



## Pre-Test Counseling

Date:

Patient name:

Session conducted by:

# Introduction

Pharmacogenomic Test

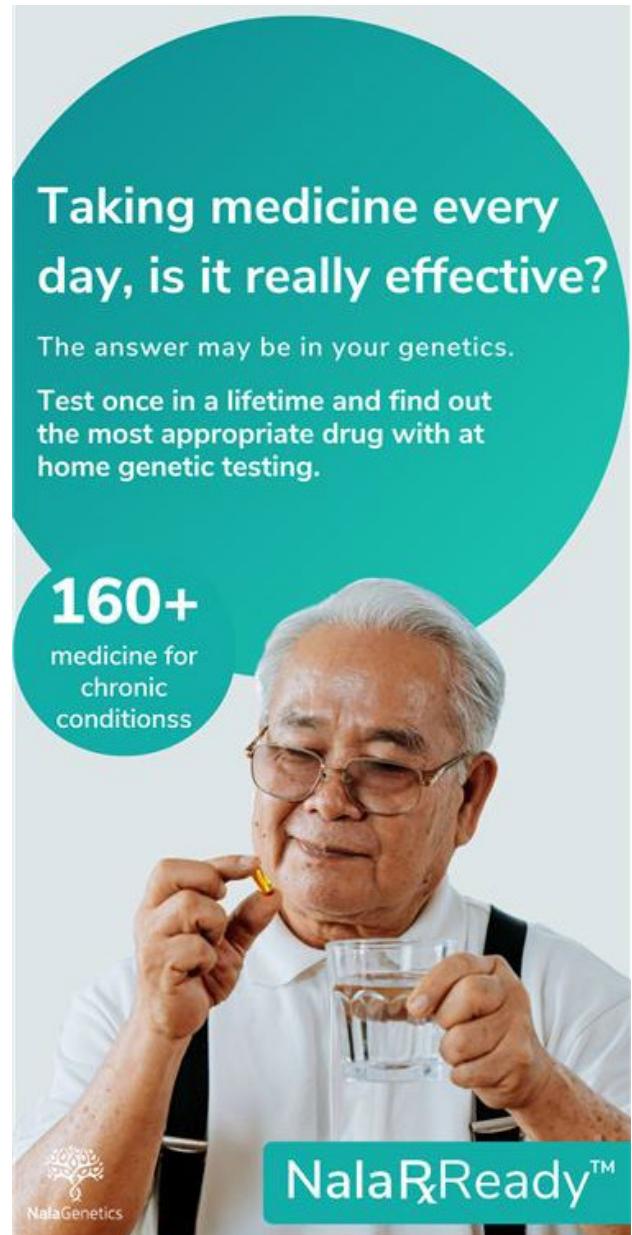
# What is Pharmacogenomic Test\*?

## RxReady™



Non-invasive DNA test to investigate drug-gene interaction of 160+ drugs. By taking this test, you are able to:

- Personalized your medication based on your genetics profile
- Avoid adverse drug reaction (ADR)\*\*
- Increase drug efficacy and maximize therapeutic effect
- Plan out preventive actions, because this test is valid for your whole life
- Consult with medical doctor on the type of medication and dosage that fits your genetic profile



Taking medicine every day, is it really effective?

The answer may be in your genetics.

Test once in a lifetime and find out the most appropriate drug with at home genetic testing.

160+ medicine for chronic conditions

NalaRxReady™

\*: Pharmacogenomic test is a non-diagnostic test

\*\*: About 70% of ADR incidence are related with patient's genetics profile

# What is Pharmacogenomic Test\*?

## RxReact™

Non-invasive DNA test to investigate drug-gene interaction of drugs within the same drug classes.



In particular for patients with heart condition, breast cancer, etc.

*\*: Pharmacogenomic test is a non-diagnostic test*

### RxReact™ Opioids

For patients with cough or medium to severe pain, get your personalized opioids therapy.

- Oxycodone
- Tramadol
- Codeine
- Opium derivatives & expectorants
- Dextromethorphan

### RxReact™ Antiplatelet

For CAD patient undergoing PCI, choose the most suitable antiplatelet based on their gene.

- Ticagrelor
- Clopidogrel
- Prasugrel

### RxReact™ Beta Blocker

For high blood pressure patients, choose your personalized beta blocker based on your gene.

- Carvedilol
- Nebivolol
- Atenolol
- Bisoprolol
- Metoprolol
- Propranolol

### RxReact™ Statins

For hyperlipidemia patients, choose the right statins based on their body response to avoid rhabdomyolysis adverse effect.

- Rosuvastatin
- Pitavastatin
- Atorvastatin
- Fenofibrate
- Fluvastatin
- Simvastatin
- Rosuvastatin & Ezetimibe
- Simvastatin & Ezetimibe

### RxReact™ NSAIDs

For patients with mild to moderate pain, get the right NSAIDs for you.

- Tenoxicam
- Piroxicam
- Meloxicam
- Lornoxicam
- Flurbiprofen
- Celecoxib
- Ibuprofen

### RxReact™ PPI

For patients with GERD, high gastric acid production problem, or H.Pylori infection choose the right PPI to get the optimized efficacy based on their gene.

- Esomeprazole
- Dexlansoprazole
- Lansoprazole
- Omeprazole
- Pantoprazole
- Rabeprazole

