

# Guardant Health Multi Cancer Detection (MCD) test\*

## Frequently Asked Questions (FAQ)

### Introduction

This Frequently Asked Questions (FAQ) document is designed to help you better understand the Multi Cancer Detection (MCD) test\* by Guardant Health, under the promotion offered by Manulife.

It provides detailed information of the following areas: background and overview of the MCD test by Guardant Health, Eligibility, test procedures, result checking and follow up, Manulife's complimentary follow up service, Claims information relating to in-force policies that do not require underwriting changes, and impact of MCD test results on future underwriting-triggering events<sup>^</sup>. Unless otherwise specified, information relating to the MCD test\*, is provided by Guardant Health.

Please note that this MCD test\* is not intended to replace medical diagnosis, professional advice, or recommended cancer screening tests. This MCD test\* is provided by a third-party service provider that is independent of Manulife. It is not provided by Manulife and does not form part of any contractual benefits or any part of Manulife's insurance plans.

This FAQ is for general information purposes only and should not be regarded as medical advice. For more details, please refer to the Important Notes at the end of this document. This FAQ is for distribution in Hong Kong only, but not in Chinese Mainland or Macau.

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\*Your clinical eligibility will be determined by the medical provider with whom you have scheduled your appointment.

<sup>^</sup> underwriting-triggering events shall mean applications for new policies or policy changes (e.g. sum assured increase, rider addition, reinstatement, etc) that require underwriting.

## 1. Background and Overview of the MCD Test by Guardant Health

### 1.1 What is a Multi-Cancer Detection (MCD) blood test?

The multi-cancer detection (MCD) test\* offered by Guardant Health, is a blood-based test which is intended to detect 10 cancers: Bladder, Breast, Colorectal, Esophageal, Gastric (Stomach), Liver (Hepatocellular), Lung, Pancreatic, Prostate and Ovarian.

Cancer screening can help detect cancer before any symptoms appear. By the time symptoms develop, cancer is often already at a more advanced stage. <sup>1</sup> Early detection improves the chances of survival and can reduce the risk of death. <sup>1-3</sup> MCD test\* may help more people get screened by using a single blood test to look for signals of different cancers. <sup>2</sup>

For more information on the MCD test\* offered by Guardant Health, please click here: [Guardant Health MCD Fact Sheet](#).

### 1.2 Who is Guardant Health?

Guardant Health is a leading precision medicine company focused on guarding wellness and giving every person more time free from cancer. Guardant Health AMEA is a wholly owned subsidiary of Guardant Health founded in 2012. Guardant Health AMEA is transforming patient care by providing critical insights into what drives disease through its advanced blood and tissue tests, real-world data and AI analytics<sup>4</sup>. For more information, visit [guardanthealthamea.com](http://guardanthealthamea.com).

### 1.3 Who should consider the Guardant Health's MCD test? If I don't have symptoms, should I still take the test?

The Guardant Health's MCD test\* is not indicated for use in pregnant women and for people with a known diagnosis of cancer. Your clinical eligibility for Guardant Health's MCD test\* will be determined by the medical provider with whom you have scheduled your appointment. There are no other restrictions to taking the test.

The Guardant Health's MCD test\* is intended to complement, not replace standard age-appropriate guideline-recommended cancer screening tests.

#### **1.4 Am I clinically eligible for the Guardant Health's MCD test\*?**

Your clinical eligibility for Guardant Health's MCD test\* will be determined by the medical provider with whom you have scheduled your appointment. The MCD test\* is not indicated for use in pregnant women and for people with a known diagnosis of cancer.

#### **1.5 Is MCD test\* safe and has it received relevant approvals or accreditations?**

The Guardant Health's MCD test\* is a blood-based diagnostic test, which means it involves a routine blood draw and has no inherent safety concerns for the general population. As with any blood test, risks are minimal and typically limited to minor discomfort or bruising at the draw site.

Guardant Health's MCD test has received US FDA breakthrough device designation#.

Guardant Health's MCD test\* is intended to complement, not replace guideline recommended cancer screening tests. Individuals with positive results should follow healthcare provider recommendations for diagnostic follow-up and evaluation. A negative result does not eliminate the possibility that cancer is present or will occur in the future. Individuals should continue to participate in age-appropriate guidelines directed at cancer screening programs. These findings should be interpreted in the context of other clinical information, and laboratory and imaging studies as clinically indicated by a qualified medical professional.

