



Patient information

Last name:		First name:	
Phone:		Email:	
Date of birth: DD / MM / YYYY	Gender: M F	ID/passport no.:	
Address:			
Medical aid name:	Medical aid no.:		
Medical aid plan:			

Healthcare provider information

Healthcare provider:	Centre/clinic name:
Phone:	*Email for report:

Please note, this is not mandatory, however, should you include this, your healthcare provider will receive a copy of the report.

Billing information

Person responsible for account:	Contact no.:
ID/passport no.:	Email:

Payment method

☐ QR code
 ☐ Credit card
 ☐ EFT

What medication/supplements are you currently taking?

Do you consume any of the following on a frequent basis (more than once a week or daily)?

<input type="checkbox"/> Alcohol	<input type="checkbox"/> Marijuana	<input type="checkbox"/> Fermented food/sauces	<input type="checkbox"/> Foods high in protein
<input type="checkbox"/> Foods/beverages containing caffeine	<input type="checkbox"/> Smoking	<input type="checkbox"/> Foods containing liquorice	<input type="checkbox"/> Foods high in sodium
<input type="checkbox"/> Foods/beverages containing cranberry	<input type="checkbox"/> Acidic foods	<input type="checkbox"/> Leafy greens	<input type="checkbox"/> Foods high in potassium
<input type="checkbox"/> Foods/beverages containing milk	<input type="checkbox"/> Chamomile teas	<input type="checkbox"/> Tonic water	<input type="checkbox"/> Foods high in iron
<input type="checkbox"/> Grapefruit juice	<input type="checkbox"/> Chocolate	<input type="checkbox"/> Foods high in fat	<input type="checkbox"/> Foods high in calcium

By signing this form, I voluntarily request that Next Biosciences performs the pharmacogenomics test. I have read the Informed Consent included on the back of this form. The risks, benefits, costs, and limitations of this test have been adequately explained to me. I acknowledge and agree to the costs of the genetic testing, and agree to settle any and all invoices issued to me by Next Biosciences, by the stipulated date.

Patient/guardian signature:	Date: DD / MM / YYYY
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For laboratory use only

Sample type:

☐ Saliva
 ☐ Blood

Received by:	Sample ID:
Date received: DD / MM / YYYY	



INTRODUCTION

This form describes the benefits, risks, and limitations of the PharmaGene Pharmacogenomics Test.

PURPOSE

The purpose of the test is to screen for known genetic variants which affect the patient's ability to process drugs. In particular, how the body absorbs, distributes, metabolises, and excretes drugs. A report is generated that details the genetic variants present in an individual and correlates these variants to their specific drug responses.

TEST REPORT

- Access will be provided to a live portal where the healthcare provider (HCP) can see the patient's response to the listed medications (drug-gene interactions). Furthermore, the HCP will have the ability to tailor a treatment plan for the patient by inputting current medical conditions and their current treatment plan, after which they can see a risk rating score for their patient based on drug-gene, drug-drug, and drug-lifestyle interactions. They can adjust treatment plans on the portal to lower the risk rating and provide the patient with optimal medication and treatment plan.

TECHNOLOGY

DNA is extracted from the sample submitted. The DNA is then analysed, for a large number of genetic variants. Genetic variants in genes responsible for the metabolism and distribution of drugs are characterised and interpreted by Coriell Life Sciences. An individual's response to a list of drugs, based on their unique genetic profile, is compiled in a report.

LIMITATIONS OF THE TEST:

- In some cases, we may not be able to obtain a result, the causes of which may include insufficient or degraded DNA.
- Since this test requires a large effort to validate every interaction that is reported, it can only report genetic variants with well documented effects.
- Test results and interpretations are based solely on the known variant-drug associations at the time of testing, and the given current drug regimens and lifestyle factors. This test may not detect all the known genetic variants, which will result in an altered drug response. Absence of a variant does not rule out the possibility that a patient has a different response. The test does not account for other factors affecting responses to medication or their side effects.
- The interpretation provided in the test results will be current on the date the report is given. The interpretation can change over time with emerging data and/or changes in international guidelines. Next Biosciences is under no obligation to update test results in response to these changes.
- Test results may not be definitive in all individuals and there could be possible sources of error. Every attempt is made to mitigate the risks of errors and they are therefore extremely rare, but could result from trace contamination, technical errors, rare genetic variants that interfere with analysis, recent scientific developments, and alternative genetic variant classification systems.
- The test result should not be used in isolation, but as one of many aspects considered by the healthcare provider. The results generated by this report are a guideline to optimising patient care, but the ultimate choice of medication remains that of the treating physician. The aim of pharmacogenomics is to augment decision making, individualising therapy resulting in optimum patient outcomes, within the parameters of current science.
- Incidental or secondary genetic findings, which do not relate to a patient's pharmacogenomic profile, will not be reported.