### RxReact™ Tamoxifen

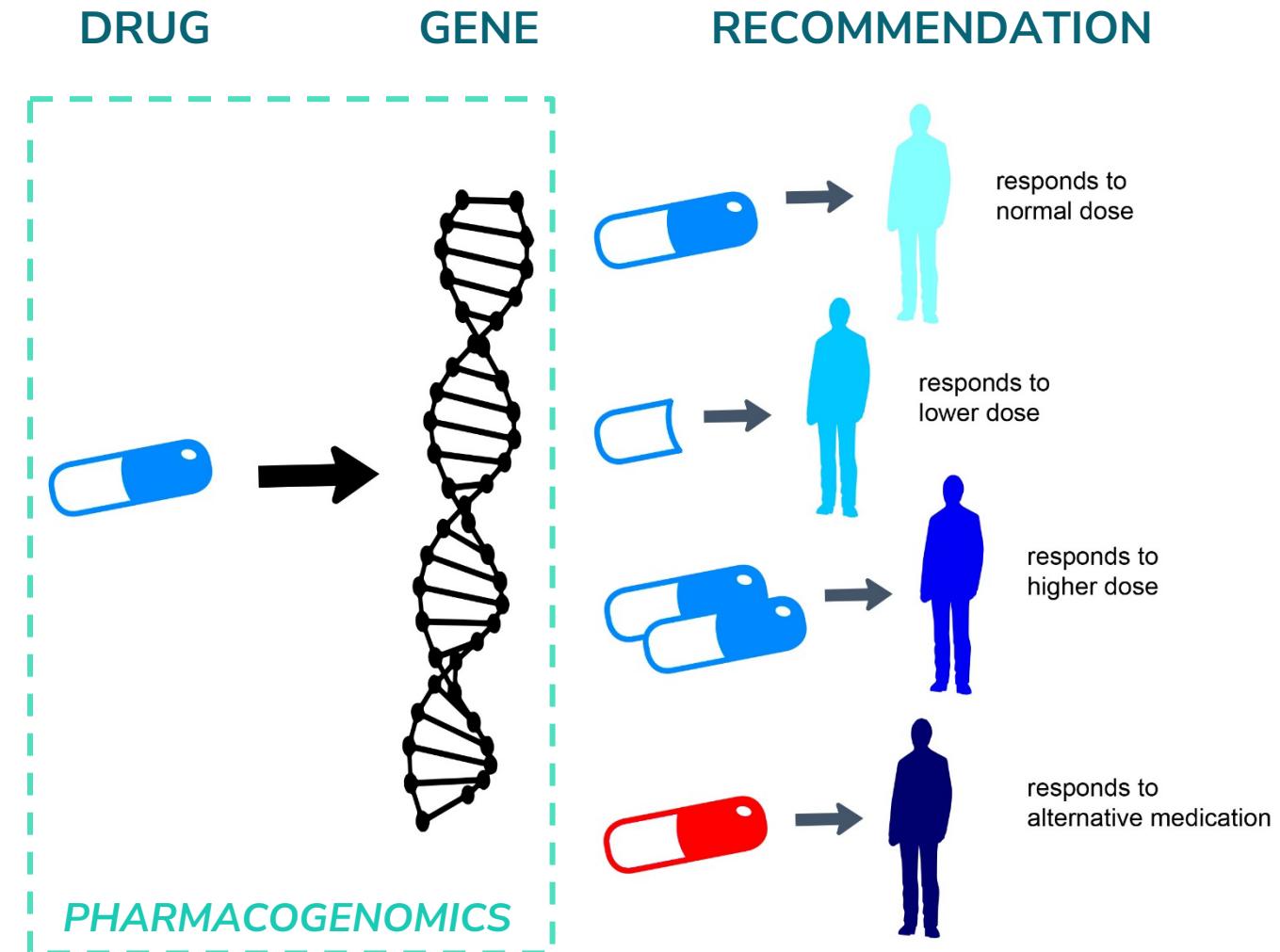
For breast cancer patient, see if tamoxifen is suited for you.

- Tamoxifen

# How Does Pharmacogenomic Test Work?

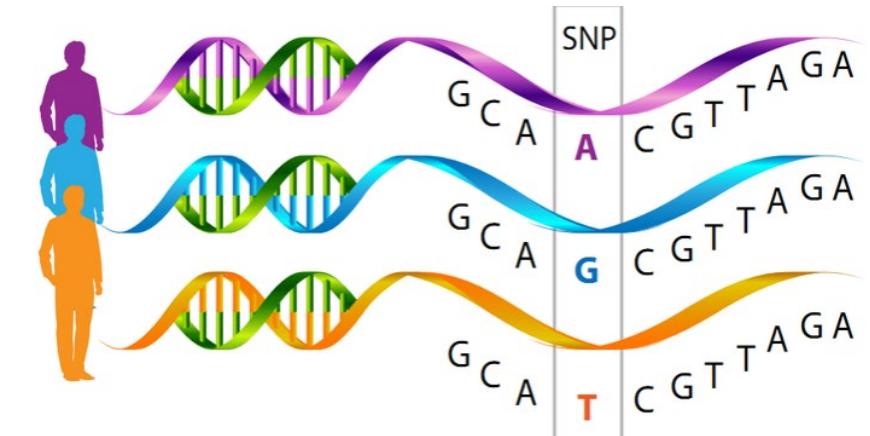
- Genes are the body's blueprint to construct enzymes. Enzymes metabolizes drugs inside the body.
- Genes varies from person to person. An identical twin may carry different gene variant from the other twin.
- Pharmacogenomic test investigates the gene variants and its impact in drug metabolism inside the body.
- 4 genes are tested:

CYP2C9      CYP2D6      CYP2C19      SLC01B1



# How Does Pharmacogenomic Test Work?

- *Single nucleotide polymorphism (SNP)* is the term used to describe the difference in our genetic code which is the cause of gene variance between individuals.
- Our system curates and summarizes clinical recommendations published by experts, regulatory bodies and other trusted resources.



## STRONG RECOMMENDATION

You can follow the recommendation confidently because its effect has been categorized to improve clinical outcome by at least one of the following medical societies or regulatory bodies. Each guideline has different kinds of strength of evidence. We reclassified the following categories from each guideline into Strong Recommendation:

**CPIC / CPNDS** - Strong recommendation, OR  
**DPWG** - level 3 or 4 level of evidence OR  
**PRO** - strong, essential or advisable test OR  
**FDA/Other regulatory bodies** - Testing required

## MODERATE RECOMMENDATION

You can consider the recommendation as it has been categorized to have some potential clinical benefit by at least one of the following medical societies or regulatory bodies. We reclassified the following categories from each guideline into Moderate Recommendation:

**CPIC / CPNDS** - Moderate or optional recommendation OR  
**DPWG** - Level 2 level of evidence OR  
**PRO** - conditional or possibly helpful test OR  
**FDA/Other regulatory bodies** - Testing recommended or actionable PGx

## INFORMATION AVAILABLE

The information provided serves as an additional point of consideration for the patient's therapy. The recommendation with insufficient data is also included as this category. We reclassified the following categories from each guideline into Information Available:

**DPWG** - Level 0 or 1 level of evidence OR  
**FDA/Other regulatory bodies** - Informative PGx



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# How Does Pharmacogenomic Test Work?

## PGx Medical Societies

### CPIC (Clinical Pharmacogenetics Implementation Consortium)

An international consortium of professionals interested in applying pharmacogenetics for patient care. Established in 2009, it consists of [PGRN](#) members, PharmGKB staff, and various experts. The guidelines are indexed in [PubMed](#) as clinical guidelines, endorsed by [ASHP](#) and [ASCPT](#), and referenced in [ClinGen](#) and PharmGKB.

### DPWG (Dutch Pharmacogenetics Working Group)

A multidisciplinary group of physicians, pharmacists, and other healthcare professionals. It was established in 2005 by the Royal Dutch Pharmacists Association ([KNMP](#)) with the objective of developing pharmacogenomic-based therapeutic (dose) recommendations. The guidelines are endorsed by the [EACPT](#) and the [EAHP](#).

### CPNDS (Canadian Pharmacogenomics Network for Drug Safety)

A pan-Canadian active surveillance network consisting of trained surveillance clinicians in 10 pediatric teaching hospitals across Canada, serving >75% of Canada's children. Established in 2005, the network's goal is to improve the safe use of medication by identifying genomic biomarkers of drug risk for serious ADRs.

