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PATIENT INFORMATION		SPECIMEN DETAILS	
NAME:	Sample Report	**SPECIMEN TYPE:**	
DOB:	dd/mm/yyyy	**ORDERED BY:**	Nordic Labs
SEX:	F	**REPORT DATE:**	dd/mm/yyyy
ACC #:	#####		

Medcheck Cardio Report

Risk Management

✓ Thrombophilia

No Increased Risk of Thrombosis

The patient does not carry the Factor V Leiden G1691A mutation or Factor II G20210A mutation (wild-type).

The patient's risk of thrombosis is not increased (average risk of clotting is about 1 in 1000 for anyone in a year). However, because this test cannot find all of the inherited reasons for abnormal clotting, other factors may affect this risk assessment.

Unless other genetic and/or circumstantial risk factors are present (e.g., smoking or obesity...), estrogen-containing contraceptive and hormone replacement therapy can be used by the patient.

⊗ Hyperhomocysteinemia - Thrombosis

Increased Risk of Hyperhomocysteinemia

The patient carries two MTHFR C677T mutations (homozygous) and no MTHFR A1298C mutation. MTHFR enzyme activity is severely reduced (30% of normal activity).

The patient's significantly reduced MTHFR activity is a risk factor for hyperhomocysteinemia, especially in the presence of low serum folate levels. Mild to moderate hyperhomocysteinemia appears to be associated with an increased risk for venous thromboembolism (VTE).

Testing total plasma homocysteine level may be beneficial. Hyperhomocysteinemia can be treated with nutritional supplementation.

⊗	A medication has potentially reduced efficacy, increased toxicity or the patient has an increased risk for the indicated condition.	**ACTIONABLE** Recommendations based upon publications by international pharmacogenetic expert groups, consortia or regulatory bodies (CPIC, DPWG, FDA. EMA). Recommendations are suitable for implementation in a clinical setting. Guidelines may change as knowledge arises.
⚠	Guidelines exist for adjusting dosage, increased vigilance or the patient has a moderate risk for the indicated condition.	
✓	The medication can be prescribed according to standard regimens or the patient's risk for the indicated condition is not increased.	**INFORMATIVE** There are insufficient or contradictory findings documenting the impact of a given genetic polymorphism or drug interaction. Recommendations are informative and implementation in a clinical setting is optional.

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Potentially Impacted Medications

CATEGORY	DRUG CLASS	STANDARD PRECAUTIONS	USE WITH CAUTION	CONSIDER ALTERNATIVES
Cardiovascular	Angiotensin II Receptor Antagonists	Azilsartan Irbesartan Losartan		
	Antianginal Agents	Ranolazine		
	Antiarrhythmics		Mexiletine Propafenone	Flecainide
	Anticoagulants		Warfarin	
	Antiplatelets	Clopidogrel		
	Beta Blockers	Carvedilol Nebivolol Propranolol Timolol		Metoprolol
	Diuretics	Torsemide		
	Statins	Fluvastatin Pitavastatin Pravastatin Rosuvastatin	Atorvastatin Lovastatin Simvastatin	
Diabetes	Meglitinides	Nateglinide Repaglinide		
	Sulfonylureas	Chlorpropamide Glimepiride Glipizide Glyburide Tolbutamide		

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Dosing Guidance

Flecainide

Altered Response to Flecainide (CYP2D6: Ultra-Rapid or Normal Metabolizer) — ACTIONABLE

Based on the genotype result, this patient MAY be a CYP2D6 ultra-rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 ultra-rapid metabolizers: titrate carefully and consider adjusting dose in response to plasma concentration and ECG monitoring, OR consider an alternative drug. Examples of alternatives drugs not affected by CYP2D6 include: sotalol, disopyramide, quinidine, and amiodarone.

Metoprolol

Possible Non-Responder to Metoprolol (CYP2D6: Ultra-Rapid or Normal Metabolizer) — ACTIONABLE

Based on the genotype result, this patient MAY be a CYP2D6 ultra-rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 ultra-rapid metabolizers: the patient may experience a decrease in the pharmacological effect when taking metoprolol at standard dosage. Heart Failure: Consider alternative beta-blockers such as bisoprolol or carvedilol, or prescribe metoprolol at a higher dose. Other indications: Consider alternative beta-blockers such as bisoprolol or atenolol, or prescribe metoprolol at a higher dose. If metoprolol is prescribed, titrate the dose to a maximum of 250% of the normal dose in response to efficacy and adverse events.

