5990 Côte-des-Neiges, Montréal, (Québec) H3S 1Z5
Tél. : (514) 344-8022 Fax : (514) 344-8024
Courriel : service@laboratoirescdl.com
Lundi au vendredi de 8h00 à 20h00
Dimanche de 10h00 à 14h00

MEMORANDUM

To: **All clients**

From: The Laboratory

Subject : **New Panorama Prenatal Test with Table Comparisons – *Second Edition***

Date: June 21st 2013

Dear client,

In order to continuously offer you innovative and high quality services, CDL is proud to be the first in Quebec to introduce the Panorama non-invasive and more accurate prenatal screening testing procedure to detect trisomy 21, 18 and 13 along with chromosome abnormalities such as monosomy X.

PANORAMA CELL FREE DNA TEST

- ➔ Identifies individualized risk score for aneuploidies of chromosomes 21, 18, 13, X and Y.
- ➔ Provides most accurate results of any non-invasive test at low fetal fractions.
- ➔ Cell Free DNA testing in maternal blood
- ➔ Performed as early as 9 weeks of gestational age.
- ➔ Simple blood draw from the mother and preferable paternal cheek swab
- ➔ Safe for the mother and baby unlike the chorionic villus sampling (CVS)
- ➔ Identifies gender results of the fetus by request.
- ➔ Uses NATUS (Next-generation Aneuploidy Testing Using SNPs) methodology.
- ➔ Decreased chance of false positives or false negatives.

INDICATION FOR USE

The Panorama test is not designed for women having:

- *A confirmed multiple gestation pregnancy.*
- *Used a surrogate.*
- *Used an unrelated egg donor.*

CDL CODE	CDL PRICE	TURNAROUND TIME
PANO	$855	14 days

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MEMORANDUM

Sensitivity / False Positive Rate	SEQUENOM MATERNIT21	VERINATA VERIFI	ARIOSA HARMONY TEST [1-6]	NATERA PANORAMA TEST [7, 8]
Trisomy 21 (Down Syndrome)	**98.6-99.1%** 0.2%	**99.9%** 0.2%	**100%** <0.1%	**>99%** 0.0%
Trisomy 18 (Edwards Syndrome)	**100%** 0.3%	**97.4%** 0.4%	**98%** <0.1%	**>99%** 0.0%
Trisomy 13 (Patau Syndrome)	**>91.7%** 0.9%	**87.5%** 0.1%	**80%** 0.05%	**>99%** 0.0%
45, X (Monosomy X)	**>96.2%** 0.3% Reported only when identified	**95%** 0.1% Does not report negatives	**NOT EVALUATED**	**>92%** 0.0% Always reports positives and negatives
Gender Determination	**Yes**	**Yes**	**NOT EVALUATED**	**Yes**
Female	Sensitivity and specificity not reported	**97.6%** 0.8%	**NOT EVALUATED**	**>99%** 0.0%
Male	**99.4%** specificity not reported	**99.1%** 1.1%	**NOT EVALUATED**	**>99%** 0.0%
Earliest Gestational Age Test Can Be Perfomed	**10 weeks**	**10 weeks**	**10 weeks**	**9 weeks**

