Rodinia®
infertility test

AFFIX
BARCODE LABEL – SIF
HERE

SAMPLE INFORMATION FORM

Please complete sections below in English.

PATIENT INFORMATION

FIRST NAME	LAST NAME
DATE OF BIRTH	PATIENT GENETIC SEX
PHONE NUMBER	EMAIL
ETHNICITY	SAMPLE COLLECTION DATE
ADDRESS	
CITY / POST CODE / COUNTRY	

ORDERING HEALTHCARE PROVIDER INFORMATION

CLINIC NAME	CLINIC ID
REFERRING HEALTHCARE PROVIDER	
PHONE NUMBER	FAX
EMAIL	
ADDRESS	
CITY / POST CODE / COUNTRY	

PARTNER TESTING

IS THE PATIENT'S PARTNER HAVING THE RODINIA TEST AS WELL?

☐ YES FIRST AND LAST NAME: DATE OF BIRTH:

☐ NO

COMMENTS:

REQUESTED TEST

Panel options are available below. For more details regarding the genes tested, please refer to Tables on pages 3 & 4.

☐ FEMALE INFERTILITY PANEL	*(55 genes)*
☐ THROMBOPHILIA AND NAIT PANEL ADD-ON TO FEMALE INFERTILITY PANEL	*(22 genetic variants)*
☐ MALE INFERTILITY PANEL	*(40 genes)*
☐ THROMBOPHILIA AND NAIT PANEL ADD-ON TO MALE INFERTILITY PANEL	*(22 genetic variants)*
☐ THROMBOPHILIA AND NAIT PANEL STAND-ALONE PANEL	*(22 genetic variants)*

TEST INDICATIONS

FAMILY HISTORY
(Please specify)

MEDICAL HISTORY
(Please specify any underlying medical condition, including polycystic ovary syndrome, erectile dysfunction, thrombotic events, miscarriages etc.)

SYMPTOMS
(Please specify all symptoms, including pain during intercourse, irregular menstrual cycle, irregular ejaculation, thrombotic events, thrombocytopenia, recurrent miscarriages etc.)

BIOCHEMICAL TEST RESULTS
(Please specify test, specimen and results)

OTHER
(Please specify)

If applicable, please attach detailed medical records and clinical information

FOR LABORATORY USE ONLY
F-OPR-01/16-V7-EN

ORDER NUMBER	LAB ID NUMBER	KIT LOT NUMBER
COMMENTS	DATE & TIME OF RECEIPT (DD/MM/YY HH:MM)	RECEIVED BY

RESTRICTED

MEDICOVER GENETICS
Neas Engomis 31, Nicosia, 2409 Cyprus
Phone: +357 22266888 Fax: +357 22266899
Web: www.medicover-genetics.com
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PATIENT CONSENT

By placing my signature below I hereby:

1. Confirm that I have read, or have had read to me, the attached Patient Informed Consent and that I understand it.
2. Declare that I have had the opportunity to receive counselling from referring healthcare provider on the Rodinia test and to discuss with the healthcare provider all aspects of the Rodinia test and this form including the benefits, risks and limitations of the Rodinia test, as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.
3. Authorize my referring healthcare provider to collect the necessary buccal swab sample, and to submit this form and transport the samples to Medicover Genetics laboratories for the purposes of conducting the tests requested with this form.
4. Authorize Medicover Genetics to use part or the entirety of the biological sample for the purposes of conducting the tests requested with this form.
5. Authorize Medicover Genetics to communicate the results of the test to my referring healthcare provider.
6. Confirm that all the information on this form is true to the best of my knowledge.

Your test results and any unused biological material can help Medicover Genetics improve and further develop the quality, accuracy and effectiveness of diagnosis and help us expand the scope of genetic testing. For this reason, Medicover Genetics would like to use your anonymized, de-identified (i.e. after removing all the personal information from which you can be identified) test results and unused biological material.

☐ For the above scope, I consent to the inclusion of my test results in Medicover Genetics' database, the coding, storing and using of biological material.

