CooperGenomics℠
a CooperSurgical company

Reprogenetics℠ Recombine℠ Genesis Genetics℠

serenity
Test Order Form

Please complete this form using capital (block) letters.

PATIENT INFORMATION

First Name _____

Last Name _____

DOB (dd/mm/yy) _____ dd / mm / yy

Medical Record No *(if applicable)* _____

Address _____

City _____

County _____ Postcode _____

Country _____

Email _____

Tel _____

CLINICAL INFORMATION

Last ultrasound date (dd/mm/yy) _____

Gestational age (weeks/days) _____

Date of blood draw (dd/mm/yy) _____

Gestational age (weeks/days) _____

Comments

PATIENT CONSENT

By signing below, I certify that I am the patient voluntarily providing the sample; I received a copy of and have carefully read, understand, and agree to the attached Patient Consent Form for genetic testing; I have discussed the benefits, risks, and limitations of genetic testing with my physician; and consent for CooperGenomics* to perform the genetic test(s) ordered by my physician. I also authorise CooperGenomics to perform the necessary steps to obtain reimbursement for the Serenity prenatal test.

Signature _____ Date _____

** Testing is performed by Reprogenetics, Recombine, Genesis Genetics or other clinical laboratories affiliated with CooperGenomics.*

ACCOUNT/ORDERING INFORMATION

Healthcare Professional Sachihiko Okuno

Name of Clinic/Hospital Yaesu CEM Clinic

CooperGenomics Account No *(if applicable)* JP0616045

Address _____

City _____ County _____ Postcode _____

Country _____

Email _____

Tel _____

TEST INFORMATION

Singleton Pregnancies: *(Select one test panel below)*

serenity basic

☐ **Chromosomes 13, 18, 21**
- ☐ Include sex chromosome aneuploidies
- ☐ Include fetal sex identification

serenity 24

☐ **All autosomes***
- ☐ Include sex chromosome aneuploidies
- ☐ Include fetal sex identification

serenity plus

☐ **Chromosomes 13, 18, 21 Plus Microdeletions****
- ☐ Include sex chromosome aneuploidies
- ☐ Include fetal sex identification

serenity comprehensive ts

☐ **All autosomes and microdeletions****
- ☐ Include sex chromosome aneuploidies
- ☐ Include fetal sex identification

Twin Pregnancies: *(Serenity Basic panel available only)*

serenity basic

☐ **Chromosomes 13, 18, 21**
- ☐ Include presence/absence of Y chromosome

This test is validated for pregnancies of at least 10 weeks gestational age. The Serenity Basic panel is CE-IVD approved and is accredited to ISO 15189:2012.

** At extra cost*

*** At extra cost and longer turnaround time. Microdeletions includes the following syndromes: 22q11 deletion (DiGeorge); 15q11 deletion (Angelman/Prader-Willi); 1p36 deletion, 4p- (Wolf-Hirschhorn); 5p- (Cri-du-chat).*

TEST INDICATIONS

- ☐ Advanced maternal age
- ☐ Maternal anxiety / low risk / personal choice
- ☐ High risk serum screen
- ☐ Ultrasound Anomaly
- ☐ History of pregnancy with T13, T18, T21, MX or other sex chromosomes aneuploidy

HEALTHCARE PROFESSIONAL CONSENT

I verify that the patient and prescriber information in this form is complete and accurate to the best of my knowledge and that I have requested the Serenity powered by the Illumina NIPT technology, based on my professional judgment of medical necessity. I have addressed the limitations of this test, and have answered any questions to the best of my ability. I understand that CooperGenomics may need additional information, and I agree to provide it as needed for purposes of reimbursement.

Signature _____ Date _____

CooperGenomics℠
a CooperSurgical company

Reprogenetics℠ Recombine℠ Genesis Genetics℠

serenity
Test Order Form

PATIENT INFORMED CONSENT FOR SERENITY NONINVASIVE PRENATAL TEST

Before signing this form, you should ask your healthcare provider if you have any questions about this test, or have questions about what the results could mean.

This blood test is designed to measure the combined maternal and fetal DNA present in maternal blood, and is considered a genetic test. Your written consent is required to perform a Serenity prenatal test. This consent form provides information about the Serenity prenatal test utilizing the Illumina NIPT test technology, including what the test is for, the testing process, and what results may mean. Before signing this document, you should ask your healthcare provider to answer any questions you may have about this test.

Please note that this is NOT a diagnostic test and despite all research and professional efforts to ensure the accuracy of test results, there remains a small possibility (as detailed below) of error, such that a Down's fetus screens negative, or a healthy fetus screens positive.

ABOUT THE SERENITY PRENATAL TEST

The Serenity prenatal test looks at the DNA (genetic material) in your blood. When pregnant, there is maternal and fetal DNA circulating in your maternal blood. The test can tell if there are too many or too few copies (called an "aneuploidy") of any chromosomes circulating, which if you yourself do not have an aneuploidy, suggests that it has to be present in your fetus. The test can also look at sex chromosomes (X and Y), and can determine if there are too many or too few copies of the sex chromosomes.

The Serenity prenatal test has been developed to identify patients who have an increased risk for having a baby with an incorrect number of chromosomes. Your healthcare provider discussed your concerns regarding your pregnancy with you, and determined that you are an appropriate candidate for this test.

COMMON ANEUPLOIDIES: TRISOMY 21 (DOWN SYNDROME), TRISOMY 18 (EDWARDS' SYNDROME), TRISOMY 13 (PATAU SYNDROME)

Trisomies occur when three, instead of the usual two, copies of a chromosome are present. Trisomy 21, trisomy 18, and trisomy 13 are three of the most commonly occurring trisomies seen in babies at birth. Although the outcomes are variable, these conditions can cause mild to severe intellectual disabilities, and can cause multiple physical problems including congenital heart defects, defects in other organs, and a shortened life span. The chance of having a baby with one of these conditions gets higher as a woman gets older.

