

Detection of Prostate Cancer Through a Semen-Based Screening Test

TKS

x



**SWITCH
HEALTH**

Executive Summary

Problem

Scope:

67 Canadian men will be diagnosed with prostate cancer every day (1)

Stigma:

Many men find it invasive and embarrassing to take current prostate cancer diagnosis, causing for late diagnosis and preventable deaths (2)

Accuracy:

The status quo of diagnosing are inaccurate.

- PSA test ~25% accurate (3)
- Digital Rectal Exam ~ 28.6% accurate (4)

Solution

Diagnosing prostate cancer using the AMACR proteins in patient's semen specimen to improve disease diagnosis accuracy and conveniency.

- Patients will collect their semen specimen at home to make diagnosing more convenient.
- Patients should add RNAlater Solution to preserve semen specimen.
- Mail sample to a Switch Health clinic to receive quick results.

Impact

Scope:

Our test will make testing for prostate cancer easier for over 1.4 million patients who get diagnosed with it annually (5)

Stigma:

Patients will be able to privately get a prostate cancer diagnosis at home, promoting earlier diagnosis.

Accuracy:

Our prostate cancer test is almost 100% accurate which will decrease the 23% to 50% of patients misdiagnosed or overdiagnosed (6)

Prostate Cancer in Canada

Prostate Cancer is highly prevalent within Canada, accounting for many of the cancer related cases and deaths

1

Prostate cancer is the second most common cancer in males (2) and makes up 10% of Male Cancer deaths in Canada (1)

2

67 Prostate cancer cases are diagnosed everyday (4)

3

50% of testing inaccurately diagnoses the severity of the disease (3)

According to a study done by Cambridge University study which followed hundreds of men who were given a prostate cancer diagnosis, **half of the patients** were told they had a **less serious** cancer then there was in reality **highly** severe



(1,2, 3, 4)

The Status Quo often produces False Positives and Unwarranted Grief for patients

Further testing is covered by OHIP if the disease is suspected by the doctor (1). Thus not as many people get testing despite the sheer number of cases of cancer.

01

PSA TESTS

Price: \$100-300 **Accuracy:** 25%

PSA tests measure a substance produced by the prostate gland in the blood. However, they have a history of overdiagnosis and false positives, which can lead to unnecessary and potentially harmful procedures, such as a prostate biopsy, with various side effects. (2)

02

DIGITAL RECTAL EXAMS

Price: \$250+ **Accuracy:** 28.6%

Rectal exams involve the insertion of a finger into the rectum to feel for irregularities. This method can cause pain, tear the perianal skin, and lead to infection and **discomfort** for the patient. It is also an invasive and potentially embarrassing procedure. (3)

The Stigma of Prostate Cancer prevents men from getting tested and clogs space in the healthcare system

This develops in three main stages:

01

Men don't get tested frequently

Due to the stigma associated with the disease many men don't get tested for the cancer until it becomes a bigger problem. Studies have identified stigma leading to **poorer** outcomes and **unnecessary death** along with prostate cancer (1)

02

The cancer grows

When men don't get tested for the cancer, the cancer can **grow more** and further spread to other parts of the body.

03

Once the cancer reaches stage 4 there is a 28% success rate (2)

In many cases, waiting too long can conclude with prostate cancer stage IV spreading to multiple parts of the body

This leads to **space filled up** unnecessarily in the healthcare system and is one of the main reasons prostate cancer patients end up having to do **complicated procedures** and leading to **preventable death**.

