LifeLabs Genetics™
175 Galaxy Blvd., Suite 105 Toronto, Ontario M9W 0C9
Tel: 1-844-363-4357 **Fax:** 647-943-2804 **Web:** www.lifelabsgenetics.com

R. F. Carter, PhD, FCCMG
Lab Director

PATIENT INFORMATION

Patient Name:	Doe, Jane
Date of Birth:	1990-01-01
Maternal Age at EDD:	26
Gestational Age:	9 Weeks / 6 Days
Maternal Weight:	-
Health Card #:	-
Order ID:	BIR1232
Accessioning ID:	ABC1234567
Collection Kit:	-
Collection Centre:	LifeLabs

PROVIDER INFORMATION

Ordering Physician:	Dr. M. Goodbirth
Genetic Counsellor:	-
Additional Reports:	-
	-
Test Requested:	Panorama Prenatal Test
Report Date:	2016-04-18
Samples Collected:	2016-04-14
Samples Received:	2016-04-15
	Maternal Blood

ABOUT THIS SCREEN

Panorama® is a screening test, not diagnostic. It evaluates genetic information in the maternal blood, which is a mixture of maternal and placental DNA, to determine the chance for specific chromosome abnormalities. The test does NOT tell with certainty if a fetus is affected, and only tests for the conditions ordered by the healthcare provider. A low risk result does not guarantee an unaffected fetus.

REPORT SUMMARY

Result	*Fetal Sex*	*Fetal Fraction*
NO RESULT	**No Result**	**2.5%**

Fetal fraction was below the threshold for analysis. Submission of a repeat specimen is required for testing.

Further genetic counseling with the option of comprehensive ultrasound evaluation and diagnostic testing should be considered because of an increased risk of aneuploidy when there is a no call test result (ACOG committee opinion 640, 2015). Please refer to the table at the bottom of the supplemental page to determine the success of obtaining a result with a redraw based on the patient weight and fetal fraction.

RESULT DETAILS

Condition Tested[1]	*Result*	*Risk Before Test[2]*	*Panorama Risk Score[3]*
Trisomy 21	No Result	-	-
Trisomy 18	No Result	-	-
Trisomy 13	No Result	-	-
Monosomy X	No Result	-	-
Triploidy/Vanishing twin	No Result		

1. Excludes cases with evidence of fetal and/or placental mosaicism. 2. Based on maternal age, gestational age, and/or general population, as applicable. References available upon request. 3. Based on a priori risk and results of analysis of circulating placental DNA.

TESTING METHODOLOGY: DNA isolated from the maternal blood, which contains placental DNA, is amplified at specific loci using a targeted PCR assay, and sequenced using a high-throughput sequencer. Sequencing data is analyzed using Natera's proprietary algorithm to determine the fetal copy number for chromosomes 13, 18, 21, X, and Y, thereby identifying whole chromosome abnormalities at these locations, and if ordered, the microdeletion panel will identify microdeletions at the specified loci only. If a sample fails to meet the quality threshold, no result will be reported for the specified chromosome(s). The test requires sufficient fetal fraction of at least 2.8% to produce a result. Fetal fraction refers to the percentage of fetal (placental) DNA in the maternal plasma compared to the amount of maternal DNA.

DISCLAIMERS: This test has been validated on women with a singleton pregnancy and of at least nine weeks gestation. This test cannot be performed on patients who are carrying multiple babies (twins, triplets, etc.). A result will not be available where the maternal blood cells and oocytes are not of the same genetic lineage, as in the case of an egg donor, surrogate, or bone marrow transplant recipient. This test is not intended to identify pregnancies at risk for open neural tube defects. Findings of unknown significance and possible non-paternity will not be reported. As this assay is a screening test and not diagnostic, false positive and false negatives can occur. High risk test results need diagnostic confirmation by alternative testing methods, such as chorionic villus sampling (CVS) or amniocentesis. Low risk results do not fully exclude the diagnosis of any of the syndromes nor do they exclude the possibility of other chromosomal abnormalities or birth defects, which are not part of this test. Potential sources of inaccurate results include, but are not limited to, mosaicism, low fetal fraction, limitations of current diagnostic techniques, or misidentification of samples. This test has the potential to uncover blood relationships between the couple or family members. Test results should always be interpreted by a clinician in the context of the clinical and familial data with the availability of genetic counselling when appropriate. The Panorama prenatal test was developed by Natera, Inc., 201 Industrial Road Suite 410, San Carlos, CA 94070., a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). This test has not been cleared or approved by the U.S. Food and Drug administration (FDA).

APPROVED BY **R.F. Carter, PhD, FCCMG (Laboratory Director)**

IF THE ORDERING PROVIDER HAS QUESTIONS OR WISHES TO DISCUSS THE RESULTS, PLEASE CONTACT US AT 1-844-363-4357. Ask for the NIPT genetic counsellor on call. For more information, please visit www.lifelabsgenetics.com. LifeLabs Genetics is licensed by the Ontario Ministry of Health and Long-Term Care to operate as a clinical genetic laboratory: MOHLTC license 5806.

