



ADVANCE SENTRY *NP* Screen™

a d v a n c e s e n t r y

The highest accuracy, simple, non-invasive, and painless early detection plan for nasopharyngeal carcinoma

About Us

Advance Sentry Corporation is a Canadian Company specializing in viral genetic-based diagnostic technology. Our mission is to safeguard the health and well-being of patients through early detection of viral-related cancers at the onset of tumour transformation while improve their treatment response, and post treatment conditions.



- NP Screen - the first product in the diagnostic series; is designed for the screening and detection of Nasopharyngeal Carcinoma

- FDA approved Class II medical devices

- The ONLY FDA approved, direct, ambulatory, non-invasive, early detection method currently available in the market

- Over 99% accuracy

- Realize extremely early detection of nasopharyngeal carcinoma

- Over 4000 clinical trials have been conducted in Canada and Hong Kong

- Recognized by the World Health Organization (WHO)

Founding Scientist



Dr. Raymond Ng

Dr. Raymond Ng led the medical team throughout the entire R&D process, including clinical trial design, planning, and regulatory approval stages. He received his MD degree in 1988 and became a Fellow in Otolaryngology – Head and Neck Surgery of the Royal College of Physicians and Surgeons of Canada in 1993. Dr. Ng has over 30 years of surgical experience in this field and extensive medical expertise in treating high-risk patients with various ENT-related conditions. He was involved in the original EBV DNA research in 1999 and developed the concept of the trans-oral brushing biopsy method for the nasopharynx. He also designed, planned, and conducted the clinical trials for NP Screen™. Dr. Ng is a prolific scientific researcher and investigator who has published articles on the use of EBV DNA measurement for detecting EBV-associated NPC in renowned scientific journals, and has presented his findings in the U.S., Canada, and Hong Kong. Dr. Raymond Ng graduated from the University of Toronto Medical School and obtained his PhD in Biochemistry and Oncology from the University of Toronto's School of Graduate Studies.



Dr. John Phillips is responsible for overseeing various aspects of product design and development, as well as quality assurance throughout all regulatory submission processes. He received his MD degree in 1980 and became a Fellow in Plastic and Craniofacial Reconstructive Surgery of the Royal College of Physicians and Surgeons of Canada in 1985. Dr. Phillips is a qualified plastic and craniofacial surgeon with over 30 years of surgical experience. He has an extensive publication record, including 75 papers presented at international meetings, 61 peer-reviewed articles, and 19 book chapters. He also has significant experience with regulatory processes related to launching medical devices in North America. He previously served as the Medical Director of the Craniofacial Program at the Hospital for Sick Children and is currently a surgeon at The Hospital for Sick Children. Dr. John Phillips graduated from the University of Toronto Medical School and completed his fellowship in Plastic Surgery. He further sub-specialized in Craniofacial Surgery and previously served as a facial trauma surgeon at Sunnybrook Medical Centre in Toronto.



Dr. John Phillips

FDA Fully Approves

Cancer Facts

- Cancer is the 2nd most common cause of death worldwide, following cardiovascular disease
- Approximately 10 million deaths per year globally

Existing Diagnostic

- Invasive & not sensitive or accurate
- Requires a medical practitioner
- Triggered by the appearance of symptoms
- Early detection for mass population is difficult to achieve — a major unmet need

NP Screen Diagnostic

- Approved in the U.S. and commercially available in the U.S., Canada and Hong Kong
- Fully FDA-approved in 2020
- Supports home testing
- The only direct cancer genetic screening test on the market
- The only non-invasive and ambulatory test available
- The only test of its kind approved by the FDA



May 11, 2020



Advance Sentry Corporation
Leo Chui
Director of Operations
7155 Woodbine Ave., Suite 202
Markham, ON
Canada

Re: DEN190031
Trade/Device Name: NP Screen
Regulation Number: 21 CFR 866.3236
Regulation Name: Device to detect or measure nucleic acid from viruses associated with head and neck cancers
Regulatory Class: Class II
Product Code: OJY
Received: June 24, 2019

Dear Leo Chui:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the NP Screen, a prescription device with the following indications for use:

NP Screen is a semi-quantitative in vitro diagnostic test that uses real-time PCR to determine the level of Epstein-Barr Virus Nuclear Antigen-1 (EBNA-1) DNA in nasopharyngeal cellular specimens collected using the NP Screen Trans-Oral Nasopharyngeal Brush. The test is intended for use in conjunction with endoscopy and other clinical information to assess the likelihood that EBV-associated nasopharyngeal carcinoma (NPC) is present. The test is indicated for use in adults of Chinese descent with signs and symptoms of nasopharyngeal carcinoma. The NP Screen assay is a single-site assay performed at Primex Clinical Laboratories, Inc.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the NP Screen, and substantially equivalent devices of this generic type, into Class II under the generic name device to detect or measure nucleic acid from viruses associated with head and neck cancers.

FDA identifies this generic type of device as:

Device to detect or measure nucleic acid from viruses associated with head and neck cancers. A device to detect or measure nucleic acid from viruses associated with head and neck cancers is an in vitro diagnostic test for prescription use in the detection of viral nucleic acid in nasopharyngeal or