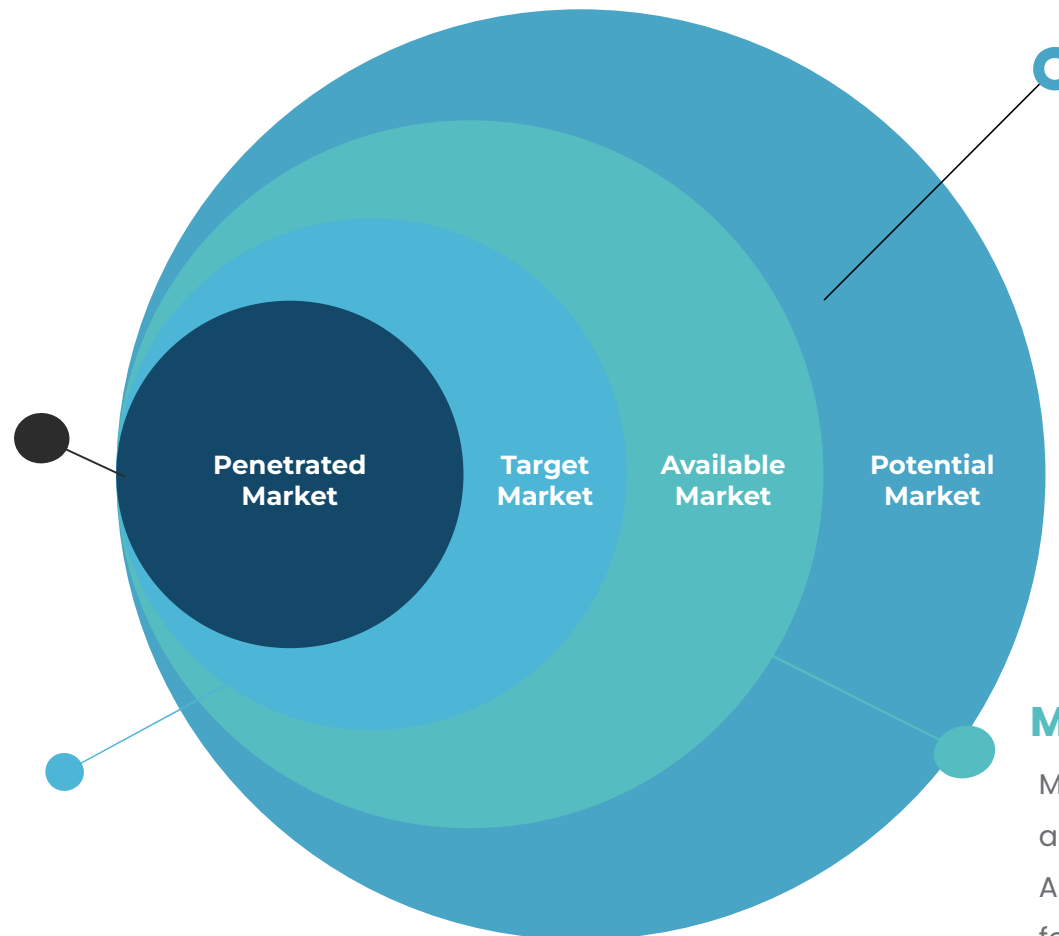
Our Target Market

African Canadian Men or men with family history of the disease

1 in 6 African Canadian men develop prostate cancer in their lifetime (2). Further it is common to get prostate cancer if it is in your **family history** (3)

Men with suspicion of the disease

In a study, **100%** of the patients agreed that it takes **too long** to get a testing appointment (4)



Men under 40

It is rare for men under the age of 40 to have prostate cancer (1)

Men 50+

Most prostate cancer cases show when men are in the age bracket of 50 and older (1). About 6 in 10 cases of prostate cancer are found in men older than 65 (5)

Gaps in the Current Industry that we will Address



Reliability

The current tests aren't **accurate** causing patients to need to take unnecessary treatments.



Accessibility

Wait times often prevent men from getting treatment (1). Ordering it online would let men to get treated earlier and prevent people from ending up in the hospital.



Convenience

The **stigma** associated with the disease prevents the patients from getting the treatment. Taking the test at home allows patients to have a more convenient diagnosis in their own home, **clearing up** space in the healthcare system.



