Pharmacogenomics Testing

Guidance for Patients

An overview of pharmacogenomics (PGx) testing in B.C. and considerations for incorporating PGx testing into health care decisions

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BRITISH COLUMBIA | Ministry of Health

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PHARMACOGENOMICS TESTING: GUIDANCE FOR PATIENTS AND PROVIDERS

OVERVIEW

The purpose of this document is to inform patients and health care providers about pharmacogenomics (PGx) testing and to promote a patient-oriented, cost-effective, appropriate and safe approach to PGx testing in B.C.

This document contains two sections. The first is directed at patients and their families and aims to help inform their decision about whether pharmacogenomics testing is right for them. The second section is directed at health care providers and aims to establish appropriate standards of care, quality, safety and access to PGx testing for B.C. residents. The document also provides a foundation for the development of PGx standards of practice in B.C.

FOR PATIENTS

What is pharmacogenomics (PGx) testing?

PGx looks at how individuals' genes affect the way they respond to drugs. An individual inherits genes from their parents. Genes are like instructions that tell the body how to grow, develop and function. Just as there are genes that determine eye color and blood type, there are also genes that tell the body how to respond to a medication. Sometimes differences in these genes can cause differences in how fast or slow certain medications work or can cause the person to have more (or fewer) side effects. A PGx test looks at how an individual's genes could affect their response to medication. A PGx test has the potential to help patients and providers select medications that are most likely to work and to limit side effects and reduce the need for a trial-and-error approach to finding the right medication.

What are the objectives and recommendations of this document?

The goal of this document is to provide a summary of PGx testing and its appropriate use, and to describe how it can help B.C. patients and health care providers make informed decisions.

PGx testing is not paid for by the public health care system in B.C., so patients who want to undertake it must pay out of pocket. This document encourages patients to consult their health care provider before accessing PGx testing, to consider their options and understand the risks and benefits. This document also examines the need for education around PGx testing, how PGx testing and its results can be used, the lack of public health care coverage and regulatory processes for them, and the importance of informed patient consent.

Why is PGx testing important?

PGx testing has the potential to:

- help providers understand whether or how well a specific medication will work for a patient;
- help providers choose the best medication and dosage for a patient;
- help providers understand a patient's risk of experiencing an adverse drug reaction (serious side effect) to a medication;
- help patients and providers make more informed decisions about medication use;
- reduce the trial-and-error approach to medication selection; and
- allow patients to manage and resolve their health conditions more quickly.

When is PGx testing considered or recommended?

A PGx test may be considered or recommended if:

- a person has an ongoing health concern; and
- a PGx test, supported by clinical evidence, exists for the health concern and the medications of interest; and
- clinical guidelines are available to help clinicians understand how available PGx test results can be used to optimize drug therapy.

When these conditions are met, a PGx test may help a health care provider choose the right dosage for a patient and avoid serious side effects from the medication.

Someone may also choose to have PGx testing if they do not have an ongoing health concern, but they want to have the PGx testing results available to inform future medication decisions.

What does a PGx test tell you?

PGx testing can help guide health care providers to choose appropriate medications and dosages for patients. A PGx test does not always provide definitive information that can be used to make decisions about medications, and it does not guarantee that a medication or dose will work for a patient. In addition, since PGx tests are both person-specific and medication-specific, not all medications will have an associated PGx test available.

How can I get a PGx test?

PGx tests in B.C. are not covered by the public health system. At the time of writing, the Ministry of Health (the Ministry) is examining existing barriers to clinical adoption of PGx testing, such as evidence of clinical utility, economic feasibility, and public and professional awareness of its existence and utility.

In B.C., commercial PGx tests are available for patients, with or without the involvement of a health care provider. The patient has to pay for the testing. People can also discuss their options with a pharmacist[i].

What happens when I get a PGx test?

