

# Catalogue Products and Services





Solutions for Diagnostic Tests, Life Science, Health Supplies and Medical Licence

Gene Bio Medical (604) 370-0166 www.genebiomedical.com sales@genebiomedical.com Gene Bio Medical is a licensed supplier and distributor of COVID-19 rapid test Class IV medical devices. Headquartered in Vancouver – ensuring the medical devices are safe, effective, and of high quality.

# **About Gene Bio Medical**

Gene Bio Medical is a one stop comprehensive in vitro diagnostic biomedical technology company based in Vancouver, BC.

We are MDEL licensed supplier and distributor of Class IV medical devices, with an extensive sales network all over North America.

# **Our vision**

Our team of biomedical experts is dedicated to the R&D of *high accuracy*, *low-cost*, and *fast* diagnostic technology, and we aim to contribute and improve human health and response capabilities towards future diseases.



### Head office

800 W Pender St #1510, Vancouver, BC, Canada, V6C 2V6





126 Strategic business partners across the globe

# Summary

# PRODUCTS

# COVID-19

- 5 COVID-19 Rapid Antigen Tests
- 7 COVID-19 Rapid Antibody Tests

# Nutraceuticals / Supplements

- 9 ArtrmiC
- **10** Ensonkan NMN

# **Diagnostic Test Kits**

**12** Fertility Tests

Infectious Disease Tests

Drugs of Abuse Tests

# **13** Tumor Marker Tests

Cardiac Marker Tests

Food Safety & GMO Tests

### Lab & Medical Consumables

- **15** Sampling Swabs
- **16** Sample Collection Kits
- **18** Dessicants

# Hospital/Medical Supplies

- 20 Medical Masks Face Shields
- 21 Gloves Gowns

# SERVICES

### Consultation

- **23** Global Medical Device Licence
- **24** Clinical Trial Consultation
- **25** Health Canada Interim Order
- 26 FDA/EUA
- 27 CE Marking

This brochure is intended for the Canadian Market and may not cover all our products. For clients in other locations, please contact us for more information regarding products available for your region.



As one of the largest distributors of COVID-19 rapid test kits in Canada, we carry multiple brands and all rapid antigen test kits are authorized by **Health Canada** under Interim Order.

# **COVID-19** Rapid Antigen Tests



### ABBOTT PANBIO™

COVID-19 Rapid Antigen Test 25-test/kit, Nasal/Nasopharyngeal

#### High-performance Rapid Test with Quick Result in 15 minutes

#### Specification

Variants

Delta, Omicron

Relative Sensitivity: 98.1% (Nasal); 91.4% (NP) Relative Specificity: 99.8% (Nasal); 99.8% (NP)

#### Intended Use

POCT, can be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

MADE IN GERMANY



### **BTNX Rapid Response**

COVID-19 Rapid Antigen Test 5-test/kit, Nasal

High-performance Rapid Test with Quick Result in 15 minutes

#### Specification

Relative Sensitivity: 90.2% Relative Specificity: 100%

Variants Omicron

#### Intended Use

POCT, can be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

MADE IN CANADA



### CovClear

COVID-19 Rapid Antigen Test 2-test/kit, Nasal

Reliable, Easy Self-Testing At Home or Anywhere

#### Specification

Relative Sensitivity: 95.5% Relative Specificity: 100%

# Variants

Delta, Omicron

#### Intended Use

Over-the-counter (OTC) use and other non-laboratory sites. Self-collected by an individual 18 or older or collected by an adult from an individual aged 2 years of age and older.

#### MADE IN UNITED STATES



### Artron

COVID-19 Rapid Antigen Test

5/25-test/kit, Nasal/Nasopharyngeal

### Rapid, Efficient, Professional Canada-made Test Kit

### Specification

Relative Sensitivity: 91.3% (Nasal) Relative Specificity: 99.56% (Nasal)

### Variants

Delta, Omicron

#### Intended Use

POCT, can be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

#### MADE IN CANADA



### Roche COVID-19 Rapid Antigen Test 5-test/kit. Nasal

High-quality Self-testing Kit with Result in 15 Minutes

Specification Relative Sensitivity: 91.1% Relative Specificity: 99.6%

Variants Omicron Intended Use Over-the-counter (OTC) use and other non-laboratory sites.