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

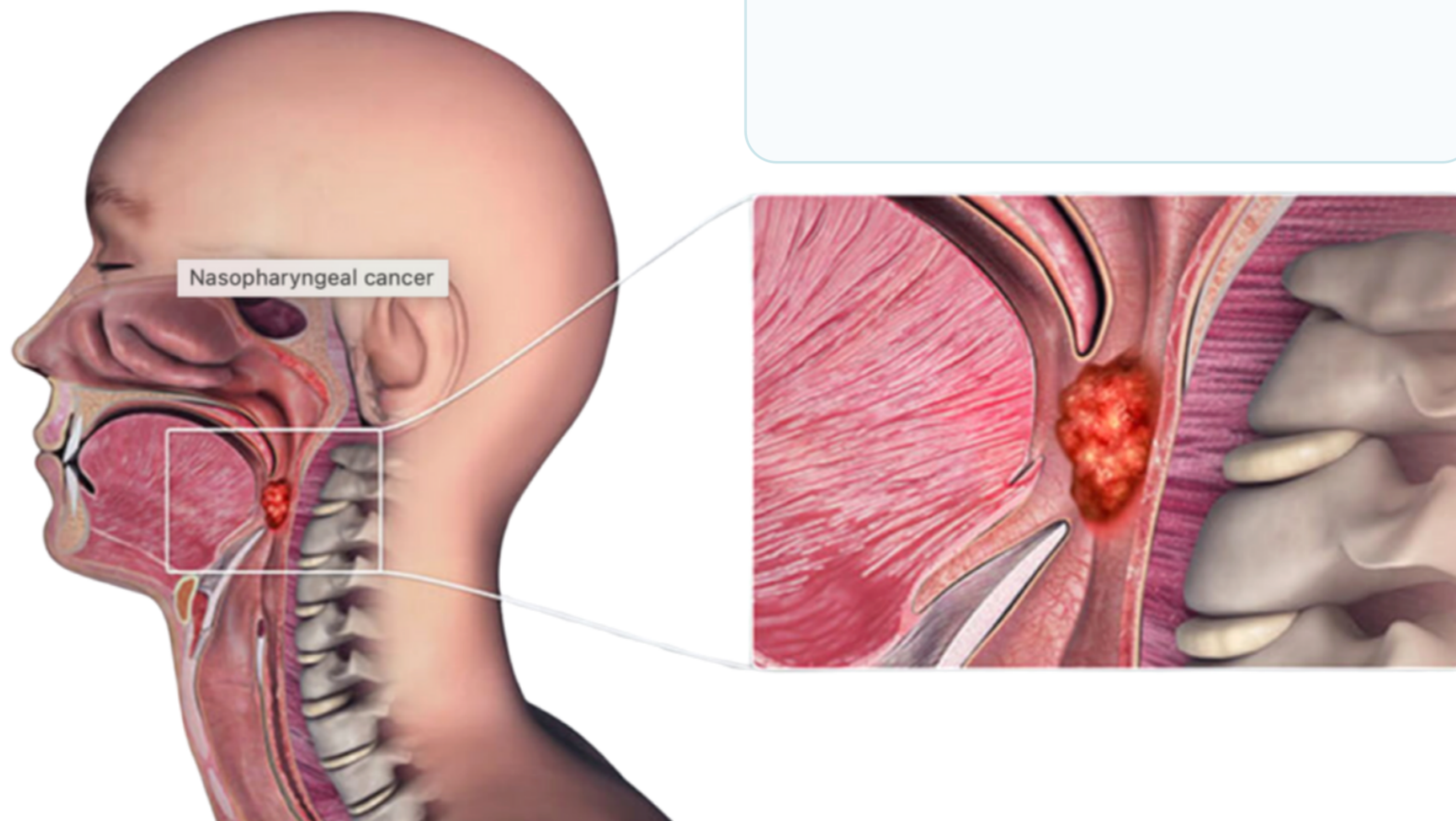
Nasopharyngeal Cancer

- Cancer of the Nasopharynx(Located at the center of the skull)
- Top 10 cancer in China; Top 5 in Southern China(accounts for ~80% of global cases)
- Common age range:15-90 years;peak incidence:35-55 years
- Male-to-female ratio:3:1 Most cases diagnosed at late Stage III-IV
- Treatment is complex, painful, and costly
- Survival rate: <50% when diagnosed late

High-risk Population

- Most common in Southern China, Southeast Asia,the Arctic, North Africa, and the Middle East
- Approximately 1 billion people globally are at risk

WARNING

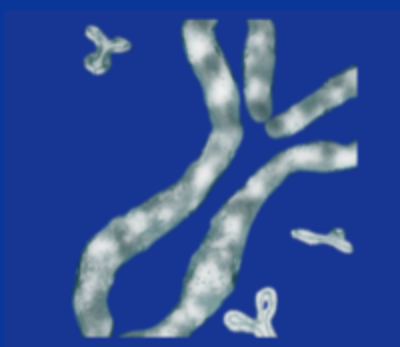


Others

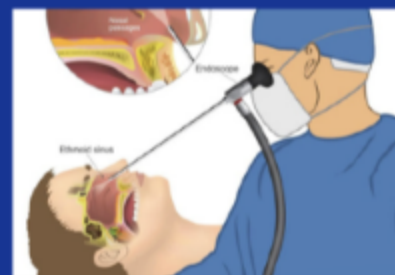
Blood Test (Serology & Plasma EBV DNA) & Biopsy

- Difficult accessibility -lab based testing
- Painful procedures
- Needle and biopsy - highly invasive
- 11-75% accuracy
- No early detection

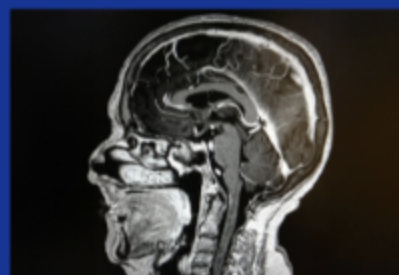
China
Serology
Plasma Indirect
Test



international
Standard Practice



Endoscopy



MRI



Biopsy



CT scan

Our Solution

The NP Screen Solution

- Fast, painless, and ambulatory - no anesthetics required.
- Eliminates human subjectivity in clinical decision-making
- No complications
- Preserves DNA at room temperature
- Provides rapid results
- Only available test capable of effectively detecting local recurrence
- Over 99% accuracy