You can get a PGx test done through a Direct to consumer (DTC) test[ii]. For example, there are PGx tests available on several testing companies' websites[i]. The price of DTC PGx tests ranges from about $300 to $1,500, depending on the conditions tested for and how the company maintains test results[ii]. The company will send a kit which includes a patient consent form. You will collect a sample (this could be a swab from inside your mouth or another sample; technology varies and is evolving). The sample is mailed to a laboratory for testing. When the results are ready, you can review the test report with your health care provider(s) and/or pharmacist. They will discuss any recommendations for medication changes––with your consent.

There are many private health insurance companies in Canada that offer partial or full coverage of PGx testing, including Canada Life[iii], Manulife[iv], Sunlife[v] and Green

Shield Canada[vi]. The coverage of each plan may vary. Consult your coverage documents or contact your insurance provider for more information.

Secondary findings in PGx testing

Secondary or incidental findings are those that aren't related to the reason for doing the test[vii]. They may, however, still be important to a person's health.

PGx testing has the potential to reveal incidental findings. Some genes provide instructions for responding to many medications. However, if the test is targeting a specific condition, such as mental or cardiovascular health, only certain gene drug interactions are reported from the test (and usually not the incidental findings). Some genes may be involved in predicting someone's chance of developing an unrelated health condition. Examples of this include learning you have genetic risk factors for a condition like cancer, dementia or heart disease.

Some DTC PGx test providers assure patients that they do not record incidental findings in their test results, and that they will not inform patients or their health care provider of any incidental disease-associated risk detected by the test[viii]. Other test providers will ask the patient if they want to receive incidental or secondary findings. This choice would be included in a provider's consent process.

PGx tests are not all the same

PGx tests are available to patients through testing laboratories all around Canada and the US. The tests vary in the way the gene-drug interactions are examined, the nature of the test, and the laboratory that carries out the analysis. It is important to consider your options and consult your health care provider to choose the PGx test that best fits your needs. Be sure to choose a PGx testing company with a good reputation and that uses an accredited laboratory to analyse the tests.

How is your data collected/accessed/used/disclosed/retained?

For DTC PGx tests, patients give consent for the company to collect their information, and patients (and providers, if applicable) receive the results in a written report. Most DTC PGx tests do not give patients or health care providers access to associated records such as raw data. Different PGx test manufacturers have different policies for collecting, accessing, using, disclosing and retaining patient information. Patients should conduct their own research, with the help of a health care provider, prior to taking the test, to understand how their information

will be handled. Patients should also be aware that information collected by manufacturers may be used for non-medical purposes, such as research and product development. In some cases, this is a condition of the service.

FOR PROVIDERS

POLICY OBJECTIVES

This guidance document informs health care providers and patients on the appropriate use of PGx testing and supports informed decision-making in the current PGx testing environment. The majority of PGx testing in B.C. is conducted through direct-to-consumer (DTC) testing, which the patient pays for out of pocket. This document encourages the development of standards, regulations and processes to promote quality, safety and appropriate access to PGx testing for B.C. residents.

This document recommends that health care providers performing or recommending PGx testing educate patients and have processes in place for discussing results with patients, performing follow-up care, and ensuring patient safety and testing quality. The Ministry recommends that the health professions' regulatory colleges work with the Ministry to determine how PGx tests can or would fall within the scope of practice of each health care profession—with respect to recommending them, performing them and interpreting their results.

POLICY RECOMMENDATIONS

1. Patient Education

Educating patients about PGx testing allows them to make informed decisions about whether to take a PGx test and what type of PGx test is appropriate for them. Educating and engaging with patients provides them with a sense of control over their health care, which tends to lead to improved health outcomes and satisfaction.