1. Ashoor, G., Syngelaki, A., Nicolaides, K.H., et al. Trisomy 13 detection in the first trimester of pregnancy using a chromosome-selective cell-free DNA analysis method, ULTRASOUND Obstet Gynecol. (2012), DOI: 10.1002/uog.12299.
2. Nicolaides KH, Syngelaki A, Ashoor G, et al. Noninvasive prenatal testing for fetal trisomies in a routinely screened first-trimester population. Am J Obstet Gynecol (2012);207:374.e1-6.
3. Norton, M., Brar, H., Weiss, J., Karimi, A., et al. Non-Invasive Chromosomal Evaluation (NICE) Study: Results of a Multicenter, Prospective, Cohort Study for Detection of Fetal Trisomy 21 and Trisomy 18, Am J Obstet Gynecol. (2012), doi:10.1016/j.ajog.2012.05.021.
4. Sparks, A.B., Wang, E.T., Struble, C.A., Barrett, W., et al, Selective analysis of cell-free DNA in maternal blood for evaluation of fetal trisomy. Prenat Diagn (2012);32(1):3-9. doi: 10.1002/pd.2922. Epub 2012 Jan 6.
5. Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A., Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal Blood: Evaluation for Trisomy 21 and Trisomy 18, Am J Obstet Gynecol. (2012), doi: 10.1016/j.ajog.2012.01.030.
6. Ashoor, G., Syngelaki, A., Wagner, M., Birdir, C., Nicolaides, K.H., Chromosome-selective sequencing of maternal plasma cell-free DNA for first trimester detection of trisomy 21 and trisomy 18, Am J Obstet Gynecol. (2012), doi: 10.1016/j.ajog.2012.01.029.
7 Zimmermann, B, et al(2012), Noninvasive prenatal aneuploidy testing of chromosomes 13, 18, 21, X and Y, using targeted sequencing of polymorphic loci. Prenat. Diagn. Doi: 10.1002/pd.3993.
8 Natera Internal Data

*For additional information, please contact **Radouane** at **(514) 344-8022 extension 226** or **Ciara** at **(514) 344-8022 extension 251** to confirm gestational age (9 weeks).*

Please note that we offer this service at our 2 other branches:

- CDL Downtown: Please call at 514-982-9696 to make an appointment.
- CDL Pierrefonds: Please call at 514-684-8460 ext. 211 to make an appointment.

Please use and complete the attached requisition

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Tel: (514) 344-8022 Fax: (514) 344-8024 E-Mail: service@cdllabs.com
Monday to Friday from 8am to 8pm - Sunday from 10am to 2pm

PANORAMA CELL FREE DNA TEST

PATIENT

Specimen collected by _____ Date and time _____ ID#: _____

First name: _____ Last name: _____ Medicare: _____

Date of birth : _____ Telephone: _____ Dossier: _____

Did this pregnancy involve an egg donor? ❑ Yes ❑ No

Did this pregnancy involve a surrogate? ❑ Yes ❑ No

Is this a multiple gestation pregnancy? ❑Yes ❑ No

Did the mother of this pregnancy receive a bone marrow transplant? ❑ Yes ❑ No

Estimated due date : _____ (YYYY – MMM – DD)

Date of last menstrual period : _____ (YYYY – MMM – DD)

Please include gender results on this report : ❑ Yes ❑ No

Have you completed the Patient Informed Consent? ❑ Yes ❑ No

Are you submitting a paternal sample with this order? ❑ Yes ❑ No

If yes, provide name and date of birth of father : _____ _____

LIMITATIONS

This test has been validated on women with a singleton pregnancy and of at least nine weeks gestational age. Tests run prior to nine weeks have an increased no result rate. This test will not return results on pregnancies conceived with an egg donor or those which used a surrogate and cannot be performed on women who have received a bone marrow transplant.

If a paternal sample is submitted and non paternity is identified, it will not be reported and the paternal sample will not be used in the analysis.

Samples are analyzed for aneuploidy of chromosomes 13, 18, 21, X and Y only. Abnormalities on other chromosomes or those involving only a portion of the chromosomes tested cannot be excluded.

This test may not be able to identify abnormalities or may report a positive result in the presence of mosaicism (which may be confined to the placenta).

Gender will be reported as male or female based on presence or absence of a Y chromosome and does not confirm presence or absence of SRY (Sex-determining Region Y). Pregnancies involving multiples or abnormal ultrasound findings may be better served by other screening or testing options. There is a chance of detecting maternal sex chromosome abnormalities during this testing process (either in full or mosaic form) which, if present, may interfere with the accuracy of the results on the fetal sex chromosomes.

Although this test has a high accuracy, the results are not diagnostic. These results should always be interpreted by a clinician in the context of clinical and familial data.

PATIENT'S CONSENT

I, _____ hereby have read and understood the requirements and the limitations related to this test.

Date : _____ Signature : _____

Name of the doctor : _____

Licence # : _____ Date : _____ Signature : _____