INAGENE PERSONALIZED INSIGHTS™ PHARMACOGENETIC TEST SUMMARY

Inagene Personalized Insights™ is a CLIA* – accredited pharmacogenetic** test that provides a personalized review of medications that should either be avoided or used with caution, based on the detection of specific gene variants that are known to affect individual response (efficacy and side effect risk) to certain drugs.

Our Personalized Insights Pain and Mental Health™ test is **focused exclusively in the areas of Pain and Mental Health,** evaluating **55 genes** that have been shown to impact individual response to **over 140 medications** commonly used in the treatment of these conditions. Our test evaluates the most comprehensive and extensive list of genes and alleles in pain and mental health commercially available in Canada (including testing for both pharmacokinetic and pharmacodynamic gene variants, as well as rare variants occurring in >1/1000 patients).

Our Personalized Insights PrecisionRx™ test helps predict response to commonly used medications across a number of medical conditions, evaluating **40 genes** that have been shown to impact individual response to **over 140 medications** commonly used in the treatment of these conditions.

Please see our complete drug list at: https://patients.inagene.com/drug-list.

Recommendations in our report are taken directly from published pharmacogenetic guidance (publicly available) from well-recognized governing bodies*** including the FDA, The Clinical Pharmacogenetics Implementation Consortium (CPIC), The Pharmacogenomics Knowledge Base (PharmGKB), and the Dutch Pharmacogenetics Working Group (DPWG).

THE TEST AND PROCESS:

Inagene's Personalized Insights™ test is a simple buccal swab test that is **easy and fast to do at home or in a pharmacy/clinic in less than 5 minutes**. Each test is ordered online on Inagene's website (www.inagene.com) at a retail cost of CAD$299.00 (or both can be bundled together for CAD $399.00) . The DNA sample is mailed directly back to Inagene's Toronto lab in the postage – paid envelope provided in the kit. The patient or health care provider register an account on the secure Inagene Portal (www.patients.inagene.com) and confidential results are available in approximately **7 days** (sent via email link from the secure Inagene Patient Portal). Any questions or concerns regarding the test results, or requests to speak with a member of our medical team can be directed to Inagene at info@inagene.com.

Purchasers of our tests receive the following:

1) **Buccal Swab Test Kit:** containing the Inagene Kit box, Detailed Instruction Card, Activation Code, Sample Sticker, Kit Code sticker card, Pre-Paid Return Envelope, and Buccal Cheek Swab (more details can be found under the Cheek Swab Kit tab of our website, inagene.com).

2) **Online Report**: a detailed review of the individual's predicted response based on the presence or absence of specific gene variants we test for. Four categories are used to help patients and clinicians quickly determine which medications are most likely to be effective and well tolerated based on the individual's unique genetic profile (see next page).

 **Do Not Use**	 **Use With Caution**	 **Use As Directed**	 **Use As Directed/ Preferred**
This medication is NOT recommended. Using an alternative medication is recommended based on possible therapeutic failure or adverse side effects.	A gene-drug interaction has been identified that may impact the medication's effectiveness or tolerability. Response is expected to be different from most people, and individualized recommendations are provided in the full report.	No gene variants have been detected that are known to impact the metabolism of this medication. Response to this medication is expected to be similar to most other individuals, and no unique prescribing recommendations are provided as a result.	Based on one or more gene-drug interactions identified and as compared to others, this individual has an increased likelihood of an optimal response with this medication.

Key features of our test report include:

a. **A detailed report of predicted responses and personalized recommendations for the medications in the test purchased**
b. **A summary of results by drug** (can be sorted by either drug class or alphabetical order, and by generic name or brand name).
c. **Drug search functionality**, allowing users to search for and select specific drugs to build and download customized reports.
d. **Generation of a Personalized Summary Letter for healthcare provider(s)** summarizing key results and recommendations.
e. **Secure report access sharing**: access to results can be securely shared between patient and healthcare provider(s) via the secure Inagene portal platform. Reports can be printed, emailed or faxed, or uploaded to electronic medical records.

2) **Support**: The opportunity to connect with Inagene's pharmacist or geneticists with any questions regarding the report.

3) **Regular report updates**: Results are updated every 6 – 8 months with new medications or updated recommendations to reflect the most current pharmacogenetic data and recommendations.

Who is Inagene Diagnostics Inc?

Inagene Diagnostics is a pharmacogenetic lab specializing in providing patients and their health care teams personalized insights based on leading genetic analysis and technology. We are a

100% Canadian owned and operated company, and all genetic analyses are performed in our Toronto based laboratory, where we endeavor to ensure quality testing for every sample we receive. This means consistently upholding stringent quality standards and employing highly trained staff who ensure accuracy and reliability of results. Our pharmacogenetic lab and pharmacogenetic test are CLIA* certified, and we subscribe to the College of American Pathologists (CAP) proficiency testing program. Our test has also been issued a Medical Device Establishment License with Health Canada (MDEL license #9922).