MADE IN SOUTH KOREA



# Flowflex (ACON)

**COVID-19 Rapid Antigen Test** 5-test/kit, Nasal/Nasopharyngeal

#### The most accurate test\* for the Omicron variant

#### Specification

Relative Sensitivity: 97.1% (Nasal); 99.5% (NP) Relative Specificity: 97.6% (Nasal); 99.4% (NP)

Variants

Delta, Omicron

#### Intended Use

POCT and lab-based, can be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

#### MADE IN CHINA

\*Independent validation study: https://www.hvidovrehospital.dk/presse-og-nyt/pressemeddelelser-og-nyheder/nyheder-fra-hvidovre-hospital/PublishingImages/Sider/Antigentests-svinger-voldsomt-i-kvalitet/A%20nationwide%20analytical%20and%20clinical%20evaluation%20of%2046%20rapid%20antigen%20tests%20for%20SARS-CoV-.pdf



### FaStep (Assure Tech.)

COVID-19 Rapid Antigen Test 5-test/kit, Nasal

### Reliable Rapid Test with Quick Result in 15 Minutes

#### Specification

Relative Sensitivity: 92.3% Relative Specificity: 100%

### Intended Use

POCT and lab-based, can be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

# Variants

#### MADE IN CHINA



### **Clinitest** COVID-19 Rapid Antigen Test 1/5-test/kit. Nasal

Great performance: High sensitivity and specificity

#### Specification

Relative Sensitivity: 97.25% Relative Specificity: 100%

Variants Omicron Intended Use Over-the-counter (OTC) use and other non-laboratory sites.

MADE IN UNITED STATES

# **COVID-19** Rapid Antibody Tests



### Artron COVID-19 IgG/IgM Antibody Test

- >> Sample Type: Serum, Plasma, and/or Whole Blood
- >> Detection Time: 15-30 minutes
- Sensitivity = 92.16% (igG) >14 days
- » Only For professional use and POCT use
- » Health Canada (IO#318801) & CE approved



# **POST COVID-19 & NEW NORMAL** WE SURVIVED. WHAT'S NEXT?

Two years after the global breakout of COVID-19, we are now adapting to the 'new normal': new variants keep emerging, thousands of long COVID patients have been feeling exhausted for months, and there is still no panacea to date. Still, we are all trying our best to restore our health individually and also collectively as a society.

To maintain optimal immune system function, aprat from exercising regularly and having nutritious meals, various supplements can also help to support the normal function of our immune system and promote recovery from chronic symptoms following infection with COVID-19.

# Nutraceuticals/Supplements

If your immune system is weakened, the effects can last for months. In addition to shortness of breath, headache and loss of smell / taste, the most common complaint is exhaustion.

ArtemiC<sup>™</sup> products contain active ingredients that are known to support the normal function of your immune system and promote recovery from lasting symptoms. ArtemiC<sup>™</sup> was developed with an innovative technology that optimizes the dissolution of ingredients in water so that they may be effectively absorbed by the body. The combination of a unique formulation and this patented MyCell<sup>™</sup> technology makes ArtemiC<sup>™</sup> products the best and most effective nutritional supplements available on the market.



# ARTEMIC RESCUE

Water based emulsion, oral spray

#### **RESCUE: for ACUTE Immune Support**

#### INGREDIENTS

#### DOSAGE

### VOLUME

5mL

Water, Vitamin C (L-ascorbic acid), Curcuma longa L. extract (rhizome), Arabic gum, Boswellia serrata extract (trunk, branches), artemisinin, potassium sorbate, sodium benzoate. 2 x per day 5 sprays at a time (5 x 200µl)

ENHANCED FORMULATAION



### ARTEMIC SUPPORT

FOOD SUPPLEMENT Water based emulsion, oral drops

#### SUPPORT - for DAILY Immune Support

#### INGREDIENTS

Water, Vitamin C (L-ascorbic acid), Curcuma Longa L extract (rhizome), Arabic gum, Boswellia Serrate extract (trunk, branches), sodium benzoate, potassium sorbate.

#### DOSAGE

2 x per day 10 drops at a time (2 x 0.5mL)

### VOLUME

30mL

ENHANCED FORMULATAION



NMN 200MG + PQQ 20MG is an anti-aging supplement made in Canada. It provides antioxidants that help fight/protect cell against/reduce free radicals and help support mitochondrial function. In times of COVID-19, this supplement can optimize human cell functions and is made to boost immunity.