### PRO (Professional Societies)

A source that includes the French National Network of Pharmacogenetics (RNPGx), the Cystic Fibrosis Foundation and the [American College of Rheumatology](#) for appropriate drug presented.

## Regulatory Bodies

### FDA (Food and Drug Administration)

An agency within the US Department of Health and Human Services. It is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.

### PMDA (Pharmaceuticals and Medical Devices Agency)

A Japan agency that was established and came into service on April 1, 2004, under the Law for the Pharmaceuticals and Medical Devices Agency, as a part of the Japan Association for the Advancement of Medical Equipment ([JAAME](#)).

### Swissmedic

The Swiss authority responsible for the authorisation and supervision of therapeutic products. The activities of Swissmedic are based on the Law on Therapeutic Products.

### EMA (European Medicines Agency)

A decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. EMA is a networking organisation whose activities involve thousands of experts from across Europe. These experts carry out the work of EMA's scientific committees.

### HCSC (Health Canada Santé Canada)

A federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances.

Each guideline and label annotation has its own strength of evidence for every drug-gene pair interaction. For more information, please [click here](#).

- PGx Medical Societies: expert consortia related with Pharmacogenomics



- Regulatory Bodies: regulatory bodies related with Pharmacogenomics



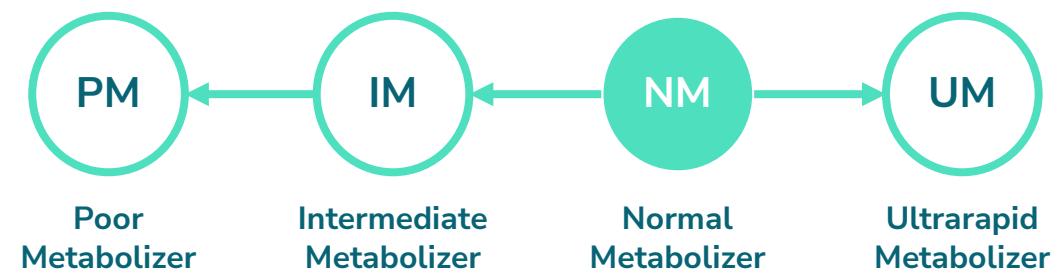
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pharmacogenomic  
test result

# Pharmacogenomic Test Result

- Our report shows your genetic variants and the enzyme's metabolic performance
  - Poor metabolizer (PM)
  - Intermediate metabolizer (IM)
  - Normal metabolizer (NM)
  - Ultrarapid metabolizer (UM)
- Each enzyme variant will have different recommendation for the different types of drugs

## Genotype

Gene	Genotype	Phenotype
CYP2C9	*1/*1	CYP2C9 Normal metabolizer
CYP2D6	*10/*36, copy number: >=3	CYP2D6 Intermediate metabolizer
CYP2C19	*2/*3	CYP2C19 Poor metabolizer
SLCO1B1	rs4149056(TT)	SLCO1B1 Normal function



Antithrombotic Agents			
	MEDICATION	PHENOTYPE	THERAPEUTIC INFORMATION
✓	Acenocoumarol	CYP2C9 NM	Follow the standard dosing guideline.
✗ ⏱	Clopidogrel	CYP2C19 IM	Alternative antiplatelet therapy (if no contraindication); e.g., prasugrel, ticagrelor.
✓	Phenprocoumon	CYP2C9 NM	Follow the standard dosing guideline.
✓	Prasugrel    CYP2C9	CYP2C9 NM	Follow the standard dosing guideline.
✓	Prasugrel    CYP2C19	CYP2C19 IM	No actionable recommendation available for this drug-gene pair.

# Pharmacogenomic Test Result

Analgesics			
	MEDICATION	PHENOTYPE	THERAPEUTIC INFORMATION
✓	Codeine and Paracetamol	CYP2D6 NM	Follow the standard dosing guideline.
✓	Eletriptan	CYP2D6 NM	Clinical studies indicate that there is no clinically relevant effect of CYP2D6 polymorphism on the PK of eletriptan.
✓	Oxycodone	CYP2D6 NM	Use oxycodone label recommended age- or weight-specific dosing.

Drugs For Acid Related Disorders			
	MEDICATION	PHENOTYPE	THERAPEUTIC INFORMATION
✓	Dexlansoprazole	CYP2C19 IM	Initiate standard starting daily dose.
✓	Esomeprazole	CYP2C19 IM	No action is required for this gene-drug interaction.
✓	Lansoprazole	CYP2C19 IM	Initiate standard starting daily dose.
✓	Omeprazole	CYP2C19 IM	Initiate standard starting daily dose.
✓	Pantoprazole	CYP2C19 IM	Initiate standard starting daily dose.
✓	Rabeprazole	CYP2C19 IM	No action is required for this gene-drug interaction.

Lipid Modifying Agents			
	MEDICATION	PHENOTYPE	THERAPEUTIC INFORMATION
✓	Amlodipine, Atorvastatin, and Perindopril Arginine	SLCO1B1 Normal function	Follow the standard dosing guideline.
✓	Atorvastatin	SLCO1B1 Normal Function	No actionable recommendation available for this drug-gene pair.
✓	Rosuvastatin and Ezetimibe	SLCO1B1 Normal function	Follow the standard dosing guideline.
?	Simvastatin and Ezetimibe	SLCO1B1 Normal function	The absence of this gene in genotyping does not exclude the possibility of myopathy.
✓	Fenofibrate	SLCO1B1 Normal function	No actionable recommendation available for this drug-gene pair.

Antihypertensives			
	MEDICATION	PHENOTYPE	THERAPEUTIC INFORMATION
✓	Clonidine	CYP2D6 NM	Follow the standard dosing guideline.

# Disclaimer

- Genetic test results are not for diagnosis purpose. 
- Genetic test recommendations are not substitute for health professional's recommendation.
- You are encouraged to always consult with health professionals before changing your dosage or prescriptions.
- Our medication list includes medications with more evidence of genetic correlation. There are medications with less evidence of genetic correlation, these medications are not included in the list.
- The medication list and recommendations might change with updates on the knowledge in the future.

