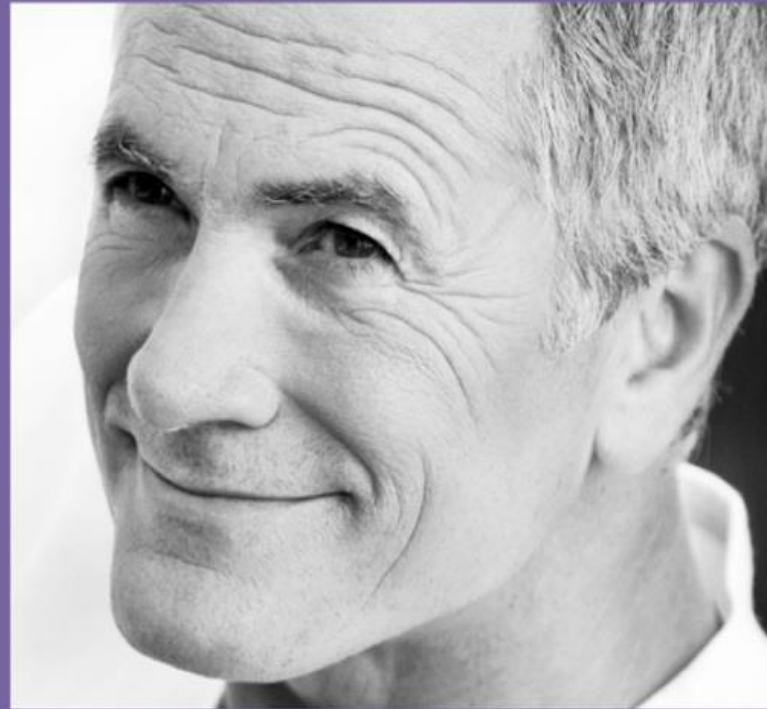




# R

# Restalyst

Abundant Life Through Restfulness







# INTRODUCTION

# COMPANY PROFILE

## Restalyst

- a member of the Reste Group
- privately-owned biomedical clinical diagnostic company from Singapore with a global presence.



## We are committed to:

- Provide innovative, reliable and clinically-proven diagnostic solutions
- Our mission of harnessing technological advancements for the improvement of disease diagnosis and management of patient health



# MILESTONES

- 2007: Restalyst Pte Ltd was founded
- 2009: R&D and production facilities achieved ISO13485 certification
- 2011: NPC-REAAD received CE Mark
- 2012: NPC-REAAD listed on Singapore Medical Device Register
- 2015: Launched GC-REAAD & received CE mark
- 2016: Launched HCC-REAAD & received CE mark
- 2017: GC-REAAD listed on Singapore Medical Device Register
- 2019: HCC-REAAD listed on Singapore Medical Device Register
- 2020: Launched RAPIT COVID-19 IgM/IgG Test Kit & received CE & HSA PA
- 2020: Launched COVID19N-REAAD & received CE & HSA PA



# PRODUCTS & QUALITY ASSURANCE

- Design & manufacturing of IVD medical devices for testing of markers for cancer & infectious diseases
  - NPC-REAAD™
  - GC-REAAD™
  - HCC-REAAD™
  - RAPIT COVID-19 IgM/IgG Test Kit
- ISO13485:2016, EN ISO13485:2016 (since 2009)
- Singapore Medical Device Register Listing
- CE mark
  - Certificate No: CE/SGP/2014/12/01





# PRODUCTS - REAAD™ SERIES



# REAAD™ Series

- A range of innovative diagnostic solutions for early detection of oncology diseases
- Employ the use patented or proprietary protein biomarkers
- Clinical-based approach to generate evidence-based results
- Intended for the early diagnosis for diseases
- Products span from specialised manual testing to full integration onto automated routine clinical laboratory testing solutions
- Our clinically-proven diagnostic solutions includes:
  - NPC-REAAD™ EBV EA IgA ELISA
  - GC-REAAD™ ITIH3 ELISA
  - HCC-REAAD™ ERBB3 ELISA



# REAAD™ Series

- Stomach cancer detection kit
  - Early detection for Stomach cancer in blood samples
  - Incorporates the use of patented technology
  - Product brand: GC-REAAD™ ITIH3 ELISA
- Liver cancer detection kit
  - Early detection for Liver cancer in blood samples
  - Employs the use of patented technology and proprietary algorithm
  - Product brand: HCC-REAAD™ ERBB3 ELISA
- Nose cancer detection kit
  - Early detection for Nose cancer in blood samples
  - Uses proprietary technology
  - Product brand: NPC-REAAD™ EBV EA-IgA ELISA