We recommend that providers who undertake or recommend PGx testing make education available to their patients and that this education covers:

- The purpose, use and impact of PGx testing, including:
    - predicting the effectiveness of a medication for each patient;
    - determining appropriate medication dosages for a patient;
    - predicting or quantifying the risk of adverse drug reactions; and
    - the potential to alter existing treatment plans based on PGx test results and for the results to inform future treatment plans
- How and where to access tests

- The variations in available, clinically meaningful data and the benefits and limitations of PGx testing
- The implications of how test information is collected, accessed, used, disclosed, and retained
- The absence of a provincial or federal regulatory approval process for DTC PGx testing (as of the writing of this document)
- The variation in quality of PGx testing kits, processes and results
- Information about costs, including that PGx tests are not covered by public health care
- Health care provider and test manufacturers' roles in follow-up care, sample collection, testing, data storage, and subsequent uses and disclosures of personal information.

2. Secondary/incidental findings

PGx testing has the potential to return incidental findings. We recommend developing informed consent processes for addressing potential incidental findings.
The American College of Medical Genetics and Genomics (ACMG) and the Canadian College of Medical Geneticists (CCMG) have policy recommendations around the analysis and reporting of incidental findings in clinical genetic sequencing. They recommend obtaining written, informed patient consent by a qualified genetics health care professional who has described the nature of the test and the potential to generate data not immediately relevant to the clinical indication of the test[ix].

No such guidelines have been developed for PGx testing by either the ACMG or the CCMG[x] at the time of this report's writing. Most PGx tests on the market do not report on incidental findings.

3. Privacy and Data Implications of PGx

In B.C., two distinct pieces of legislation, the Freedom of Information and Protection of Privacy Act[xi] and the Personal Information Protection Act,[xii] govern the protection of privacy for residents. However, providers and patients should be aware that private PGx companies may store and share patient data at the company's discretion, depending on the company's policies and the jurisdiction where the data is analyzed and stored. This may be outside of Canada where Canadian laws are not enforceable. The companies could use the data for

research, product testing, development and market assessment, and disclose it to other parties, unless there is a specific provision for a patient to refuse. At minimum, patient consent should be obtained regarding subsequent uses, disclosures, and retention of data. There must be a provision for the patient's consent to be withdrawn without negative impact on their care.

Patients should be made aware of the guidance document on DTC genetic testing and privacy published by the Office of the Privacy Commissioner of Canada[xiii], which outlines some of the key privacy risks associated with these tests, informs individuals of their rights, and encourages them to consider specific questions before purchasing a DTC genetic test.

Providers and patients should be aware that privacy risks of distributing or sharing identifiable genetic data extend beyond the patient. Individuals who are genetically related to the patient can be affected by the release of the patient's genetic data. This includes direct and extended relatives, as well as individuals who share the patient's ancestry.

Sample storage may differ based on the company and may be stored outside of B.C. or outside of Canada. Personal information held outside the country is subject to local privacy and data legislation, which may not be comparable to B.C. or Canadian law.

Providers and patients should be aware of the frameworks in place to store and access PGx test results, made available to a health care provider, in the patient's personal health record.

4. Safety and Training

A thorough understanding of the indications, benefits and risks of PGx testing allows health care providers to educate their patients and offer safe and appropriate services. Continuous education of the health care workforce should be supported through training to enable and update the understanding of the pros, cons and implications of PGx testing, and to pass this knowledge on to their patients. Provider education should be undertaken in collaboration with partners such as provincial health profession regulatory colleges and universities.

The Ministry recommends that health care providers requesting, interpreting and/or performing PGx tests be knowledgeable about the purpose of the tests and their implications, including:

- what the results may reveal about future prescribing actions for an individual as well as the health of direct and extended relatives and individuals who share the patient's ancestry;
- that the federal Genetic Non-Discrimination (GND) Act protects individuals from having their genetic test results used in areas outside of medical care and medical research, such as insurance and employment[xiv]. Patients should be informed, however, that despite the GND Act, there may still be potential for insurance or other discrimination. The GND Act specifies that the patient must consent in writing to any collection, use, or disclosure of their information;
- that it is not permitted to require patients to consent to any use of information beyond what is necessary to provide them with the testing services; and
- acknowledging the possibility of receiving test results that are difficult to interpret.