- >> Promotes Vascular Health and Blood Flow
- >> Improves Muscle Endurance and Strength
- >> Protects Against Heart Disease
- >> Lowers Risk of Obesity
- >> Enhances Maintenance of DNA Repair
- >> Increases Mitochondrial Function





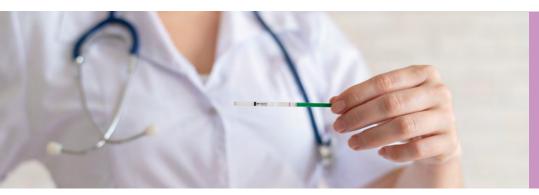








# **Fertility** Tests



Fertility Rapid Tests are based on lateral flow immunoassay for the detection of human chorionic gonadotropin (hCG), Ovulation (LH), and Human Follicular Stimulating Hormone (FSH) in urine.

The tests are reliable, accurate, and easy to use.

# Infectious Disease Tests

Infectious Disease Rapid Tests – a simple, quick and reliable method for the detection of Hepatitis B Virus surface Antigen (HBsAg) in serum, plasma or whole blood sample, and more.



# **Drugs of Abuse** Tests

Safely and easily use the Drug Test and receive fast and accurate results. Includes AMP, BAR, BZO, COC, B-COC, MDMA, MET, MOR, OPI, MTD, TCA, THC, BUP, and more.



# **Tumor Marker** Tests



A simple and quick method to aid in the diagnosis of colon polyps, colorecal carcinoma, ulcerative colitis, Crohn's Disease, peptic ulcers, gastritis, and gastric cancer.

# Cardiac Marker Tests

A simple, quick and reliable method for the detection of myoglobin and troponin and more.



# Food Safety & GMO Tests



A simple and quick method to aid in the diagnosis of colon polyps, colorecal carcinoma, ulcerative colitis, Crohn's Disease, peptic ulcers, gastritis, and gastric cancer.



# Sampling Swabs



Used for cell & virus specimen collection. They are designed for flu testing and clinical diagnostics too.

Application: Clinical diagnostics, molecular diagnostics, laboratory, hospital, reagents manufacturers

### **Brand**

# Category

#### **Product name**

Mandelah Mandelab Mandelab

Flocked swabs Flocked swabs

MS-ENS002 Nasal Foam Swah MS-FLS002 Foam Swab MS-FLS001 Foam Swab MS-FNS001 Nasal Foam Swab MS-NF7801 Nasal Flocked Swab MS-93050P with Polyster Tip MS-FOS001 Oral Foam Swab MS-NF7802 Nasal Flocked Swab MS-FOS002 Oral Foam Swab MS-CP006A Cotton Swab PP Stick MS-LF7801 Throat Flocked Swab MS-VP006S Ravon Swab PS Stick MS-OF3601 Oral Flocked Swab MS-VP006A Rayon Swab with PP Stick MS-VF4501 Cervical Flocked Swab MS-CW006A Cotton Swab Wooden Stick MS-NFK001 Nasal Flocked Swab For Kid

Brand	Category	Product name
Mandelab	Foam swabs	MS-FNS002 Nasal Foam Swab
Mandelab	Foam swabs	MS-FLS002 Foam Swab
Mandelab	Foam swabs	MS-FLS001 Foam Swab
Mandelab	Foam swabs	MS-FNS001 Nasal Foam Swab
Mandelab	Foam swabs	MS-FOS001 Oral Foam Swab
Mandelab	Foam swabs	MS-FOS002 Oral Foam Swab
Mandelab	Cotton swabs	MS-93050P with Polyster Tip
Mandelab	Cotton swabs	MS-CP006A Cotton Swab PP Stick
Mandelab	Cotton swabs	MS-VP006S Rayon Swab PS Stick
Mandelab	Cotton swabs	MS-VP006A Rayon Swab with PP Stick
Mandelab	Cotton swabs	MS-CW006A Cotton Swab Wooden Stick



MANDELAB

Established in 2010, MandeLab is a manufacturer specialized in producing disposable sampling swabs (flocked swabs, cotton swabs, viscose swabs), transport mediums, and saliva collection kits. The company has passed **ISO13485** quality management system, and **all products have been certified by CE & FDA**.



# Sample Collection Kits

Sampling kit is used for collection, stabilization and transportation of Covid-19, Influenza H1N1, Chlamydia, Mycoplasma and Ureaplasma.