# Sample Taking

# Kit Completeness

# ORDER FORM CONSENT FORM

BUCCAL SWAB



# BIOHAZARD BAG



# Test Request Form

<p><b>Test Request Form</b> PM-CLAB-010-FM-001-03 Release Date 25 Mar 2022</p> <p> <b>NalaGenetics</b></p> <p><b>Sample ID (tube barcode number):</b> _____</p> <p><b>Relevant Clinical Information (Diagnosis / History / Transplant Date)</b> _____</p> <p><b>Declaration by Ordering Physician</b>          I _____ (Full Name)              (Specialty)          with _____ (Contact)          and _____ (MCR Number as Doctor ID)          certify that:  <input type="checkbox"/> I am a registered medical practitioner  <input type="checkbox"/> Informed consent has been obtained from the patient to conduct the test  <input type="checkbox"/> Appropriate pre-test counselling has been provided to the patient and post-test counselling (where applicable) shall be provided to the patient when test results are available            _____ Signature      _____ Date       </p> <p><b>Previous Medications</b>          Drug Name      Dose (mg)      Frequency      Duration          _____          _____          _____          _____          _____          _____       </p>	<p><b>NALAGENETICS DIAGNOSTICS LABORATORY (SG)</b> Nalagenetics Pte Ltd 1093 Lower Delta Road, #04-05/06/07/08, Singapore 162204 Co. Reg. No. 201610000H</p> <p><b>Patient Detail Label</b></p> <p>Full Name based on IC (underline the last name) _____          NRIC/FIN/Passport No. (strike-off where not applicable) _____</p> <p>Nationality _____          Date of Birth (DD/MM/YYYY) _____</p> <p>Gender <input type="checkbox"/> Female <input type="checkbox"/> Male  <input type="checkbox"/> Chinese <input type="checkbox"/> Malay <input type="checkbox"/> Indian <input type="checkbox"/> Others: _____</p> <p>Patient Address _____          Contact Number _____          Email Address _____</p> <p><b>Reason for Ordering the Test</b></p> <p><input type="checkbox"/> Patient at risk of or has the following diseases (tick all that applies)  <input type="checkbox"/> Type 2 Diabetes Mellitus <input type="checkbox"/> Rheumatoid Arthritis  <input type="checkbox"/> Hypertension <input type="checkbox"/> Osteoarthritis  <input type="checkbox"/> Gout <input type="checkbox"/> Hyperlipidemia  <input type="checkbox"/> Anxiety <input type="checkbox"/> Ischaemic Heart Disease  <input type="checkbox"/> Stroke <input type="checkbox"/> Major Depressive Disorder</p> <p><input type="checkbox"/> Patient has ≥1 family member(s) taking any of the 10 drugs in the panel  <input type="checkbox"/> Patient is interested in validating a potential adverse reaction they experienced  <input type="checkbox"/> Other reason(s): _____ (Please specify)</p> <p><b>Specimen Details</b>          Specimen type: Buccal Swab          How long did you not eat and/or drink before sample collection? _____ minutes          What did you last eat or drink before sample collection? _____</p> <p><b>Healthcare Institution (HCI)</b>          HCI Name: _____          HCI Address: _____          Contact Number: _____          Email address: _____          Specimen collector name: _____          Specimen collection date (DD/MM/YYYY): _____ Time: _____          Consultant-in-charge (if applicable): _____</p>	<p><b>Test Request Form</b> PM-CLAB-010-FM-001-03 Release Date 25 Mar 2022</p> <p><b>NALAGENETICS DIAGNOSTICS LABORATORY (SG)</b> Nalagenetics Pte Ltd 1093 Lower Delta Road, #04-05/06/07/08, Singapore 162204 Co. Reg. No. 201610000H</p> <p><b>Current Medications</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Drug Name</th> <th>Dose (mg)</th> <th>Frequency</th> <th>Duration</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> <p><b>Test Order</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Order</th> <th>Panel</th> <th>Gene</th> </tr> </thead> <tbody> <tr><td><input type="checkbox"/></td><td>Nala RxRead™ Siponimod</td><td>CYP2C9</td></tr> <tr><td><input type="checkbox"/></td><td>Nala RxRead™ Allopurinol</td><td>HLA-B*58:01</td></tr> <tr><td><input type="checkbox"/></td><td>Nala RxReady™</td><td>CYP2D6, CYP2C9, CYP2C19, SLC01B1, HLA-B*58:01</td></tr> <tr><td><input type="checkbox"/></td><td>Nala RxReady™-RMG (Research)</td><td>CYP2D6, CYP2C9, CYP2C19, SLC01B1, HLA-B*58:01</td></tr> <tr><td><input type="checkbox"/></td><td>Other panel: _____</td><td>(Please Specify)</td></tr> </tbody> </table> <p><b>To be completed by Nalagenetics Diagnostics Laboratory (SG)</b></p> <p>Upon visual checks, sample is: Accepted / Rejected (please delete where applicable)</p> <p>Inspection Date and Time: _____</p> <p>Inspector Name &amp; Signature: _____</p> <p>Nalagenetics Sample ID: _____</p> <p><b>Remarks/Instructions/Special Request</b></p> <p><b>NOTE:</b>    1. Please fill all information appropriately. All fields are MANDATORY unless otherwise stated.    2. Please state NIL or NA when information is not available or not applicable.    3. Please provide full names where indicated. Do not abbreviate.</p> <p>Call us at +65 6718 4730 or    Email us at <a href="mailto:sglab@nala genetics.com">sglab@nala genetics.com</a></p>	Drug Name	Dose (mg)	Frequency	Duration																									Order	Panel	Gene	<input type="checkbox"/>	Nala RxRead™ Siponimod	CYP2C9	<input type="checkbox"/>	Nala RxRead™ Allopurinol	HLA-B*58:01	<input type="checkbox"/>	Nala RxReady™	CYP2D6, CYP2C9, CYP2C19, SLC01B1, HLA-B*58:01	<input type="checkbox"/>	Nala RxReady™-RMG (Research)	CYP2D6, CYP2C9, CYP2C19, SLC01B1, HLA-B*58:01	<input type="checkbox"/>	Other panel: _____	(Please Specify)
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<input type="checkbox"/>	Nala RxRead™ Allopurinol	HLA-B*58:01																																														
<input type="checkbox"/>	Nala RxReady™	CYP2D6, CYP2C9, CYP2C19, SLC01B1, HLA-B*58:01																																														
<input type="checkbox"/>	Nala RxReady™-RMG (Research)	CYP2D6, CYP2C9, CYP2C19, SLC01B1, HLA-B*58:01																																														
<input type="checkbox"/>	Other panel: _____	(Please Specify)																																														

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# Test Request Form

## Test Request Form

PM-CLAB-010-FM-001-03  
Release Date 25 Mar 2022



# NalaGenetics

**Sample ID (tube barcode number):**

XXXXXXXXXXXXXXXXXXXX



Patient Detail Label	
Full Name based on IC (underline the last name)	-----
NRIC/FIN/Passport No. (strike-off where not applicable)	-----
Nationality	-----
Date of Birth (DD/MM/YYYY)	-----
Gender	<input type="checkbox"/> Female <input type="checkbox"/> Male
Ethnicity	<input type="checkbox"/> Chinese <input type="checkbox"/> Malay <input type="checkbox"/> Indian <input type="checkbox"/> Others: _____
Patient Address	-----
Contact Number	-----
Email Address	-----
<b>Reason for Ordering the Test</b>	
<input type="checkbox"/> Patient at risk of or has the following diseases (tick all that applies)	



## Patient Detail Label

- Make sure all fields are filled, especially patient full name and NRIC, to avoid delays in reporting.