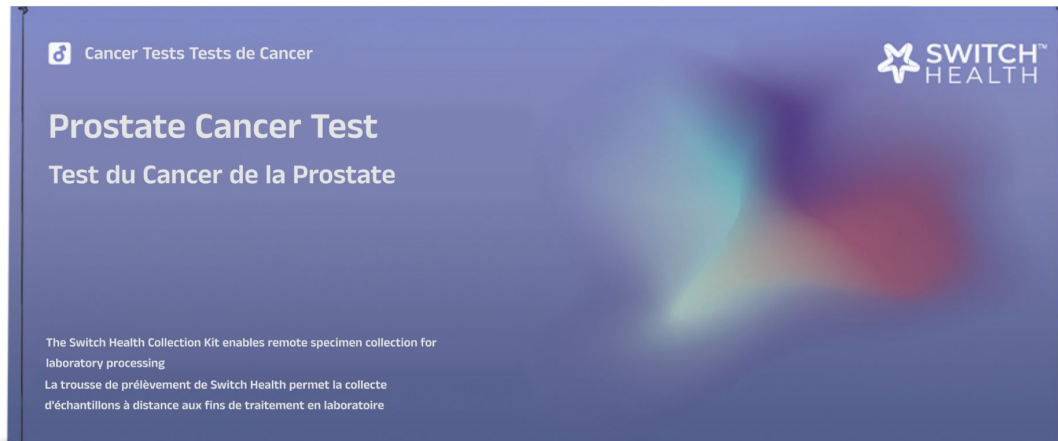
Comfort

Many patients find taking current prostate tests to be **uncomfortable** and **invasive**. Allowing patients to test at home would allow them to feel more comfortable.

Our Solution

At home semen biomarker test that uses the new technology of **AMACR protein semen sample analysis**.

- ★ This test should be used to screen patients to see if they have the disease or not
- ★ Once the patient is diagnosed with prostate cancer, they should further investigate the problem with the doctor.



Overview of how the test will work:

- 01 Delivered to Patient**
Patients order the test online
- 02 Patient follows kit procedure**
Full kit is further expanded on slide 9
- 03 Sent back to lab + testing is done through ELISA tech**
This is expanded on slide 11
- 04 Results given back online**
Shown on slide 13

Prostate Cancer Testing Kit

1

Order Testing Kit

The patient should order a Switch Health Prostate Cancer Test **every two years** after the age of 50 as they are most vulnerable (1). The testing kit should arrive at the patient's location in **5-8 business days**.

2

Collect Semen Specimen

The solution approximately only needs one ejaculation to collect the required amount (around 1.5 ml per ejaculation) (2). This must be done **without** the aid of other substances and all body parts in contact should be **clean**.

3

RNAlater

The patient should then **add 5 ml** of the RNAlater Solution to their 1 ml semen sample. Once the solution is added, the patient can carefully close the specimen container.

*Check slide number 10 to see how RNAlater solution works

4

Package Sample

The patient can then package their semen sample and RNAlater in the box it arrived in and **mail it to a Switch Health clinic**. They can then dispose of the other material including the RNAlater Solution and the instruction manual.



Preserving the Specimen Using RNAlater Solution

Problem

AMACR proteins deteriorate in semen within 3 hours (1)

Without a way to preserve the proteins, they would deteriorate before they could be shipped and tested at the clinic.