Technical Comparison

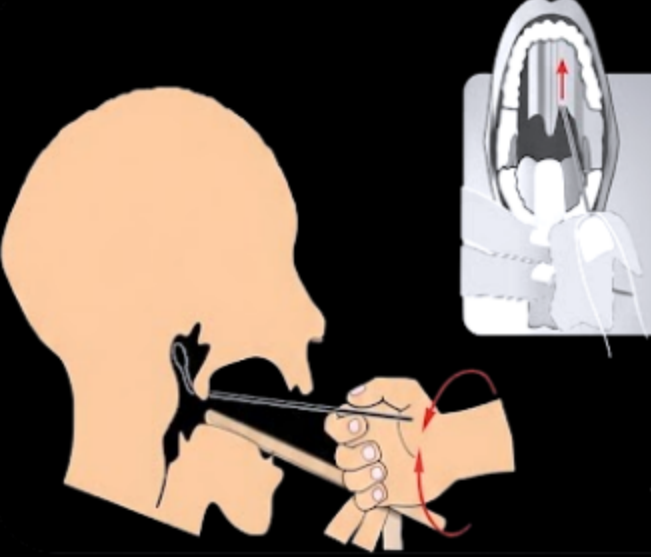
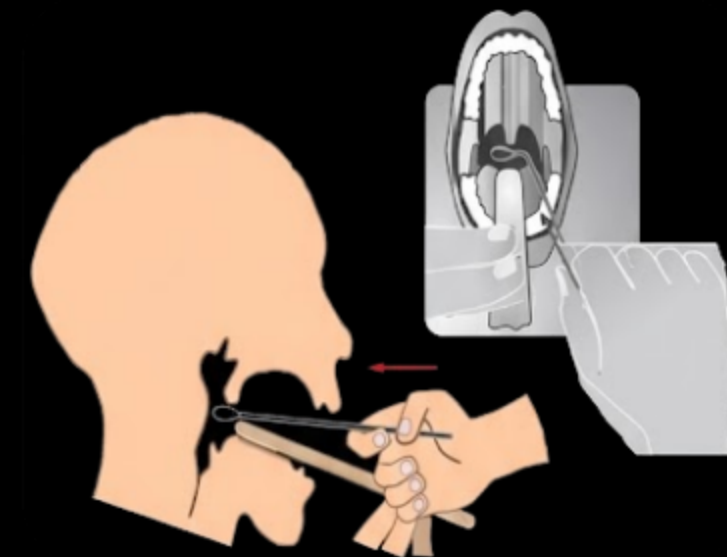
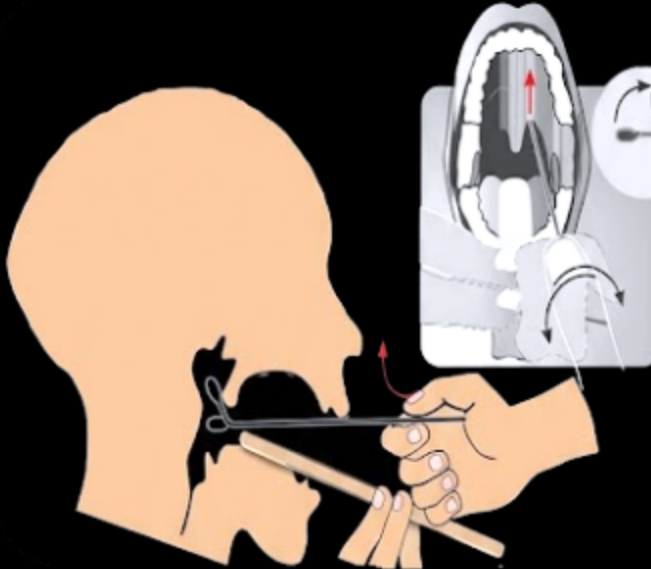
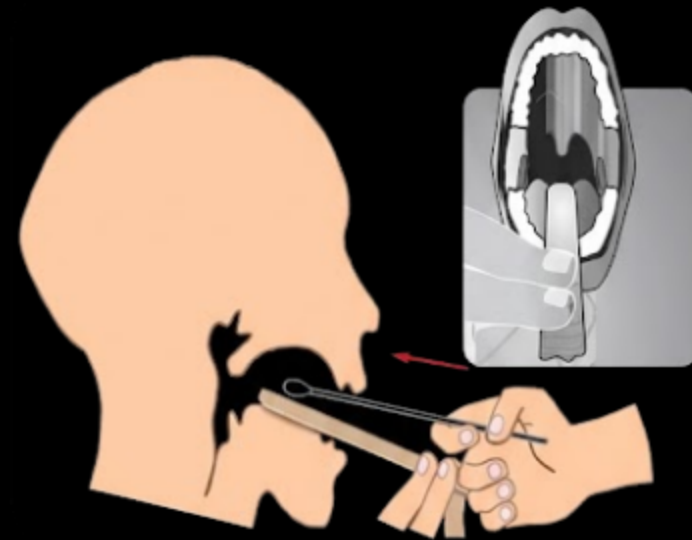
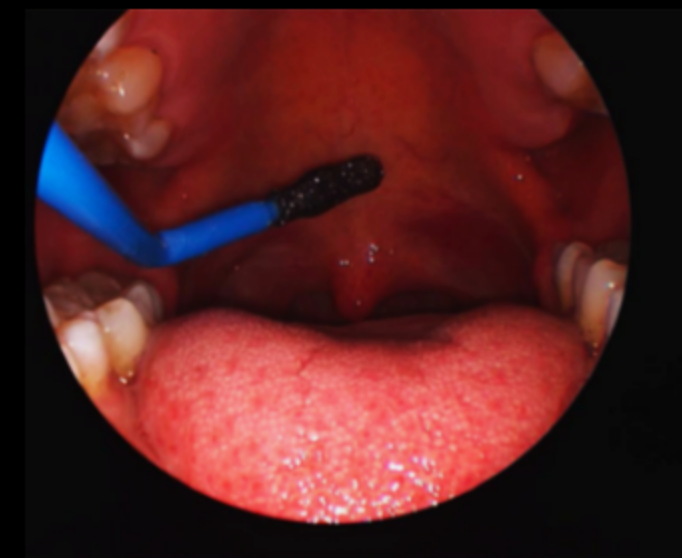
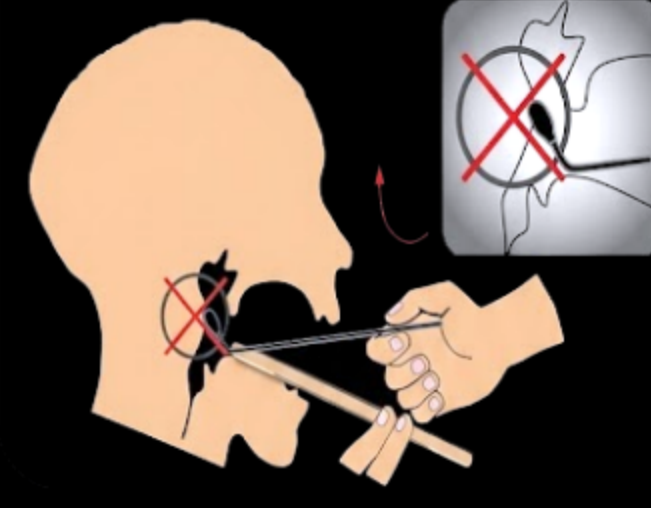
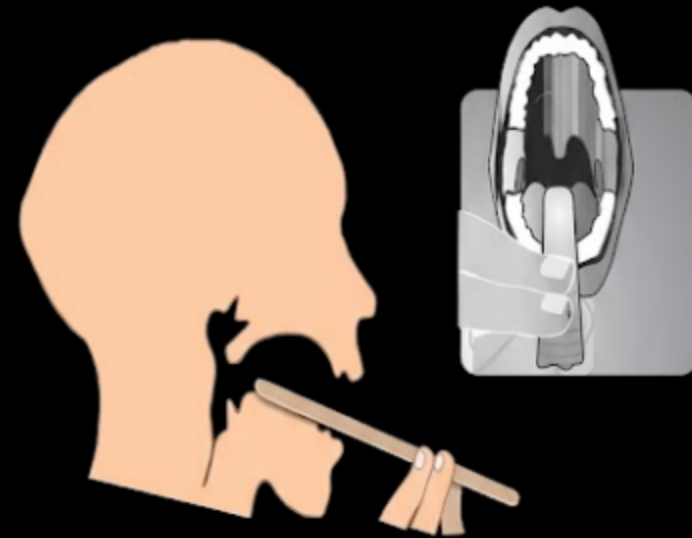
Global cancer screening market
The global cancer screening market is estimated to be
between \$123-133 billion in 2018

