REQUEST FORM VeriSeq Premium® Cod. 16207

BIOCLINICA REFERENCE LABORATORY GENETICS

Customer code: .....

Required fields are marked with an asterisk (*)

PATIENT INFORMATION

*Last name:	*Name:	*Birth date: dd/mm/yyyy
Patient Id.:	*Weight (kg):	*Height (cm): .....
Address:		
Country:	City:	ZIP code: .....

BLOOD SAMPLE

*Date of draw: dd/mm/yyyy	*Time of draw: .....

OBSTETRIC HISTORY

Number of previous deliveries:	Number previous miscarriages:	Number of abortions: .....
Date of last birth/abortion or miscarriage (month/year): mm/yyyy		History of pregnancies with chromosomal abnormalities or genetic diseases: ....
Number of previous anomalous pregnancies:		

REASON FOR REFERRAL

☐ First trimester biochemical screening ☐ Advanced maternal age ☐ Ultrasound findings suggestive of chromosomal abnormalities ☐ Anxiety

DISCLOSURE OF FETAL GENDER

☐ Yes, I wish to know the fetal gender (default option) ☐ No, I don't want to know the fetal gender (If no checkbox is ticked, fetal sex is provided by default)

CURRENT PREGNANCY

*Gestational age (weeks/days):	Method to determine gestational age:	
IVF PREGNANCY: ☐ Yes ☐ No Vanishing twin ☐ Yes ☐ No	If IVF, own eggs: ☐ Yes ☐ No Surrogate mother ☐ Yes ☐ No	If egg donation, indicate donator's age: dd/mm/yyyy ..... date of eggs' collection: .....

ULTRASOUND INFORMATION

Date of last ultrasound:	Gestational age by ultrasound (Weeks/days):	
*Type of pregnancy: ☐ 1 fetus ☐ 2 fetuses	Fetal measurements: ☐ Normal	☐ Fetus smaller than gestational age ☐ Fetus bigger than gestational age
Morphological study: ☐ Normal ☐ Undone ☐ with abnormalities (specify: .....)		

SCREENING PREVIO DE TRISOMÍA 21

☐ Yes Test type:	☐ TN + T1st trimester biochemical test	☐ 2nd trimester biochemical test	☐ No
	☐ 1st trimester biochemical test	☐ Combined test: 1st and 2nd trimester	Family history of genetic disease .....
	☐ 2nd trimester ultrasound markers		Carrier of a genetic disease .....
	☐ Only TN 1st T (or other ultrasound markers)		

ORDERING HEALTH CARE PROFESSIONAL INFORMATION (Reporting Address)

*Last name:	*First name:	**Email:**	
Institution:	Department:	Phone:	Fax: .....
Address:	ZIP code:	City:	Country: .....

***I herewith confirm the correctness of the above given information.**

..... dd/mm/yyyy
Place, Date

.....
Signature of ordering health care professional

TEST INFORMATION AND CONSENT FORM

Required fields are marked with an asterisk (*)

Test limitations

1. Although the latest research data indicate that the test is highly accurate, with a detection rate of trisomy 21 close to 100% and a false positive rate of less than 1%, this test can not be considered diagnostic. It should only be considered as a very efficient screening test. Therefore, an abnormal result must always be confirmed by an invasive prenatal test, and a normal result can not exclude with total certainty an affected fetus due to these pathologies. This is due to several limitations of the current methodology.

2. This test is designed as screening for chromosomal aneuploidies and is validated for chromosomes 13, 18, 21, X and Y. It has been validated for single and twin pregnancies with a gestational age of 10 weeks or more. Currently, in twin pregnancies, sex chromosome aneuploidies cannot be detected. Through the used test, no other possible chromosomal, subchromosomal or genetic alterations are detected. A false positive or negative may occur due to the presence of maternal chromosomal alterations, a high maternal body mass index, confined placental mosaicism, or the existence of an evanescent/deferred twin (see yield table).

3. If the pregnant mother has received an allogeneic blood transfusion, transplant or stem cell therapy, there is a possibility of non-interpretable results due to the presence of exogenous DNA.

Informed Consent

1. I fully understand the indication of the test, the objective, its characteristics and potential risks of this test. My doctor, Dr . *..... ....., has answered all my questions about it.

2. I fully understand the limitations of this test, in particular that the detection rate of the changes studied (chromosome 13, 18, 21, X and Y) is close but is NOT 100%. In cases of twin pregnancies, only trisomies of chromosomes 13, 18 and 21 and presence of the Y chromosome can be reported.

3. I confirm all the provided information about me is true and correct.

4. I understand that test result will be ready in about 10 days from when the lab receives the sample, but it could be ready in less time.

5. I was informed that it may be necessary to re-provide blood (<1% of cases).

6. I understand that the results are reference values and do not represent an element of clinical diagnosis. The results obtained should be considered in the context together with other clinical criteria, so it is recommended that these results be communicated in medical consultation.

7. I agree to provide information about my pregnancy, especially if my future baby is affected by some kind of genetic disease. I understand and authorize my doctor to contact me to know this information.

8. I give my consent for the use of clinical data by my laboratory for auditing, quality assurance and research purposes, provided that my person remains anonymous and not identifiable, and all the information I have provided is excluded from any publication. I can exercise my rights and revoke that consent at any time by contacting my laboratory.

9. About personal data: According to Spanish Law 41/2002, regulating Patient Autonomy, and Spanish Law 3/2018 on the Protection of Personal Data, The test applicant must have the written consent of the patient (and/or their legal representatives) to carry out this test and the treatment of their personal data. The information collected in this form will be incorporated into a confidential automated file registered in the Spanish Agency for the Protection of Data, under the terms established in Spanish Law 3/2018, with the purpose of carrying out the genetic study requested here. The patient, or their legal representatives, may at any time exercise their rights of access, rectification, deletion, limitation, opposition and portability by requesting it through his/her laboratory.

* Patient's name and last name:	* Patient's signature:	* Place and date:

* Healthcare professional prescriber name:	* Healthcare professional prescriber signature:	* Place and date: