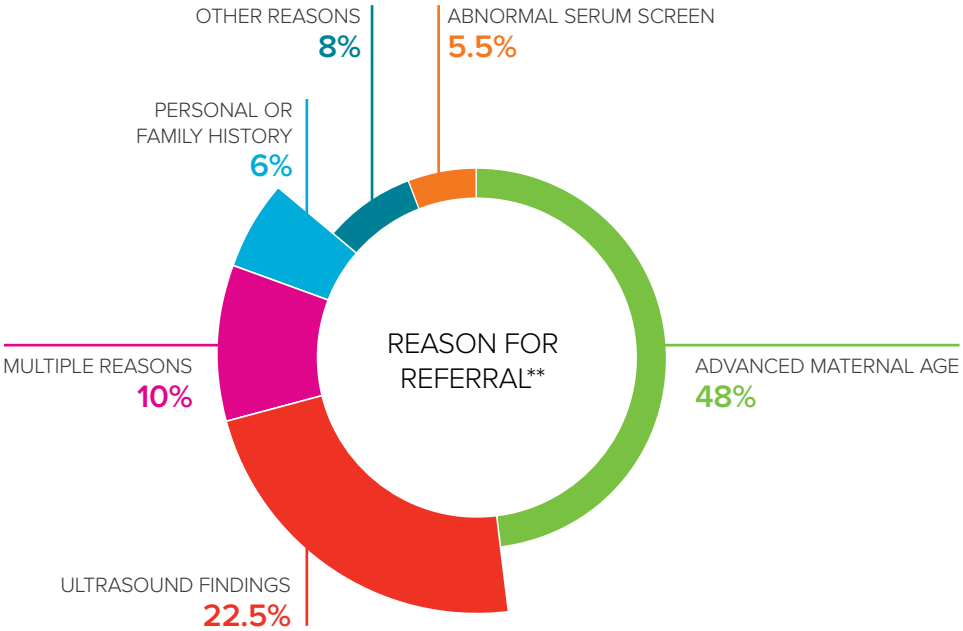
The MaterniT® GENOME laboratory-developed test screens all 23 pairs of chromosomes in the entire genome, with high sensitivity, specificity, and proven commercial reliability. It is designed to detect whole chromosome abnormalities, sex chromosome aneuploidies (SCAs), subchromosomal copy number variants (CNVs) ≥ 7 Mb, and select microdeletions.

Performance*



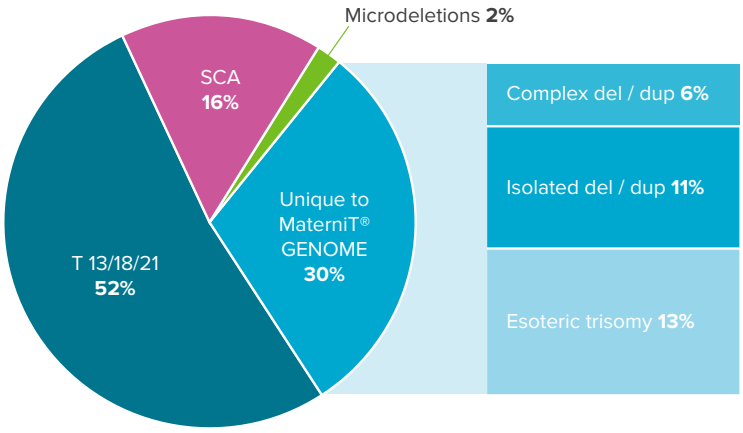
When should you use the MaterniT GENOME test?[1]

Based on peer experience, look for complex cases beyond advanced maternal age (AMA)



What will you see with the MaterniT GENOME test?[1]

Summary of the first 554 positive results



* Sensitivity estimated from the samples in the published clinical validation study[2] and across the observed range of fetal fractions.

Actual sensitivity may also be influenced by other factors such as the size of the event, total sequence counts, amplification bias, or sequence bias.