## Sample ID

- 16-digit barcode on specimen tube.
- Must be replicated on the form.
- Sample ID & Patient Label must match between the tube and form.



# Test Request Form

	<b>Reason for Ordering the Test</b>										
<b>Relevant Clinical Information</b> (Diagnosis / History / Transplant Date)	<input type="checkbox"/> Patient at risk of or has the following diseases (tick all that applies) <table> <tr> <td><input type="checkbox"/> Type 2 Diabetes Mellitus</td> <td><input type="checkbox"/> Rheumatoid Arthritis</td> </tr> <tr> <td><input type="checkbox"/> Hypertension</td> <td><input type="checkbox"/> Osteoarthritis</td> </tr> <tr> <td><input type="checkbox"/> Gout</td> <td><input type="checkbox"/> Hyperlipidemia</td> </tr> <tr> <td><input type="checkbox"/> Anxiety</td> <td><input type="checkbox"/> Ischaemic Heart Disease</td> </tr> <tr> <td><input type="checkbox"/> Stroke</td> <td><input type="checkbox"/> Major Depressive Disorder</td> </tr> </table> <input type="checkbox"/> Patient has ≥1 family member(s) taking any of the 10 drugs in the panel	<input type="checkbox"/> Type 2 Diabetes Mellitus	<input type="checkbox"/> Rheumatoid Arthritis	<input type="checkbox"/> Hypertension	<input type="checkbox"/> Osteoarthritis	<input type="checkbox"/> Gout	<input type="checkbox"/> Hyperlipidemia	<input type="checkbox"/> Anxiety	<input type="checkbox"/> Ischaemic Heart Disease	<input type="checkbox"/> Stroke	<input type="checkbox"/> Major Depressive Disorder
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<input type="checkbox"/> Anxiety	<input type="checkbox"/> Ischaemic Heart Disease										
<input type="checkbox"/> Stroke	<input type="checkbox"/> Major Depressive Disorder										
<input type="checkbox"/> Patient is interested in validating a potential adverse reaction they experienced <input type="checkbox"/> Other reason(s): _____ (Please specify)											

**Reason for Ordering the Test**

- Select reason for ordering the test.
- Specify the reason if it's not in the list above.

**Relevant Clinical Information**

- State any relevant clinical information (diagnosis / history / transplant date).
- State “NA” or “NIL” if there is no information



# Test Request Form

<p><b>* Declaration by Ordering Physician</b></p> <p>I _____ (Full Name) _____ (Specialty) with _____ (Contact) and _____ (MCR Number as Doctor ID)</p> <p>certify that:</p> <p><input type="checkbox"/> I am a registered medical practitioner  <input type="checkbox"/> Informed consent has been obtained from the patient to conduct the test  <input type="checkbox"/> Appropriate pre-test counselling has been provided to the patient and post-test counselling (where applicable) shall be provided to the patient when test results are available</p>	<p><b>Specimen Details</b></p> <p>Specimen type: Buccal Swab</p> <p>How long did you not eat and/or drink before sample collection? <u>45</u> minutes      What did you last eat or drink before sample collection? <u>Chicken rice</u></p> <p><b>Healthcare Institution (HCI)</b></p> <p>HCI Name: <u>Nalagenetics Diagnostics Laboratory (SG)</u>      HCI Address: <u>1093 Lower Delta Road, #04-05/06/07/08, Singapore 169204</u>      Contact Number: <u>+65 6718 4730</u>      Email address: <u>sglab@nalagenetics.com</u>      Specimen collector name: <u>Staff name</u>      Specimen collection date (DD/MM/YYYY): <u>01/01/2022</u> Time: <u>4.30PM</u>      Consultant-in-charge (if applicable): <u>NA</u></p>
<u>Signature</u>	<u>Date</u>

**Declaration by Ordering Physician**

- All fields must be filled in. Physician's stamp/chop can be used here if it contains all the information mentioned.
- Samples with missing physician's signature and/or incomplete declaration will be put on hold and TAT will be delayed.

**Specimen Details**

- All fields must be filled in. Clinic's stamp/chop can be used here if it contains all the information mentioned.
- Remind patient to not consume any food/drink besides water 30 minutes before specimen collection).



# Test Request Form

Previous Medications			
Drug Name	Dose (mg)	Frequency	Duration

Current Medications			
Drug Name	Dose (mg)	Frequency	Duration

Test Order		
Order	Panel	Gene
<input type="checkbox"/>	Nala RxReact™-Siponimod	CYP2C9
<input type="checkbox"/>	Nala RxReact™-Allopurinol	HLA-B*58:01
<input type="checkbox"/>	Nala RxReady™	CYP2D6, CYP2C9, CYP2C19, SLCO1B1, HLA-B*58:01
<input type="checkbox"/>	Nala RxReady™-RMG (Research)	CYP2D6, CYP2C9, CYP2C19, SLCO1B1, HLA-B*58:01
<input type="checkbox"/>	Other panel:	(Please Specify)

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## Previous & Current Medications

- Fill in if information is available.
- Please state “NA” or “NIL” if the information is not available / patient does not wish to disclose / can’t recall this information.
- Do not leave any blank field in the forms.



## Test Order

- Select the test order unambiguously.
- If “Other panel” is selected, please fill in the blank to specify the panel ordered.
- Missing / ambiguous test selection may result in delays in reporting.