PATIENT/GUARDIAN SIGNATURE	DATE

HEALTHCARE PROVIDER ATTESTATION

I hereby certify and undertake that:

1. I am the referring healthcare professional ordering this test.
2. The test results will determine my patient's medical management and treatment options.
3. The patient has been informed about the nature and purpose of the testing.
4. The patient has been duly and thoroughly counseled about the test and has received all the advice necessary to provide their informed consent, including the benefits, risks, and limitations of the Rodinia test.
5. I have answered all the patient's queries about the Rodinia test.
6. This form has been completed according to the wishes and instructions of the patient.
7. I have obtained the patient's informed consent and have attested their signature.

HEALTHCARE PROVIDER SIGNATURE	DATE

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FEMALE INFERTILITY PANEL

Testing of **55 genes** and whole, partial and mosaic sex chromosome aneuploidies.

Disorders tested include primary ovarian insufficiency, ovarian hyperstimulation syndrome and hypogonadotropic hypogonadism such as Kallmann syndrome.

AIRE	EIF2B3	GALT	IRS2	PROKR2
ANOS1	FEZF1	GDF9	KISS1	PSMC3IP
BMP15	FGF8	GNAS	KISS1R	SEMA3A
CAPN10	FGF17	GNRH1	LHB	SPRY4
CHD7	FGFR1	GNRHR	LHCGR	STAG3
CYP11A1	FIGLA	HESX1	NOBOX	TAC3
CYP17A1	FLRT3	HS6ST1	NR5A1	TACR3
CYP19A1	FMR1	IL17RD	NSMF	THADA
DENND1A	FOXL2	INS	POF1B	WDR11
DUSP6	FSHB	INSR	POLG	WT1
EIF2B2	FSHR	IRS1	PROK2	ZP1

MALE INFERTILITY PANEL

Testing of **40 genes** and whole, partial and mosaic sex chromosome aneuploidies, including Y chromosome microdeletions.

Disorders tested include hypogonadotropic hypogonadism such as Kallmann syndrome.

ANOS1	DUSP6	FSHR	LHB	SPRY4
AR	FEZF1	GNRH1	LHCGR	SRD5A1
AURKC	FGF8	GNRHR	NR5A1	SRY
CATSPER1	FGF17	HESX1	NSMF	TAC3
CFTR	FGFR1	HS6ST1	PRM1	TACR3
CHD7	FLRT3	IL17RD	PROK2	USP26
DAZL	FMR1	KISS1	PROKR2	USP9Y
DDX25	FSHB	KISS1R	SEMA3A	WDR11

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THROMBOPHILIA AND NAIT PANEL