#The US FDA Breakthrough Device Designation referenced includes eight cancer types—bladder, colorectal, esophageal, gastric, liver, lung, ovarian, and pancreatic cancer.<sup>5</sup>

#### **1.6 Is there scientific evidence supporting the MCD test's performance?**

Kindly refer to information on the scientific evidence supporting Guardant Health's MCD test\* performance on the [Guardant Health MCD Fact Sheet](#).

#### **1.7 Is the Guardant Health's MCD test\* approved in Hong Kong?**

The Guardant Health's MCD test\* is developed and performed entirely in an overseas laboratory and therefore fall outside the scope of Medical Device Administrative Control System (MDACS) in Hong Kong as it applies to medical devices. In Hong Kong, overseas laboratory-developed tests (LDTs) are generally regarded as "clinical testing services" rather than regulated medical devices under the MDACS. Regulatory oversight is primarily exercised through the ordering healthcare providers in Hong Kong, with emphasis on ensuring that the test is developed, validated, and performed in a laboratory that meets internationally recognized accreditation

standards, including the Clinical Laboratory Improvement Amendments of 1988 (CLIA), College of American Pathologists (CAP), or ISO 15189.

The Guardant Health's MCD test\* is a Laboratory Developed Test (LDT), it was developed and its performance characteristics were determined by Guardant Health, Inc. Guardant Health's clinical laboratory is duly certified under CLIA for high-complexity testing and accredited by CAP, demonstrating adherence to established quality and performance standards.

### **1.8 Does the MCD test\* detect early-stage cancers or non-cancer conditions?**

The Guardant Health's MCD test\* under this Promotion has been designed to detect designated 10 cancers all stages (Stage I to IV). Generally, sensitivity of MCD tests is higher in later stages of cancer. The test has not been designed to detect non-cancer conditions.

### **1.9 Does the MCD test\* indicate where in the body the cancer signal might be coming from?**

The Guardant Health's MCD test\* has a highly accurate cancer signal origin (CSO) caller and can ascertain with 93% accuracy the tissue of origin for detected cancers<sup>6</sup>. Identifying the CSO is critical for defining appropriate follow-up for patients with positive results. This is only clinically meaningful when the CSO is known, as this enables an effective diagnosis and timely referral to the appropriate medical specialist.

### **1.10 Could benign conditions trigger a positive signal of the MCD test\*?**

The test was trained to distinguish between cancers and other common conditions and reports positive results when a cancer signal is detected.

### **1.11 Does this screening test diagnose cancer?**

No, Guardant Health's MCD test\* does not diagnose cancer. Even with a positive signal, the individual should follow up with his/her physician for diagnostic follow-up to confirm the presence of specific cancer.

### **1.12 With so many other multi-cancer detection tests available, why should I get Guardant Health's MCD test\*?**

Guardant Health is a leader in blood-based cancer tests for over a decade. The MCD test\* by Guardant Health is backed by over 1 million oncology blood samples tested by Guardant Health<sup>5</sup>, a company that has demonstrated scientific rigour through over 600 peer reviewed publications<sup>5</sup>.

Guardant health's MCD test has received US FDA breakthrough device designation#.

#The US FDA Breakthrough Device designation referenced includes eight cancer types—bladder, colorectal, esophageal, gastric, liver, lung, ovarian, and pancreatic cancer.<sup>5</sup>

### **1.13 Does the test replace the Hong Kong government's Colorectal Cancer Screening Programme (CRCSP)?**

No. Guardant Health's MCD test\* is intended to complement, not replace standard age-appropriate guideline-recommended cancer screening tests.

### **1.14 Does this MCD test\* replace standard screenings like mammograms or colonoscopies?**

No. Guardant Health's MCD test\* is intended to complement, not replace guideline recommended cancer screening tests.

### **1.15 Does this MCD test\* replace traditional tumor marker tests?**

No. Guardant Health's MCD test\* is intended to complement, not replace guideline recommended cancer screening tests.