# GC-REAAD™

CE-IVD Certified *in-vitro* diagnostic ELISA kit  
for early detection of Gastric Carcinoma  
(stomach cancer)

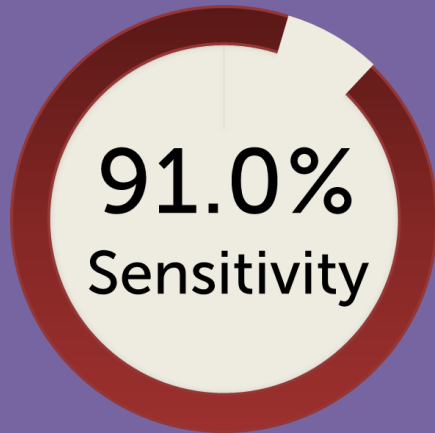
# GC-REAAD™ - Stomach cancer detection kit

GC-REAAD™ is *in-vitro* diagnostics employed the use of patented biomarker, intended for the qualitative & semi-quantitative detection of Inter-alpha-trypsin inhibitor heavy chain H3 (ITIH3) protein in human plasma for early detection of stomach cancer.

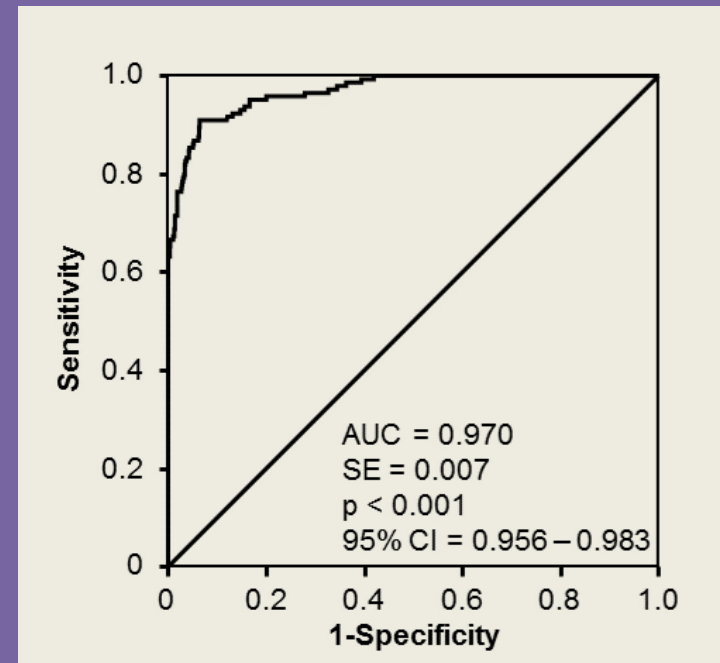
## The ITIH3 Protein

- Protease inhibitor found in extracellular matrix
- One of the heavy chain belonging to family of inter-alpha-trypsin inhibitors
- Function: Ability to covalently link to hyaluronic acid (HA)
- Important factor to stabilise extracellular matrix
- Evidence showing its antagonistic relationship with tumour invasion & metastasis – tumour suppressor role

# Clinical Validation for GC-REAAD™



Validation Results	Values
ROC Area Under Curve	0.97
Sample Size	998
Positive Cases	144
Negative Controls	854
Positive Predictive Value	86.23%
Negative Predictive Value	97.09%





# HCC-REAAD™

CE-IVD Certified *in-vitro* diagnostic ELISA kit for  
early detection of Hepatocellular Carcinoma  
(liver cancer)

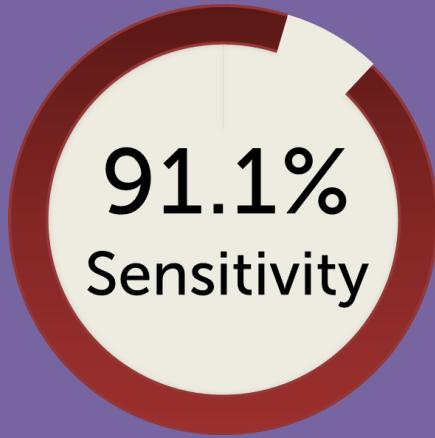
# HCC-REAAD™ - Liver cancer detection kit

HCC-REAAD™ an *in-vitro* diagnostics employed the use of patented biomarker, intended for the qualitative & semi-quantitative detection of the human epidermal growth factor 3 (ERBB3) protein in human plasma. An algorithm integrating the measurement of ERBB3 and AFP for the early detection of liver cancer.