DISORDER / COMMON NAME	GENE	VARIANT	ALTERNATIVE NOMENCLATURE
Factor V Leiden	F5	NM_000130.4(F5):c.1601G>A (p.Arg534Gln)	G1691A F5, ARG506GLN R506Q Factor V Leiden
Factor V R2	F5	NM_000130.4(F5):c.3980A>G (p.His1327Arg)	FV R2 H1299R A4070G R2 allele
Factor XIII	F13A1	NM_000129.3(F13A1):c.103G>T (p.Val35Leu)	p.Val34Leu F13A1 VAL34LEU V34L
HPA-1	ITGB3	NM_000212.2(ITGB3):c.176T>C (p.Leu59Pro)	L33P
HPA-2	GP1BA	NM_000173.7(GP1BA):c.482C>T (p.Thr161Met)	rs6065
HPA-3	ITGA2B	NM_000419.5(ITGA2B):c.2621T>G (p.Ile874Ser)	I843S
HPA-4	ITGB3	NM_000212.2(ITGB3):c.506G>A (p.Arg169Gln)	R143Q
HPA-5	ITGA2	NM_002203.4(ITGA2):c.1600G>A (p.Glu534Lys)	Not available
HPA-6	ITGB3	NM_000212.2(ITGB3):c.1544G>A (p.Arg515Gln)	R489Q
PAI-1 4G/5G	SERPINE1	NM_000602.5(SERPINE1):c.-820G[(4_5)]	4G/5G
MTHFR	MTHFR	NM_005957.5(MTHFR):c.665C>T (p.Ala222Val)	C677T MTHFR 677C-T ALA222VAL (rs1801133)
MTHFR	MTHFR	NM_005957.4(MTHFR):c.1286A>C (p.Glu429Ala)	MTHFR 1298A-C A1298C GLU429ALA (rs1801131)
ACE (I/D)	ACE	NM_000789.3(ACE):c.2306-117_2306-116insAF118569.1: g.14094_14382	ACE/ID polymorphism INS/DEL (rs1799752)
Apo B	APOB	NM_000384.3(APOB):c.10580G>A (p.Arg3527Gln)	R3500Q 9775G>A
Apo E	APOE	NM_000041.2(APOE):c.526C>T (p.Arg176Cys)	R158C R148C
Apo E	APOE	NM_000041.4(APOE):c.388T>C (p.Cys130Arg)	C112R ApoE4
MTR	MTR	NM_000254.2(MTR):c.2756A>G (p.Asp919Gly)	p.D919G:GAC>GGC 2756A-G
MTRR	MTRR	NM_002454.3(MTRR):c.66A>G (p.Ile22Met)	p.I49M:ATA>ATG
AGT	AGT	NM_000029.4(AGT):c.803T>C (p.Met268Thr)	M235T NM_000029.3:c.803T>C
AGTR1	AGTR1	NM_031850.3(AGTR1):c.*86A>C	A1166C
GSTP1	GSTP1	NM_000852.4(GSTP1):c.313A>G (p.Ile105Val)	rs1695 GSTP1*B
Prothrombin	F2	NM_000506.5(F2):c.*97G>A	F2 rs1799963 20210G-A G20210A

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PATIENT INFORMED CONSENT

Rodinia TEST

Rodinia is a genetic test for infertility that screens for mutations in individuals who have difficulty achieving pregnancy. By identifying genetic variants associated with infertility and disorders of sex chromosomes, Rodinia can provide accurate prognostic assessment and identify treatment options.

Rodinia is applicable for individuals experiencing pregnancy delay, women with irregular or absent menstruation, men with low sperm count, irregular sperm form or movement, individuals with a suspected disorder of sex development, individuals that will undergo assisted reproductive technology (ART) treatment, candidates for sperm or oocyte donation and individuals with family history of infertility. Rodinia is also applicable to couples or individuals that have had more than one miscarriage, or have a family history of Neonatal Alloimmune Thrombocytopenia (NAIT), among other reasons.

SAMPLE COLLECTION

Your healthcare provider will take two buccal swab samples following the provided sample collection instructions and send it to Medicover Genetics laboratories for analysis. Occasionally, additional sample may be needed if there is a shipping delay, breakage of the sample collection device, sample degradation, sample contamination, inadequate sample or if the sample has been submitted incorrectly.

RESULT INTERPRETATION

The results are communicated within approximately 2-4 weeks directly to your healthcare provider. The healthcare provider ordering this test is responsible to understand the specific uses and limitations of the test, communicate this information to you and answer any questions you may have. The following describes the possible results from the female or male infertility test:

Clinically significant variant detected: A clinically significant variant (change) indicates that a pathogenic or likely pathogenic genetic variant has been identified in a gene associated with infertility. It is possible that the test identifies more than one clinically significant variant. The results should be interpreted in the context of the patient's clinical findings, symptoms, biochemical profile or family history.

No clinically significant variant detected: No clinically significant variant detected indicates that no disease-causing genetic variant has been identified for the test performed. A 'no clinically significant variant detected' result does not rule out any pathogenic variants in areas not assessed by the test, or in regions that were covered at a level too low to be assessed. A result of 'no clinically significant variant' does not guarantee that the individual will be healthy or free from genetic disorders or medical conditions.

Variant of Uncertain Significance (VUS): A VUS indicates that a genetic change has been detected, but it is currently unknown whether that change is associated with a genetic disorder. More scientific research and data are needed to clarify VUS and their role in disease. VUS will only be reported in cases of potential pathogenicity. The carrier status in recessive conditions will not be reported. In case of a VUS result, further analysis may be recommended by your healthcare provider. Detailed medical records or information from other family members may also be needed by your healthcare provider, in combination with clinical counseling to help clarify results.