Technical comparison				
Accessibility	Endoscopy, biopsy, and MRI	Antibodies and serology	Blood/plasma EBV DNA	NP Screen
Skill Requirements	very high	moderate	moderate	low
operator	physician	Physicians, nurses, or blood	Physicians, nurses, or blood extractors	Physicians, nurses, or clinical assistants
location	operating room	laboratory	laboratory	office
traumatic	Highly traumatic - cellular	Trauma - Blood	Trauma - Blood	Brush inspection - non-invasive
pain	tall	moderate	moderate	none
Mark positioning	direct	indirect	indirect	direct
early detection	Endoscopy, biopsy, and MRI	Antibodies and serology	Blood/plasma EBV DNA	NP Screen
sensitivity	< 30%	<20%	??	98%
specificity	< 30%	<20%	??	99%
Pseudo negative	moderate	very high	very high	0%
False positive	low	tall	very high	0.83%
Post detection	Endoscopy, biopsy, and MRI	Antibodies and serology	Blood/plasma EBV DNA	NP Screen
sensitivity	93%	83%	75%	99%
specificity	93%	85%	87%	99%
Pseudo negative	moderate	Medium to high	Medium to high	very low
False positive	low	tall	low	very low
Inferences per 2000 test errors	N/A	32	194	2

Comparison Of Existing Products In The Market

Comparison between plasma testing and NPScreen			
indicator	PLASMA EBV DNA		NP Screen
Sample collection method	- Blood collection needle - Highly invasive - Risk of cross infection caused by needle contamination		- Oral brush examination - Painless, non-invasive - No risk of cross infection (disposable brush testing equipment)
Sample source	Venous blood (fragmented EBV DNA released into the bloodstream by tumor necrosis or larger tumors)		Nasopharyngeal epithelial cells (1-2000 fresh cells with complete DNA directly taken from the primary tumor site)
Sample storage	4 ° C refrigeration -Long term storage at 20 ° C and -80 ° C - DNA degrades over time		- Store at room temperature in proprietary DNA preservation solution (short-term and long-term) - A very stable storage method
Sample processing	Within the same day (based on the short half-life of DNA)		Can be processed within 4-6 weeks - samples can be stored for more than 4 weeks, up to 7 years, with only trace DNA degradation
Laboratory analysis	Short DNA fragments - from a single region		Longer sequences - from complete DNA and multiple regions
indicator	PLASMA EBV DNA - First round	PLASMA EBV DNA - Second round	NP Screen only requires one round of testing
Sensitivity	97.14%	97.14%	100.00%
Specificity	94.65%	98.63%	99.59%
Positive predictive value	3.06%	11.00%	86.27%
Negative predictive value	99.99%	99.99%	100.00%
Early screening potential	Low indirect sampling - DNA fragments in blood	Low indirect sampling - DNA fragments in blood	Very high - direct sampling of early tumors at the primary site - nasopharynx