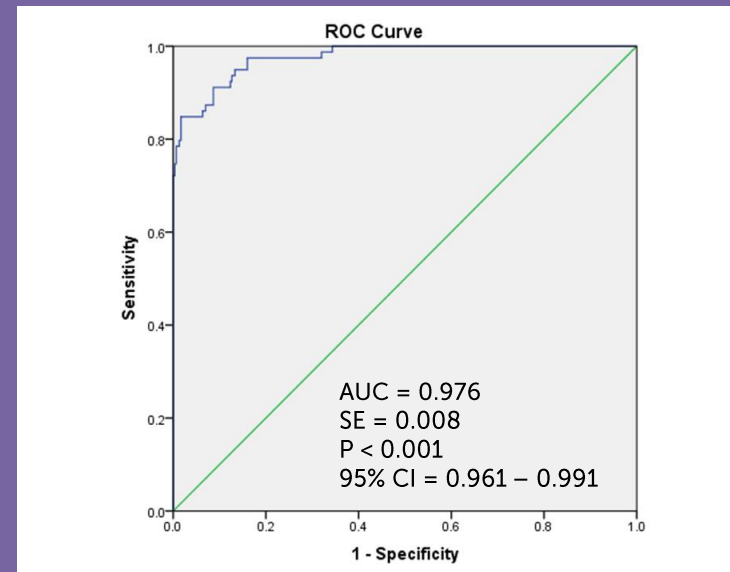
## ERBB3 Protein

- A member of ERBB family of receptor tyrosine kinase (RTK)
- Plays a role in regulating cell proliferation, and differentiation
- Deregulation of ERBB signalling is associated with several human cancers

# Clinical Validation for HCC-REAAD™



Validation Results	Values
ROC Area Under Curve	0.976
Sample Size	379
Positive Cases	79
Negative Controls	300
Positive Predictive Value	86.81%
Negative Predictive Value	95.24%







# NPC-REAAD™

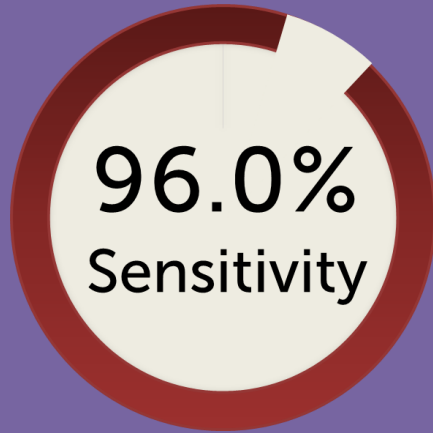
CE-IVD Certified *in-vitro* diagnostic ELISA kit for early detection of Nasopharyngeal Carcinoma (nose cancer)

# NPC-REAAD™ - Nose cancer detection kit

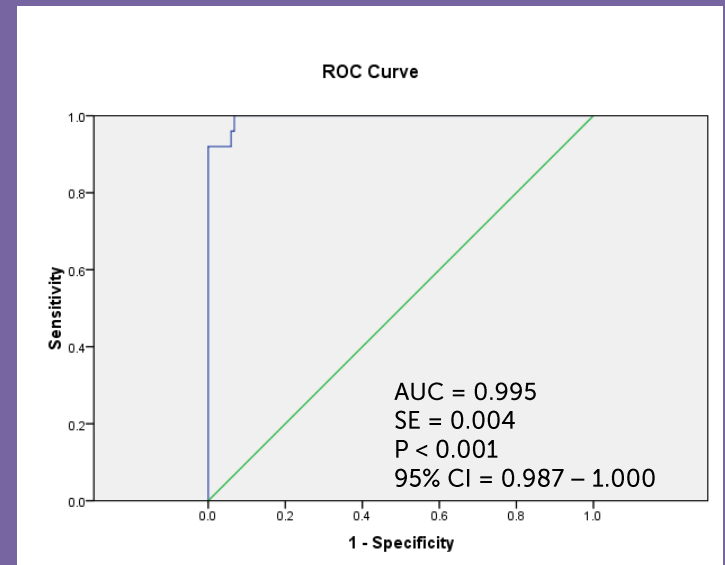
NPC-REAAD™ is an *in-vitro* diagnostic intended to screen for IgA antibodies specific to EBV EA as an indicator of risk for NPC

- A cocktail of 4 (out of more than 20) specific proprietary proteins derived from the EBV Early Antigen (EA) is utilised in the test kit
  - Ribonucleotide Reductase Large subunit
  - Ribonucleotide Reductase Small subunit
  - DNA Polymerase Accessory subunit
  - Novel proprietary protein
- Test results help distinguish NPC from non-NPC cases to facilitate patient diagnosis & treatment
- Clinically validated using NPC patients (instead of EBV positive patients) unlike other EBV assays