# Informed Consent Form

<p><b>Informed Consent Form for Genetic Testing &amp; Tissue Banking</b></p> <p>NALAGENETICS DIAGNOSTICS LABORATORY (SG) PM-CLAB-010-FM-002-05 Release Date 25 Mar 2022</p> <p>1093 Lower Delta Road, #04-05/06/07/08, Singapore 169204 Co. Reg. No. 201610009H</p> <p>Testing for genetic conditions can be complex. If warranted, obtain professional genetic counseling prior to giving consent to fully understand what the risks and benefits are to have the testing completed. Refer to test specific information (general description of the test, purpose, and description of associated disease(s) found at: <a href="http://www.nalagenetics.com">www.nalagenetics.com</a>)</p> <p>This test is voluntary, and your consent is required to proceed. You should take your time to ask all questions you may have to make an independent personal decision. If you wish to think this over, you may make another appointment. After you have given consent, you may withdraw your consent at any time or postpone the disclosure of the results. Fees should be paid prior to the tests and are non-refundable.</p> <p>I hereby consent to participate in testing for: _____ using a genetic test.</p> <p>I understand that a biological specimen (e.g. blood, buccal swab, or other tissues) will be obtained from me and/or members of my family.</p> <p>I understand that this biological specimen will be used for the purpose of attempting to determine if I and members of my family are carriers of the disease gene, or are affected with, or at increased risk to someday be affected with this genetic disease.</p> <p>It has been explained to me and I understand that:</p> <ol style="list-style-type: none"> <li>1. The result may indicate that I am predisposed to have a specific disease or condition. Further testing may be needed to confirm the diagnosis. I understand I will be given the opportunity to talk with my physician or a genetic counselor about these results.</li> <li>2. There is a chance that I will have this genetic condition but that the genetic test results will be negative. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease, may not be detected by the test.</li> <li>3. There may be a possibility that the laboratory findings will be uninterpretable or of unknown significance. In rare circumstances, findings may be suggestive of a condition different than the diagnosis that was originally considered.</li> <li>4. Molecular testing may detect a change in the DNA (mutation). Most tests are highly sensitive and specific; however, it is test dependent. Biochemical methods are sometimes used to look at abnormalities in the protein products that are produced by the genes.</li> <li>5. An erroneous clinical diagnosis in a family member can lead to an incorrect result for other family members in question.</li> <li>6. The tests offered are considered to be the best available at this time. This testing is often complex and utilizes specialized materials. However, there is always a small chance of error.</li> <li>7. Because of the complexity of genetic testing and the important implications of the test results, results will be reported only through a physician, genetic counselor, or other identified health care provider. The results are confidential to the extent allowed by law. They will only be released to other medical professionals or other parties with my written consent or as otherwise allowed by law.</li> <li>8. There are choices regarding storage and usage of my data samples, and I can change my decision by sending an email to <a href="mailto:siglab@nalagenetics.com">siglab@nalagenetics.com</a>. Test results and personal information will be stored in a secure server with compliance with the global and local standards of data privacy and security.</li> <li>9. Accurate interpretation of the DNA test result depends on the correct information that is provided by physicians, including clinical diagnosis, previous medications, family history, and other information provided in the order form.</li> <li>10. It has been explained to me the major medical facts regarding this test and the nature and purpose of the genetic test and alternatives to this test.</li> <li>11. I consent that the collected tissue might be exported to other affiliates of Nalagenetics outside of Singapore for genetic test performance if this test is not possible to be performed within the country.</li> <li>12. I, and/or members of my family will be contacted for re-sampling when necessary in the future (e.g tissue that was collected previously is accidentally damaged, collected tissue does not meet expected quality and/or minimum quantity, etc).</li> <li>13. After DNA testing is completed (please select one option):       <ul style="list-style-type: none"> <li><input type="checkbox"/> I consent to a portion of the remaining DNA to be stored and used for quality control, medical education, research, and/or future diagnostic testing. I may be contacted and re-consented should there be a new diagnostic test offering new information about my genetic profile and/or asked for other health information beyond what was requested for this test.</li> <li><input type="checkbox"/> I consent to a portion of the remaining DNA to be made anonymous and used for quality control, medical education and research. Since the sample has been made anonymous, any results obtained cannot be traced to the original source and no results will be reported.</li> <li><input type="checkbox"/> I do not wish for any remaining DNA to be used for quality control, medical education and research. My specimen and DNA will be discarded 2 months after the release of the report.</li> </ul> </li> <li>14. Nalagenetics intends to use the collected tissues to conduct a population genomics program to validate genetic and clinical risk scores in different populations. This program will help to predict the complex diseases to identify patients who can be screened and treated earlier according to guidelines.</li> <li>15. The collected tissues will not be used for any purpose other than research.</li> <li>16. There are foreseeable risks, only minor discomfort related to buccal swab sampling might arise from the removal of the tissue from a living donor.</li> <li>17. The tissue donor's right to the tissue and any intellectual property rights that may be derived from the use of the tissue have been renounced.</li> <li>18. No compensation or treatment will be made available to the donor in the event of injury arising from participation in the process of tissue donation as Nalagenetics does not foresee any potential injury arising from reasonable use of the sample collection and the pre-test preparation.</li> <li>19. There are no anticipated expenses that the donor is likely to incur as a consequence of donating tissue.</li> <li>20. I, and/or members of my family will be contacted for further consent when re-consent is necessary in the future (e.g. changes in the intended use of tissue samples/ adverse events, etc)</li> <li>21. All the tissue collected will not be used or be involved in any restricted human biomedical research involving human-animal combinations.</li> </ol>	<p><b>Informed Consent Form for Genetic Testing &amp; Tissue Banking</b></p> <p>NALAGENETICS DIAGNOSTICS LABORATORY (SG) PM-CLAB-010-FM-002-05 Release Date 25 Mar 2022</p> <p>1093 Lower Delta Road, #04-05/06/07/08, Singapore 169204 Co. Reg. No. 201610009H</p> <p>22. After I have given consent, I may withdraw my consent at any time in the circumstances and limitations specified as stated below:</p> <ol style="list-style-type: none"> <li>(a) the tissue has not been used for the research</li> <li>(b) the tissue has been used for the research but it is practicable to discontinue further use of the tissue for the research</li> <li>(c) the withdrawal does not affect the research information obtained before the consent is withdrawn and such information may be retained and used for the research</li> <li>(d) any penalty or damages imposed solely by reason of the withdrawal of consent permitted by this section is void and unenforceable</li> </ol> <p>23. After patient/ guardian/ voluntary tissue donor agreed that their tissue sample will be collected and stored for future research use (please select one option):</p> <p><input type="checkbox"/> I consent that the collected tissue might be exported to other affiliates of Nalagenetics outside of Singapore for research use</p> <p><input type="checkbox"/> I do not wish for the collected tissue to be exported to other affiliates of Nalagenetics outside of Singapore for research use</p> <p><b>Signatures:</b></p> <p>The Patient signature is always required unless: Patient is a minor who does not have sufficient understanding and intelligence to enable the minor to understand about the removal of tissue and the proposed procedure – then only the Guardian signature will be required and Patient signature can be exempted.</p> <table border="1"> <tr> <td>Patient signature</td> <td>Date (DD/MM/YYYY)</td> </tr> <tr> <td>Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female</td> <td></td> </tr> <tr> <td>Patient name (First, Middle, Last)</td> <td>Ethnicity</td> </tr> <tr> <td></td> <td>Email</td> </tr> <tr> <td></td> <td>Phone number</td> </tr> </table> <p>Provider's or Counselor's Statement: I have explained genetic testing (including the risks, benefits, and alternatives) to this individual. I have addressed the limitations outlined above, and I have answered this person's questions to the best of my ability.</p> <table border="1"> <tr> <td>Physician signature</td> <td>Date (DD/MM/YYYY)</td> </tr> <tr> <td>Physician name (First, Middle, Last)</td> <td></td> </tr> </table> <p>Patient Guardian (always needed for tests or tissue removal of minor):</p> <table border="1"> <tr> <td>Guardian signature</td> <td>Date (DD/MM/YYYY)</td> </tr> <tr> <td>Guardian name (First, Middle, Last)</td> <td>Relationship</td> </tr> <tr> <td></td> <td>Email</td> </tr> <tr> <td></td> <td>Phone number</td> </tr> </table> <p>Call us at +65 6718 4730 or e-mail us at <a href="mailto:siglab@nalagenetics.com">siglab@nalagenetics.com</a></p>	Patient signature	Date (DD/MM/YYYY)	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female		Patient name (First, Middle, Last)	Ethnicity		Email		Phone number	Physician signature	Date (DD/MM/YYYY)	Physician name (First, Middle, Last)		Guardian signature	Date (DD/MM/YYYY)	Guardian name (First, Middle, Last)	Relationship		Email		Phone number
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	Phone number																						