Brand	Category	Product name
Mandelab	Genetics	GTK001 DNA Collection Kit
Mandelab	Genetics	GTK002 Genetic Testing Kit
Mandelab	HPV	HPV Sampling Kit HPV001
Mandelab	Virus	VTM001 Virus Sampling Kit with 1 Swab
Mandelab	Virus	VTM002 Virus Sampling Kit with Inactivated Transport Medium
Mandelab	Virus	VTM003 Virus Sampling Kit with 2 Swabs
Mandelab	Virus	VTM004 Virus Sampling Kit with 2 Swabs Inactivated Transport Medium
Mandelab	Saliva	SCK001 Saliva Collection Kit
Mandelab	Saliva	SCK002 Saliva Collection Kit
Mandelab	Saliva	SCK003 Saliva Collection Kit
Mandelab	Saliva	SCK004 Saliva Collection Kit



#### Virus Sampling Kit with 2 Swabs Classification: IVD 20-pack

Purpose: Virus specimen collection

### Specification

150 mm nasal swab, 78 mm breakpoint-1pc 150 mm throat flocked swab, 78 mm breakpoint-1pc 3ml interactive virus transport medium-1pc Application

Clinical diagnostics, molecular diagnostics, laboratory, hospital, reagents manufacturers

### Brand

### Category

### **Product name**



Crown Mutual Group (CMG) is a Canadian based consortium that provides domestic manufacturing and supplying of medical grade Personal Protective Equipment (PPE) along with locally produced Health Canada certified antiseptic skin cleanser







Blood Collection **Blood Collection** Blood Collection Blood Collection Blood Collection **Blood Collection Blood Collection Blood Collection** Blood Collection Blood Collection

ACD Tubes **Blood Collection Sets** Cell Free DNA Tube **Citrate Tubes Clot Activator Tubes Disposable Tourniquets EDTA** Tubes ESR Tubes Gel & Clot Activator Tubes Gel & EDTA.K2 Tubes Gel & Heparin Tubes **Glucose Tubes** Heparin Tubes **IMPROMINI Plus IMPROSAFE Blood Collection Sets** IMPROSAFE Blood Collection Sets w/PreAttached Holder **IMPROSAFE** Multi-Sample Needles **IMPROSWAB** Microbiological Transport Swab **IMPROVIRALTM NAT Medium (NAT)** IMPROVIRALTM Viral Preservative Medium (VPM) Luer Adapters M11 Type M2 Type M3 Type **Microbiological Transport Swabs** Multi-Sample Needles Multi-Sample Needles (Flashback) No Additive Tubes **Sharps Containers** Tourniquets **Urinalysis** Tubes Urine Collection Container Urine Culture Tubes

# Dessicants

Odorless, tasteless, non-toxic, high activity adsorption material with strong adsorption capacity



Brand	Category	Product name
Dingxing	Desiccant	DMF Free Silica Gel Desiccant
Dingxing	Food Preservatives	FDA Passed Food Oxygen Absorber
Dingxing	Food Preservatives	Best oxygen absorber for food in stock
Dingxing	Food Preservatives	Oxygen Absorber for Preventing Package Defo
Dingxing	Food Preservatives	Food Grade Iron Powder FDA Approval
Dingxing	Food Preservatives	Oxygen absorber/oxygen scavenger/oxygen clearing
Dingxing	Food Preservatives	Wholesale Food Grade Oxygen Absorber
Dingxing	Food Preservatives	Oxygen absorber for food packaging/deoxidizer/oxygen scavenger
Dingxing	Food Preservatives	Fruit Ethylene Gas Absorber Extend Shelflife
Dingxing	Food Preservatives	Best quality ethylene absorber for fresh fruit
Dingxing	Food Preservatives	best quality ethylene absorber for fresh
Dingxing	Food Preservatives	Ethylene Eliminator Pack Ethylene Absorber
Dingxing	Food Preservatives	Purple Activated Alumina Ball For Ethylene Absorber
Dingxing	Food Preservatives	Food Grade fruit and vegetable ethylen absorbent sachet
Dingxing	Food Preservatives	Fruit Keeping Fresh Agent ethylene absorber

# Hospital/Medical Supplies (Face Masks, Face Shields, Gloves, Gawns)

Our personal protective equipment including medical-grade face masks, face shields, gloves and gawns. Our extensive distribution network offers fast nationwide and global shipping. We can also ship online orders directly to your patients with patient home delivery.