Screening Process

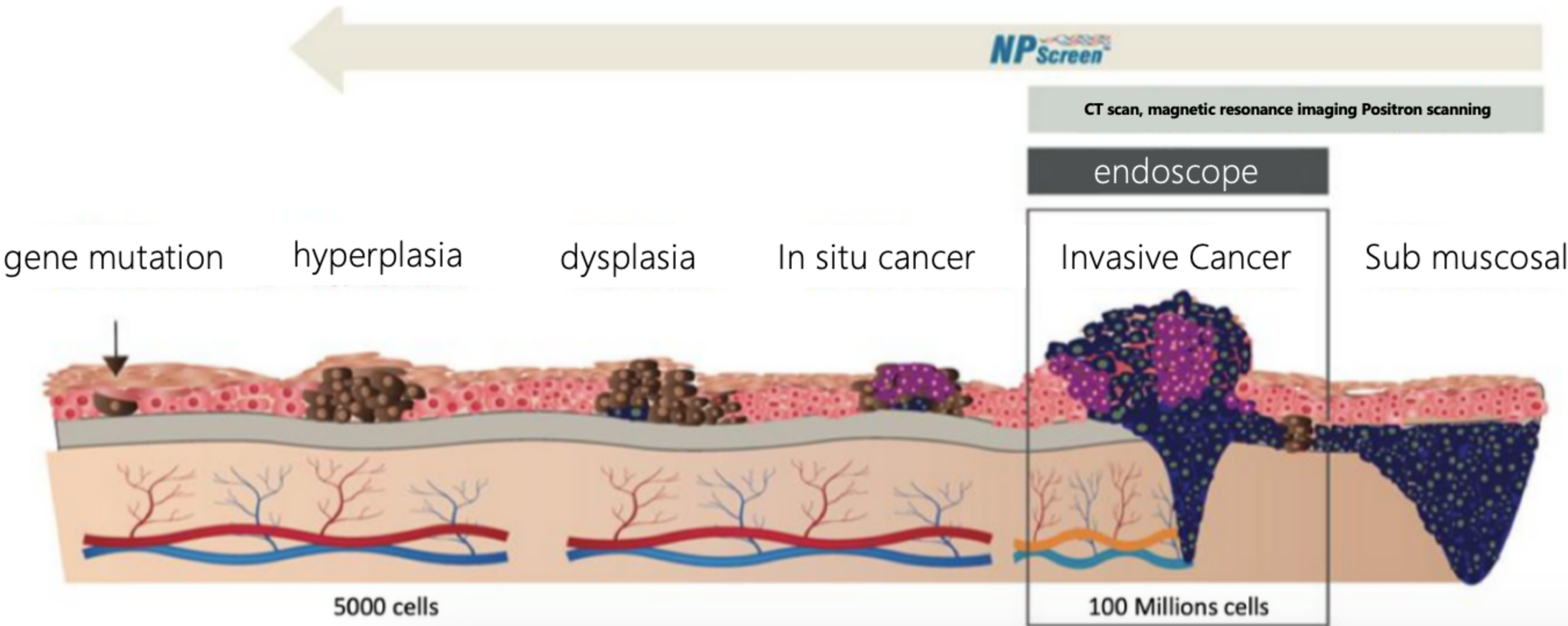


Detection Process

Transformation process of NPC and detection thresholds of various diagnostic methods.

NP Screen™ has the potential to detect nasopharyngeal carcinoma (NPC) at the earliest onset of tumor transformation, requiring only approximately 500–2,000 cells for EBV DNA testing.

In contrast, conventional NPC diagnostic methods—such as endoscopy, MRI, CT, and PET scans—can only detect NPC at later stages, when cancerous cells have accumulated to millions.



