NEXT BIOSCIENCES

PharmaGene
Pharmacogenomic Testing
Healthcare Provider Test Requisition Form

NH-OUT-PMG-FRM-001 REV-000 | 2023.07.01

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:	

Test Selection

☐ PharmaGene ☐ PharmaGene+

Billing Information

Person Responsible for Account:		Contact No.:	
ID/Passport No.:		Email:	

Payment Method

☐ QR Code ☐ Credit Card ☐ EFT

Is the patient pregnant? Y N

Is the patient taking any current medication/supplements?

Does the patient consume any of the following on a frequent basis?

☐ Alcohol	☐ Marijuana	☐ Fermented food/sauces	☐ Foods high in protien
☐ Foods/beverages containing caffeine	☐ Smoking	☐ Foods containing liquorice	☐ Foods high in sodium
☐ Foods/beverages containing cranberry	☐ Acidic foods	☐ Leafy greens	☐ Foods high in potassium
☐ Foods/beverages containing milk	☐ Chamomile teas	☐ Tonic water	☐ Foods high in iron
☐ Grapefruit juice	☐ Chocolate	☐ Foods high in fat	☐ Foods high in calcium

By signing this form, the patient voluntarily requests that Next Biosciences performs the pharmacogenomics test. The patient has 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 the patient. The patient acknowledges and agrees acknowledge and agree to the costs of the genetic testing, and agrees to settle any and all invoices issued to the patient by Next Biosciences, by the stipulated date.

Patient/Guardian signature:	Date: DD / MM / YYYY

For Laboratory use only

Sample Type:

☐ Saliva

Received By:	Sample ID:
Date Recevied: DD / MM / YYYY	Client No.: PGX/

For next steps, please send your form to **pharmagene@nextbio.co.za.**
For any queries, please contact us on **011 697 2900.**

INTRODUCTION:

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

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 in an individual and correlates these variants to their specific drug responses.

TEST OPTIONS:

PharmaGene
- Provides a static report with the individual's response to listed medications, based on drug-gene interactions, their demographics as well as other lifestyle factors.
- Should the patient be on medication currently, the interaction of those drugs with each other (drug-drug interactions) will be detailed.

PharmaGene+
- Must be ordered by a Healthcare Provider (HCP).
- Link to a live portal where the HCP can see your 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 tweak treatment plans on the portal to lower the risk rating and provide you with the optimal medication and treatment plan.

TECHNOLOGY:

DNA is extracted from the saliva 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. The test does not account for other factors affecting responses to medication or their side effects.
- The clinical 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 HCP.

TEST PROCEDURE:

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 Healthcare Provider. 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:

1. Your test results are confidential to the extent required by law.
2. Results will only be disclosed to the patient, and a HCP.
3. Only authorised and requested tests will be performed on the sample provided.
4. Should DNA be leftover after testing, it will be stored for five years unless there is any requirements for longer storage.
5. Collecting information after testing is part of follow up done by Next Biosciences. As such, Next Biosciences may contact you to obtain this information.
6. 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.
7. 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.
8. 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 more fully provided for in Next Biosciences' POPIA Manual.
- 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 set out in Next Biosciences' POPIA Manual.