# Clinical Validation for NPC-REAAD™



Validation Results	Values
ROC Area Under Curve	0.99
Sample Size	143
Positive Cases	25
Negative Controls	118
Positive Predictive Value	100.00%
Negative Predictive Value	98.33%





# PRODUCTS – COVID-19 TESTS



# RAPIT COVID-19 IgM/IgG Test Kit

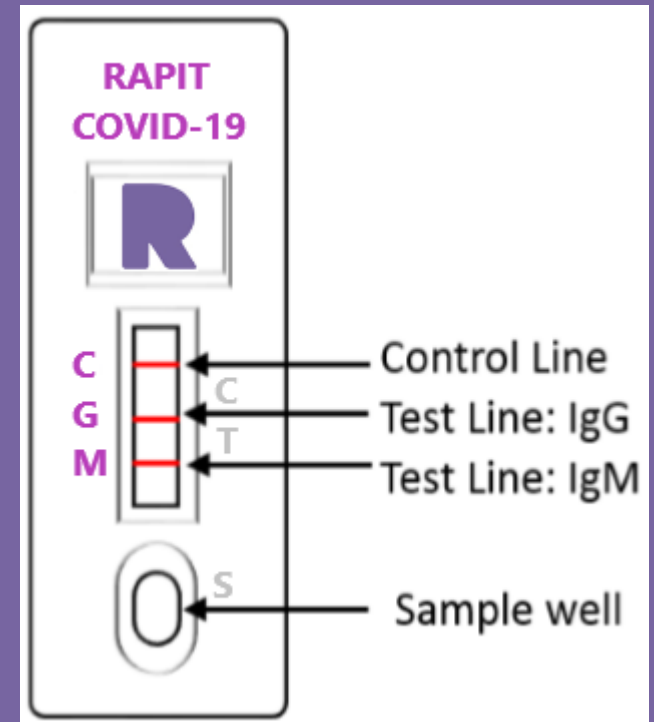
Rapid Test for Detection and Differentiation of  
SARS-CoV-2 IgM and IgG Antibodies

# RAPIT COVID-19 IgM/IgG Test Kit

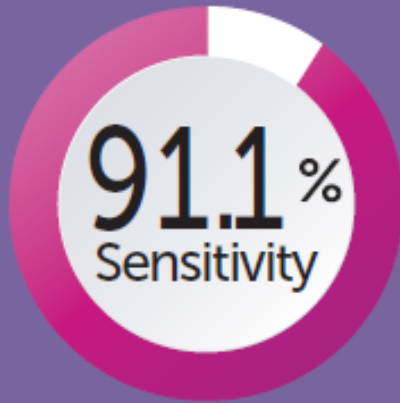
RAPIT COVID-19 IgM/IgG Test Kit is a lateral flow chromatography immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in human plasma, serum, finger pricked whole blood or whole blood.

- IgM and IgG antibodies of COVID-19 Spike and Nucleocapsid proteins are detected

RAPIT COVID-19 IgM/IgG Test Kit aids in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentations and the results of other laboratory tests.



# Clinical Validation - RAPIT COVID-19 IgM/IgG



Validation Results	Values
Sample Size	276
Positive Cases	168
Negative Controls	108
Positive Predictive Value	96.84%
Negative Predictive Value	87.29%



# COVID19N-REAAD™

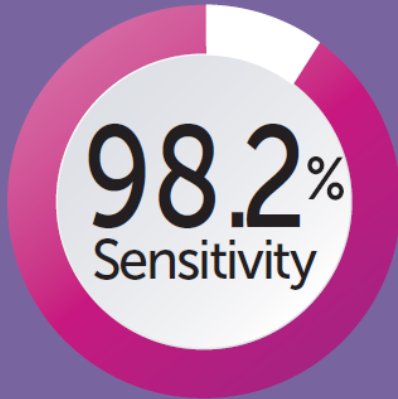
Enzyme-linked immunosorbent assay for qualitative detection of IgG antibodies to SARS-CoV-2 Nucleocapsid Protein