Core technology

Brush or sample collection device

DNA preservation solution

Primer and probe set and PCR protocol

Collection of cellular samples directly

Room temperature sample handling and storage

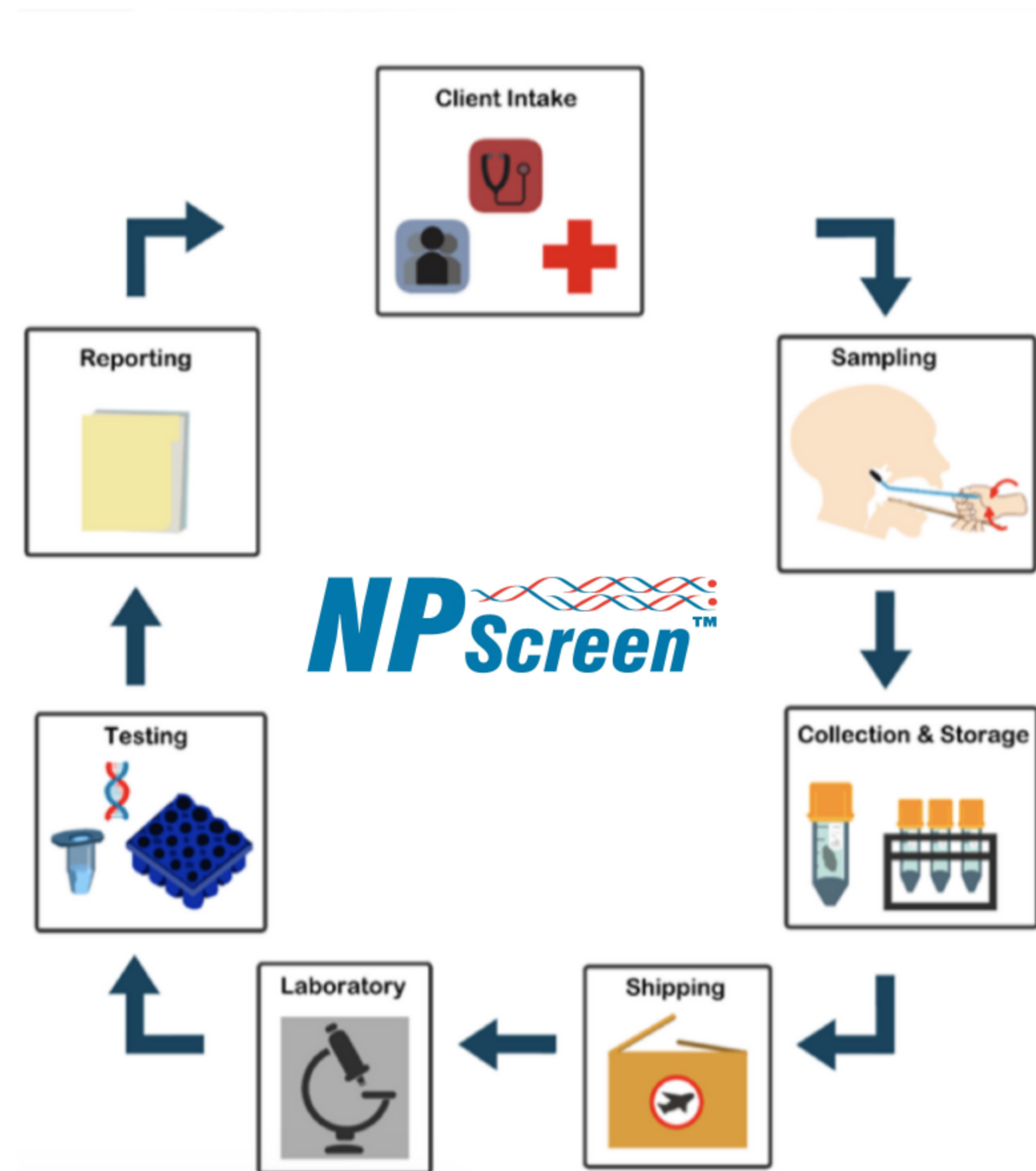
Essential features

Direct Non-invasive
Ambulatory
Easy to use

Enables large-scale commercialisation

Accurate
Reliable
Consistent

Performance

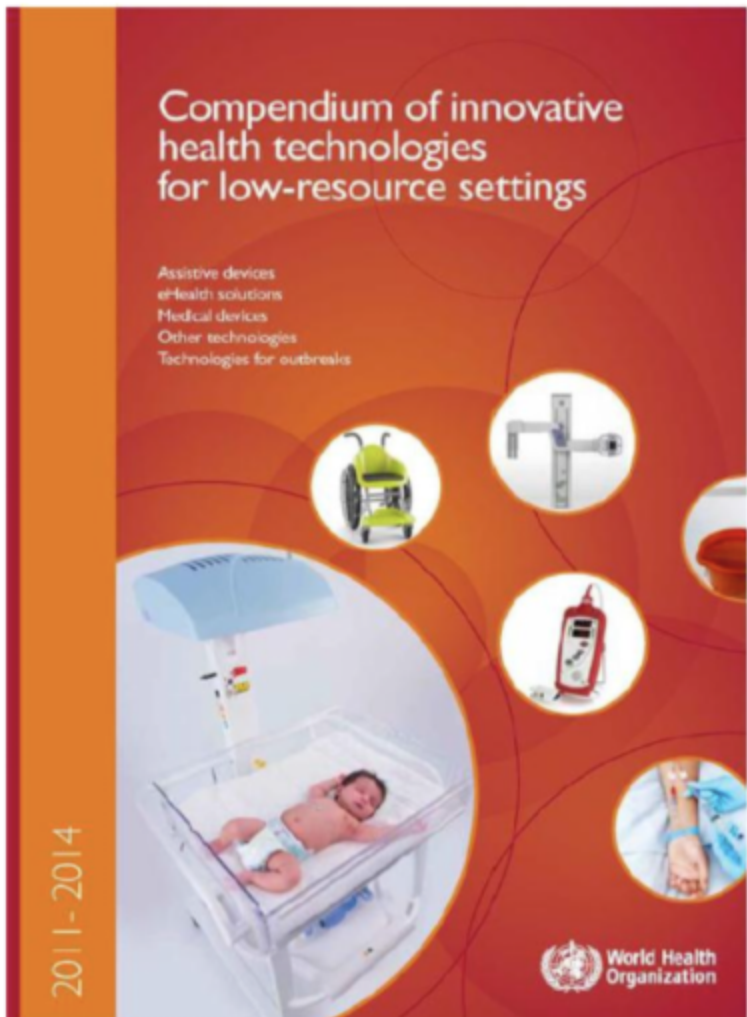


Sensitivity	Specificity
98.0% [95%CI 89.3-100%]	99.1 % [95%CI 98.4-99.6%]

Positive Predictive Value	Negative Predictive Value
84.48	99.90%

Using quantitative and semi-quantitative real-time PCR, the amount of EBV DNA in the sample is measured, and a validated algorithm is applied to determine the risk of nasopharyngeal carcinoma (NPC) with a high degree of diagnostic accuracy.

References – WHO Compendium



Trans-oral nasopharynx brush biopsy-quantitative PCR for Epstein Barr virus DNA detection

Country of origin | United States of America

Health problem addressed

Nasopharyngeal cancer (NPC) affects over 80,000 individuals a year globally with the vast majority in southern China, Southeast Asia, Africa, and the Middle East/North Africa, most living in rural, less developed areas. NPC originates in obscure location of the head, lacks early signs and symptoms and often present to medical care very late with advanced prognosis. Currently there is no suitable simple, inexpensive, non-invasive, field utilisable screening test for early detection.

Product description

The technology is a non-invasive early stage nasopharynx cancer (NPC) screening test that can be used in rural locations by trained healthcare workers. A sample of NP epithelial cells is collected perfectly by means of a swab of the upper throat area. The sample can then be preserved in room temperature and is analyzed for the presence of Epstein Barr virus DNA in the nuclear region of the cells. This technology is presently the only direct NPC screening test that is 98% accurate, specific in correlation with the diagnosis and able to identify NPC at its earliest stages, when treatment is most effective. Samples are easily collected and stored in remote communities, without a need for a visit to a medical specialist in a major city.

Developer's claims of product benefits

Currently, non-specific blood tests to detect the presence of antibodies to EBV or EBV DNA in the blood are used. These tests simply measure the levels of a tumor marker indirectly, have much lower sensitivity and specificity and only detect cancer when tumor is large and therefore has no value for early stage cancer detection. In addition, these methods require specific sample preservation methods such as refrigeration that is not practical for testing of patients from rural areas.

Future work and challenges

Cancer screening is an important public health measure. A major challenge to screening efforts is public education and awareness about the importance of screening, especially in the absence of obvious symptoms. Education and awareness are crucial to success and provides a strategic platform for Oral Cancer (OPV) screening, which has a higher at-risk population. If the test is made available to a broader user group, it can be a model for simple, accurate, testing for widely triggered cancers of the oral cavity of susceptible individuals in developing regions.

Regulatory status

The amputary early stage screening test for nasopharyngeal cancer has been approved for sale under CLIA/IDEA in the USA, based on its 98% accuracy rate for detection of oral cancer (less than 1% false positive or negative). The test provides a direct measurement of whether or not epithelial cells from the nasopharynx have been infected with EBV and certain EBV DNA, indicating that the cells have been malignantly transformed. The DNA-based genetic assay is sold as a Laboratory Developed Test under CLIA, Clinical Laboratory Improvement Amendments (CLIA) in USA, Canada and Hong Kong. Additionally, a Pre-Submission for Market Approval has already been filed with the FDA in the USA. This was submitted in order to establish further precedence for the vally-triggered cancer detection platform, so that it can be made available for other diseases.

Suitability for low-resource settings

The circumplex tool, Polyesters and rural North African villages are at high-risk for nasopharyngeal cancer. A large population has inaccessibility to medical resources and a steadily growing cancer incidence makes healthcare delivery impossible for these patients. This technology would allow early stage cancer screenings for patients in these remote locations at a fraction of health care cost and minimal dependency on specialists and health care infrastructure. The test used in a number of primary care settings, both in Canada and Hong Kong. In addition, it meets standards for training health-care workers, sampling methodology, and test procedures have been worked out for community hospital settings and certain offices in these locations, in anticipation of staging into more low resource settings. The sample preservation technology is robust, allowing storage for up to 12 months at 4°C.

Use and maintenance

User intended to be used by a physician, technician, nurse or EBV specialist.

Training: Persons required to use the tool will already have been trained on how to take samples.

Environment of use

Setting: Designed for use in health care facility at all levels of care.

