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PATIENT INFORMATION	
NAME:	Sample Report
DOB:	dd/mm/yyyy
SEX:	F
ACC #:	###-##-###

SPECIMEN DETAILS	
SPECIMEN TYPE:	Buccal Swab
ORDERED BY:	Nordic Labs
REPORT DATE:	dd/mm/yyyy

Medcheck Psych Report

Risk Management

⚠ Antipsychotic-Induced Tardive Dyskinesia

Increased Risk of Antipsychotic-Induced Tardive Dyskinesia

The patient does not carry the Taq1A variant (homozygous for the A2 allele).

The genotype results predict that the patient has normal dopamine receptor DRD2 density and functioning. The patient has increased risk for tardive dyskinesia when treated with antipsychotics.

Closely monitor the patient for signs of tardive dyskinesia.

✓ Antipsychotic-Induced Hyperprolactinemia

Normal Risk of Antipsychotic-Induced Hyperprolactinemia

The patient does not carry the Taq1A variant (homozygous for the A2 allele).

The genotype results predict that the patient has normal dopamine receptor DRD2 density and functioning. The patient has normal risk of hyperprolactinemia when treated with antipsychotics.

Monitor the patients closely for any signs of hyperprolactinemia.

✓ Antipsychotic-Induced Weight Gain

Low Risk of Antipsychotic-Induced Weight Gain

The patient does not carry the Taq1A variant (homozygous for the A2 allele).

The genotype results predict that the patient has normal dopamine receptor DRD2 density and functioning. The patient has a normal risk for weight gain when treated with antipsychotics.

Monitor the patient closely for signs weight gain.

✓ Hyperhomocysteinemia - Depression

No Increased Risk of Hyperhomocysteinemia

The patient carries one MTHFR C677T mutation (heterozygous). MTHFR enzyme activity is reduced (60% of normal activity).

Patients diagnosed with depression often have low folate levels and homocysteine is a highly sensitive marker of folate status. Functional folate deficiency is indicated by elevated homocysteine. The patient's small reduction in MTHFR activity is not a risk factor for hyperhomocysteinemia.

Patients diagnosed with depression: as lower folate levels are associated with poorer antidepressant response, and baseline levels of folate within the normal range predict antidepressant response, testing for homocysteine levels and serum folate levels may be informative for this patient before prescribing methylfolate as an antidepressant-augmenting agent.

⊗ 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
Psychotropic	Antiaddictives	Bupropion	Naltrexone	
	Anti-ADHD Agents	Atomoxetine Clonidine	Amphetamine Dexmethylphenidate Dextroamphetamine Lisdexamfetamine Methylphenidate	
	Anticonvulsants	Brivaracetam Fosphenytoin Lacosamide Phenobarbital Phenytoin Primidone Zonisamide		
	Antidementia Agents	Donepezil Galantamine		
	Antidepressants	Amoxapine Desipramine Desvenlafaxine Duloxetine Fluoxetine Fluvoxamine Maprotiline Mirtazapine Nefazodone Nortriptyline Paroxetine Protriptyline Venlafaxine Vortioxetine	Sertraline	Amitriptyline Citalopram Clomipramine Doxepin Escitalopram Imipramine Trimipramine
	Antipsychotics	Aripiprazole Brexpiprazole Chlorpromazine Fluphenazine Haloperidol Iloperidone Perphenazine Pimozide Thioridazine Zuclopenthixol	Clozapine Olanzapine Paliperidone Quetiapine Risperidone	
	Benzodiazepines	Clobazam Lorazepam Oxazepam	Diazepam	
	Mood Stabilizers		Lithium	
	Other Neurological Agents	Deutetrabenazine Dextromethorphan / Quinidine Flibanserin Valbenazine	Tetrabenazine	

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Dosing Guidance

Amitriptyline

Increased Sensitivity to Amitriptyline (CYP2C19: Rapid Metabolizer) — INFORMATIVE

Consider an alternative drug, or consider prescribing amitriptyline at standard dose and monitor the plasma concentrations of amitriptyline and nortriptyline to guide dose adjustments.

