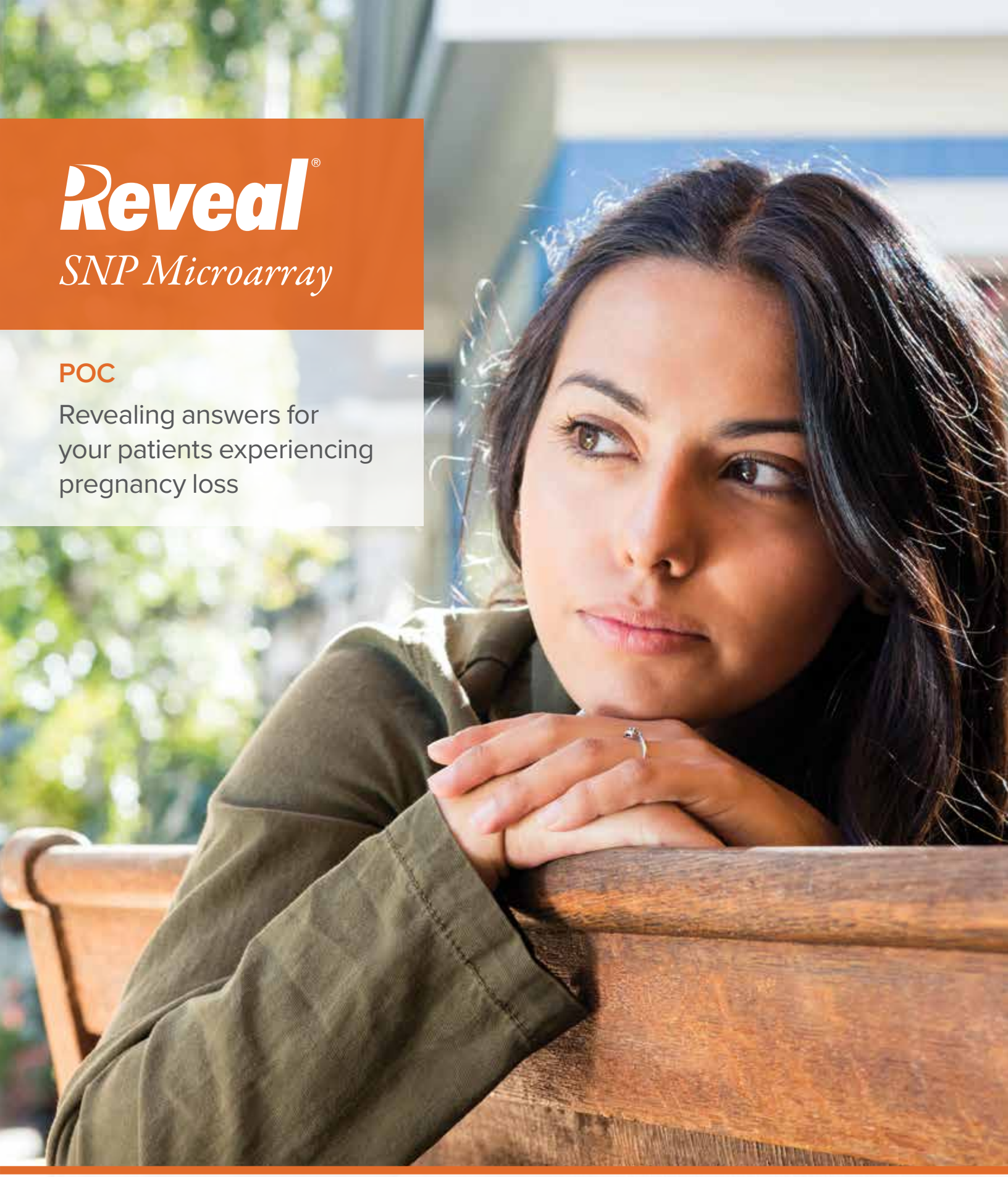
Reveal®

SNP Microarray

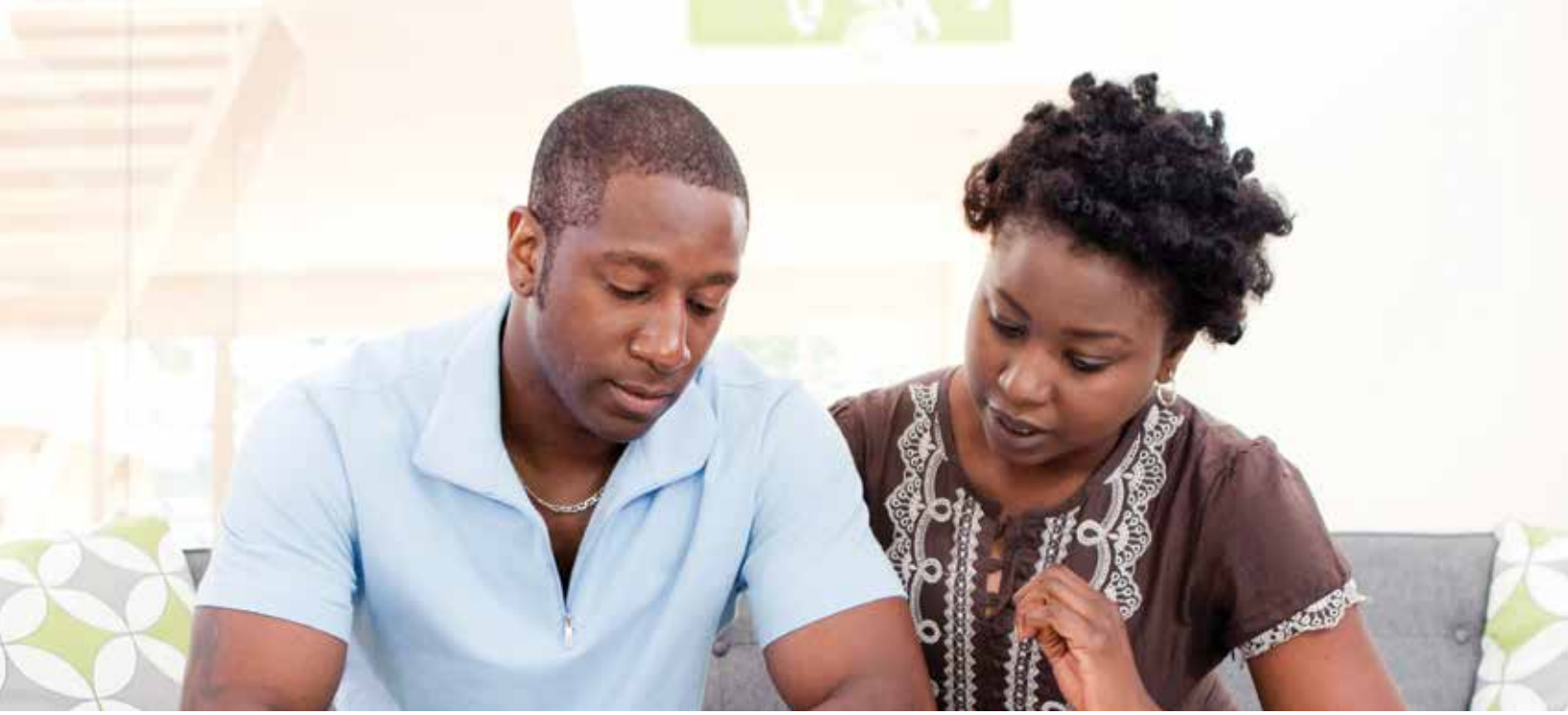
POC

Revealing answers for your patients experiencing pregnancy loss



Integrated GENETICS

LabCorp Specialty Testing Group



Integrated Genetics 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 first-trimester 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	
>230,000 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 are 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

SNP microarray is recommended for the evaluation of intrauterine fetal death or stillbirth according to ACOG guidelines[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 for helping 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 Integrated Genetics for your SNP microarrays?

Years of experience	Access to experts	Comprehensive test menu
35+ years experience performing genetic testing **11+** years experience in microarray testing **300+** combined years cytogenetics experience for array laboratory directors	**~140** genetic counselors nation-wide **~100** dedicated to direct patient care **15+** laboratory directors involved in microarray analysis	**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	9.4%	42.6%
Structural > 5Mb	5.5%	4.9%
Aneuploid	60.3%	48.3%
Triploid	12.2%	1.6%
Monosomy X	12.6%	2.5%

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 cut-offs 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 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	7-14 days

*Turnaround time is calculated from the time the specimen arrives at the lab in North Carolina.

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).

Integrated Genetics 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 2018, 65% of patients paid $0 out-of-pocket for a POC microarray.

*Based on managed care claim data in 2018. For 52% of patients, insurance paid in full and 13% 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.**

Toll-free (within the US)
800.345.GENE (4363)

www.integratedgenetics.com

askCMBP@labcorp.com
Fax: 919.361.7700

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View short videos on genetic testing:
www.integratedgenetics.com/videos

Integrated GENETICS
LabCorp Specialty Testing Group

Test codes

Integrated Genetics client	LabCorp client
478 Reveal® SNP Microarray- POC	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®)

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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
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