



**GENETIC TEST APPLICATION FORM**

**1. Applicant’s personal information**

Doctor (First and Family name):  
Center:  
Department/medical service:  
Full address:  
Telephone number: e-mail:

**2. Sample data**

Sample reference number\*:  
(Please fill in with the reference number shown on the tube containing the sample)  
Sample type: Blood DNA Saliva Other (specify)  
Specify origin if the sample is DNA: \_\_\_\_\_

**3. Clinical information**

Purpose of the requested genetic test:  
Confirmation of clinical diagnosis Carrier testing Other purpose  
**Medical history**  
Personal background of genetic diseases or anomalies: Yes No  
Diagnosis. Please specify medical diagnosis:

Relevant family’s medical history ( please include family tree )

Relationship with patient	Type of disease	Age at which the diagnosis was made
<b>Maternal line</b>		
<b>Paternal line</b>		
<b>Additional (siblings/offspring)</b>		

**4. Statement of medical necessity**

The doctor, or the authorized professional, hereby declares the medical necessity of the genetic test and that:

- The patient has been sufficiently informed about the genetic tests.
- The patient has given his/her informed consent to perform the genetic tests requested.
- The patient’s informed consent has been archived in his/her medical files.

**Requesting doctor’s statement:**

I hereby declare that this test is necessary from a medical point of view for the diagnosis or detection of a disease, disability, disorder or syndrome, and that the results will be used in the decision on the treatment of the concerned patient.





**5. Requested genetic test**

Reference	Description

\* Please, if you know it, fill in the reference number of the requested test. In other case, fill in the description of the disease the genetic test is for.

**6. Invoice information**

(If you have requested other tests before and your invoice information has not changed, you may skip this point)

Full Name:

National Identity Number:

Send invoice to:

(Fill in with the department or personal responsible for its execution)

Address:

City:

Region:

Country

ZIP Code:

Telephone number:

e-mail:

Signature from the Doctor:

Date:

Name:.....

*All personal information provided in the present document, as well as the subsequent information of diagnosis, research and/or statistics, will be handled in the strictest confidentiality and under the protection and regulations of the LOPD (Ley 15/1999, de 13 de diciembre), and will be kept in the files owned by AC-Gen Reading Life S.L. This information will be used to fulfill the diagnosis, research, statistical and monitoring purpose by the responsible entity AC-Gen Reading Life S.L. as explained in the present document.*

*You have the right to access, correct and cancel your personal file. You can exercise these rights sending a written request to “Edificio CTTA, Parque Científico de la Universidad de Valladolid, Paseo de Belén 9, 47011 de Valladolid”, under the reference: “Protection of personal information”, and including a copy of your Passport or equivalent identity card.*





### **Patient’s Informed consent for the performance of genetic testing**

The patient’s informed consent is mandatory for the performance of genetic testing. The patient (or his/her parent or legal guardian if the patient is under age or incapacitated) must sign the following consent. In the case of anonymous samples, the doctor’s declaration that the patient has been informed and has given his/her informed consent, will be sufficient.

#### **Name of the genetic test to be performed:**

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The purpose of this genetic and molecular testing is to determine whether you are the carrier of one or more mutation(s) that may be the cause of may heighten the probability to suffer from a genetic-hereditary disease or disorder. This study will include the reading and analysis of the gene or genes associated with the disease for which the test is requested. Your doctor can provide you with further information about the specific disease associated to the gene or genes included in the requested test.

The biological sample (blood, biological fluids or tissue) is necessary for the isolation and purification of DNA from which the genetic and molecular analysis will be made

I understand the information explaining the purpose of the test and its methodology.

Due to the complexity of DNA testing and the implications of the results, the outcome of the test will be sent directly to your doctor. You must get in touch with your doctor in order to know the test’s results.

In addition, the test’s results may be communicated to all those who, by law, may have access to such information.

I understand the information concerning AC-Gen Reading Life’s disclosure policy.

**Genetic testing results have implications on the members of your family.** Once the test is performed, it may be determined that you are the carrier of a genetic mutation in the analyzed gene or genes. This may have important consequences for the members of your family. The implications and the significance of the results for you and your family should be further explained by your doctor.

It is highly advisable for anyone who is going to subject his/herself to genetic testing, to gather previous advice prior to the test and reception of the results. This procedure should be carried out by a qualified specialist, such as a genetic counselor or medical geneticist.

I understand the information concerning the consequences and risks involved in genetic testing.

Although the methods employed in genetic testing are highly specific and detailed, there is a possibility that the results may not be conclusive. There are three possible outcomes from genetic testing:

*Positive:* In this case, a genetic mutation associated with a specific disease is found. This result confirms the diagnosis or implies a higher risk to develop that specific disease. Your doctor will make the appropriate recommendations aimed to the prevention, monitoring and, if needed, medical treatment of the disease, based on the knowledge of the mutated gene or genes.

*Negative:* No genetic mutation is identified in any of the analyzed genes. This outcome reduces the probability of having a genetic mutation in the analyzed genes (see genetic testing limitations). Your doctor will take the necessary control measures and will give you recommendations for your medical treatment based on your medical history and family’s background.

*Variable:* A genetic mutation is identified in one or more genes. However, there is not sufficient information to determine whether this mutation is associated with a clinical diagnosis or a higher risk to





develop the disease, or not. In this case, further bibliographical research, bioinformatic and functional studies may be made to determine the pathogenic nature of the mutation found. Even with this extra information, the result may not be conclusive.

I understand the information explaining the technical limitations of genetic testing

An inaccurate outcome may occur due to the following reasons:

- Mistaking of samples.
- Critical relatives' samples not available.
- Inaccurate medical information about your clinical condition or that of your relatives.
- Technical problems.

I understand the information concerning the laboratory's limitations.

Once the genetic test is carried out, your DNA may be disposed of or be kept indefinitely for research, validation tests or educational purposes in AC Gen Reading Life. In all these cases, your privacy will be guaranteed. You will not receive any economic compensation for the results of the research that may be conducted with your sample. You have the right to deny the use of your sample for the purposes above mentioned, and also to cancel your consent at any time, by giving notice to your doctor. In no case the results of your genetic testing will be affected by your consent or your denial to use your biological sample for research purposes.

I hereby give my consent to the use of my DNA sample for research or educational purposes.

I do not give my consent to the use of my DNA sample for any purposes.

AC Gen Reading Life may suggest additional genetic testing if it deems it helpful and appropriate to solve your diagnostic case. You can decline the performance of the test, if any of the informed consent conditions are not met.

You have the right to change your mind at any time and cancel your authorization to perform the genetic test included in this document, and withdraw from the whole analysis process. If your cancellation request is received before the test has been performed, there will be no economic charges. Otherwise, the full price of the test must be paid.

I have read (or someone has read to me) all the previous statements and I understand the information concerning genetic testing. I have also had the opportunity to make all questions I may have about the test, the procedure, its risks and the existing alternatives before giving my informed consent.

I give my consent to the performance of the genetic testing on my biological sample.

If it applies, I authorize the extraction of biological samples and the genetic testing of my underage children to be used in the terms above mentioned, in the genetic study of the disease above described.

Patient's signature (or Parent or legal guardian)

Date:

Patient's name:

Name and relation ( Parent/legal guardian)