TEST PROCEDURE

A collection kit will be sent to the patient when the test is requested. A saliva sample is collected and sent to the laboratory, which will then analyse the sample. After analysis the test results will be returned to the patient and HCP. In the event of another sample being required, Next Biosciences shall arrange for this to be done. Another sample may be required in the event of a quality control failure or when sample acceptance criteria is not met upon sample receipt.

SAMPLE TRANSPORT AND ASSOCIATED RISKS:

- Samples will be sent by Next Biosciences to its designated laboratory via courier.
- Next Biosciences is not responsible for delays or failures in transit due to factors outside of its reasonable control, including but not limited to weather or air travel conditions.
- Loss or damage of samples can occur and result in the inability to perform the test(s) or report test results, following which a new sample may need to be obtained.

IMPORTANT POINTS ABOUT THE TESTING AND REPORTING PROCESS:

- Your test results are confidential to the extent required by law.
- Results will only be disclosed to the patient, and the HCP designated by the patient.
- Only authorised and requested tests will be performed on the sample provided.
- Should DNA be leftover after testing, it will be stored for two years unless there is any requirements for longer storage.
- Collecting information after testing is part of follow up done by Next Biosciences. As such, Next Biosciences may contact you to obtain this information.
- Pursuant to best practices and clinical laboratory standards, leftover de-identified specimens, as well as de-identified genetic and other information learned from your testing, may be used by Next Biosciences for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement. All such uses will be in compliance with applicable laws.
- Next Biosciences may use your leftover specimen and your health information, including genetic information, in an anonymised or de-identified form for research purposes. Such uses may result in the development of commercial products and services. You will not receive notice of any specific uses and you will not receive any compensation for these uses. All such uses will be in compliance with applicable law.
- The patient accepts that the maximum amount of any and all liability which Next Biosciences may incur in terms of genetic testing, or in any respect of any and all actions or omissions of Next Biosciences under any and all circumstances shall be the total amount paid by the patient to Next Biosciences hereunder.

COMPLIANCE WITH THE PROTECTION OF PERSONAL INFORMATION ACT (POPIA):

- You understand that Next Biosciences takes the privacy of its patients seriously and has implemented reasonable security measures to guard against the unauthorised disclosure of your private patient information (personal information) in line with the Protection of Personal Information Act (POPIA), and as fully provided for in the Privacy Policy available at: <https://nextbio.co.za/Legal/Privacy-Policy>.
- You acknowledge that your personal information may be disclosed to Next Biosciences personnel, or to Next Biosciences' affiliates, sub-contractors, and vendors, solely for the purposes of providing the testing services.
- You acknowledge that your personal information may be disclosed by Next Biosciences in response to a specific request by a law enforcement agency, subpoena, court order, or as required by law.
- You confirm that the personal information supplied by you is true and correct and that you are responsible for updating your information to ensure that it remains correct.
- You acknowledge that your personal information will be retained by Next Biosciences for the required retention periods applicable to the medical and healthcare industry.
- In providing the testing services to you, your personal information may be transferred outside of South Africa, which you agree and consent to. Next Biosciences has ensured that all information transferred is done in an encrypted format.
- Next Biosciences may from time to time provide you with marketing information relating to testing services which may be relevant to you personally. You agree and consent to Next Biosciences using your personal information for these purposes and to inform you about any changes to the testing services offered by any of the companies forming part of the Next Biosciences group of companies. You can agree to opt out of this information at any time.
- By sharing personal information with Next Biosciences, you agree and consent to the use of your personal information as set out above and more fully provided for in the Privacy Policy available at: <https://nextbio.co.za/Legal/Privacy-Policy>.
- You warrant that you are entitled to provide Next Biosciences with the information and data that you provide and you indemnify Next Biosciences against any claims of a data breach by a third party.