Solution

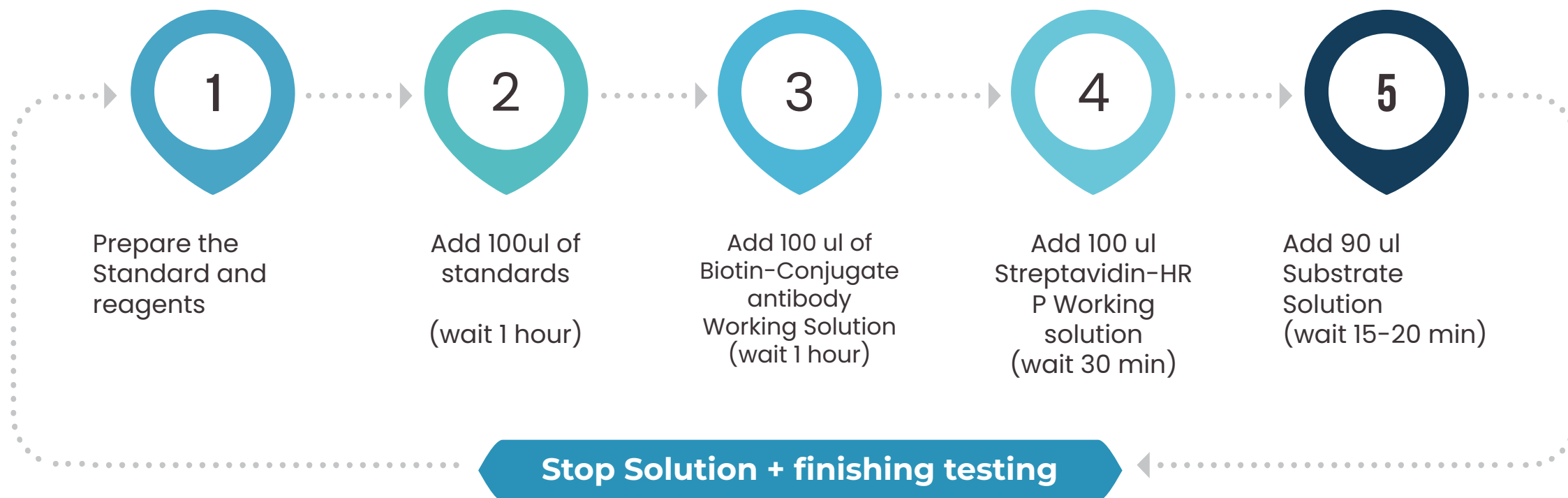
RNAlater Solution is an aqueous stabilizer that rapidly permeates specimens and minimizes the need to immediately process or freeze samples. (2)

Submerging the semen in a 1:5 ratio to the RNAlater solution can preserve the semen sample for 1 week at 25 °C and 1 month at 4 °C while keeping the integrity of the AMACR proteins (3)



Assay Procedure Summary

Using the ELISA Technology (1)



Total time: ~3 hours

[Click here for more on the procedure](#)

AMACR Protein



Alpha-methylacyl-CoA racemase (AMACR) is an enzyme that is involved in the metabolism of fatty acids found in the mitochondria and peroxisomes in the prostate carcinoma cells (1)

Why use Semen for AMACR?

AMACR is found in little concentrations in the blood and urine making it more harder to detect (2). Further, AMACR comes directly from the prostate gland to make the fluid found in semen making the protein concentrations higher (3)

How to use AMACR to Diagnose Prostate Cancer ?

AMACR levels are overexpressed in prostate cancer, thought to be due to the cancerous transformation of prostate cells. (4)

AMACR found in the patient's semen can distinguish cancer from healthy and benign prostate cells with high sensitivity and specificity (5)

AMACR proteins have a high expression in prostate cancer patients and have a low expression in normal tissue or in benign prostatic tissue (5)

AMACR in Semen Test Evidence

AMACR Levels Difference

Average AMACR levels in prostate cancer patients was 10-folds higher than in the controls of HGPIN patients. Due to the extensive difference in AMACR levels, the PCa patients were distinguished from the controls with 100% accuracy (6)

Detection of AMACR

Overexpression of AMACR detected in 82% of prostate cancer patients' semen sample. The 14% of the patients with undetected semen AMACR had small tumor volumes (7)

Greater Accuracy in Larger Tumors

Overexpression of AMACR detected in 96% of prostate cancer patients' semen sample with significant tumor volume (7)

Patients Results

3 Possible Results



Low Chance of Prostate Cancer

No presence of disease in sample (negative)



