GENETICS & WOMEN'S HEALTH

Reveal® SNP Microarray POC

Revealing answers for your patients experiencing pregnancy loss

labcorp

Labcorp is your trusted partner for managing irreplaceable products of conception (POC) specimens, revealing potentially important information to the complex diagnostic questions sought by you and your patients.

Given that chromosome anomalies can be identified in up to 50% of miscarriages[1], it is essential to have an effective chromosomal analysis tool to help identify the etiology of pregnancy loss. Reveal POC SNP microarray finds abnormalities undetectable by routine chromosome analysis[2], which may be meaningful to your patient's prognosis, but would otherwise remain undiagnosed using karyotype alone.

Reveal SNP microarray has more than 2.6 million genomic markers and is constructed with dense probe coverage in regions of known genetic function to maximize detection of pathogenic variants. The array uses a combination of more than 1.9 million region-specific structural probes to detect copy number changes and ~750,000 SNP probes to detect copy number changes, copy neutral changes, triploidy and molar genotypes.

Reveal POC - Features	
>300,000 arrays analyzed*	Extensive experience and database of abnormalities from specimens tested over time, providing an exceptional resource to support interpretation
Low variants of uncertain significance (VUS) rate	Low VUS rate of 1-2%[3] due to extensive variant database and use of conservative reporting cutoffs in genes of unknown function
High success rate	>95%[3] overall success rate, including samples embedded in paraffin wax. Reveal POC can be performed directly on POC tissue without having to grow cells, increasing the success rate and reducing turnaround time
Comprehensive analysis	Improved detection of chromosomal abnormalities compared to routine karyotyping to better understand cause of fetal loss and risk for recurrence
One microarray utilized for all sample types	One SNP microarray platform for prenatal, POC and pediatric testing, providing a robust database for variant interpretation

*Prenatal, postnatal, products of conception

Services	
Access to genetic experts	Network of cytogeneticists, lab genetic counselors, medical geneticists and lab directors is available to support your results interpretation and patient management protocols
>400 managed care plans	Extensive in-network coverage and patient-friendly financial programs to increase patient access to genetic testing
~140 genetic counselors on staff, plus educational materials and online resources	Largest national commercial network of genetic counselors to assist clinicians and support patients

Leading medical guidelines recommend the use of SNP microarray testing for the evaluation of intrauterine fetal death or stillbirth[4]

Reveal POC can be more effective at determining the reason for pregnancy loss than routine chromosome analysis. At times, karyotyping may fail for a POC sample due to the lack of dividing cells,[4] but SNP microarray can be performed without living tissue. Reveal POC is a powerful tool that can help your patients understand the reason for their pregnancy loss.

Standard chromosome analysis is unsuccessful in obtaining a result 20-40% of the time because cells fail to grow in culture[5]

Benefits of Reveal POC

- Ability to analyze various POC specimen types, including formalin fixed paraffin-embedded (FFPE) tissue, and does not require live tissue or dividing cells in order to perform the test
- Easy-to-understand reports provide clinically relevant interpretations
- Detects copy neutral changes associated with an increased risk for autosomal recessive conditions, uniparental disomy (UPD) and identity by descent (IBD)[6]
- Can differentiate between complete molar pregnancies and partial molar pregnancies,[7] which may have different implications for patient management
- Familial testing may be requested and performed at no additional cost if required to clarify the result

Why choose Labcorp for your SNP microarrays?

Years of experience

- **35+** years' experience performing genetic testing
- **13+** years' experience in microarray testing
- **300+** combined years' cytogenetics experience for array laboratory directors

Access to experts

- **100+** genetic counselors nationwide:
- **~100** dedicated to direct patient care
- **15+** lab directors involved in microarray analysis

Comprehensive test menu

- Additional testing available following abnormal Reveal POC
  - Parental chromosome analysis to rule out balanced rearrangements
  - Familial studies via qPCR, FISH or microarray
  - Testing of chorionic villi or amniotic fluid for future at-risk pregnancies

Reveal SNP microarray is a clinically validated, highly reliable test, supported by clinical guidelines

A review of over 15,000 Reveal POC specimens confirmed that microarray analysis detected additional cytogenetic abnormalities not identified by standard chromosome analysis.[3]