# Informed Consent Form



## Informed Consent Form for Genetic Testing & Tissue Banking

PM-CLAB-010-FM-002-05  
Release Date 25 Mar 2022

NALAGENETICS DIAGNOSTICS LABORATORY (SG)

Nalagenetics Pte Ltd  
1093 Lower Delta Road, #04-05/06/07/08, Singapore 169204  
Co. Reg. No. 201610006H

Testing for genetic conditions can be complex. If warranted, obtain professional genetic counseling prior to giving consent to fully understand what the risks and benefits are to have the testing completed. Refer to test specific information (general description of the test, purpose, and description of associated disease(s) found at: [www.nalagenetics.com](http://www.nalagenetics.com)

This test is voluntary, and your consent is required to proceed. You should take your time to ask all questions you may have to make an independent personal decision. If you wish to think this over, you may make another appointment. After you have given consent, you may withdraw your consent at any time or postpone the disclosure of the results. Fees should be paid prior to the tests and are non-refundable.

I hereby consent to participate in testing for: \_\_\_\_\_ using a genetic test.

I understand that a biological specimen (e.g. blood, buccal swab, or other tissues) will be obtained from me and/or members of my family.

I understand that this biological specimen will be used for the purpose of attempting to determine if I and members of my family are carriers of the disease gene, or are affected with, or at increased risk to someday be affected with this genetic disease.

**It has been explained to me and I understand that:**

- 1 The result may indicate that I am predisposed to have a specific disease or condition. Further testing may be needed to confirm the diagnosis. I understand I will be given the opportunity to talk with my physician or a genetic counselor about these results.
- 2 There is a chance that I will have this genetic condition but that the genetic test results will be negative. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease, may not be detected by the test.
- 3 There may be a possibility that the laboratory findings will be uninterpretable or of unknown significance. In rare circumstances, findings may be suggestive of a condition different than the diagnosis that was originally considered.
- 4 Molecular testing may detect a change in the DNA (mutation). Most tests are highly sensitive and specific; however, it is test dependent. Biochemical methods are sometimes used to look at abnormalities in the protein products that are produced by the genes.
- 5 An erroneous clinical diagnosis in a family member can lead to an incorrect result for other family members in question.
- 6 The tests offered are considered to be the best available at this time. This testing is often complex and utilizes specialized materials. However, there is always

## Informed Consent Form

- Fill in the blank with the name of the test ordered.
- The physician needs to go through with the patient the content of the ICF and make sure the patient understands it.



# Informed Consent Form

13 After DNA testing is completed (please select one option):

- I consent to a portion of the remaining DNA to be stored and used for quality control, medical education, research, and/or future diagnostic testing. I may be contacted and re-consented should there be a new diagnostic test offering new information about my genetic profile and/or asked for other health information beyond what was requested for this test.
- I consent to a portion of the remaining DNA to be made anonymous and used for quality control, medical education and research. Since the sample has been made anonymous, any results obtained cannot be traced to the original source and no results will be reported.
- I do not wish for any remaining DNA to be used for quality control, medical education and research. My specimen and DNA will be discarded 2 months after the release of the report.

23. After patient/ patient guardian/ voluntary tissue donor agreed that their tissue sample will be collected and stored for future research use (please select one option):

- I consent that the collected tissue might be exported to other affiliates of Nalagenetics outside of Singapore for research use
- I do not wish for the collected tissue to be exported to other affiliates of Nalagenetics outside of Singapore for research use

## Informed Consent Selection

- The options must be explained to the patients.
- If patient select the 1<sup>st</sup> or 2<sup>nd</sup> option in Q13, Q23 needs to be filled in (Tissue banking).
- Missing / ambiguous selection may result in delays in reporting.



# Informed Consent Form

## Signatures:

**The Patient signature is always required unless:**

Patient is a minor who does not have sufficient understanding and intelligence to enable the minor to understand about the removal of tissue and the proposed procedure – then only the Guardian signature will be required and Patient signature can be exempted.

<b>Patient signature</b>		Date (DD/MM/YYYY)
		Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female
Patient name (First, Middle, Last)	Ethnicity	Email
		Phone number

**Provider's or Counselor's Statement:** I have explained genetic testing (including the risks, benefits, and alternatives) to this individual. I have addressed the limitations outlined above, and I have answered this person's questions to the best of my ability.

<b>Physician signature</b>		Date (DD/MM/YYYY)
Physician name (First, Middle, Last)		

**Patient Guardian (always needed for tests or tissue removal of minor):**

<b>Guardian signature</b>		Date (DD/MM/YYYY)
Guardian name (First, Middle, Last)	Relationship	Email
		Phone number