### **1.16 How is this MCD test\* different from genetic testing for cancer risk?**

Guardant Health's MCD test\* is intended to screen an individual for the presence of designated cancer types. It does not provide information on an individual who may have developing cancer in the future or the genetic cancer risk.

### **1.17 How is this MCD test\* different from routine tumor marker tests?**

Guardant Health's MCD test\* is designed to screen suitable populations for 10 cancer types by analysing methylation patterns in cell-free DNA from blood. Individual Tumour marker tests generally assess the presence of proteins in blood that may be associated with individual cancers and are used for detection and monitoring of individual cancers. Many cancers do not have associated tumour markers.

### **1.18 How does this MCD test\* compare with regular health checkups or wellness screenings?**

Guardant Health's MCD test\* is intended as a complement to routine cancer screening procedures. It is not intended and should not be used as a replacement to standard age-appropriate cancer screening. In the case of a positive MCD test\* result, additional evaluation

which may include invasive diagnostic procedures may be recommended by the treating physician.

### **1.19 Will this MCD test\* help me avoid invasive procedures?**

No. Guardant Health's MCD test\* is intended as a complement to routine cancer screening procedures. It is not intended and should not be used as a replacement to standard age-appropriate cancer screening. In the case of a positive MCD test\* result, additional evaluation which may include invasive diagnostic procedures may be recommended by the treating physician.

### **1.20 How accurate is this MCD test\*?**

Kindly refer to information on the performance of the Guardant Health's MCD test\* on [Guardant Health MCD Fact Sheet](#).

### **1.21 Where can I get more information about the MCD test\*?**

For more information about the test, kindly refer to [Guardant Health MCD Fact Sheet](#). You can contact Guardant Health's appointed distributor, Codex Genetics on their hotline: +852 3008 2562 or WhatsApp at: +852 9504 7481 or WeChat at: +852 9504 7481.

### **1.22 Who should I contact if I have questions on the use, quality, performance, purpose, clinical eligibility, results interpretation or scientific evidence of the Guardant Health's MCD test\* offered under this Promotion?**

If you have questions about Guardant Health's MCD test\*, you can contact Guardant Health's appointed distributor, Codex Genetics on their hotline: +852 3008 2562 or WhatsApp at: +852 9504 7481 or WeChat at: +852 9504 7481.

Service Hours: Monday – Friday from 9:00 am to 5:00 pm (excluding Hong Kong public holidays)

Manulife does not make any warranties or representations regarding the quality, merchantability, fitness for any purpose, or for the use or consumption thereof, or any other implied terms or conditions with respect to the service provided by Guardant Health, Guardant Health's appointed distributor and the select medical providers.

## **2. Eligibility — Complimentary advanced Multi-Cancer Detection test**

This section features the complimentary advanced Multi-Cancer Detection test promotion (“Promotion”).

### **2.1 What is this Promotion?**

Eligible customers who successfully apply for designated plan(s) and meet the specified premium requirements during the Promotion Period (“Designated Plan”) will be eligible to receive one complimentary Multi-Cancer Detection (MCD) Test by Guardant Health (“MCD test”).

Please refer to the leaflet of this Promotion for full details, subject to the applicable Terms and Conditions.

### **2.2 Am I eligible to this Promotion?**

Customers who successfully apply for any Designated Plan(s) and meet the corresponding requirements during the Promotion Period will be eligible.

Please refer to the leaflet of this Promotion for full details, subject to the applicable Terms and Conditions.

### **2.3 Can I transfer the complimentary MCD test to my family or friend?**

Yes. This complimentary MCD test is transferable to another person in Hong Kong on a one-time basis to a single person.

This complimentary test can only be used once.

### **2.4 How do I redeem the complimentary test ?**

For eligible customers under this Promotion, the redemption notification shall be mailed to the policyowner’s correspondence address within 60 days after the end of cooling-off period of the Eligible Policy.

Please refer to your redemption notification for the details of redemption arrangements.

### **2.5 By when I need to take the complimentary test?**

To take the test, the policyowners should schedule and complete their MCD test within 2 months from the date of issuance of the redemption notification, subject to the applicable Terms and Conditions in the Promotion leaflet.

### **3. Test Procedures**

#### **3.1 Are there any preparation needed prior to taking the Guardant Health MCD test?**

Upon calling the appointment hotline, Guardant Health's appointed distributor in Hong Kong, Codex Genetics will advise you on any preparation required.