Citalopram

Insufficient Response to Citalopram (CYP2C19: Rapid Metabolizer) — ACTIONABLE

At standard label-recommended dosage, citalopram plasma concentrations levels are expected to be low which may result in a loss of efficacy. Consider an alternative medication. If citalopram is warranted, consider increasing the dose to a maximum of 150% and titrate based on the clinical response and tolerability.

Clomipramine

Increased Sensitivity to Clomipramine (CYP2C19: Rapid Metabolizer) — INFORMATIVE

Consider an alternative drug, or consider prescribing clomipramine at standard dose and monitor the plasma concentrations of clomipramine and desmethyl-clomipramine to guide dose adjustments.

Doxepin

Increased Sensitivity to Doxepin (CYP2C19: Rapid Metabolizer) — INFORMATIVE

Consider an alternative drug, or consider prescribing doxepin at standard dose and monitor the plasma concentrations of doxepin and desmethyl-doxepin to guide dose adjustments.

Escitalopram

Insufficient Reponse to Escitalopram (CYP2C19: Rapid Metabolizer) — ACTIONABLE

At standard label-recommended dosage, escitalopram plasma concentrations levels are expected to be low which may result in a loss of efficacy. Consider an alternative medication. If escitalopram is warranted, consider increasing the dose to a maximum of 150% and titrate based on the clinical response and tolerability.

Imipramine

Increased Sensitivity to Imipramine (CYP2C19: Rapid Metabolizer) — INFORMATIVE

Consider an alternative drug, or consider prescribing imipramine at the standard dose and monitor the plasma concentrations of imipramine and desipramine to guide dose adjustments.

Trimipramine

Increased Sensitivity to Trimipramine (CYP2C19: Rapid Metabolizer) — INFORMATIVE

Consider an alternative drug, or consider prescribing trimipramine at standard dose and monitor the plasma concentrations of trimipramine and desmethyl-trimipramine to guide dose adjustments.

Amphetamine

Poor Response to Amphetamine salts (COMT: Low COMT Activity) — INFORMATIVE

The patient's genotype result predicts a reduced therapeutic response to amphetamine stimulants. If prescribed, amphetamines should be administered at the lowest effective dose, and dosage should be individually adjusted.

Clozapine

Increased Risk of Clozapine-Induced Weight Gain (MC4R: Homozygous for A Allele (rs489693)) — INFORMATIVE

The genotype result predicts that the patient has an increased risk of weight gain and hypertriglyceridemia following clozapine treatment. These changes may occur after 6 to 12 weeks of therapy. Consider closer monitoring of the patient's weight and metabolic markers.

Clozapine

Non-Response to Clozapine (CYP1A2: Normal Metabolizer - Higher Inducibility) — INFORMATIVE

Smokers have a high risk for non-response at standard doses and may require higher doses. There is an association between high clozapine doses and the risk of seizures, and therefore careful monitoring is recommended during dosing adjustment. Smoking cessation will increase plasma drug levels, leading to adverse events. Therefore, therapeutic drug monitoring accompanied by dose reduction is recommended in patients who have quit smoking.

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Dexmethylphenidate

Poor Response to Dexmethylphenidate (COMT: Low COMT Activity) — INFORMATIVE

The patient's genotype result predicts a reduced therapeutic response to dexmethylphenidate. Dosage should be individualized according to the needs and response of the patient. Therapy should be initiated in small doses, with gradual weekly increments.

Dextroamphetamine

Poor Response to Dextroamphetamine (COMT: Low COMT Activity) — INFORMATIVE

The patient's genotype result predicts a reduced therapeutic response to amphetamine stimulants. If prescribed, dextroamphetamine should be administered at the lowest effective dose, and dosage should be individually adjusted.

Diazepam

Possible Altered Sensitivity to Diazepam (CYP2C19: Rapid Metabolizer) — INFORMATIVE

CYP2C19 rapid and ultra-rapid metabolizers metabolize diazepam and nordiazepam more rapidly than normal metabolizers. However, there is insufficient data to allow calculation of dose adjustment when diazepam is prescribed. Monitor the patient's response and adjust the dose accordingly.