With over 25 years of genetic research and patient counselling experience, we have a unique capability for incorporating the newest knowledge and technology into our genetic testing panels. Dr. Katherine Siminovitch FRCP(C), ABIM, co-founder of Inagene Diagnostics Inc., is an acclaimed leader in genomic medicine, and the senior investigator at the Lunenfeld-Tanenbaum Research Institute of Mount Sinai Hospital. Owning and operating our own lab enables us to deliver fast results with stringent quality-control of all steps in the testing and reporting process.

Additional information regarding Inagene, and the Personalized Insights™ pharmacogenetic test, can be found at **www.inagene.com** or by contacting Inagene directly at **info@inagene.com**.

CLIA stands for **Clinical Laboratory Improvement Amendments. The Centers for Medicaid and Medicare Services (CMS) regulates laboratory testing through the CLIA certification program. The objective of CLIA is to ensure the accuracy, reliability and timeliness of patient test results through quality laboratory standards.*
*** Pharmacogenetics is the study of interindividual variations in the DNA sequence of our genes, and how those variations impact our individual response to different medications.*
****Pharmacogenetic recommendations are based on peer-reviewed reports providing high levels of evidence of the link between specific genetic variations and drug responses. Since 2000, government funded governing bodies (in the USA, Europe, Asia) have been established to 1) review and grade the available pharmacogenetic evidence 2) develop peer reviewed recommendations to guide incorporation of pharmacogenetics profiles into healthcare. Many of these recommendations are now incorporated into FDA drug labels.*

Pharmacogenetic testing/reports are not a substitution for professional medical advice. Treatment decisions should only be made in consultation with a health care provider/team and should be based on many factors, including, but not limited to health status, medical history, current treatment regimen, and ongoing treatment response.

INAGENE PERSONALIZED INSIGHTS™ PHARMACOGENETIC TEST REQUISITION

Please complete this form when the Inagene Personalized Insights™ Test is being ordered by a Healthcare Provider on behalf of a patient, and the intent is to submit the cost of the test to the patient's private insurance plan seeking reimbursement.

PATIENT DETAILS

Full Name:	Date of Birth:
Address:	
Email Address:	Telephone Number:

I hereby confirm that I (please check ALL boxes that apply):

- ❑ have reviewed the full Inagene Privacy Policy (found at www. https://inagene.com/en/legal) and agree to the terms and conditions therein
- ❑ Provide my consent to this test being performed
- ❑ Provide my consent to the healthcare provider named below receiving a copy of my test results

Patient Signature:	Date (dd/mm/yyyy):

HEALTHCARE PROVIDER DETAILS

Full Name:	Telephone Number:
Address:	
Email Address:	Fax:

- ❑ ***I hereby order the Inagene Personalized Insights™ Pain & Mental Health pharmacogenetic test for the above-named patient, which tests for the presence of specific variants of 55 unique genes, including but not limited to for CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, COMT, HLA-A, HLA-B, HTR2A, MTHFR, OPRM1, SLCO1B1, TNF, UGT1A4***
- ❑ ***I hereby order the Inagene Personalized Insights™ PrecisionRx pharmacogenetic test for the above-named patient, which tests for the presence of specific variants of 38 genes, including but not limited to CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP3A4, CYP3A5, COMT, HLA-A, HLA-B, CYP4F2, HTR2A, MTHFR, APOE, DPYD, G6PD, NUDT15, TPMT, VKORC1, SLCO1B1***
- ❑ ***I hereby order both of the aforementioned tests***

This test is being ordered to evaluate expected response to treatment for the following pain and/or mental health-related condition(s) (please list):

I confirm that this test is required to (and will be used to) support treatment decisions for the above-named patient for the medical conditions listed above.

Healthcare Provider signature:

Date (dd/mm/yyyy):	Healthcare Provider License #:

IMPORTANT NOTES:

- If you will be submitting the cost of your Personalized Insights™ Test Kit to your private insurance benefits provider seeking reimbursement, this completed and signed form should be submitted with your claim, along with the receipt for your kit, and a copy of the "INAGENE PERSONALIZED INSIGHTS™ PHARMACOGENETIC TEST SUMMARY. Check with your insurance provider whether they cover "pharmacogenetic testing" before submitting.

- The patient or healthcare provider must register an account with Inagene Diagnostics (at https://patients.inagene.com) using the 14 – digit code found in the kit to receive the test results. Online access to the results can be securely shared between patient and healthcare provider via the Inagene Portal system.

- If submitting the cost of the test to a private insurer/benefits plan for reimbursement, this form, along with the receipt for the test itself, should be submitted with the claim to the healthcare benefits plan provider. Before submitting, check with your insurance provider to confirm that pharmacogenetic tests are covered under your benefits plan.