genesis serenity®

TEST ORDER FORM

Account/Ordering Information

Healthcare Professional:	Sachihiko Okuno
Name of Clinic/Hospital:	Okuno Hospital
Genesis Genetics Account No: (if applicable)	P08[illegible]45
Address:	
City:	
County:	
Postcode:	
Country:	
Tel:	
Email(s):	

Patient Information *(attach label when available)*

Name: Last First M.I.

Date of birth: DD / MM / YYYY

Sex: FEMALE

Medical Record No

Address:

City:

County: Post code:

Country:

Email:

Tel:

Patient Consent

By signing this form, I voluntarily request that Genesis Genetics perform the Serenity prenatal test®. I have read and have received a copy of the patient consent included on the back of this form from my provider. The risks, benefits, and limitations of this test have been adequately explained to me. I authorise Genesis Genetics to perform the necessary steps to obtain reimbursement for the verifi® prenatal test.

Signature:

Date: DD / MM / YYYY

Test Information *(choose singleton OR twin with required options)*

For singleton pregnancy:

- ☑ **Serenity prenatal test for chromosomes 13, 18, 21**
  - ☐ Sex aneuploidy chromosomes option
    - ☐ Include foetal sex/gender on report

For twin pregnancy:

- ☐ Serenity prenatal test for chromosomes 13, 18, 21
  - ☐ Presence of Y chromosome option

This test is validated for twin and singleton pregnancies of at least 10 weeks gestational age.

Test Indications

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

Clinical Information

Last ultrasound date: DD / MM / YYYY

Gestational age: Weeks / Days

Date of blood draw: DD / MM / YYYY

Gestational age: Weeks / Days

Comments:

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 Genesis Serenity® powered by the verifi® prenatal test, based on my professional judgment of medical necessity. I have addressed the limitations of this test, and have answered any question to the best of my ability. I understand that Genesis Genetics may need additional information, and I agree to provide it as needed for purposes of reimbursement.

Signature: Sachihiko Okuno

Date: DD / MM / YYYY

genesis genetics

Genesis Genetics UK
London Bioscience Innovation Centre
2 Royal College Street, London, NW1 0NH

GGUK: Genesis Serenity Test Order Form V7. Review Date: August 2018

Patient Informed Consent For Genesis Serenity® Prenatal Test

Powered by verifi® technology

Before signing this form, you should ask your health care 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 genetic test. This consent form provides information about the Genesis Genetics prenatal test utilizing the verifi® prenatal test technology, including what the test is for, the testing process, and what results may mean. Before signing this document, you should ask your health care 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 pregnancy DNA circulating in your maternal blood. The test can tell if there are too many or too few copies (also called an "aneuploidy") of certain chromosomes—13, 18, and 21—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 certain chromosomes. Your health care provider has discussed your concerns regarding your pregnancy with you, and has determined that you are an appropriate candidate for this test.

Common Aneuploidies: Trisomy 21 (Down's syndrome), Trisomy 18 (Edwards' syndrome), Trisomy 13 (Patau's 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.

For more information on these conditions, please visit: http://www.genesis-serenity.com. Your healthcare provider or genetic counsellor can also give you more information about these conditions.

If you choose the sex chromosome option, and no sex chromosome aneuploidies are found, then the test report can state (if you so request) whether you are expecting a girl or boy. If you do not wish to know the gender of your baby, please let your healthcare provider know in advance to not disclose this information to you. Please note that again this is not a diagnostic test, but it is accurate in over 99% of tests.

The Testing Process: To analyze the DNA from your blood, your health care provider will take a blood sample from you (between 7 and 10ml, in a standard blood draw). The physical risk to you of 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 and 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.
- Your sample will be destroyed at the end of the testing process, in accordance with national guidelines
- 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. As such, Genesis Genetics may contact your healthcare provider to obtain this information, and you agree to our sharing such information with Genesis Genetics.

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 pregnancy DNA. After analysis in Genesis Genetics 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 Genesis Genetics. The results will be reported by Genesis Genetics only to the qualified health care 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 a genetic disorder 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 three possible results for chromosomes 13, 18, and 21: No Aneuploidy Detected, Aneuploidy Detected, or Aneuploidy Suspected (Borderline Value). Sex Chromosomes will be reported as No Aneuploidy Detected, or Aneuploidy Detected.

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, and has been validated for chromosomes 13, 18, 21 and sex chromosomes 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 newest 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 tested 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® using verifi® technology.

Performance Data Table

(Based on Illumina and Genesis Genetics 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)	
All	98.89%	99.79%

- 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

Your health care 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 health care provider if you have any questions about this test, or have questions about what its results could mean.**

Genesis Genetics UK
London Bioscience Innovation Centre
2 Royal College Street, London, NW1 0NH

genesis serenity®

必須事項見本

必須事項：赤字部分
必要に応じて記入する事項：青字部分

Account/Ordering Information

Healthcare Professional: Sachihiko Okuno

Name of Clinic/Hospital: Okuno Hospital

Genesis Genetics Account No: P08[illegible]6845 *(if applicable)*

Address:

City:

County:

Postcode:

Country:

Tel:

Email(s):

Patient Information *(attach label when available)*

氏名: Last First M.I.

生年月日: DD / MM / YYYY

Sex: FEMALE

患者様識別番号

Address:

City:

County: Post code:

Country:

Email:

Tel:

Patient Consent

By signing this form, I voluntarily request that Genesis Genetics perform the Serenity prenatal test®. I have read and have received a copy of the patient consent included on the back of this form from my provider. The risks, benefits, and limitations of this test have been adequately explained to me. I authorise Genesis Genetics to perform the necessary steps to obtain reimbursement for the verifi® prenatal test.

患者様サイン:

サイン記入日付 DD / MM / YYYY

Test Information *(choose singleton OR twin with required options)*

For singleton pregnancy:

☑ セレニティー出生前診断の13、18、21番染色体の検査
- ☐ 性染色体の異数性検査オプション
  - ☐ 性別の情報通知

For twin pregnancy:

☐ Serenity prenatal test for chromosomes 13, 18, 21
- ☐ Presence of Y chromosome option

This test is validated for twin and singleton pregnancies of at least 10 weeks gestational age.

検査を受ける理由

- ☐ 高年齢出産
- ☑ 妊婦様がご不安を持っている
- ☐ 血清マーカー等で異常があった
- ☐ 超音波検査で異常があった
- ☐ 過去に13、18、21染色体のトリソミーや、モノソミーXまたは他の性染色体で異数性の胎児の妊娠経験がある

Clinical Information

最終の超音波検査日： DD / MM / YYYY

超音波検査時の妊娠週数: Weeks / Days

採血日： DD / MM / YYYY

採血時の妊娠週数: Weeks / Days

Comments:

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 Genesis Serenity® powered by the verifi® prenatal test, based on my professional judgment of medical necessity. I have addressed the limitations of this test, and have answered any question to the best of my ability. I understand that Genesis Genetics may need additional information, and I agree to provide it as needed for purposes of reimbursement.

Signature: Sachihiko Okuno

Date: DD / MM / YYYY

genesis genetics

Genesis Genetics UK
London Bioscience Innovation Centre
2 Royal College Street, London, NW1 0NH