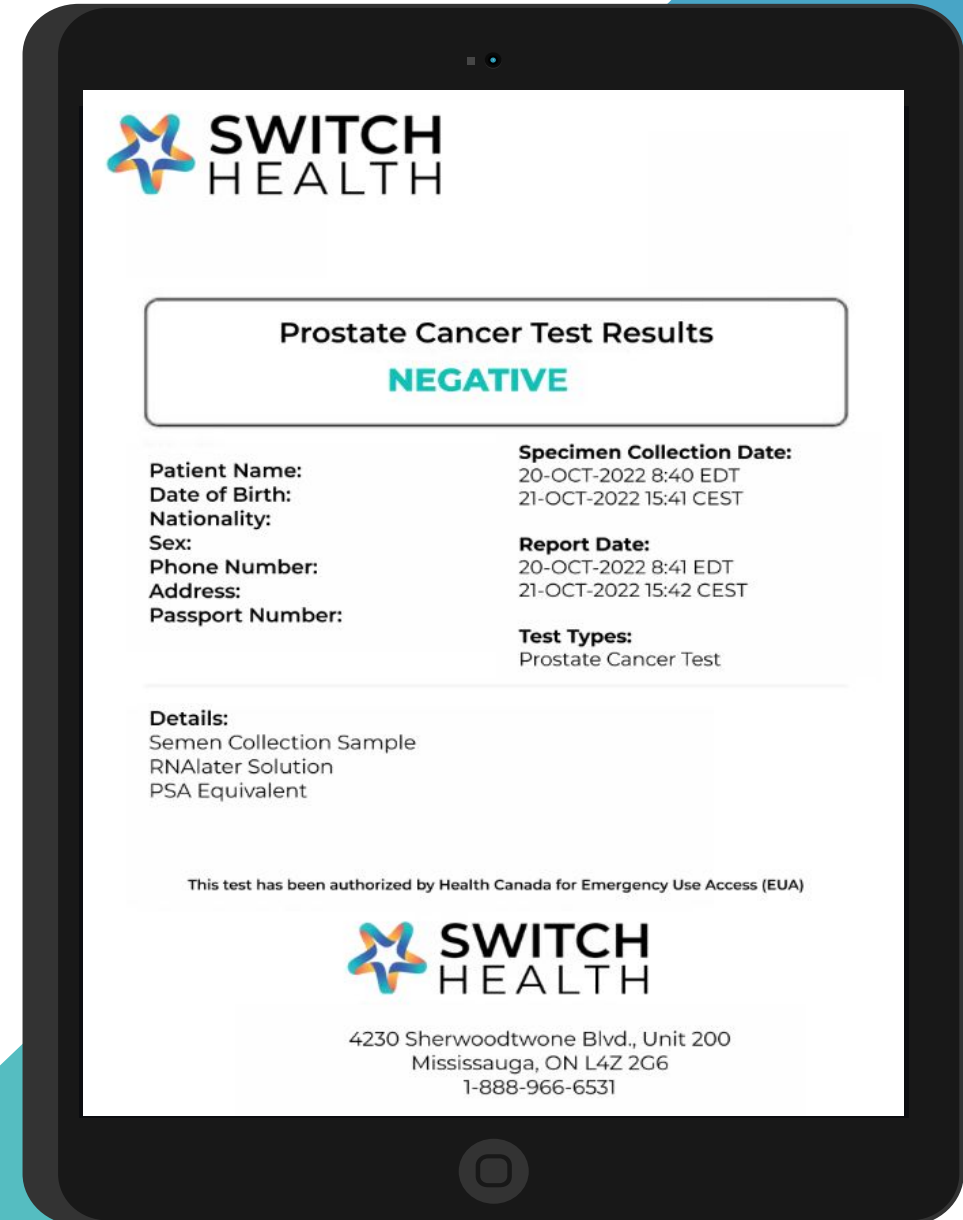
Mid Range Chance of Prostate Cancer

Some presence of disease in sample (inconclusive)



High Chance of Cancer

Large presence of disease in sample (positive)



Impact on Healthcare

Through the use of the Prostate Cancer Collection Kit

Early Detection

Prostate cancer is a leading cause of cancer deaths in men. To solve this, our test can accurately detect the cancer in early stages can save many lives (1)



Cost Effective

This test can reduce unnecessary biopsies and treatments, which can reduce costs for the healthcare system. Our test is \$45 which is 300% cheaper than the average \$100-300 spent on PSA Tests (2)



Improved Patient Outcomes

This test can help doctors make informed decisions about treatment options. This can dramatically reduce the average 23% to 50% of patients who get misdiagnosed or overdiagnosed. (3)