#### **3.2 What documents or identification do I need to bring? Do I need to sign a consent form?**

On the day of the test, please bring your identification document (HKID/passport).

To proceed with the test, you will need to fill up a few consent and patient waiver forms. Do rest assured that Codex Genetics (the appointed distributor of Guardant Health in Hong Kong) and relevant clinic providers will guide you through the forms.

#### **3.3 How do I schedule the MCD test? Is it arranged by my agent/ Manulife?**

The test will be arranged by Guardant Health's appointed distributor, Codex Genetics, not by your agent or Manulife.

Eligible customers can contact Guardant Health's appointed distributor, Codex Genetics: +852 3008 2562 or WhatsApp/ WeChat at: +852 9504 7481 to book an appointment. Please refer to your redemption notification for booking procedure.

#### **3.4 What if I lose the redemption notification?**

If you misplace or lose your redemption notification, please contact Manulife Customer Service at +852 2510 2282 for assistance.

#### **3.5 Will I get reminders or notifications about my appointment?**

Yes. Upon successful registration, you will receive your booking details via WhatsApp or WeChat from Guardant Health's appointed distributor in Hong Kong, Codex Genetics. You should also receive a reminder 1-2 days from Codex Genetics before your appointment.

If you have any questions on your appointment, please reach out to the Codex Genetics helpline at: +852 3008 2562 or Whatsapp / Wechat at +852 9504 7481.

### **3.6 Will there be any extra charges for the blood draw or doctor's consultation during the test?**

The services covered under this test include one pre-test doctor consultation, blood draw service, and one post-test doctor consultation (if the result is positive). This test scope is provided by Guardant Health, which is irrelevant to Manulife.

If your test result is negative but you would like to see a doctor, your clinic may assist you in scheduling a follow-up consultation at your own cost upon request.

Do note also that you may incur late fees if you cancel or reschedule less than 24 hours before your appointment. Please note that all cancellations and reschedules happen in advance. Additionally, payment made via a credit card issued outside of Hong Kong may incur additional administrative charges.

### **3.7 Where can I take the test in HK? Is home sample collection available?**

You may choose either home testing or testing at a designated clinic by appointment.

Home testing can be arranged at your home or office, provided that there is a suitable room on-site that is safe and offers a high level of privacy.

Designated clinics are located in Hong Kong. Please refer to your booking information for the exact test location and appointment details.

### **3.8 Are there service providers in Macau or Chinese Mainland?**

Please note that the test is currently unavailable in Macau and Chinese Mainland. The MCD test under this Promotion is only available in HK.

### **3.9 Will there be pre-consultation prior to the test?**

Yes, you will be arranged to see a doctor to assess your eligibility for the test. You may also direct any additional queries to the doctor about the MCD Test.

For customers opting for home testing, the pre-consultation will be conducted virtually via telemedicine. For other customers, the pre-consultation will take place at the designated clinic.

### **3.10 How is the test done? / What is the general testing procedure?**

➤ At clinic:

Registration: Please arrive 5-10 minutes before your scheduled appointment at the clinic with your identification documents (ID/ passport). Upon arrival, the clinic staff will assist you with registration.

Medical Consultation: A doctor will meet you to explain the MCD test and determine your eligibility for the test. The doctor will also guide you through the patient waiver forms required.

Blood Drawing: Blood drawing will be conducted after the consultation, followed by nursing guidance to ensure post-draw comfort.

Rest: You are recommended to rest for at least 10 minutes. You may leave and resume normal activities after clinic staff have confirmed that you are feeling well and ready to leave.

➤ At home:

Pre-test consultation: Please follow the directions provided by Codex Genetics for your online consultation with the doctor that has been assigned to you. You will also need have your identification documentation (HKID / Passport) with you.

Blood Draw: The phlebotomist will arrive at your designated address for the blood draw. The phlebotomist will also guide you through the forms required as part of the submission of your sample.

Rest: You are recommended to rest for at least 10 minutes. You may leave and resume normal activities after the phlebotomist has confirmed that you are feeling well and ready to leave.

### **3.11 How many tubes of blood does this MCD test require?**

MCD test requires 4 (10 mL) blood collection tubes.