The Ministry recommends that health care providers consider the risks and benefits of PGx testing, the quality of the testing, and the potential impact on the patient's treatment plan when deciding whether to pursue it.

5. Reporting Results

Protecting patients' privacy and adhering to existing legislation are key considerations when developing recommendations for the storage, access and use of genetic data. We recommend that the following safeguards be established in order to ensure patient privacy and safety during PGx testing and to emphasize the importance of informed patient consent:

- The type of PGx test ordered, the equipment used, and its results are recorded in a permanent record in a manner compliant with existing legislation and guidelines
- PGx testing and results are reported and made available to the patient, as well as to the appropriate health care provider(s), in accordance with patient consent obtained prior to conducting the test
- Written procedures, guidelines and/or instructions are developed to govern the reporting and documentation of results and that these instructions

address informed consent and incidental findings procedures, if applicable (see Section 1. Patient education, for more details)

- Any genetic variants of uncertain significance are addressed in these written procedures, guidance and/or instructions. For example, gene-drug pairs that have an inadequate pharmacogenomics knowledge base of clinical evidence at levels C and D in the Clinical Pharmacogenetics Implementation Consortium (CPIC) classification have the potential to move to levels A and B as sufficient evidence emerges for at least one prescribing action to be recommended[xv]

6. Follow-Up Care

Providing quality follow-up care after the PGx test will optimize the patient experience, improve clinical outcomes and increase patient satisfaction. Follow-up care provides opportunities for patients and health care providers to discuss results, make informed therapeutic decisions, and seek further testing if necessary.

The Ministry recommends that health care providers administering PGx testing have a system in place to review the test results. If further input is necessary to provide appropriate patient care, the Ministry suggests that a follow-up with the appropriate health care provider (e.g., a physician or genetic counsellor) be arranged with patient consent. Ordering and interpreting PGx tests does not currently fall within the scope of practice of a specific health care practitioner in B.C.[xvi,xvii]. In the current private-pay environment, pharmacists and physicians are primarily supporting patients in choosing PGx tests, interpreting results and making changes to treatments as appropriate. It is recommended that each health profession's regulatory college develop its own scope of practice to include or exclude ordering and interpreting PGx test results as qualified providers.
Health care providers who advise on PGx testing, conduct PGx tests and interpret test results are recommended to follow CPIC guidelines. If health care providers are unable to perform result interpretation and provide clinical instructions, the patient should be referred to a medical clinic or practitioner with expertise in PGx testing.

The CPIC has guidelines to help clinicians understand how PGx test results should be used to optimize drug therapy[xviii]. The Ministry recommends that health care providers refer to available clinical guidelines, such as those developed by CPIC,

the Dutch Pharmacogenetics Working Group, and the Canadian Pharmacogenomics Network for Drug Safety when interpreting PGx test results and implementing changes to patients' treatment regimes.

While recognizing that DTC testing fulfils a consumer need, it is recommended that patients consult with a doctor, nurse practitioner, pharmacist or a genetic counsellor before making any changes to their medications or health regimens based on PGx test results.

Where applicable, written procedures, guidance and/or instructions may be developed by primary care providers to guide individual and/or specimen referrals to an accredited laboratory for further testing.