** Per test requisition

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LabCorp Specialty Testing Group

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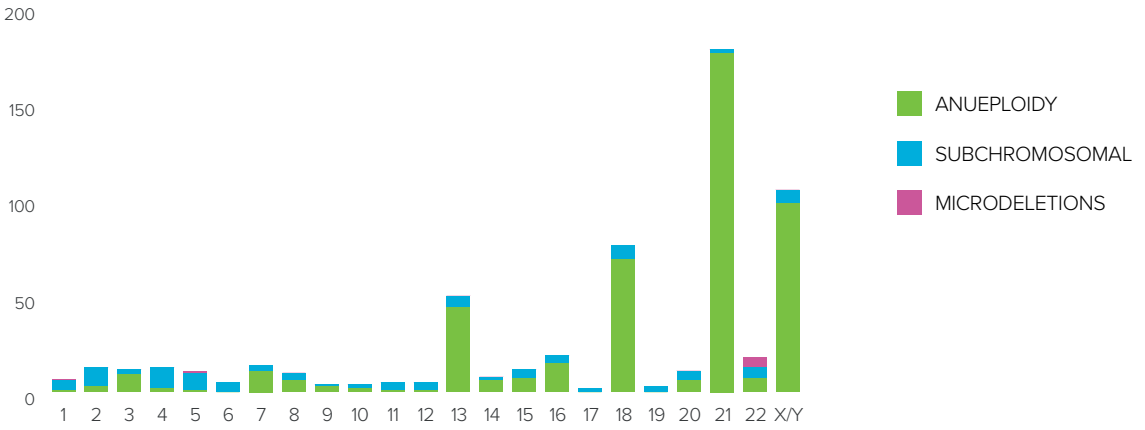
Key points[1]

- Genome-wide screening, 23 pairs of chromosomes
- Detection of trisomies and CNVs >7 Mb
- September 2015 - May 2016
- n = 10,272
- Leading reasons for referral beyond AMA
  - 23% Ultrasound findings
  - 10% Multiple reasons
  - 8% Other reasons
- Positive results were observed for every chromosome
  - 5.5% of all tests positive (n=554)
    - 52% common trisomies
    - 16% sex chromosomal aneuploidies
- Of 31 events detected in samples with personal or family history as high risk indication, 50% of these would only have been detectable by genome-wide screening

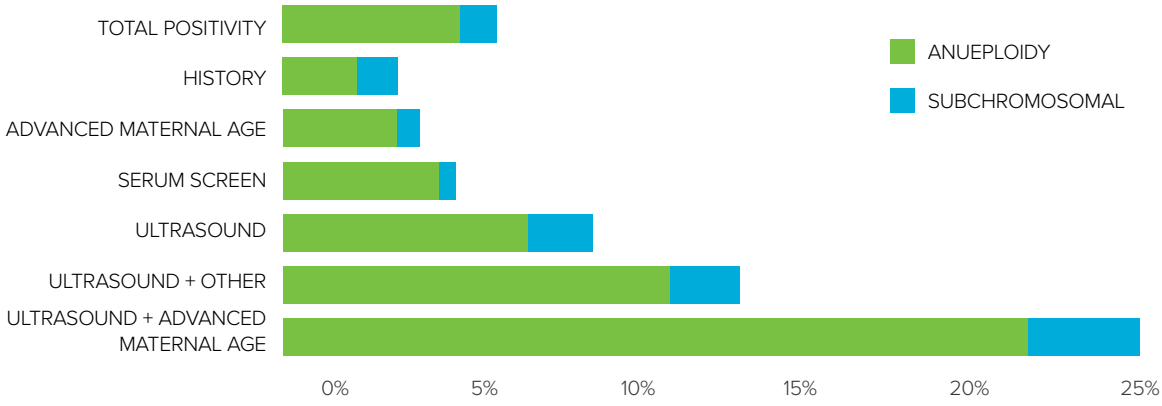
MaterniT GENOME clinical experience finds up to 30% more chromosomal information than traditional NIPT as test adoption continues.[3]

Abnormal findings identified across the entire genome[4]

Every chromosome is represented among the positive cases (n = 554)



Positivity rate varies by reason(s) for referral[4]



Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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1. Lefkowitz R, Tynan J, Liu T, et al. Genome wide detection of chromosomal gains and losses greater than 7 Mb by cfDNA analysis. Poster presented at: 2016 International Society for Prenatal Diagnosis; July, 2016; Berlin, DE.
2. Lefkowitz RB, Tynan JA, Liu T, et al. Clinical validation of a noninvasive prenatal test for genomewide detection of fetal copy number variants. *Am J Obstet Gynecol.* 2016 Aug; 215(2):227.e1-227.e16. doi: 10.1016/j.ajog.2016.02.030.
3. Ehrich M, Tynan J, Mazloom A, et al. Genome-wide cfDNA screening: clinical laboratory experience with the first 10,000 cases. *Genet Med.* 2017;19(12):1332-1337.
4. Internal data