### **3.12 What will the clinic do after collecting my blood sample?**

The samples will be transported to Guardant Health's US-based laboratory for testing.

### **3.13 Are there any side effects after the blood draw?**

For details on blood draw, please refer to the explanation and instructions by the practitioner at the designated clinic.

The MCD Test is just a blood draw. There may be discomfort, bruising, sensitivity and other blood draw procedure associated risks. Please speak to your designated doctor if you have any concerns relating to the blood draw.

### **3.14 What is the cancellation or rescheduling policy?**

You can contact Codex Genetics Hotline for assistance with rescheduling or cancelling the appointment. Please refer to your redemption notification for the procedure.

Customers are encouraged to reschedule at least 24 hours ahead of their appointment, otherwise charges may apply for late rescheduling or no show on the appointment time.

## **4. Result checking & follow-up**

### **4.1 Is the report in English or Chinese?**

The report will be provided in English only. However, you may reach out to designated clinic to request for a copy of the results translated in simplified / traditional Chinese.

### **4.2 What will my results look like? What does a “positive”/ “negative” result mean?**

MCD test result will report either “positive” or “negative”. If your result is “positive”, the results will provide a cancer signal of origin (CSO).

For queries on results interpretation, please direct them to the doctor who has been assigned to you for your MCD test. Your clinic will also provide a Fact Sheet together with your test results which can help you to understand the MCD test better.

### **4.3 If I get a positive result, what does that mean for me? What happens next?**

A positive result is not a diagnosis of cancer but means that an abnormal signal was detected that may require follow-up. The doctor that is providing your results interpretation will advise you on the next steps for follow-up and evaluation.

For queries on results interpretation, please direct them to the doctor who has been assigned to you for your MCD test. Your clinic will also provide a Fact Sheet together with your test results which can help you to understand the Guardant Health MCD test better

### **4.4 If I get a negative result, am I “cancer-free”? What should I do next?**

A negative result does not eliminate the possibility that cancer is present or will occur in the future. Individuals should continue to participate in age-appropriate, guideline-directed cancer screening programs.

For details on how to interpret your results, please refer to the patient brochure provided at the designated clinic and the explanation by the practitioner at the designated clinic.

### **4.5 What should I do if my sample is rejected?**

If a sample is cancelled due to quantity not sufficient (QNS) or quality control (QC) issues, Guardant Health’s Client Services team will notify the ordering clinic.

You will then be contacted by the clinic to schedule a re-draw. The re-draw will be provided at no additional cost to you.

#### **4.6 Who will see my result? Will my result be automatically sent to my doctor?**

Test results will be made available to you, your doctor or clinic that ordered the test . Manulife and Manulife's agents/ financial representatives/ financial advisors will not have access to your customer's test result.

#### **4.7 Who can help me interpret my result?**

You may reach out to the doctor or clinic that ordered your test to discuss the report finding.

#### **4.8 Can I access my raw data or more detailed analysis?**

No, you will have access only to your finalized test results. Raw data and detailed analytical outputs are not available.

#### **4.9 How often should I take a MCD test?**

Currently, there is no official guideline on how often a patient should undergo MCD test. You should consult your medical practitioner for personalized medical advice.

## **5. Complimentary Follow-up Service by Manulife**

### **5.1 Is participation in Complimentary Follow-up Service mandatory?**

No. Participation in the follow-up call and support service is entirely voluntary.

### **5.2 If I no longer need this service, can I cancel it?**

You may decline or withdraw your consent at any time without affecting your insurance coverage, policy benefits, claims, or relationship with Manulife (if any).

### **5.3 What is the scope of Follow-up Service?**

Manulife may provide follow-up calls conducted by Dedicated Healthcare Manager. The support may include discussion of test results and further clarification upon request, provision of general health information and health tips, and referral to or guidance on relevant support services where appropriate. The service period will last for up to six (6) months from the initial follow-up call, with additional follow-up provided as and when appropriate based on individual needs and progress.

### **5.4 Will Manulife automatically receive my MCD test results if I signed the consent form?**

No, Manulife will not receive your MCD test results.

Your MCD test results will only be known to Manulife if you voluntarily disclose it to the Dedicated Healthcare Manager during the follow-up call.