LifeLabs Genetics™
175 Galaxy Blvd., Suite 105 Toronto, Ontario M9W 0C9
Tel: 1-844-363-4357 **Fax:** 647-943-2804 **Web:** www.lifelabsgenetics.com

R. F. Carter, PhD, FCCMG
Lab Director

PATIENT INFORMATION

Patient Name:	Doe, Jane
Date of Birth:	1990-01-01
Maternal Age at EDD:	26
Gestational Age:	9 Weeks / 6 Days
Maternal Weight:	-
Health Card #:	-
Order ID:	BIR1232
Accessioning ID:	ABC1234567
Collection Kit:	-
Collection Centre:	LifeLabs

PROVIDER INFORMATION

Ordering Physician:	Dr. M. Goodbirth
Genetic Counsellor:	-
Additional Reports:	-
	-
Test Requested:	Panorama Prenatal Test
Report Date:	2016-04-18
Samples Collected:	2016-04-14
Samples Received:	2016-04-15
	Maternal Blood

ABOUT THIS SCREEN

Panorama™ is a screening test, not diagnostic. It evaluates genetic information in the maternal blood, which is a mixture of maternal and placental DNA, to determine the chance for specific chromosome abnormalities. The test does NOT tell with certainty if a fetus is affected, and only tests for the conditions ordered by the healthcare provider. A low risk result does not guarantee an unaffected fetus.

REPORT SUPPLEMENT for NO RESULT

What does "No Result" mean on a Panorama report?

Occasionally, Panorama cannot obtain enough information from a blood sample to determine a result. This could happen for several reasons: not enough blood in the sample, an uninformative DNA pattern or other reason. Depending on the reason for "No Result", a second draw may or may not help resolve the issue.

What are the next steps for the patient when a repeat specimen (redraw) IS NOT indicated?

A small number of individuals have a DNA pattern that cannot be interpreted clearly with this screening test. Women who do NOT receive a result from NIPT may be at an increased risk to be carrying a fetus with a chromosome abnormality and should receive additional genetic counselling. The option of further evaluation using ultrasound, diagnostic testing, or other screening modality should be discussed.

What are the next steps for the patient when a repeat specimen (redraw) IS required?

It is recommended that the healthcare provider alert the patient that a redraw is required. There is no charge for a redraw.

- If a patient sample was drawn at a LifeLabs, CML or BC Biomedical location, your patient will be contacted within ~24 hours of the time the report was issued for a redraw by the lab location where she initially went for blood draw. All documentation required will be provided at the lab and no additional documentation is required from the healthcare provider.
- If the patient sample was drawn at a third party location, LifeLabs Genetics will resend a collection kit to your patient with appropriate paperwork and the patient will need to arrange a redraw at the location of the previous blood draw.

The most common reason for "No Result" is insufficient fetal DNA (low fetal fraction). In samples with low fetal fraction, it may not be possible to determine the patient's risk of carrying a fetus with a chromosome abnormality. In such cases, a redraw is requested to try to obtain a sample with sufficient fetal DNA in order to be able to produce a result. The following factors have been associated with low fetal fraction:

- Sample collection technique not optimal
- Specimen drawn too early: Fetal fraction increases with gestational age. Panorama should only be done after 9 weeks of gestation.
- Fetal fraction is inversely related to maternal weight (heavier women have lower average fetal fractions)
- Certain chromosomal abnormalities: peer-reviewed literature suggests "an increased aneuploidy rate is observed in samples… with a low fetal fraction."[1]

If a redraw is suggested, the table below can help determine the probability of obtaining a result on a second specimen. Simply reference the fetal fraction observed on the first draw and the patient's weight. Patient should be informed that she may be at a slightly higher risk to be carrying a fetus with a chromosome abnormality, and all options for further screening/diagnostic testing should be reviewed.

Probability of Success with Second Blood Draw

	Fetal Fraction Observed in First Specimen				
Maternal Weight	**FF <2.0%**	**2.0 < FF < 2.4%**	**2.4 <FF < 2.9%**	**2.9 < FF < 3.4%**	**FF > 3.4%**
< 165 lbs (75kg)	57%	66%	73%	82%	87%
165 -220 lbs (75-100kg)	45%	56%	65%	68%	86%
> 220 lbs (100kg)	41%	46%	63%	65%	85%

Source: Internal Natera data. Probabilities based on historical success rates across overall sample size of 1874 cases

1. Pergament E, et al. Obstet Gynecol 2014;124:210–218. Single-Nucleotide Polymorphism – Based Noninvasive Prenatal Screening in a High-Risk and Low-Risk Cohort.