Atorvastatin

Altered Response to Atorvastatin (CYP3A4: Intermediate Metabolizer) — INFORMATIVE

The genotype result indicates that the patient carries the CYP3A4*22 allele (this allele is associated with lower CYP3A4 enzyme activity). Preliminary studies have shown that patients carrying the CYP3A4*22 allele may achieve an optimal lipid control goal with lower atorvastatin dose requirements.

Lovastatin

Altered Response to Lovastatin (CYP3A4: Intermediate Metabolizer) — INFORMATIVE

The genotype result indicates that the patient carries the CYP3A4*22 allele (this allele is associated with lower CYP3A4 enzyme activity). Preliminary studies have shown that patients carrying the CYP3A4*22 allele may achieve an optimal lipid control goal with lower lovastatin dose requirements.

Mexiletine

Altered Response to Mexiletine (CYP2D6: Ultra-Rapid or Normal Metabolizer) — INFORMATIVE

Based on the genotype result, this patient MAY be a CYP2D6 ultra-rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 ultra-rapid metabolizers: because mexiletine plasma concentrations may be decreased, consider adjusting dose in response to mexiletine plasma concentration and ECG monitoring, until a favorable response in achieved.

Propafenone

Altered Response to Propafenone (CYP2D6: Ultra-Rapid or Normal Metabolizer) — ACTIONABLE

Based on the genotype result, this patient MAY be a CYP2D6 ultra-rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 ultra-rapid metabolizers: titrate carefully and consider adjusting dose in response to plasma concentration and ECG monitoring, OR consider an alternative drug. Examples of alternatives drugs not affected by CYP2D6 include: sotalol, disopyramide, quinidine, and amiodarone.

Dose adjustments with co-medications: concurrent use of propafenone along with CYP3A4 inhibitors and CYP2D6 inhibitors may significantly increase the plasma concentration of propafenone and thereby increase the risk of proarrhythmia and other adverse events. Therefore, avoid simultaneous use of propafenone with both a CYP2D6 inhibitor and a CYP3A4 inhibitor.

Simvastatin

Altered Response to Simvastatin (CYP3A4: Intermediate Metabolizer) — INFORMATIVE

The genotype result indicates that the patient carries the CYP3A4*22 allele (this allele is associated with lower CYP3A4 enzyme activity). Preliminary studies have shown that patients carrying the CYP3A4*22 allele may achieve an optimal lipid control goal with lower simvastatin dose requirements.

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⚠ Warfarin

Moderate Sensitivity to Warfarin (CYP2C9 *1/*1; VKORC1 -1639G>A A/A) **ACTIONABLE**

Initiation Therapy: a dose decrease may be required. Consider using the following warfarin dose range provided in the FDA-approved label: **3-4 mg/day.** OR consider using a personalized dose calculated by a pharmacogenetic algorithm. The estimated time to reach steady state is 4-5 days.

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Test Details

Gene	Genotype	Phenotype	Clinical Consequences
CYP2C9	*1/*1	**Normal Metabolizer**	Consistent with a typical CYP2C9 activity. This test did not identify risks for side effects or loss of efficacy with drug substrates.
CYP2C19	*1/*1	**Normal Metabolizer**	Consistent with a typical CYP2C19 activity. This test did not identify risks for side effects or loss of efficacy with drug substrates.
VKORC1	-1639G>A A/A	**High Warfarin Sensitivity**	VKORC1 is the site of action of warfarin. The patient may require a substantial decrease in warfarin dose.
CYP2D6	*1/*4 XN	**Ultra-Rapid or Normal Metabolizer**	Consistent with typical or increased CYP2D6 activity. Potential risk for side effects or loss of efficacy with drug substrates.
SLCO1B1	521T>C T/T	**Normal Function**	Consistent with a typical SLCO1B1 transporter function. The patient's risk for statin-induced myopathy is not increased.
CYP3A4	*1/*22	**Intermediate Metabolizer**	Consistent with a moderate deficiency in CYP3A4 activity. Caution is advised when prescribing narrow therapeutic index drugs. Alternative drugs or dose adjustment may be required if CYP3A inhibitors or inducers are co-prescribed.
ABCG2	421C>A C/C	**Normal Function**	Consistent with a normal ABCG2 transporter function. The patient's risk for statin-induced adverse events is normal.
CYP4F2	1347G>A G/G	**Homozygous for the G allele (rs2108622)**	
F5 **F2**	1691G>A GG 20210G>A GG	**No Increased Risk of Thrombosis**	Unless other genetic or circumstantial risk factors are present, the patient is not expected to have an increased risk for thrombosis.
MTHFR	1298A>C AA 677C>T TT	**Increased Risk of Hyperhomocysteinemia**	The patient has a significantly reduced MTHFR function, leading to mild to moderate hyperhomocysteinemia. This appears to be associated with an increased risk for venous thromboembolism.