Under this service, what follow-up support will Manulife provide if my MCD test result is positive?

If your MCD test result is positive and you voluntarily disclose your MCD test results to the Dedicated Healthcare Manager during the follow-up call, Manulife may provide follow-up calls conducted by Dedicated Healthcare Manager. The Healthcare Manager may facilitate the process of accessing necessary medical services such as providing a list of network of specialist doctors within the Manulife's network, if needed.

Please note that the relevant information is used solely to assist the Dedicated Healthcare Manager in providing you with more appropriate follow-up support, and does not represent, nor shall it be deemed to represent, Manulife's actual knowledge of such information.

## **6. Claims information relating to in-force policies that do not require underwriting changes**

### **6.1 Will taking this MCD test affect my in-force policy(s) coverage or premium?**

Participating in the MCD test and its results do not, on their own, change your in-force policy(s) coverage or premiums.

Claims will continue to be assessed under your policy's terms and conditions, including any requirements to submit necessary diagnostic reports and medical evidence as part of standard claims procedures.

### **6.2 Is the MCD test covered by my in-force policy(s)?**

MCD test is a non-diagnostic screening.

If your insurance plan includes wellness benefit, the MCD screening may be covered under that benefit; otherwise, MCD test is generally not covered under insurance product.

Please refer to your policy provision(s) or consult your insurance advisor to understand the coverage details.

### **6.3 If the MCD test recommends follow-up diagnostic test(s), are those covered by my in-force policy(s)?**

MCD test is a non-diagnostic screening.

Coverage for follow-up diagnostics depends on your plan's benefits (e.g., diagnostic, outpatient, preventive, or wellness). Doctor-recommended, medically necessary tests and a confirmed diagnosis are typically required for claim assessment.

Please refer to your policy provision(s) or consult your insurance advisor to understand the coverage details.

### **6.4 For in-force policy(s), do I need to proactively disclose that I have taken the MCD test and the corresponding result to Manulife/ my agent?**

If you don't have any underwriting-triggering events<sup>^</sup>, you do not need to proactively disclose that you took the MCD test and the corresponding result for your in-force policy(s).

If you have any underwriting-triggering events<sup>^</sup> in the future, you may be required to disclose relevant health information in accordance with the application and policy procedures, which include your MCD participation and test results. Please refer to FAQ section 7 for more details.

<sup>^</sup>underwriting-triggering events shall mean applications for new policies or policy changes (e.g. sum assured increase, rider addition, reinstatement) that require underwriting.

## **7. Impact of MCD test results on future underwriting-triggering events<sup>^</sup>**

<sup>^</sup> underwriting-triggering events shall mean applications for new policies or policy changes (e.g. sum assured increase, rider addition, reinstatement, etc) that require underwriting.

### **7.1 Will the MCD test result affect my future underwriting-triggering events<sup>^</sup>?**

Customers are required to fully and truthfully disclose any MCD test results and/or any related medical information during underwriting-triggering events<sup>^</sup> processes where such information is requested, in accordance with applicable disclosure obligations. Please also disclose the details of follow-up consultation and investigations (if applicable).

### **7.2 Is the MCD test considered a genetic test?**

The MCD test is not deemed as a genetic test. Therefore, you should disclose your MCD test results when having underwriting-triggering events<sup>^</sup>.

### **7.3 If I receive a negative MCD test result, do I need to declare if I have underwriting-triggering events<sup>^</sup> in the future?**

Customers need to disclose negative MCD results. Manulife's existing underwriting procedures will continue to apply.

### **7.4 If I receive a positive MCD test result and went for follow-up diagnostics with confirmation results, do I need to declare if I have underwriting-triggering events<sup>^</sup> in the future?**

Customers need to disclose both positive MCD results and the result of confirmatory diagnostic results (Positive or Negative) ; Manulife's existing underwriting procedures will continue to apply.

### **7.5 If I receive a positive MCD test result and did not go for follow-up diagnostics, do I need to declare if I have underwriting-triggering events<sup>^</sup> in the future ?**

Customers need to disclose their positive MCD test results. If the customers with positive MCD test results did not go for follow-up consultation, The request of underwriting-triggering events<sup>^</sup> are most likely to be rejected.