7. Proficiency and Quality Control

Effective PGx testing ensures accurate test results and appropriate treatment. Taking a PGx test with guidance from a health care provider enables patients to access an appropriate PGx test offered by a reputed manufacturer to meet their specific needs. In order to ensure proficiency and quality control of the PGx testing, the Ministry has the following recommendations:

- Individuals providing or overseeing PGx have a framework to actively manage safety and quality risks in PGx delivery
- To ensure safe and quality patient care, the health professions regulatory colleges, such as the College of Physicians and Surgeons of B.C.[xix] and the College of Pharmacists in B.C.,[xx] have professional programs on quality improvement approaches. All health care providers in B.C. are guided by the Health Professions Act[xxi] and the Health Professions General Regulation[xxii] to mitigate safety and quality risks to patients. However, there are no regulations or policies in the province that directly manage safety and quality risks in PGx delivery
- Patients consult a health care provider when choosing a PGx test and that health care providers consider PGx tests offered by reputed manufacturers, where tests are processed in accredited laboratories
- Providers should be aware that the utility of PGx test-guided treatment varies between different tests
- Providers should be aware of the variability of clinically meaningful data and of treatments guided by PGx testing based on the indication, medication or treatment, and the patient

POLICY CONTEXT

Most PGx testing analyzes single nucleotide polymorphisms in people's genes that are known to affect their response to medications. PGx tests can assess single nucleotide polymorphisms for a single gene or for multiple genes, and then report on either a single gene-drug interaction, or on all drugs for which there are clinical interactions. While PGx testing serves as guidance for choosing medications and dosages for individual patients, it does not guarantee the efficacy of specific medications or doses[xxiii].

The complexity and diversity of PGx testing services available underscore the need for a comprehensive regulatory environment. Establishing provincial standards for quality and safety has the potential to lead to more consistent, reliable, and safe results and improved patient privacy. This policy highlights opportunities for education and regulation within the PGx testing landscape. Currently, ordering and interpreting PGx tests does not fall explicitly within the scope of practice of any specific health care practitioner in B.C.[xxiv,xxv].

Data on the clinical efficacy and cost effectiveness of PGx testing is variable and inconclusive, although there is evidence to suggest that incorporating PGx testing into treatment plans may reduce the risk of adverse drug reactions[xxvi]. Even though an individual's inherited genotype does not change over time, and genetic test results are not altered by changing health conditions or pregnancy, the clinical interpretation of genetic test results could change with time as genome research evidence is continuously updated[xxvii]. Therefore, repeating PGx testing over the years may be required to make care decisions based on up-to-date results.

For genes of uncertain significance or with limited known gene-drug interactions, evidence may become more meaningful as new data becomes available. For example, CPIC assigns levels A to D to gene-drug pairs, based on available pharmacogenomics knowledge base clinical evidence[xxviii]. Only level A and B gene-drug pairs have sufficient evidence for at least one prescribing action to be recommended. Level C and D gene-drug pairs are not considered to have adequate evidence to have prescribing recommendations. The gene-drug pairs that are currently in levels C and D have the potential to move to levels A or B with actionable prescribing recommendations as new evidence emerges.

Currently, PGx tests are available for multiple gene-drug panels in the areas of psychiatry, cardiology, gastroenterology, hematology, oncology, neurology, pain

management, infectious diseases, pulmonary medicine, rheumatology, transplant and urology.[xxix,xxx] New PGx tests are continuously being developed. However, the amount of evidence on the clinical efficacy and cost effectiveness of using PGx testing as a decision support tool for treatment of psychiatric disorders[xxxi,xxxii] and cancer[xxxiii,xxxiv] is higher compared to other clinical settings.

PGx tests are currently not covered under B.C.'s Medical Services Plan (MSP) or PharmaCare program; however, B.C. Children's Hospital may provide clinically valuable PGx tests for selected patients within research initiatives and with explicit patient consent to use data for research outside of medical management[xxxv].

Coverage for PGx testing may be available to patients through third-party insurance companies. Additionally, people can purchase commercial PGx tests directly from private companies for between $300 and $1500, depending on the range of conditions covered and how the results are maintained[xxxvi].

Such tests may be accessed with or without the involvement of a B.C.-based health care provider. However, the Ministry strongly recommends that patients consult with a health care provider before accessing PGx testing. Despite the absence of public coverage, the diversity of PGx testing is increasing, as is demand from patients and health care providers.