Lisdexamfetamine

Poor Response to Lisdexamfetamine (COMT: Low COMT Activity) — INFORMATIVE

The patient's genotype result predicts a reduced therapeutic response to amphetamine stimulants. If prescribed, lisdexamfetamine should be administered at the lowest effective dose, and dosage should be individually adjusted.

Lithium

Decreased Response to Lithium (BDNF: Homozygous for rs6265 C Allele) — INFORMATIVE

BDNF encodes the brain-derived neurotrophic factor involved in neuroprotection and neuroplasticity. The patient is homozygous for the C allele of BDNF variant rs6265. This genotype is associated with a poor response to lithium treatment for bipolar disorder.

Methylphenidate

Poor Response to Methylphenidate (COMT: Low COMT Activity) — INFORMATIVE

The patient's genotype result predicts a reduced therapeutic response to methylphenidate. Dosage should be individualized according to the needs and response of the patient. Therapy should be initiated in small doses, with gradual weekly increments.

Naltrexone

Altered Response to Naltrexone (OPRM1: Normal OPRM1 Function) — INFORMATIVE

Treatment of alcohol dependence: the patient has the OPRM1 118AA wild-type genotype that is associated with a poorer outcome with naltrexone therapy. Naltrexone-treated patients not carrying the OPRM1 118A>G G allele are less likely to respond to this drug, and may have higher relapse rates than those who are carriers of this allele. This association has not been reported consistently across studies.

Olanzapine

Increased Risk of Olanzapine-Induced Weight Gain (MC4R: Homozygous for A Allele (rs489693)) — INFORMATIVE

The genotype result predicts that the patient has an increased risk of weight gain and hypertriglyceridemia following olanzapine treatment. These changes may occur after 6 to 12 weeks of therapy. Consider closer monitoring of the patient's weight and metabolic markers.

Olanzapine

Non-Response to Olanzapine (CYP1A2: Normal Metabolizer - Higher Inducibility) — INFORMATIVE

There is little evidence regarding the impact of CYP1A2 genetic variants on olanzapine response. Smokers may be at risk for non-response at standard doses. Careful monitoring is recommended during dosing adjustment. Smoking cessation may increase plasma drug levels, leading to adverse events. Therefore, therapeutic drug monitoring accompanied by dose reduction may be needed in patients who have quit smoking.

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Paliperidone

Increased Risk of Paliperidone-Induced Weight Gain (MC4R: Homozygous for A Allele (rs489693)) — INFORMATIVE

The genotype result predicts that the patient has an increased risk of weight gain and hypertriglyceridemia following paliperidone treatment. These changes may occur after 6 to 12 weeks of therapy. Consider closer monitoring of the patient's weight and metabolic markers.

Quetiapine

Increased Risk of Quetiapine-Induced Weight Gain (MC4R: Homozygous for A Allele (rs489693)) — INFORMATIVE

The genotype result predicts that the patient has an increased risk of weight gain and hypertriglyceridemia following quetiapine treatment. These changes may occur after 6 to 12 weeks of therapy. Consider closer monitoring of the patient's weight and metabolic markers.

Risperidone

Increased Risk of Risperidone-Induced Weight Gain (MC4R: Homozygous for A Allele (rs489693)) — INFORMATIVE

The genotype result predicts that the patient has an increased risk of weight gain and hypertriglyceridemia following risperidone treatment. These changes may occur after 6 to 12 weeks of therapy. Consider closer monitoring of the patient's weight and metabolic markers.

Sertraline

Possible Reduced Response to Sertraline (CYP2C19: Rapid Metabolizer) — INFORMATIVE

Sertraline can be prescribed at standard label-recommended dosage and administration. If patient does not respond to recommended maintenance dosing, consider an alternative medication.