SEX CHROMOSOME ANEUPLOIDIES

The Serenity prenatal test also gives you the option to test for changes in the number of sex chromosomes. Sex chromosome aneuploidies are conditions in which there is a change from the usual 2 copies of sex chromosomes in males (XY) or females (XX). About 1 in 400 babies that are born will have a sex chromosome aneuploidy. The most common sex chromosome aneuploidies are caused by a missing sex chromosome in girls (45,X or monosomy X, also called Turner's syndrome) or an extra chromosome in boys or girls (47,XXY (Klinefelter syndrome), 47,XYY, or 47,XXX). Children with a sex chromosome aneuploidy can have difficulties with language skills, motor skills, and learning, but can lead healthy and productive lives. Foetal sex may also be reported if no sex chromosome aneuploidies are found, ask your healthcare provider to include this option if desired.

Other test add on options available only for singleton pregnancies include a microdeletion panel and/or an option to screen for aneuploidies in all chromosomes. For further information, visit our website https://www.coopergenomics.com/products/nipt/. Your healthcare provider or genetic counsellor can also give you more information about these conditions.

THE TESTING PROCESS

To analyze the DNA from your blood, your healthcare provider will take a blood sample from you (single 10ml tube, in a standard blood draw). The physical risk to you from obtaining the blood sample is minimal. Some important points about the testing and reporting process:

- Your test results are confidential to the extent required by law.
- Only experienced personnel will have access to your blood sample, testing information and results. All results will be kept confidential as per applicable laws and guidelines. Results will only be disclosed to your ordering healthcare provider(s).
- Only authorised and requested tests will be performed on your identifiable blood sample.
- Collecting information on your pregnancy after prenatal diagnosis is part of a laboratory's standard practice for quality purposes, and is required by laboratory accreditation bodies. As such, CooperGenomics may contact your healthcare provider to obtain this information, and you agree to sharing such information with CooperGenomics.

The test is performed after 10 weeks, 0 days of pregnancy. Adequate DNA in the blood sample is required to complete the test. Additional samples may be needed if the sample is damaged in shipment, incorrectly submitted or has a low amount of DNA. After analysis in CooperGenomics laboratory, the test results will be returned to your healthcare provider, who will discuss them with you.

OBTAINING AND INTERPRETING TEST RESULTS

Your test results will be returned to your healthcare provider after analysis by CooperGenomics. The results will be reported by CooperGenomics only to the qualified healthcare provider(s) indicated on the front of this form. Your results will tell your healthcare provider whether too few or too many copies of the chromosomes being tested for are present. It is the responsibility of the healthcare provider ordering this test to understand the specific uses and limitations of this test, and to make sure you understand them as well. If aneuploidy is detected, follow up testing (such as amniocentesis or chorionic villus sampling) is recommended to confirm the result.

Your test report will include one of two possible results. No Aneuploidy Detected or Aneuploidy Detected. In samples where aneuploidy is detected, the report will also specify which chromosome is involved.

The Serenity prenatal test does not test for all health problems. Normal results do not eliminate the possibility that your pregnancy may have other chromosomal/genetic conditions, birth defects, or other complications. A 'No Aneuploidy Detected' result on this test does not completely rule out the presence of the conditions being tested for and does not guarantee the health of your baby. The Serenity prenatal test is designed to look at full chromosome aneuploidies only. There is a small possibility that the test results might not reflect the chromosomes of the baby, but instead might reflect chromosomal changes to the placenta (confined placental mosaicism), or in the mother (chromosomal mosaicism).

This test represents the latest service currently available for prenatal testing. However, as with any complex genetic test, there is always a chance of failure or error in sample analysis. Extensive measures are taken to avoid these errors. The Serenity prenatal test has been validated in a multi-center clinical study, in a population of high risk patients, and the test performance is indicated in the table below.

Please see the chart below for detailed performance on the Serenity prenatal test.

In the course of performing the analysis for the indicated tests, information regarding other chromosomal alterations, also known as "secondary findings" may become evident. Our policy is to NOT REPORT on any secondary findings that may be noted in the course of analysing the test data.

Your healthcare provider may recommend additional testing (e.g.,amniocentesis, or chorionic villus sampling) after receiving the results from this test. **Before signing this form, you should ask your healthcare provider if you have any questions about this test, or have questions about what its results could mean.**

PERFORMANCE DATA TABLE

(Based on Illumina and CooperGenomics data on file – available on request)

	SENSITIVITY	SPECIFICITY
Chromosome 13	98.15%	99.95%
Chromosome 18	98.31%	99.90%
Chromosome 21	99.14%	99.94%
Monosomy X	95.00%	99.00%
XX	97.60%	99.20%
XY	99.10%	98.90%
XXX/XXY/XYY	Other sex aneuploidies will be reported if detected *(limited data precludes performance data calculations)*	
Microdeletions & other autosomal aneuploidies	Microdeletions and other autosomal aneuploidies if requested and detected will be reported *(limited data of these rare abnormalities preclude performance calculations)*	

- For chromosome 21 PPV = 0.9581 and NPV = 0.9999
- For combined 13,18,21 aneuploidies PPV = 0.835 and NPV = 0.999
- Overall False Positive (FP) % = 0.2 and False Negative (FN) % = 0.026

CE

UKAS MEDICAL
8993
Accredited to
ISO 15189:2012