SCOPE

	Type of PGx test	**Points of access and care environments**	**Current funding model**
This policy applies to:	DTC PGx test	Self-guided test carried out at home	Private pay
	PGx test conducted at community-based point of care setting	Primary care provider-assisted test done in a primary care setting	Private pay
	Self-testing under the guidance of a health care provider	At home test done under the guidance of a physician (virtual) or pharmacist	Private pay

This policy does not apply to:	PGx tests conducted at acute and chronic care settings	Hospitals, academic health centres conducting PGx testing as part of research	Clinically valuable special tests are publicly funded through research grants

REVIEW AND QUALITY IMPROVEMENT

- This guidance document will be reviewed and updated every 1 to 3 years[xxxvii] from the date of publication and after the summative evaluation is complete.
- The guidance document may also be reviewed ad hoc, in consultation between the Ministry and external partners.
- The guidance document reviews will be used to inform ongoing monitoring, evaluation and quality improvements.

ADDITIONAL RESOURCES

Relevant legislation

PROVINCIAL	FEDERAL
Laboratory Services Act (LSA[xxxviii]): Regulates laboratory testing in B.C.	Genetic Non-Discrimination Act (GNDA)[xxxix]: Prohibits the requirement of any individual to undergo genetic testing and forbids the disclosure of genetic test results in a labour or consumer setting.
Declaration on the Rights of Indigenous Peoples Act[xl]: Harmonizes B.C.'s laws with the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). Article 31 states "Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, including human and genetic resources."	United Nations Declaration on the Rights of Indigenous Peoples Act[xli]: Affirms UNDRIP as a universal human rights instrument with application in Canadian law and provides framework for federal implementation of UNDRIP. Article 31 of states that "Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expression, including human and genetic resources."

Personal Information Protection Act (PIPA)[xlii]: Governs the collection, use and disclosure of personal information by organizations in a manner that recognizes both an individual's right to privacy and the need of organizations to collect, use or disclose personal information for appropriate purposes.	Personal Information Protection and Electronic Documents Act (PIPEDA)[xliii]: Governs the collection, use and disclosure of personal information by private bodies in a manner that recognizes an individual's right to privacy.
Freedom of Information and Protection of Privacy Act (FOIPPA)[xliv]: Governs the collection, use and disclosure of personal information by public bodies in a manner that respects an individual's right to privacy.	Privacy Act[xlv]: Dictates the collection, use and disclosure of personal information by public bodies in a manner that recognizes an individual's right to privacy.
Medicare Protection Act (MPA)[xlvi]: Defines guidelines that regulators must adhere to when determining benefits.	Food and Drugs Act[xlvii]: Statutory Order and Regulation 98-282 governs the sale, advertising, and importation of medical devices.
E-Health Act[xlviii]: Regulates the storage and disclosure of personal health information in the provincial health information banks.	
Pharmaceutical Services Act[xlix]: Defines procedures for covering medications under B.C.'s public drug plan and offers guidelines for assessing special drug or health technology coverage. This act also stipulates the requirements for the collection, use and disclosure of all data collected under the act.	
Health Professions Act[l]: Provides a common regulatory framework for health professions in B.C.	
Health Care (Consent) and Facility (Admission) Act[li] Identifies patient rights, elements of consent, when consent is required, who can provide consent and protocols when an individual is incapable of giving, refusing, or revoking consent.	
Public Health Act[lii]	

Confers information gathering, inspection, ordering and other powers to the minister, public health officials and other authorities to promote and protect public health and well-being.

Provincial Regulatory Bodies

B.C. Health Regulators (BCHR)[liii]: Encompasses 19 regulatory colleges operating in B.C. These colleges establish standards of practice for their registrants.
The College of Physicians and Surgeons of B.C. Diagnostic Accreditation Program (DAP)[liv]: Assesses and monitors diagnostic facilities to ensure they meet provincial standards of quality. Facilities that meet these standards receive official accreditation. The scope of the DAP includes public and private diagnostic facilities within British Columbia.