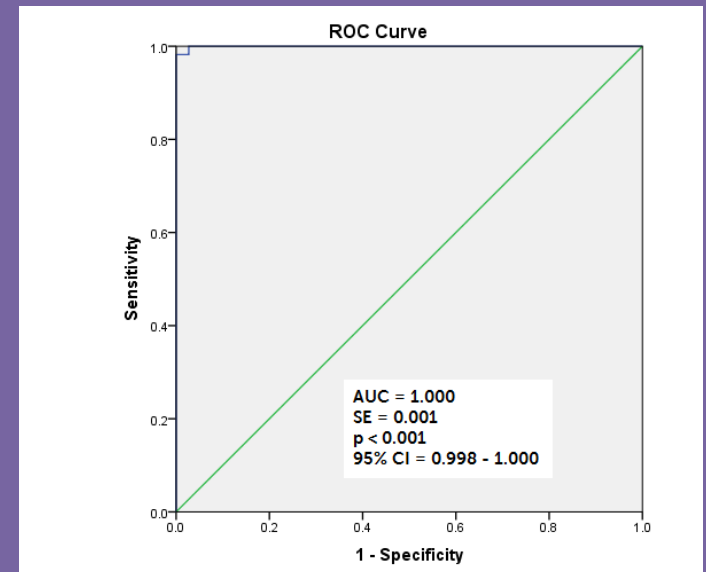
# COVID19N-REAAD™

- COVID19N-REAAD™ is an enzyme–linked immunosorbent assay intended for qualitative detection of IgG antibodies to SARS-CoV-2 Nucleocapsid Protein in human serum and plasma (EDTA).
- COVID19N-REAAD™ is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

# Clinical Validation for COVID19N-REAAD™



Validation Results	Values
ROC Area Under Curve	1.000
Sample Size	387
Positive Cases	56
Negative Controls	331
Positive Predictive Value	100.00%
Negative Predictive Value	99.70%





# SERVICES & COLLABORATION

# SERVICES

## Contract Testing Services

- Offers a variety of testing services with our range of analytical instruments and expertise in immunological and molecular based assays.
- Services can be customized to support the Research & Development pipeline from Discovery to Pre-clinical phases.

## Contract Development Services

## Contract Manufacturing Services



# COLLABORATION

## Licensing of IPs

- Req'd for product development & commercialization

## Joint product development

## Evaluation studies

- Req'd for product validation
- Publication and/or report for product promotion

## Supply of biological materials

- Req'd by Company for product development & manufacturing
- Req'd by Partner for R&D

*Note: Services & Collaboration rendered are subject to agreement by parties involved after review over terms & mutual benefits.*



# BIOLOGICAL MATERIALS

## Whole/Processed Blood, Plasma/Serum

- Biological and Clinical material for use in R&D/ QC/ Validation
- Individual clinical data
- Detailed COA & De-linked IRB Protocol
- Anonymized Clinical Data
- Customized requirements



Infectious Disease/ Virology	EBV (VCA, EA, EBNA), H. Pylori, HBV DNA, Influenza A/B, Saccharomyces, Tetanus, Zika, etc.
Hematology	Hemolytic anemia, Hemophilia, Hereditary spherocytosis, Hodgkin's lymphoma, etc.
Oncology	Carcinoma, Sarcoma, Lymphoma, Leukemia, etc.
Others	Ulcerative Colitis, Systemic Lupus Erythematosus, etc.

# BIOLOGICAL MATERIALS

## FFPE Tissue Organs

- Database containing more than 10,000 FFPE pathological and normal tissue specimens from all organs (except brain) and diseases/cancers
- A wide range of liquid-based cytology specimens
- Raw biological pathology material or characterized by pathologists
- Sample originated from EN ISO 15189 accredited facility
- Individual clinical data
- Detailed COA & De-linked IRB Protocol
- Anonymized Clinical Data
- Customized requirements

## Isolated Cell Samples from Diseased & Health Cohorts

- Immune cells (PBMCs, BMMCs, MNCs, CD4, CD25, etc.)
- Primary Respiratory cells (HuBECs, parenchymal fibroblasts, etc.)
- Primary and Immortalized cancer cells
- Joint Tissue cells (Chondrocytes, synovial fibroblasts etc.)

Skin	Ovary	Endometrium
Breast	Cervical	ENT
Colon	Stomach	Thyroid
Prostate	Testicle	Lung
Bladder	Tissue	Liver
Melanoma	Pancreas	Bone Marrow
Kidney	Myometrium	Oesophagus



# SUMMARY

- Restalyst is an IVD company which successfully develops and produces cancer tests and infectious disease tests (COVID-19)
- Established in 2007, Restalyst is ISO 13485 certified as early as 2009
- Restalyst's IVD products are CE marked & locally registered. Products are sold globally through distributor partnerships.
- Based on the many years of experience, Restalyst offers contract services in testing, product development, production, regulatory & commercialization.
- Restalyst is also interested to collaborate with partners to supply biological materials and bring inventions from lab to be developed, produced and distributed as IVD products for the global market.



**END**