Increased Demand

Since this test is more accurate + convenient, more men will be screening for prostate cancer, leading to a larger demand for testing. The Prostate Cancer Test Market in North America is estimated to be 5.83 Billion by 2028. (4)



Different Components needed:

01

ELISA Testing Device

The technology needed to complete this procedure could be either outsourced or bought through different companies. If bought, the technology is around \$100 CAD per kit (1)

02

RNAlater

Within the kit there will be a small quantity of RNAlater added to preserve the semen solution during transportation. 500ml costs \$684.00 CAD (2)

03

Other kit components

Bottles:

- \$54/ Per 25 (3)
- \$93.00/Per 96 (4)

Total Cost

	Cost	Quantity	Cost per kit
ELISA Testing Kit	\$100	96	~ \$1.04
RNAlater	\$684	500ml	\$6.84
RNAlater bottle	\$93.00	96	~\$0.97
Semen Collection Bottle	\$54	25	\$5.82
Total Shipping costs (both ways)			\$32.98

Net Cost: \$47.95**Selling Cost: ~\$80**

Improved Patient Journey

After using the Switch Health Prostate Cancer Detection Kit



Order

The patient will go onto the Switch Health website to order their Prostate Cancer Testing Kit. The kit will arrive in their mailbox in 5-8 business days.



Testing

Using the manual and the products in the testing kit, the patient will collect their semen in the semen collection bottle. They will then add a drop of RNA later to their sample.



Shipping

The patient will package their semen sample in the box it arrived in and ship it to their nearest Switch Health clinic.



Diagnosis

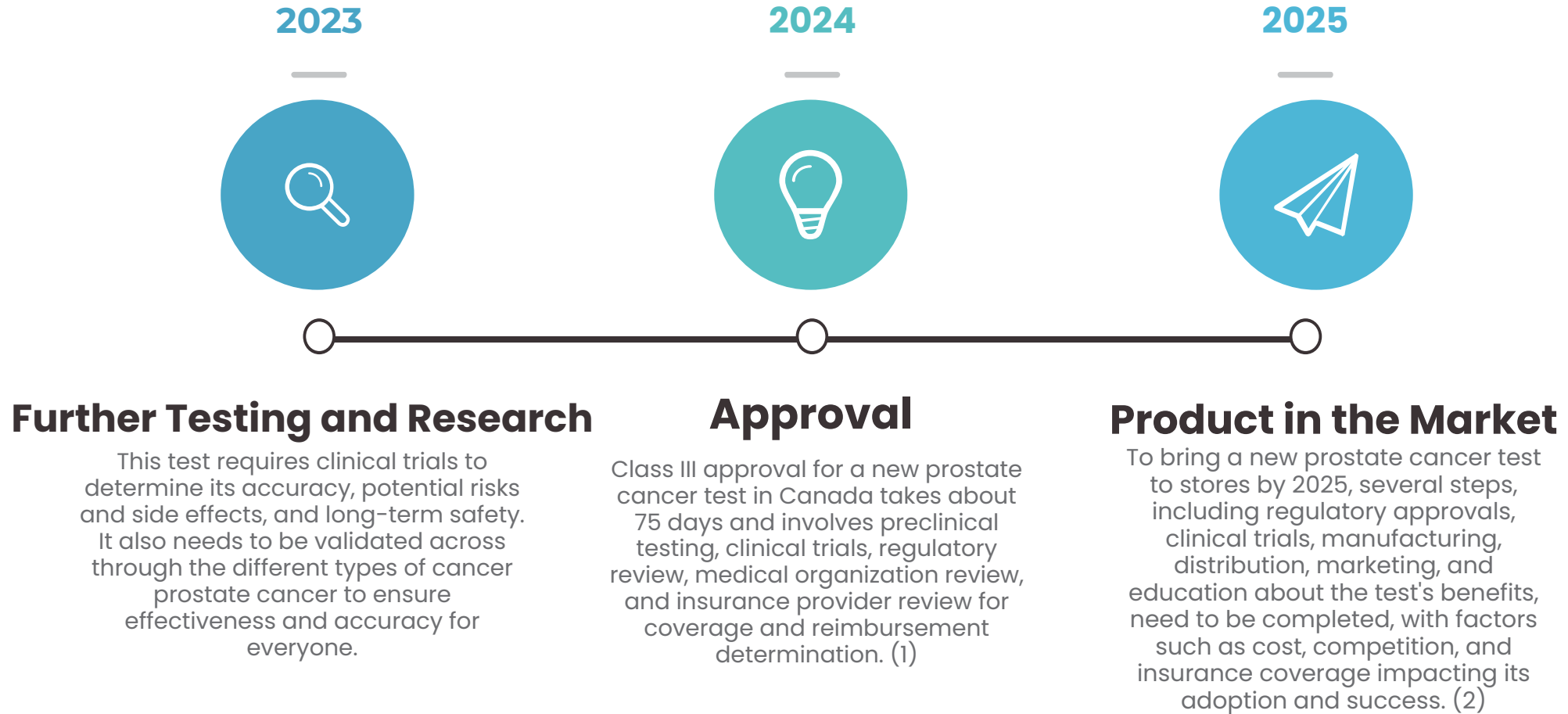
The Switch Health clinic will use the patient's semen sample to diagnose them for prostate cancer. The clinic will post their results on the patient's Switch Health account within 5 days of receiving the sample.