Alleles Tested: ABCG2 421C>A; **CYP2C19** *2, *3, *4, *4B, *6, *7, *8, *9, *10, *17; **CYP2C9** *2, *3, *4, *5, *6, *8, *11, *27; **CYP2D6** *2, *3, *4, *4M, *6, *7, *8, *9, *10, *12, *14A, *14B, *17, *29, *35, *41, *5 (gene deletion), XN (gene duplication); **CYP3A4** *3, *12, *17, *22; **CYP4F2** 1347G>A; **Factor II** 20210G>A; **Factor V Leiden** 1691G>A; **MTHFR** 1298A>C, 677C>T; **SLCO1B1** 521T>C; **VKORC1** -1639G>A

Limitation: This test will not detect all the known alleles that result in altered or inactive tested genes. This test does not account for all individual variations in the individual tested. Absence of a detectable gene mutation does not rule out the possibility that a patient has different phenotypes due to the presence of an undetected polymorphism or due to other factors such as drug-drug interactions, comorbidities and lifestyle habits.

Methodology: Array based assays detect listed alleles, including all common and most rare variants with known clinical significance at analytical sensitivity and specificity >99%.

Lab Disclaimer: DNAlysis Biotechnology developed the Genotype test. The performance characteristics of this test were determined by DNAlysis Biotechnology. It has not been cleared or approved by the U.S. Food and Drug Administration.

Translational Software Disclaimer: The information presented on this report is provided as general educational health information. The content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Only a physician, pharmacist or other healthcare professional should advise a patient on the use of the medications prescribed.

The pharmacogenetic assay involves use of reporting software and genotype-phenotype associations performed by Translational Software (www.translationalsoftware.com). The software has not been evaluated by the Food and Drug Administration. The software, and the report generated by the software, is not intended to diagnose, treat, cure, or prevent any disease. A qualified designee within the lab uses Translational Software to generate and subsequently review the report. The pharmacogenetic report is one of multiple pieces of information that clinicians should consider in guiding their therapeutic choice for each patient. It remains the responsibility of the health-care provider to determine the best course of treatment for a patient. Adherence to dose guidelines does not necessarily assure a successful medical outcome.

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Patient Information Card

This is a summary genetic report for your patient to share with other healthcare providers. The card can be cut out along the dashed line and carried with the patient.

DNALYSIS BIOTECHNOLOGY

REPORT DETAILS

Name: Sample Report
DOB: d/mm/yyyy
ACC #: TST-NL-#####

Pharmacogenetic Test Summary

ABCG2	421C>A C/C	Normal Function
CYP2C19	*1/*1	Normal Metabolizer
CYP2C9	*1/*1	Normal Metabolizer
CYP2D6	*1/*4 XN	Ultra-Rapid or Normal Metabolizer
CYP3A4	*1/*22	Intermediate Metabolizer
CYP4F2	1347G>A G/G	Homozygous for the G allele (rs2108622)
Factor II	20210G>A GG	Normal Thrombosis Risk
Factor V Leiden	1691G>A GG	Normal Thrombosis Risk
MTHFR	1298A>C AA	Normal MTHFR Activity
MTHFR	677C>T TT	Reduced MTHFR Activity
SLCO1B1	521T>C T/T	Normal Function
VKORC1	-1639G>A A/A	High Warfarin Sensitivity

For a complete report contact DNAlysis Biotechnology
www.dnalysis.co.za

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