Tetrabenazine

Normal Sensitivity to Tetrabenazine (CYP2D6: Normal Metabolizer) — ACTIONABLE

For treating chorea associated with Huntington's disease: Individualization of dose with careful weekly titration is required. The first week's starting dose is 12.5 mg daily; second week, 25 mg (12.5 mg twice daily); then slowly titrate at weekly intervals by 12.5 mg to a tolerated dose. **The maximum daily dose in CYP2D6 normal metabolizers is 100 mg, with a maximum single dose of 37.5 mg**. If serious adverse events occur, titration should be stopped and the dose of tetrabenazine should be reduced. If the adverse event(s) do not resolve, consider withdrawal of tetrabenazine.

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Test Details

Gene	Genotype	Phenotype	Clinical Consequences
ADRA2A	C-1291G C/G	**Heterozygous for the G Allele**	Carriers of the G allele of ADRA2A C-1291G variant, show greater reduction of inattentive symptoms when administered Methylphenidate or Dexmethylphenidate.
ANKK1/DRD2	DRD2:Taq1A G/G	**Unaltered DRD2 function**	Consistent with a normal dopamine receptor D2 function.
BDNF	434C>T C/C	**Homozygous for rs6265 C Allele**	Consistent with normal activity-dependent secretion of BDNF from neurons and normal BDNF signaling.
COMT	Val158Met A/A	**Low COMT Activity**	Consistent with a significantly reduced catechol O-methyltransferase (COMT) function.
CYP1A2	*1F/*1F	**Normal Metabolizer - Higher Inducibility**	Consistent with a typical CYP1A2 activity in absence of inducing substances. Rapid Metabolism occurs in presence of inducers such as barbiturates, cruciferous vegetables, carbamazepine, rifampin and smoking.
CYP2B6	*1/*1	**Normal Metabolizer**	Consistent with a typical CYP2B6 activity. This test did not identify risks for side effects or loss of efficacy with drug substrates.
CYP2C19	*1/*17	**Rapid Metabolizer**	Consistent with a significant increase in CYP2C19 activity. Potential risk for side effects or loss of efficacy with drug substrates.
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.
CYP2D6	*1/*35	**Normal Metabolizer**	Consistent with a typical CYP2D6 activity. This test did not identify risks for side effects or loss of efficacy with drug substrates.
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.
CYP3A5	*3/*3	**Poor Metabolizer**	Consistent with a poor CYP3A5 activity. This phenotype is the most common in the general population. 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.
MC4R	g.60215554C>A A/A	**Homozygous for A Allele (rs489693)**	Altered MC4R function
MTHFR	677C>T CT	**Reduced MTHFR Activity**	The patient carries one MTHFR C677T mutation (heterozygous) and the patient's MTHFR activity is reduced slightly. This is not associated with an increased risk of hyperhomocysteinemia.
OPRM1	A118G A/A	**Normal OPRM1 Function**	Consistent with a normal OPRM1 receptor signaling efficiency induced by exogenous opioids. This is associated with a good analgesia following standard opioid doses and a poor response to naltrexone.
UGT2B15	*1/*1	**Normal Metabolizer**	Consistent with a typical UGT2B15 glucuronidation function. This test did not identify risks for side effects with drug substrates.

Alleles Tested: ADRA2A C-1291G; **ANKK1/DRD2** DRD2:Taq1A; **BDNF** 434C>T; **COMT** Val158Met; **CYP1A2** *1F, *1K; **CYP2B6** *16, *6, *9, *11, *18; **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; **CYP3A5** *3, *3C, *6, *7; **MC4R** g.60215554C>A; **MTHFR** 1298A>C, 677C>T; **OPRM1** A118G; **UGT2B15** *2

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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.

Approved By: Laboratory Manager
Thenusha Naidoo
MS 0000990

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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.

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Pharmacogenetic Test Summary

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CYP2C19	*1/*17	Rapid Metabolizer
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CYP2D6	*1/*35	Normal Metabolizer
CYP3A4	*1/*22	Intermediate Metabolizer
CYP3A5	*3/*3	Poor Metabolizer
MC4R	g.60215554C>A A/A	Homozygous for A Allele (rs489693)
MTHFR	677C>T CT	Reduced MTHFR Activity
OPRM1	A118G A/A	Normal OPRM1 Function
UGT2B15	*1/*1	Normal Metabolizer

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

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