Treatment

If the patient tests positive for prostate cancer, they will need to book an appointment with a prostate cancer clinic. They will show their Switch Health diagnosis and begin their treatment.

Further testing, Approval and Bringing this Test to the Market



A Future with Convenience, Accuracy and Shorter Hospital Wait Times



Accurate Diagnosis

Although new, AMACR is much more accurate than the status quo being PSA and digital rectal exams and can be used to accurately diagnose even when the tumor is small (1)



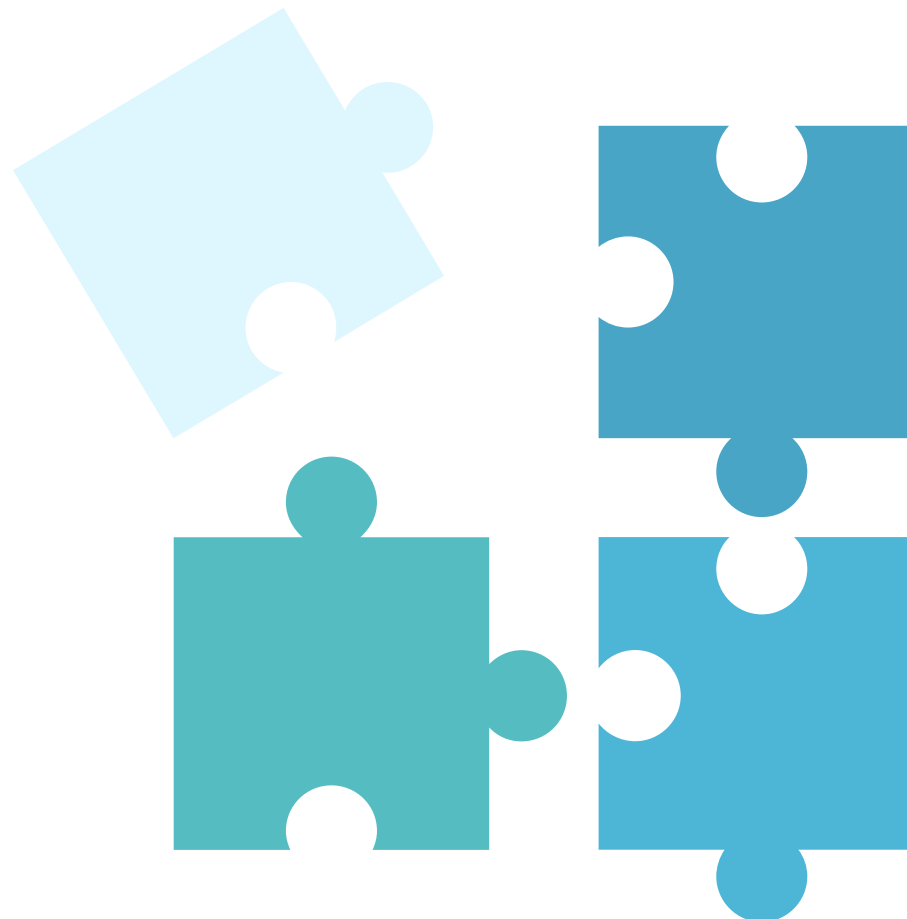
Convenience

Men can conveniently and quickly test themselves for prostate cancer from the comfort of their own homes.



