MaterniT® GENOME

CLINICAL UPDATE
COMMERCIAL EXPERIENCE n=41,634

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.

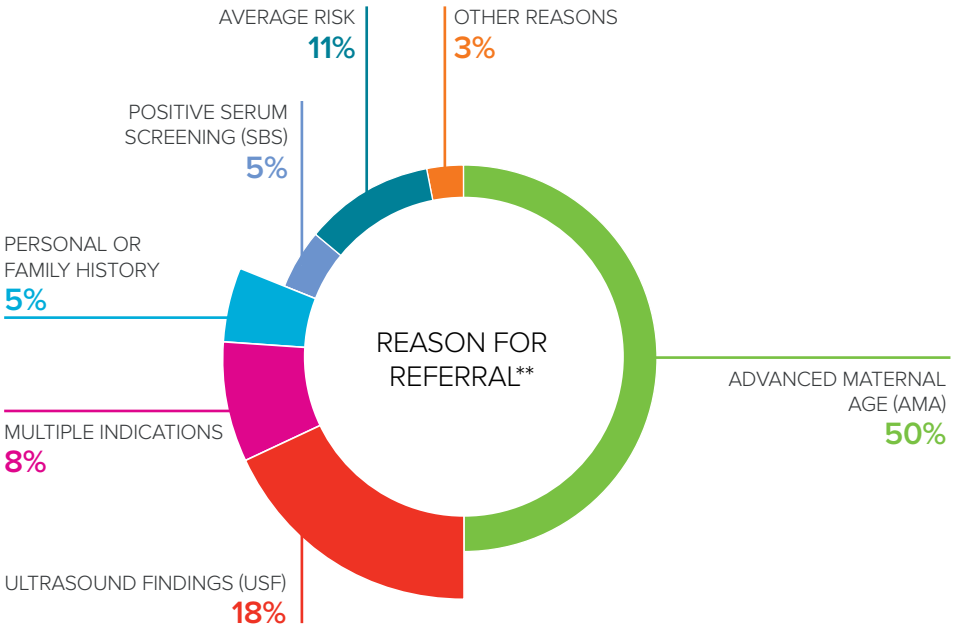
Performance*

Population sensitivity ≥97.7%

Specificity ≥99.9%

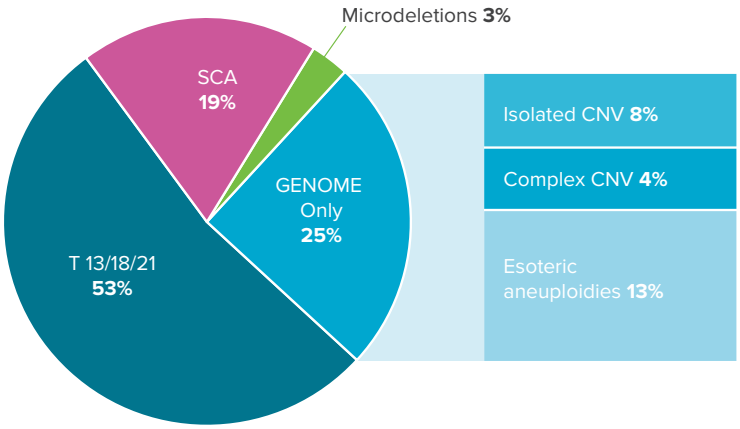
When should you use the MaterniT GENOME test?[1]

Based on peer experience, look for complex cases beyond AMA



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

Summary of the **1,957** 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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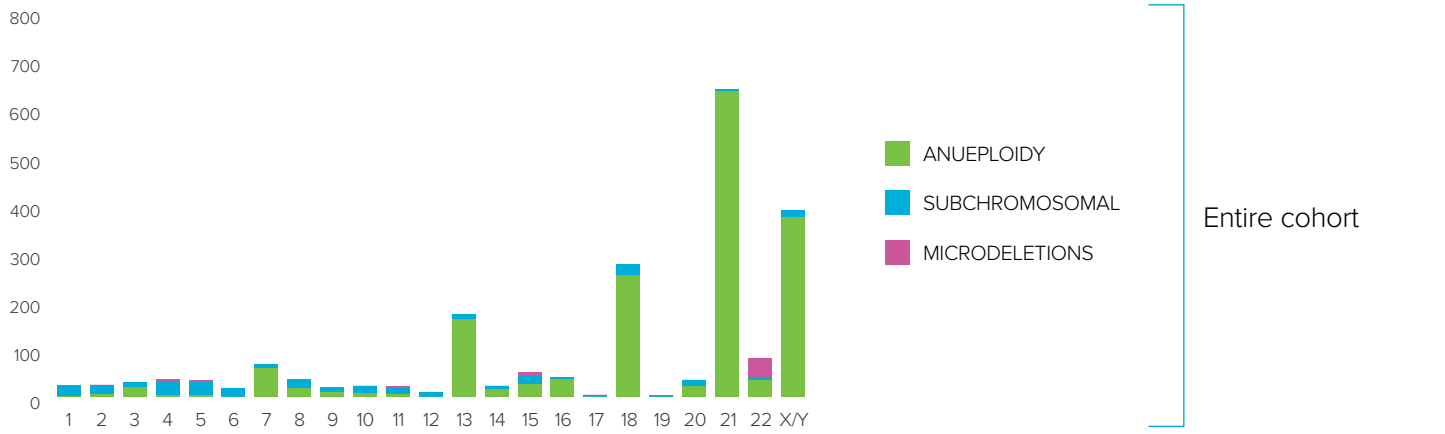
Key points[1,3]