The table below shows the relative frequency of different copy number variations (CNVs) in POCs.[3] One out of every 11 abnormal POC specimens had a structural abnormality smaller than 5 Mb.[3]

Type of Aberration	All POCs	POCs > 25 weeks
Structural < 5Mb	9.40%	42.60%
Structural > 5Mb	5.50%	4.90%
Aneuploid	60.30%	48.30%
Triploid	12.20%	1.60%
Monosomy X	12.60%	2.50%

Schwartz et al. The Impact of Microarray Studies On Prenatal Diagnosis: Analysis of 50,000 Prenatal Samples and 15,000 POCs. Poster presented at: The 10th Philadelphia Prenatal Conference. Jun 6-9, 2018. Philadelphia, PA.

Reveal's reporting cutoffs were designed to improve sensitivity and minimize VUS

In POCs earlier than 25 weeks gestation

- ≥25 kb for genes with established clinical significance
- Deletions: ≥1 Mb with at least one OMIM gene
- Duplications: ≥2 Mb with at least one OMIM gene

In POCs greater than 25 weeks gestation

- ≥25 kb for genes with established clinical significance
- Deletions: ≥200 kb with at least one OMIM gene
- Duplications: ≥500 kb with at least one OMIM gene

Partnering with you to better understand the cause of pregnancy loss

Specimen requirements

	Direct Testing
Specimen quantity	2-4 mm^3 POC specimen or placental villus biopsy; 50-100 mg direct tissue If possible, always include chorionic villi 10 unstained FFPE slides or paraffin block Transport media provided by our laboratory, Ringer's lactate or Hank's balanced salt solution
Expected turnaround time*	Tissue 12-18 days FFPE 14-21 days

*Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider.

A completed Reveal Prenatal/POC Clinical Questionnaire should accompany the specimen to aid in result interpretation. The form is available on our website or by calling Client Services at 800-345-GENE (4363).

Labcorp is contracted with 400+ managed care plans and regularly bills third-party payers for testing reimbursement. This could help minimize or eliminate your patient's expense.

In 2021, 54% of patients paid $0 out of pocket for a POC microarray.

Based on managed care claim data in 2021. For 42% of patients, insurance paid in full and 12% of patients had no patient responsibility (non-covered and coverage-related).[8]

We can help you determine your patient's out-of-pocket contribution simply by calling **855-488-8750** or emailing the Reveal Prenatal/POC Clinical Questionnaire to **PriorAuth@Labcorp.com.**

Integrated Genetics client	Labcorp client
Reveal® SNP Microarray — Prenatal	510110 SNP Microarray — Products of Conception (POC)/Tissue (Reveal®)
	511997 Microarray — Products of Conception (POC) Reveal® FFPE
	052065 Chromosome Analysis, Products of Conception (POC) With Reflex to SNP Microarray (Reveal®)

References

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2. Wapner RJ, Martin CL, Levy B, et al. Chromsomal microarray versus karyotyping for prenatal diagnosis. *N Engl J Med*. 2012. 367(23): 2175-2184. doi: 10.1056/NEJMoa1203382.
3. Schwartz S, Burnside R, Gadi I, et al. The impact of microarray studies on prenatal diagnosis: Analysis of 50,000 prenatal samples and 15,000 POCs. Poster presented at: The 10th Philadelphia Prenatal Conference. Jun 6-9, 2018. Philadelphia, PA.
4. The American College of Obstetricians and Gynecologists. Prenatal diagnostic testing for genetic disorders. Practice Bulletin No. 162. (2016). *Obstet Gynecol*. 127(5): 108-122. doi: 10.1097/ AOG.0000000000001405.
5. Sahoo T, Dzidic N, Strecker M, et al. Comprehensive genetic analysis of pregnancy loss by chromosomal microarrays: outcomes, benefits, and challenges. *Genet Med*. Jan 2017. 19(1): 83-89. doi: 10.1038/gim.2016.69.
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7. Xie Y, Pei X, Dong Y, et al. Single nucleotide polymorphism-based microarray analysis for the diagnosis of hydatidiform moles. *Mol Med Rep*. 2016; 14(1):137-144. doi: 10.3892/mmr.2016.5211.
8. Internal Labcorp billing data (2021).

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