Position Statements

Canadian College of Medical Geneticists (January 2011). CCMG Statement on Direct-to-Consumer Genetic Testing[lv].
Canadian College of Medical Geneticists (January 2008). Guidelines for DNA Banking[lvi].
College of Physicians and Surgeons of British Columbia (June 2018). DAP Accreditation of Genetic Laboratories and Direct-to-Consumer Testing[lvii].

GLOSSARY AND DEFINITIONS

Accredited laboratory: A diagnostic laboratory that meets the standards of an approved accreditation body, e.g., the Diagnostic Accreditation Program of the College of Physicians and Surgeons of B.C.

***Adverse drug reaction (ADR)*:** An unintended and unpleasant or harmful response to a drug. ADRs can occur at any dose and can range from mild to severe

Clinical efficacy: The ability to produce a desired health outcome

Community-based setting: A place where health care is delivered in "the community", such as a health clinic, physician's office, public health unit or pharmacy

Direct-to-consumer (DTC) testing: Tests available for purchase by an individual without health care provider involvement

Genotype: The genetic arrangement that makes up the traits that an individual inherited from their parents

Self-guided testing: Tests conducted by an individual on their own

Health outcomes: Changes in health resulting from health care investments or interventions

Health profession regulatory colleges: In B.C., health profession regulatory colleges have been delegated the authority under provincial legislation to govern the practice of their registrants in the public interest. Their primary function is to ensure registrants are qualified, competent and follow clearly defined standards of practice. Give examples here: (the main 2-3 colleges in B.C.)

***Health care providers*:** A general term that encompasses people who provide health care to others, whether regulated or non-regulated

Incidental findings: Additional findings revealed by a test that are not related to the primary indication of the test

Patient-centred care: A model of care that respects the patient's experience, values, needs and preferences in its planning, co-ordination and delivery

Pharmacogenomic (PGx) testing: Testing that determines a patient's potential response to medications based on their genetics

Result interpretation: Medical tests provide data/results that can be used in health monitoring, screening and diagnosis. The results are "interpreted" by comparing them to a reference sample to distinguish between "health" and "disease"

Scope of practice: Activities that a health care provider performs in the delivery of patient care based on their license, education, training and competency. It is determined by laws, regulations and health professional regulatory bodies applicable to the jurisdiction

Specimen: Anything that is removed or collected from the human body and sent to a laboratory to be examined by a pathologist. Examples include blood, urine, tissues, organs, saliva, DNA/RNA, hair, nail clippings, or any other cells or fluids

Virtual care: The delivery of health care at a distance using any forms of communication or information technologies (e.g., video conferencing, phone, text, email) with the aim of facilitating or maximizing the quality and effectiveness of patient care

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[i] Dynacare - GENECEPT ASSAY
[ii] How to Get a Pharmacogenetic Test in Canada (pillcheck.ca)
[iii] GeneYouIn and Canada Life broaden access to pharmacogenetic testing
[iv] Personalized Medicine Program - Group benefits | Manulife
[v] Sun Life Selects TreatGx Plus As A Pharmacogenomic Solution (genxys.com)
[vi] Personalized drug treatment through pharmacogenetics (greenshield.ca)
[vii] Secondary and Incidental Findings in Genetic Testing (nsgc.org)
[viii] What unexpected things might I learn from pharmacogenetic testing? - GenXys
[ix] ACMG policy statement: updated recommendations regarding analysis and reporting of secondary findings in clinical genome-scale sequencing - Genetics in Medicine (gimjournal.org)
[x] Revisiting Secondary Information Related to Pharmacogenetic Testing - PMC (nih.gov)
[xi] Table of Contents - Freedom of Information and Protection of Privacy Act (gov.bc.ca)
[xii] Personal Information Protection Act (gov.bc.ca)
[xiii] 2105 (oipc.bc.ca)
[xiv] Microsoft Word - S201 fact sheet - final copy - May 17 2017.docx (cagc-accg.ca)
[xv] Genes-Drugs – CPIC (cpicpgx.org)
[xvi] Defined scope | College of Physicians and Surgeons of BC (cpsbc.ca)
[xvii] Scope of Practice - English (pharmacists.ca)