Clearing up Space in Hospitals

Once diagnosed early, prostate cancer treatments work much better. Treatments like radiosurgery treatment take less than a week (2) meaning that less patients will have to go through long treatments such as chemotherapy



Gaps and Assumptions

Gaps:

Whether OHIP or insurances will cover the product

Further testings on AMACR need to be done

Future studies are still needed to evaluate using AMACR as a biomarker on a large scale population for the screening and to understand how the results relate to different clinical stages of prostate cancer.

Causes for overexpression of AMACR protein

Although AMACR proteins are overexpressed in prostate cancer, the reasons behind it is still unknown and in research. Future testings should be done to find the causes of the overexpression of the AMACR protein in CaP patients.

Assumptions:

People will take this test every 2 years after age 45

That RNAlater will work on semen

Most times, RNAlater is used to preserve tissue and biopsy samples. We are assuming that the RNAlater will still work on semen which is a liquid biopsy.

People are comfortable using semen to test

Our PCa semen test is a less invasive diagnosis method compared to other PCa testings like the Digital Rectal Exam. However, some patients might still feel a little uncomfortable to collect and send their semen sample to the Switch Health Clinic.



Expert Opinions

Lucy Manahi 
Intern at Shiok Meats



"The Switch Health at home semen biomarker test will revolutionise the diagnosis and further treatment of prostate cancer. Its accessibility, ease of sampling, and straightforward results may encourage more individuals who are suspected, or predisposed, to have prostate cancer to conduct a test over current screening methods. The kit's potential impacts on the patient and the healthcare system could be immense, and pave the way for similar testing methods to be utilised for other forms of cancers or genetic diseases."

Malaika Kapur 
Associate Director of Global Programs at
Creative Destruction Lab



"The idea for at-home testing for prostate cancer is unique, given that this type of cancer is one of the leading causes of male cancer deaths. The convenience, ease and accessibility of such a test leading to early cancer diagnosis and treatment could be revolutionary, especially in more remote and developing regions of the world with limited healthcare access."

George Engelmyer 
Founder of Myodenovo



"In particular, given the prevalence and mortality associated with prostate cancer, the advent of technologies capable of earlier and more robust detection would clearly be game changing. Of note, given the sensitivities around current prostate screening methods, I anticipate that an at-home sample collection option would be readily adopted by clinicians and patients alike. Overall, this new diagnostic technology shows promise as a means of facilitating early and accurate diagnosis of prostate cancer and thereby saving lives as well as healthcare burden associated with less sensitive detection approaches and concomitant morbidity and mortality."

Yan Fossat 
Vice President, Klick Labs



"This is a superb initiative. Men's health, specifically prostate screening is a challenging area suffering from low specificity tests and high stigma. Patients are often reluctant to go to a lab and get tested. A better sensitivity test, taken at home, is a massive improvement and would undoubtedly save lives. I hope this becomes a reality."

Thank you!

We are extremely grateful for this opportunity

The experience of creating and designing a new test to help improve the patient outcomes was both intriguing and exciting. We are so grateful for this opportunity to partner up with a big company such as Switch Health and help create a difference in the world of biomarker tests. We believe that once this test comes into market, it can both help patients test in a convenient and have less stress during the testing process and reduce the strain in the healthcare system

Anya Sharma



Ami Shah



Jessica Torkos



Appendix



Our kit + all relevant information

Description on all of the



Timeline

Full implementation plan



Total Cost

Details on the total cost per kit and the net profit for the company



ELISA TECHNOLOGY

Full process of how the process works + what the results are