### **7.6 Could a positive result delay or impact a pending application?**

Any material health history must be declared before issuance of an application. Thus, customers are required to declare on a form F856 if the positive result is known when applications are still pending.

**References:**

- [1] Madar, S.; Amor, R.E.; Furman-Assaf, S.; Friedman, E. Innovative Approaches to Early Detection of Cancer-Transforming Screening for Breast, Lung, and Hard-to-Screen Cancers. *Cancers* 2025, 17, 1867. <https://doi.org/10.3390/cancers17111867>
- [2] Carbonell C, Hutchinson JM, Hilsden RJ, Yang H, Brenner DR. Blood-Based Multi-Cancer Early Detection Tests (MCEDs) as a Potential Approach to Address Current Gaps in Cancer Screening. *Cancer Control*. 2024 Jan-Dec;31:10732748241307360. doi: 10.1177/10732748241307360
- [3] Montena, J. (2024). Early cancer diagnosis: A crucial step toward better outcomes. *Journal of Cancer Diagnosis*, 2024(1), 1–5.
- [4] Data on file. Guardant Health, Inc. Sep, 2025.
- [5] Guardant Health. FDA Grants Breakthrough Device Designation to Guardant Health’s Multi-Cancer Detection (MCD) Test. Published June 3, 2025. <https://investors.guardanthealth.com/press-releases/press-releases/2025/FDA-Grants-Breakthrough-Device-Designation-to-Guardant-Healths-Shield-Multi-Cancer-Detection-MCD-Test/default.aspx>
- [6] He, et al, Abstract #10550. ASCO 2025

**Important Note: on Multi-Cancer Detection (MCD) Test by Guardant Health**

The Multi-Cancer Detection (“MCD”) test and related services are third-party medical screening services provided by Guardant Health Pte. Ltd. (“Guardant Health”) and its appointed service providers (“Service”). Manulife’s role is strictly limited to providing eligible customers with access to the Service and does not constitute medical advice, diagnosis, recommendation, or endorsement. Manulife and its intermediaries do not provide any medical or clinical services, medical advice or medical recommendations, and make no representation or warranty regarding the accuracy, availability, or results of the MCD test.

Codex Genetics Limited, as Guardant Health’s appointed distributor and service operator in Hong Kong (“Codex”), and selected medical providers are solely responsible for the end-to-end delivery of the Service. Manulife is not involved in, and accepts no responsibility for, the arrangement, provision, or outcomes of any medical services. The costs of any additional services shall be borne by the customers and shall be determined between the customers and Codex.

Customers should assess for themselves whether the MCD test is appropriate for their personal circumstances and consult qualified medical professionals (including medical professionals from select medical providers arranged by Codex as part of the delivery of the Service) before undergoing the tests.

The MCD test is not a diagnostic test and does not confirm the presence or absence of cancer. Test results may involve false positives or false negatives. Customers should consult qualified medical professionals (including medical professionals from select medical providers arranged by Codex as part of the delivery of the Service) for interpretation of results and advice on any further diagnostic testing or medical management.

Customers should note that MCD test results may impact new insurance underwriting, policy change applications, and claims assessment. Any information generated or disclosed in the course of the Services, including without limitation to MCD test results, shall not constitute actual, constructive, or deemed knowledge of Manulife and shall not affect Manulife’s right to contest any policies issued or to be issued, unless the information has been formally disclosed to Manulife. Customers are required to fully and truthfully disclose any MCD test

results and/or any related medical information during the new business underwriting, policy change applications and claims application processes where such information is requested, in accordance with applicable disclosure obligations.

Guardant Health and its appointed service providers (including Codex) are independent contractors and are not employees, agents, or servants of Manulife. Manulife shall not be responsible or liable for any services, diagnosis, advice, treatment, or other acts or omissions of any service providers.

The Service is subject to the terms and conditions of Guardant Health and its appointed service providers (including Codex), including those relating to availability, operational arrangements, and applicable medical, legal, and regulatory requirements.

To the fullest extent permitted by law, Manulife accepts no liability (whether in contract, tort, negligence, or otherwise) for any death, personal injury, loss, damage, cost, or expense arising from or in connection with the use of the MCD test, including matters relating to service quality, test results, or any medical advice provided by third parties.