Result interpretation is based on currently available information in the medical literature, research and scientific databases. Because the literature, medical and scientific knowledge are constantly changing, new information that becomes available in the future may replace or add to the information currently known. It is recommended that you keep in contact with your referring healthcare professional to learn of any changes in the interpretation of your results or new developments.

DISCLOSURE

Medicover Genetics is a fully accredited state-of-the-art genetic testing laboratory. All necessary measures are taken to perform the testing reliably and under strict standards. Rodinia is highly accurate, however, there is a small possibility for false positive, false negative or inconclusive results due to technical and biological reasons. Although rare, these reasons include but are not limited to: mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other rare events such as the presence of change(s) in a small percentage of cells (extremely low-level mosaicism) which may not be detectable by the resolution of the test. The analysis is specific only for the tests ordered. This test will not detect all genetic changes in the evaluated genes. Some undetected genetic changes could be disease-related and are not tested by Rodinia. A healthy carrier status will not be reported by Rodinia. For the Thrombophilia and NAIT Add-on and Stand-alone Panels only, the genotype status of variants tested will be reported. Genetic testing is an important part of the diagnostic process. However, genetic tests may not always give a definitive answer. In some cases, testing may not identify a genetic change even though one exists. This may be due to limitations in current medical knowledge or testing technology. Accurate interpretation of test results is dependent upon the patient's clinical diagnosis or family history, as well as the fact that any reported family relationships are true biological relationships. This test does not have the ability to detect all the long-term medical risks. Other diagnostic tests may still be necessary.

BENEFITS

Your genetic test results may help you and your doctor make informed choices about your family planning, healthcare and management. The results of genetic testing may have implications for other blood relatives. It is recommended that you receive genetic counseling before and after having this genetic test.

QUALITY IMPROVEMENT

Please choose the relevant option on the consent form to grant us permission to anonymously use your remaining sample to improve the quality, accuracy and effectiveness of Rodinia.

Please make sure you read and understand the information on this document before signing and complete all relevant information accurately as incorrect information can lead to inaccurate test results. Please discuss any questions you may have with your healthcare provider. For additional information please visit our website at ***www.medicover-genetics.com.***

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PATIENT PRIVACY SUMMARY

This privacy notice provides a summary of how Medicover Genetics Limited collects and processes your personal data with this form. It is important that you read this privacy notice together with our full privacy policy which contains more detailed information about our data processing. A copy is available online at www.medicover-genetics.com

1. Important information and who we are

Medicover Genetics is responsible for processing the personal data collected on this form.

We have appointed a data protection officer (DPO). If you have any questions about this privacy notice or our data protection practices, please contact the DPO.

CONTACT DETAILS

Full name of legal entity: Medicover Genetics Limited (HE 418406)

Email address: dpo.cy@medicover.com

Postal address: 31 Neas Engomis Street, 2409 Engomi, Nicosia, Cyprus

Telephone number: + (357) 22266888

2. The data we collect about you

We collect, use, store and transfer personal data about you as follows:

- Identity Data.
- Contact Data.
- Sensitive data (ethnicity, patient genetic sex, medical/clinical data).

3. How we use your personal data

We will only use your personal data for the purpose for which we collected it. This includes the following:

- To register you as a new customer.
- To conduct your selected test and to process and deliver your results.
- To manage your relationship with us.
- To contact you on your results or for consultation purposes.
- To invoice the referring healthcare provider.

4. How we share your personal data

We share your personal data with your referring healthcare provider, so we can notify the results of your test to them.

We may also share your personal data with cloud service providers, as we store certain information online.

5. International transfers

We do not transfer, store or process your personal data outside the European Economic Area unless you or your referring healthcare provider are located outside the EEA.

6. Your legal rights

Under certain circumstances, you have rights under data protection laws in relation to your personal data including the right to receive a copy of the personal data we hold about you, the right to erasure ('right to be forgotten'), the right to restriction of processing and the right to make a complaint at any time to the Office of the Commissioner for Personal Data Protection.

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