Product specifications

Labware: Single use

Staff: Low, 10 minutes

Year of Commercialisation: 2010

Currently sold in: USA, Canada, Hong Kong

Retail Price (USD): 300

Price of Consumables (USD):

Contact: Lisa Chai | Email: lisa.chai@opcr.com | Telephone: +1 610-807-1116 | Website: www.opcr.com

http://www.who.int/medicines/

References – Paper published on JNCI National Cancer Institute Journal

COMMENTARY

Current State of PCR-Based Epstein-Barr Virus DNA Testing for Nasopharyngeal Cancer

Kelly Y. Kim, Quynh-Thu Le, Sue S. Yom, Benjamin A. Pinsky, Scott V. Bratman, Raymond H. W. Ng, Haja S. El Mubarak, K. C. Allen Chan, Miriam Sander, Barbara A. Conley

Abstract

Clinical studies have shown plasma Epstein-Barr virus (EBV) DNA level to be an independent prognostic biomarker for nasopharyngeal carcinoma (NPC). However, the proportion of NPC patients whose tumors are associated with EBV vary with geographic location, and there are a variety of assays for plasma EBV. To develop the level of evidence needed to demonstrate the clinical utility of plasma EBV DNA detection for NPC patients and encourage widespread adoption of this assay after test in clinical laboratories, validated harmonized assays are needed. In 2015, the National Cancer Institute (NCI) convened a Workshop on Harmonization of EBV Testing for Nasopharyngeal Cancer, where experts in head and neck oncology and laboratory medicine addressed the limitations of currently available polymerase chain reaction-based EBV DNA quantitation assays and discussed strategies for advancing the development of harmonized EBV DNA assays and their appropriate clinical use. This article presents the key recommendations to direct future efforts in assay harmonization and validation.

Epstein-Barr virus (EBV) is well known as the cause of infectious mononucleosis, but it is also linked to various such as Burkitt lymphoma, B- and T-cell lymphomas, Hodgkin lymphoma, gastric cancer, and nasopharyngeal carcinoma (NPC). The incidence of NPC varies dramatically by geographic region, ethnicity, and gender. NPC is a rare cancer in the United States and Europe, with an annual incidence of less than one per 100,000 person-year, but it is much more common (1.00 per 100 person-year) in certain parts of China and Southeast Asia. There have been a number of studies showing elevated light antibody titres to EBV antigens, such as EBV viral capsid antigen (VCA) and EBV early antigen (EA), in NPC patients compared with healthy individuals, supporting the use of EBV DNA testing as a screening tool for NPC in high-risk endemic populations (1-5). Some studies have shown superior sensitivity of circulating EBV DNA levels over EBV IgG testing for the detection of NPC (1-5). However, not all NPC patients have detectable circulating EBV DNA. According to a review of 15 studies involving EBV DNA quantitation, the reported sensitivities ranged from 53% to 95% (6). One explanation could be the use of assays with different performance characteristics, which would depend on PCR assay design and procedures, extraction method, and cutoff values. For example, it has been shown that there is a statistically significant correlation between polymerase chain reaction (PCR) amplification rate and the percentage of patients positive for circulating EBV DNA (5).

Submitted: September 16, 2015; Revised: December 14, 2015; Accepted: January 1, 2016

Published by National Cancer Institute Press 2017. This work is written by NCI Government employees and is in the public domain in the US.

References – Presentation Award

Gordon Research Conference

Nasopharyngeal Carcinoma

June 26 - July 1, 2016

The Hong Kong University of Science & Technology
Hong Kong, China

Outstanding Poster Presentation

Raymond Ng

Chairs: Maria Lung, Lawrence Young, George Tsao, Fei Fei Liu

Vice Chairs:

References – Paper published on International Journal of Radiation Oncology

Clinical Utility of Epstein-Barr Virus DNA Testing in the Treatment of Nasopharyngeal Carcinoma Patients

Kelly Y. Kim, PhD,* Quynh-Thu Le, MD,¹ Sue S. Yom, MD, PhD,¹ Raymond H.W. Ng, MD, PhD,¹ K.C. Allen Chan, PhD,¹ Scott V. Bratman, MD, PhD,¹ John J. Welch, MD, PhD,² Rao L. Divi, PhD,** Raymond A. Petryshyn, PhD,¹ and Barbara A. Conley, MD*

**Division of Cancer Treatment and Diagnosis, Center for Global Health, **Division of Cancer Control and Population Sciences, and Coordinating Center for Clinical Trials, National Cancer Institute, National Institutes of Health, Bethesda, Maryland; ¹Department of Radiation Oncology, Stanford University School of Medicine; ²Department of Radiation Oncology, University of California, San Francisco, California; ³Department of Radiation Oncology, University of California, San Francisco, California; ⁴Department of Radiation Oncology, Head and Neck Surgery, University of Toronto, Toronto, Ontario, Canada; ⁵Department of Chemical Pathology, The Chinese University of Hong Kong, Hong Kong SAR, China; and ⁶Department of Radiation Oncology, Princess Margaret Cancer Centre/University of Toronto, Toronto, Ontario, Canada*

Received Feb 3, 2017; Accepted for publication May 10, 2017.

Epstein-Barr virus (EBV) DNA analysis has been shown to be useful for early detection, prognostication, and monitoring of treatment response of nasopharyngeal carcinoma (NPC), and the recent literature provides growing evidence of the clinical utility of EBV DNA testing, particularly to inform treatment decisions for NPC patients. Despite the fact that NPC is a rare disease, the NRG Oncology cooperative group has successfully initiated a phase 2/3 randomized clinical trial for NPC with international partners and in that process has discovered that the development of a harmonized EBV DNA test is absolutely critical for integration into clinical trials and for future deployment in clinical and community laboratories. In November 2015, the National Cancer Institute (NCI) convened a workshop of international experts in the treatment of NPC and EBV testing to provide a forum for discussing the state of EBV DNA testing and its clinical utility, and to stimulate consideration of future studies and clinical practice guidelines for EBV DNA. This review provides a summary of that discussion, published by Elsevier Inc.

Register requests to: Kelly Y. Kim, PhD, Cancer Diagnosis Program, National Cancer Institute, National Institutes of Health, National Cancer Center, Bethesda, MD 20892. Tel: (301) 776-7911; Email: kellykim@nci.nih.gov

The authors would like to acknowledge NCI and their project, which was supported by grant U01CA193881 (NRG Oncology) sponsored from the National Cancer Institute. The authors would like to acknowledge the Radiation, Imaging and Quality of Life Studies Program (RISQ) of the National Cancer Institute for the support of EBV assay development efforts.

Conflict of interest none.