- Genome-wide screening 23 pairs of chromosomes
- Analyzes events ≥7 Mb, select microdeletions <7 Mb
- August 2015 - November 2017
- n = 41,634
- Leading reasons for referral beyond AMA
  - 18% Ultrasound findings
  - 11% Average risk
  - 8% Multiple indications
- Positive results were observed for every chromosome
  - 4.7% of all tests positive (n=1,957)
- 3 - 5 calendar days TAT from receipt of sample
- Positive/negative reporting
- The average risk cohort is growing, with a statistically significant increase in cohort size
  - Lower proportion of age-related trisomies
  - Higher proportion of sex chromosome aneuploidies and microdeletions reported
  - CNV proportional with larger screening population

MaterniT GENOME clinical experience finds up to 30% more chromosomal information than traditional NIPT as test adoption continues.[4]

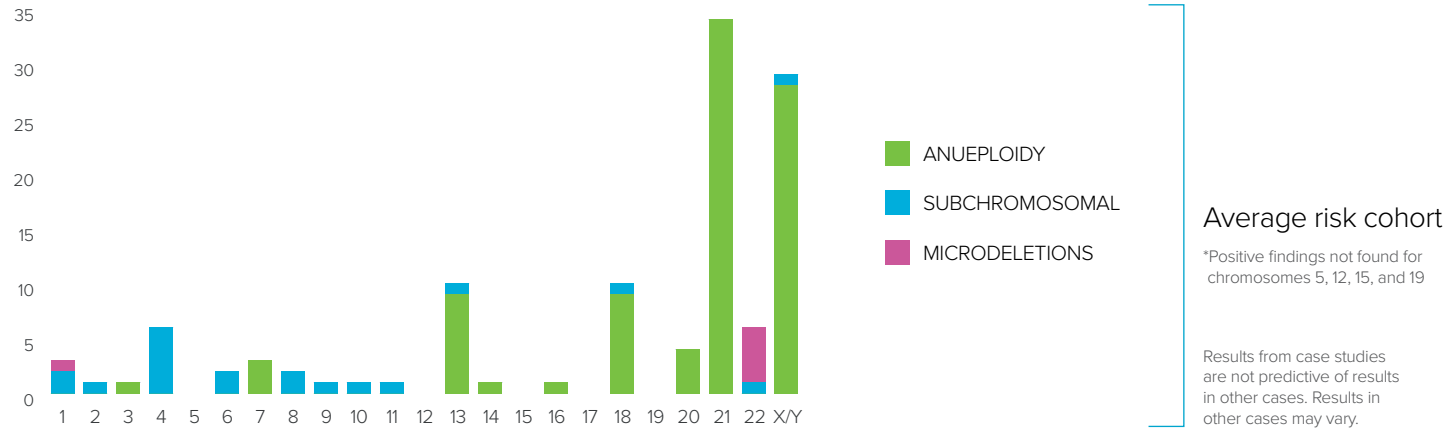
Abnormal findings identified across the entire genome[1]

All positive cases (n = 1,957)



Abnormal findings identified in the genome[3]

Average risk positive cases (n = 114)



*Positive findings not found for chromosomes 5, 12, 15, and 19

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

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1. Boomer T, Caldwell S, Almasri E, et al. Genome-wide cfDNA screening: Trends and lessons from >40,000 samples. Poster presented at: 2018 American College of Medical Genetics and Genomics Annual Clinical Genetics Meeting; April, 2018; Charlotte, NC.
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. Internal data
4. 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.