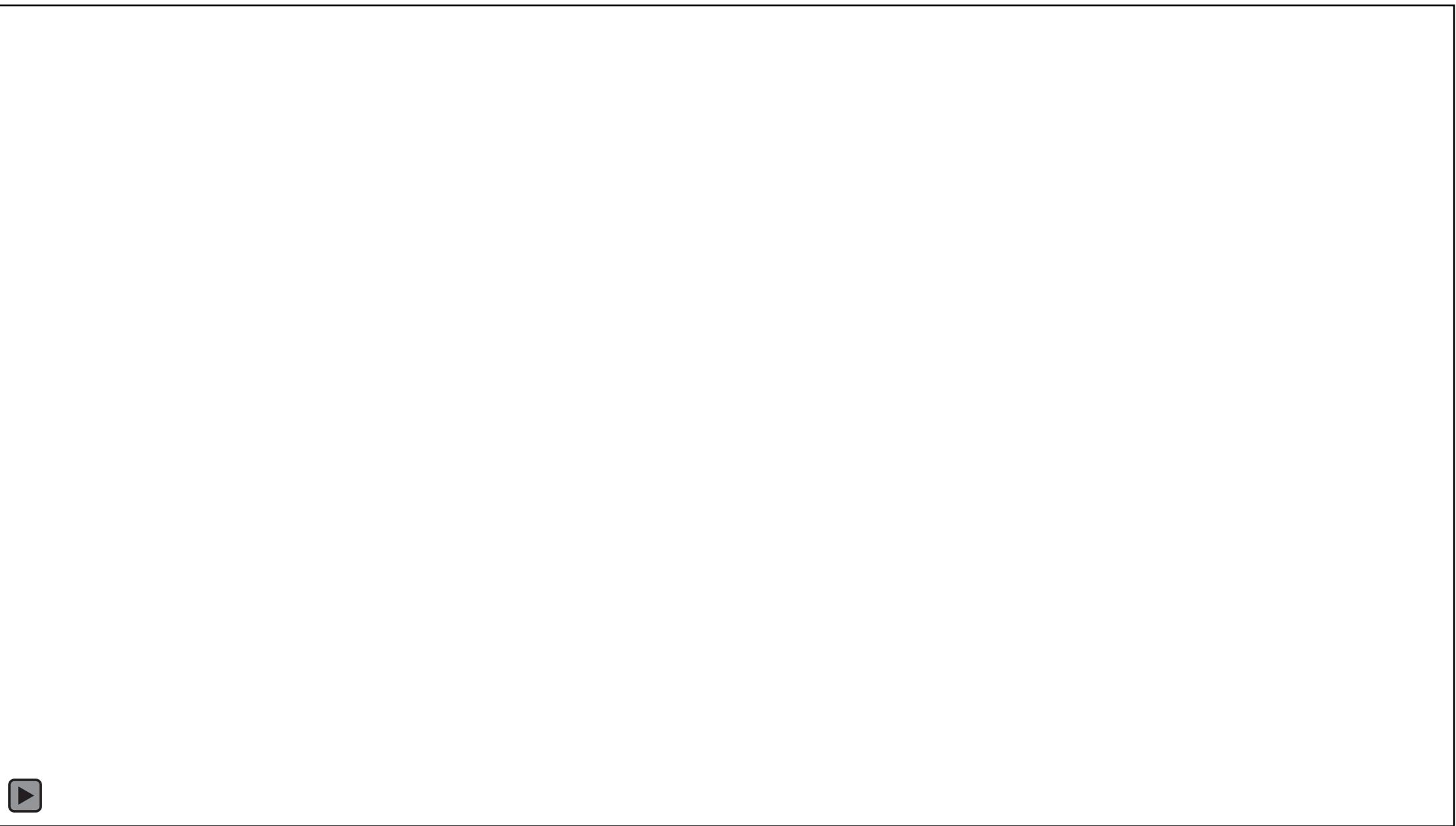
Call us at +65 6718 4730

or e-mail us at [sglab@nalagenetics.com](mailto:sglab@nalagenetics.com)

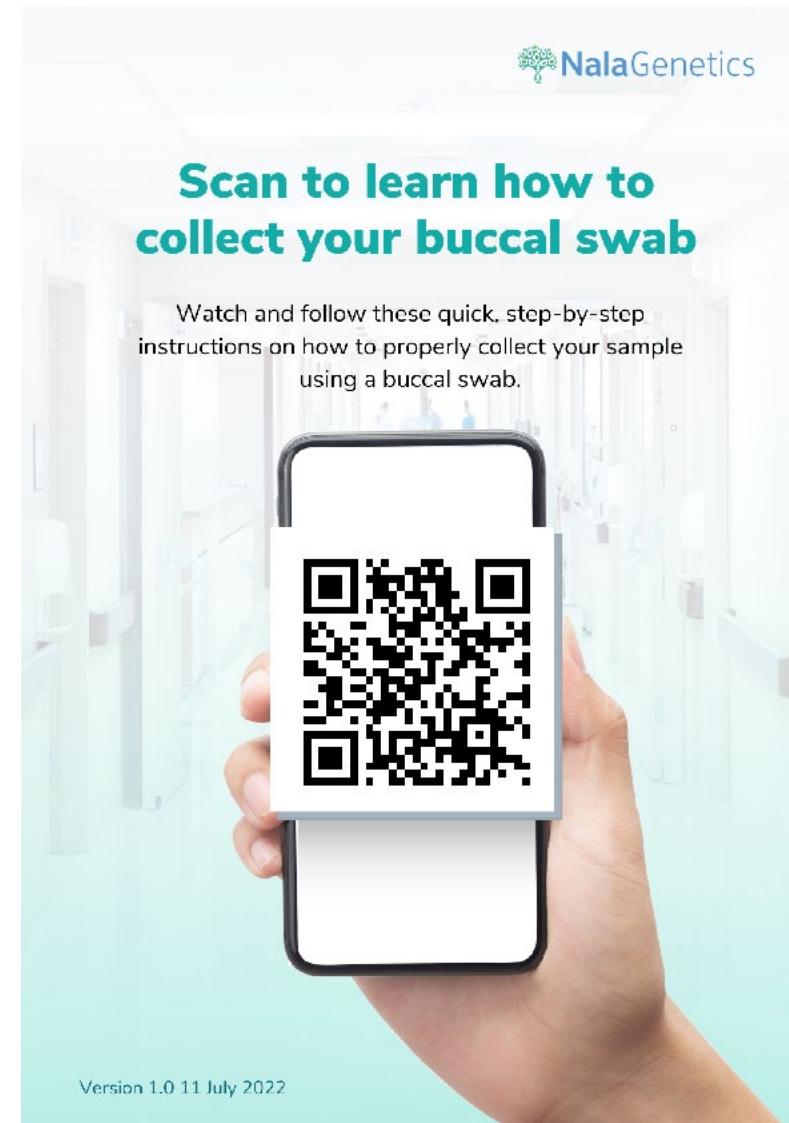
## Signatures

- Fill in all fields and sign accordingly.
- If the patient is a minor or requires a guardian, the guardian must also sign and provide the relevant contact details.
- Missing details will result in delays in reporting.





CONFIDENTIAL



1. Fasting for at least 30 minutes prior to taking the sample (do not eat, do not drink, do not gurgle, do not brush tooth, do not smoke)
2. Open the plastic containing buccal swab carefully (**not touching the head of the swab**)
3.  Swab each side of your mouth  
**15 seconds on left cheek**                           **15 seconds on upper lips**  
**15 seconds on right cheek**                           **15 seconds on lower lips**

 Use **medium pressure** (not too hard) using **up-down movement** dan **left-right movement**

 Head of the swab **not touching the gum or teeth**
4. Place the buccal swab stick inside the tube and close **tightly**
5. Flip the tube upside down slowly (**15-20x**) until the head of the swab is fullu covered by the liquid
6. Place the buccal swab tube inside the biohazard bag.



# Closing Remarks

- Pharmacogenomic Test: **within 5 working days** after the sample is received by our lab
- Nutrigenetic Test: **4-6 working weeks** after the sample is received by our lab
  
- Please reach your medical provider to coordinate on sample delivery and counselling session



# THANK YOU

Contact Us (Singapore)

+65 6718 4730

[sglab@nalagenetics.com](mailto:sglab@nalagenetics.com)

For feedback, [bit.ly/nalafeedbackform](http://bit.ly/nalafeedbackform) or SCAN:

