Breda Genetics srl
via Cipro 1, 25124 Brescia, ITALY
Tel. +39 030 22 19 32 89 Fax +39 030 22 19 32 02
bredagenetics.com

ORDER FORM v 5.0

SENDING PHYSICIAN / BIOLOGIST / COUNSELOR & BILLING INFORMATION

Title | Name | Surname | Institution / Department

Street, Number | Town (State/Province) | ( ) | Postal Code | Country

Email address | Report by email □ Yes □ No | Telephone (+intl prefix | number) +

Quotation number | Invoicing □ Physician / Institution □ Patient □ Other, please specify:

Name / Institution and address | VAT / Tax ID

PATIENT'S DETAILS

Name | Surname | Sex □ Male □ Female | Date of birth (dd/mm/yyyy)

Your patient's reference code / number (#) | Patient's legal guardian (if any)

For TRIO testing: | Name | Surname | Date of birth (dd/mm/yyyy)

Mother:

Father:

Clinical information / special requests:

SAMPLE'S DETAILS

□ DNA (TE BUFFER) □ DNA (WATER) □ EDTA-BLOOD □ FILTER CARDS (DRIED BLOOD SPOTS) □ FILTER CARD (DNA)
□ SALIVA □ BUCCAL-SWAB □ MOUTH-WASH □ AMNIOCYTES □ CHORIONIC VILLI □ URINE □ FFPE TISSUE

DNA concentration (ng/µl) | DNA purity (A260/A280) | DNA extracted from | Extraction method [optional]

Declaration on sample safety [mandatory]

I hereby declare that this diagnostic sample is NOT toxic or infective or contaminant or dangerous for human health. It's not for human consumption. It has no commercial value and it's given for free for diagnostic purposes.

Full Signature of the Sender

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TEST REQUESTED – PANELS

	Panel name and/or gene names:	Panel # (optional)
□ MENDEL PANEL		

Backbone: Mendeliome sequencing (2,800 genes).

	Panel name and/or gene names:	Panel # (optional)
□ EXOME PANEL 15MB		

Backbone: clinical exome sequencing (6,000 genes + mtDNA). Incidental findings and upgrade to full EXOME 15MB: available (costs may apply).

	Panel name and/or gene names:	Panel # (optional)
□ EXOME PANEL 60MB		

Backbone: whole exome sequencing (20,000 genes + mtDNA) without UTRs. Exonic content: 38MB. Upgrade to EXOME 33MB: available.

	Panel name and/or gene names:	Panel # (optional)
□ EXOME PANEL 90MB		

Backbone: whole exome sequencing (20,000 genes + mtDNA) with UTRs. Exonic content: 54MB. Upgrade to full EXOME 50MB: available.

	Panel name and/or gene names:	Panel # (optional)
□ GENOME PANEL		
□ CNV analysis:	□ Exon-centric (gene by gene; exon by exon) □ Genome-wide	

Backbone: whole genome sequencing + mtDNA. Exon-centric and/or genome-wide del/dup (CNV) analysis and upgrade to GENOME FULL available.

TEST REQUESTED - WHOLE

□ EXOME 15MB	□ SINGLETON □ TRIO	□ EXOME 60MB	□ SINGLETON □ TRIO
Clinical exome sequencing (6,000 genes + mtDNA).		Whole exome sequencing (20,000 genes + mtDNA) without UTRs.	
□ EXOME 90MB	□ SINGLETON □ TRIO	□ GENOME FULL	□ SINGLETON □ TRIO □ CNV analysis (Genome-wide)
Whole exome sequencing (20,000 genes + mtDNA) with UTRs.		Whole genome sequencing + mtDNA, with/without del/dup (CNV) analysis.	
INCIDENTAL FINDINGS		□ YES □ NO	

Please specify if you require incidental findings for any of the solutions above (PANELS or WHOLE, ACMG 2013 gene list, costs may apply).

TEST REQUESTED – ADD-ONS

PATIENT NUMBER:	□ ADD-ON GENE	□ ADD-ON PANEL
#	□ UPGRADE TO FULL EXOME	□ INCIDENTAL FINDINGS

Please enter below the gene or panel of genes to be added:	Panel # (optional)

Note: Panels may be given as panel name or number or as gene list. For custom panels please give the list of genes or refer to the quotation number. Special quotations apart, **incidental findings, upgrades from panels to full exome/genome, and CNV analysis are subject to additional charge**.

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TEST REQUESTED – SPECIALS

□ METABOLOME PLUS	□ EXOBOLOME	□ 15MB □ 33MB □ 50MB
All 100,000 human metabolites (urine)	Metabolome plus exome sequencing. Please select exome coverage length (15MB, 33MB or 50MB).	

□ MLPA □ qPCR	Gene(s) requested:

Gene-centric large del/dup testing based on Multiplex Ligation Probe-Dependent Amplification or qPCR. Please inquire about availability before ordering.

□ PSEUDO PLUS	Gene(s) requested:

Pseudogene testing through long-range PCR, touch-down PCR or alternative methods to discriminate variants between genes and pseudogenes.

□ SF array-CGH	□ HD array-CGH	Gene(s) requested:

Select SF (Super-Fast) service for standard, genome-wide array-CGH or HD (High Definition – Exon Centric) CGH for a panel (please give panel genes).

		Gene name	c.DNA position	Reference sequence	Patient #
□ SANGER CARRIER	Mutation #1:				
	Mutation #2:				
	Mutation #3:				

Carrier testing for known mutations by Sanger sequencing. Please give gene name, c.DNA position, reference sequence and patient ID to be tested.

TEST REQUESTED – CLASSICS

□ KÁRION-500	□ 20 plates □ 50 plates	□ KÁRION-800	□ 20 plates □ 50 plates
Standard karyotype (400 bands): select the number of plates (20 or 50).		High def karyotype (800 bands): select the number of plates (20 or 50).	

□ CFTR33	□ CFTR139	□ CFTR152	□ CFTR1000

Cystic fibrosis screening for the 33, 139 or 152 most common Caucasian mutations or by full gene sequencing (CFTR1000).

□ YDEL	□ F2 (G20210A)	□ F5 (G1691A)	□ MTHFR	□ FISH	Chromosome:

Chromosome Y microdeletions (male only), factor II, factor V, thermolabile MTHFR polymorphisms, and FISH testing (give chromosome for FISH)

□ REPEAT PLUS	

Triplet repeat expansion testing by Sanger, RPA and/or Southern blotting: please give gene names.

□ SANGER GENE	

Traditional Sanger sequencing for selected gene(s): please give gene names.

TEST REQUESTED – SEQUENCING ONLY WITH/WITHOUT BI

□ *CES*	□ *80x* □ *100x* □ *200x*	□ ***WES with UTRs***	□ *50x* □ *80x* □ *100x* □ *200x* □ *300x*
Clinical exome sequencing (6,000 genes + mtDNA).		*Whole exome sequencing (20,000 genes + mtDNA) with UTRs.*	
□ ***WES without UTRs***	□ *50x* □ *80x* □ *100x* □ *200x* □ *300x*	□ ***WGS***	□ *30x* □ *40x* □*60x* □ *90x*
Whole exome sequencing (20,000 genes + mtDNA) without UTRs.		*Whole genome sequencing with mtDNA*	
Requested deliverables:	□ *FASTQs* □ *BAM* □ *VCF* □ *QC* □ *ANNOTATION* □ *VARIANT PRIORITIZATION*		
Delivery:	□ *CLOUD* □ *HDD*		

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INFORMED CONSENT

	Name	Surame	Date of birth (dd/mm/yyyy)
Patient:			

Patient #: **Test requested:**

Consent not needed because: ☐ patient's consent was already obtained on the sender's form ➲ Go to Signature of the Sender (below).

Genetic testing is performed on human DNA, RNA or proteins in order to identify genetic variants which may cause (or predispose to) certain diseases. Genetic testing and genetic counseling are medical acts, of which contents and results are strictly confidential and subject to professional secrecy. Although sensitivity and specificity of genetic testing is high for most techniques, errors may occur which may be impossible to be avoided/recognized, at least in the first round of analysis. As exome and genome analysis consist in the sequencing of all human genes, disease-causing mutations may be found also in genes not relating to the primary clinical condition for which the patient has chosen to be tested (incidental findings). Incidental findings include mutations which may cause cancer, certain heart diseases or other severe disorders. The possibility to detect incidental findings is around 1-3%. The patient may opt-in or opt-out of incidental findings (see below). The list of genes for which incidental findings will be reported is recommended by international guidelines (http://bredagenetics.com/incidental-findings/). Additional incidental findings may be reported upon lab decision. The metabolome analysis consists in the study of all 100,000 human metabolites in a urine sample in order to identify possible abnormalities in metabolic pathways. The metabolome study is conducted on a research basis only and has therefore no diagnostic value in principle, although it may help to interpret the sequencing data. By signing this consent, the patient (or their legal guardian or support administrator) declares to have been thoroughly informed and accepts advantages, detection power, limitations and personal and familial implications of the test. The patient therefore explicitly consents to the taking of their biological sample for its shipment to Breda Genetics and the execution of the test. Moreover the patient declares that he/she:

- ☐ wants to know the results of the test.
- ☐ wants to inform the sending physician of the results.
- ☐ accepts that the sample is stored and that, under his/her additional consent, other genomic regions may be analysed.
- ☐ accepts that the sample is stored and, once anonymized, may be archived/used/transferred for research purposes and lab internal statistics.
- ☐ **wants the incidental findings to be reported.**

- ☐ DOES NOT want to know the results of the test.
- ☐ DOES NOT want to inform the sending physician of the results.
- ☐ DOES NOT accept that the sample is stored and that, under his/her additional consent, other genomic regions may be analysed.
- ☐ DOES NOT accept that the sample is stored and, once anonymized, may be archived/used/transferred for research purposes and lab internal statistics.
- ☐ **DOES NOT want the incidental findings to be reported.**

To enable genetic testing, the patient accepts that their personal and sensitive data (i.e. sample, clinical information and analysis results) are given to Breda Genetics srl (Data Holder) and is aware that, in compliance with the current Italian law (DL 193/2003) and the upcoming EU Regulation 2016/679, such data will be safely stored and treated for the time necessary to the completion of the service (genetic testing/counseling) and in accordance with principles of confidentiality, accuracy, integrity, minimization, pseudonymization, and lawfulness as prescribed and recommended by the current regulations. The patient can partially or completely revoke any part of this informed consent and can request access, modification, correction or cancellation of their data at any time by sending a registered letter to Breda Genetics srl, via Cipro 1, 25124 Brescia and actions will be taken to fulfil their request as fast as possible within 30 days. For any possible controversy regarding data treatment or the requested test/service, it is mutually agreed to elect the court of Brescia (Italy) as competent.

Date (dd/mm/yyyy)	Place	Signature of the Patient/Legal guardian

The sending physician/counselor/biologist (sender) hereby declares to have thoroughly informed the patient about the advantages and limitations of the test in a way that is understandable to the patient, clearing doubts, questions and possible misconceptions as much as possible. To enable the service, the sender accepts to give their data and their patients' data to Breda Genetics srl (Data Holder), which will treat them in compliance with the current Italian law (DL 193/2003) and the upcoming EU Regulation 2016/679 following principles of confidentiality, accuracy, integrity, minimization, pseudonymization, and lawfulness. The sender can partially or completely revoke the consent to the treatment of their or their patients' data and can request access, modification, correction or cancellation of such data at any time by sending a registered letter to Breda Genetics srl, via Cipro 1, 25124 Brescia and actions will be taken to fulfil their request as fast as possible within 30 days. For any possible controversy regarding data treatment or the requested test/service, it is mutually agreed to elect the court of Brescia (Italy) as competent.

Date (dd/mm/yyyy)	Place	Signature of the Sender (physician/counselor/biologist)

✈ **SAMPLE SHIPMENT & PAYMENT:** All our services are prepaid. Exceptions to this policy (e.g. for hospitals, laboratories and other institutions) must be agreed upon before sample shipment. Most samples can travel at room temperature. Free sample shipping policies and further recommendations on how to pack and send samples on bredagenetics.com. Please send this form and sample(s) to:

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Please notify sample shipment in advance to: info@bredagenetics.com. Thank you!

✈ **Free shipping included? Write us to request the courier waybill and sample pick-up:** info@bredagenetics.com.