[xviii] Guidelines – CPIC (cpicpgx.org)
[xix] Physician Practice Enhancement Program | College of Physicians and Surgeons of BC (cpsbc.ca)
[xx] Professional Development and Assessment Program (PDAP) | College of Pharmacists of British Columbia (bcpharmacists.org)
[xxi] Health Professions Act (gov.bc.ca)
[xxii] Health Professions General Regulation (gov.bc.ca)
[xxiii] Pharmacogenomic vs. Traditional DNA Diagnostic Testing | GeneSight
[xxiv] Defined scope | College of Physicians and Surgeons of BC (cpsbc.ca)
[xxv] Scope of Practice - English (pharmacists.ca)
[xxvi] Pharmacogenomic Testing in Depression: A 2021 Update (cadth.ca)
[xxvii] Changes in genetic variant results over time in pediatric cardiomyopathy and electrophysiology - PubMed (nih.gov)
[xxviii] Genes-Drugs – CPIC (cpicpgx.org)
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[xxxii] Using pharmacogenomics and therapeutic drug monitoring to guide drug selection and dosing in outpatient mental health comprehensive medication management - PMC (nih.gov)
[xxxiii] Economic Value of Pharmacogenetic Testing for Cancer Drugs with Clinically Relevant Drug-Gene Associations: A Systematic Literature Review - PMC (nih.gov)
[xxxiv] Cancer pharmacogenomics - PubMed (nih.gov)
[xxxv] Translational Therapeutics (bcchildrens.ca)
[xxxvi] How to Get a Pharmacogenetic Test in Canada (pillcheck.ca)
[xxxvii] Better Regulations - Province of British Columbia (gov.bc.ca)
[xxxviii] Laboratory Services Act (gov.bc.ca)
[xxxix] Genetic Non-Discrimination Act (justice.gc.ca)
[xl] Declaration on the Rights of Indigenous Peoples Act (gov.bc.ca)
[xli] United Nations Declaration on the Rights of Indigenous Peoples Act (justice.gc.ca)
[xlii] Personal Information Protection Act (gov.bc.ca)
[xliii] Personal Information Protection and Electronic Documents Act (justice.gc.ca)
[xliv] Freedom of Information and Protection of Privacy Act (gov.bc.ca)
[xlv] Privacy Act (justice.gc.ca)
[xlvi] Medicare Protection Act (gov.bc.ca)
[xlvii] Medical Devices Regulations (justice.gc.ca)
[xlviii] E-Health (Personal Health Information Access and Protection of Privacy) Act (gov.bc.ca)
[xlix] Pharmaceutical Services Act (gov.bc.ca)
[l] Health Professions Act (gov.bc.ca)
[li] Health Care (Consent) and Care Facility (Admission) Act (gov.bc.ca)
[lii] Public Health Act (gov.bc.ca)
[liii] Member Colleges - BCHR - BC Health Regulators
[liv] Diagnostic Accreditation Program | College of Physicians and Surgeons of BC (cpsbc.ca)
[lv] CCMG statement on direct-to-consumer genetic testing* - - 2012 - Clinical Genetics - Wiley Online Library
[lvi] PRIME PubMed | Policy statement concerning DNA banking and molecular genetic diagnosis. Canadian College of Medical Geneticists (unboundmedicine.com)
[lvii] DAP-PS-Genetic-Testing-and-Direct-to-consumer.pdf (cpsbc.ca)