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http://dx.doi.org/10.1016/j.ijrobp.2017.05.016

References – Hong Kong press coverage 4

喉嚨掃一掃 揪出鼻咽癌

新法取細胞樣本 較驗血內窺鏡早發現

鼻咽癌是本港七大常見癌症之一，惟早期病徵不明顯，用內窺鏡等先進儀器檢查亦可無「走漏網」，以致延誤診治。香港大學、伊利沙伯醫院與同加拿大醫學者首度以「刷拭法」為法，以特製刷子，於喉嚨「掃」附近輕輕一掃，便可取得鼻咽細胞樣本，揪出與鼻咽癌息息相關的病毒基因，準確度達百分之九十九點三。刷拭取樣的創傷性極低，遠遠低於傳統的切片活檢，患者免痛苦，有望成為鼻咽癌篩查方法。

過去醫學界，假定加拿大醫學者多學於一、二十年間，證實六至八種進行臨床試驗，最後有五百七十八人完成試驗，十二人因刷拭取樣時感到不適而中止，研究中有九十八人參與鼻咽癌篩查，其餘是鼻咽癌患者或受試者。參與研究人士，平均年齡四十五歲，參與研究受試者試驗後，再接受兩年追蹤。

傳統切片有機會「走漏」

負責研究的多倫多大學醫學院耳鼻喉咽喉科科學系教授說，部分早期刷拭取樣小，患者免痛苦，準確度達百分之九十九點三，遠低於傳統的切片活檢，患者免痛苦，有望成為鼻咽癌篩查方法。

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References – Philippine press coverage

Saving lives through technology: NP Screen™ Test

NP Screen™ Test is a non-invasive, early stage screening test for nasopharyngeal cancer (NPC). It is a simple, accurate, and field-utilizable test that can be used in rural locations by trained healthcare workers. The test involves a direct measurement of whether or not epithelial cells from the nasopharynx have been infected with EBV and certain EBV DNA, indicating that the cells have been malignantly transformed. The DNA-based genetic assay is sold as a Laboratory Developed Test under CLIA, Clinical Laboratory Improvement Amendments (CLIA) in USA, Canada and Hong Kong. Additionally, a Pre-Submission for Market Approval has already been filed with the FDA in the USA. This was submitted in order to establish further precedence for the vally-triggered cancer detection platform, so that it can be made available for other diseases.

References – Hong Kong press coverage 3

發明咽喉刷 減誤診

港產名醫 獲世衛嘉許

香港大學、伊利沙伯醫院與同加拿大醫學者首度以「刷拭法」為法，以特製刷子，於喉嚨「掃」附近輕輕一掃，便可取得鼻咽細胞樣本，揪出與鼻咽癌息息相關的病毒基因，準確度達百分之九十九點三。刷拭取樣的創傷性極低，遠遠低於傳統的切片活檢，患者免痛苦，有望成為鼻咽癌篩查方法。

References – Hong Kong press coverage 2

無創技術收集病毒細胞 「牙縫刷」驗鼻咽癌99%準

【本報訊】香港大學、伊利沙伯醫院與同加拿大醫學者首度以「刷拭法」為法，以特製刷子，於喉嚨「掃」附近輕輕一掃，便可取得鼻咽細胞樣本，揪出與鼻咽癌息息相關的病毒基因，準確度達百分之九十九點三。刷拭取樣的創傷性極低，遠遠低於傳統的切片活檢，患者免痛苦，有望成為鼻咽癌篩查方法。

References – Hong Kong press coverage 1

經口腔鼻咽取本 毋須臥床無創傷 鼻咽癌早發現治愈率高

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Product Pipeline

Product Pipeline

- Diagnostic testing device for HPV-marked anorectal cancer
- Diagnostic testing device for HPV-marked oropharyngeal cancer (OPC)
- Diagnostic testing device for HPV-marked cervical cancer

The Group Aims To:

- Design a non-invasive brushing device capable of painlessly collecting HPV-DNA-containing cellular samples from specific anatomical regions in an ambulatory setting.
- Develop HPV genetic tests using customized primers and probes to achieve a high level of analytical sensitivity and specificity.
- Enhancing the existing internal algorithm to allow easier, faster, and more accurate interpretation of test results.
- Leverage the existing proprietary DNA preservation solution to ensure robust stabilization of HPV-DNA-containing samples, enabling convenient storage, shipping, and handling, particularly suited for ambulatory environments.

Intellectual Property And Intellectual Property Protection/Patents

The following is NP testing [™] Patent aspects of technology:

Equipment

· Unique and proprietary brush types and handle designs are used to more accurately and simply reach the throat outside of bed through the oral route.

METHOD

- Non bedridden, non-invasive, and painless oral brush examination to reach the throat.
- Touch specific high-risk areas in the throat to optimize the collection of pharyngeal cancer cells.
- Real time quantitative and semi quantitative PCR analysis of EBV DNA has high predictive accuracy for NPC diagnosis.
- A proprietary laboratory result conversion algorithm used to define thresholds for positive and negative test results.

Intellectual Property Protection

The Group has signed confidentiality agreements with all contracting parties to protect its proprietary technology and trade secrets. In addition to the strategy of obtaining intellectual property protection in multiple countries through patent registration in the target market, our group has also adopted a centralized approach

The FDA approved laboratory model enables strict control over access to its proprietary primer and probe sets, as well as laboratory standardization protocols (which have not been patented due to the need to disclose details).

Recognition And Praise

The founder of our group, a doctor, has been involved in the initial EBV DNA research and its clinical application in pharyngeal cancer detection since 1999. In NP testing [™] After the launch of LDT, our group participated in numerous medical conferences and performances, and received

Recognized by medical professionals. In addition, our group has actively participated in medical professional activities for many years and published relevant scientific research papers on pharyngeal cancer in top medical journals.

Our group's intellectual property and intellectual property protection/patents

Our group has obtained NP testing [™] Related key intellectual property rights have been obtained, and the strongest intellectual property protection for throat cancer detection equipment and laws has been obtained in key jurisdictions such as China, Singapore, the United States, and Australia. In NP testing [™] Our products have obtained patents in China, the largest market for our products [™]

Chinese application number: 2020104289247

Applicant: Advanced Sentry Company

Name: Methods and equipment used for screening pharyngeal cancer



**Intellectual
Property
Representative**

Partner

Multiple general practitioners (GPs) from Canada, Singapore, and Hong Kong have provided us with samples for testing



更多…….

THANK YOU FOR YOUR ATTENTION

CREATE A SHARED FUTURE

NP  **Screen**TM

ADVANCE
SENTRY

a d v a n c e s e n t r y

The highest accuracy, simple, non-invasive, and painless early detection plan for nasopharyngeal carcinoma