Our products include high-quality national brands like **Ansell**, **Crown Mutual Group**, and **Medicom**. We back all products with our 100% satisfaction guarantee.



# Medical-Grade Face Masks

Brand	Product name	Quantity/Box	Made in
Crown	ASTM F2100 Level 1	50	Canada
Crown	ASTM F2100 Level 2	50	Canada
Crown	Folding Ear Loop ASTM F2100 Level 3	50	Canada
Crown	Pediatric Face Masks - ASTM Level 1	50	Canada
Medicom	AssureMask Balance - ASTM Level 3	50	China
Medicom	AssureMask Valiant - ASTM Level 3	50	USA
Hynaut	Disposable Medical Face Mask C010	50	China

# Medical-Grade Face Shields

Brand	Product name	Quantity/Box
Crown	Face Shield - Full Face Reusable Personal Protection	200
Crown	Children Face Shield	200

# Medical-Grade Gloves



We offer a complete range of premium quality medical examination gloves and surgical gloves. Our gloves are made using a variety of materials that provide superior protection, durability and grip without compromising flexibility, tactility or comfort.

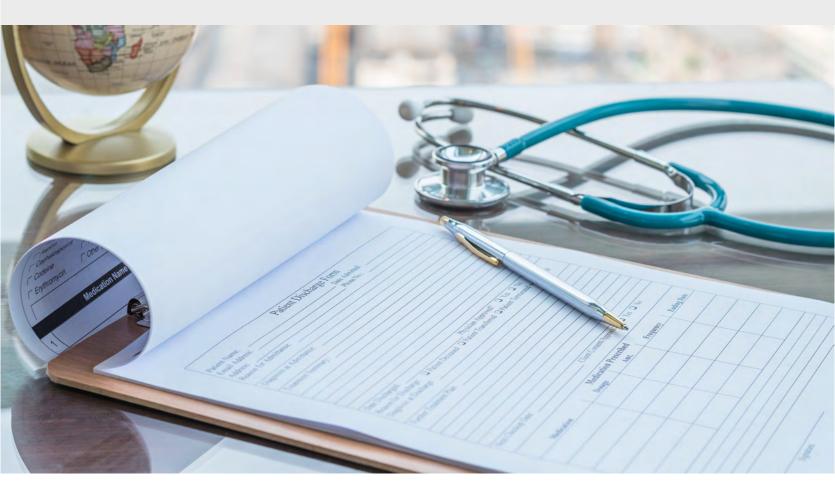
Brand	Product name	Quantity/Box
Ansell	Micro-Touch® Micro-Thin™ Nitrile Exam Gloves	200
Crown	VGlove Nitrile Examination Gloves	100
Sonic	Powder Free Nitrile Gloves	270
PRIMED	Move™ Nitrile Exam Gloves	150

# Medical-Grade Gowns

Brand	Product name	Quantity/Box
PRIMED	Overhead Protective Film Gown	20

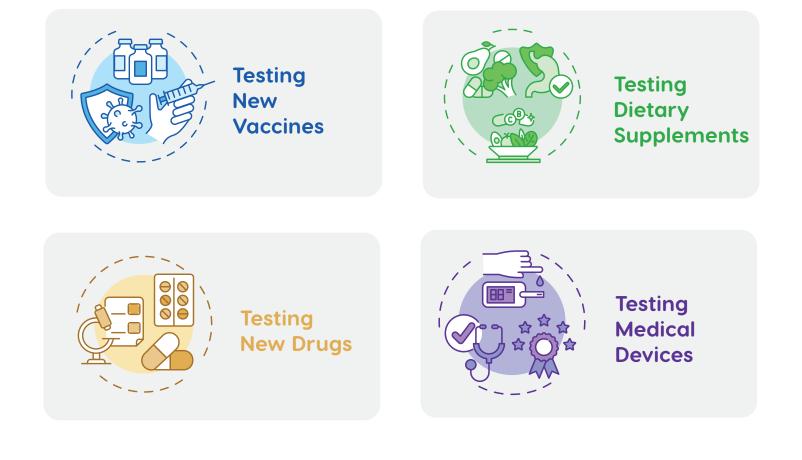


# **Global Medical Device Consulting**



# Health Canada | FDA/EUA | CE Medical Device Registration

# Gene Bio Medical Clinical Trial Consultation



# Health Canada under Interim Order



The Interim Order provides an expedited authorization pathway for: new COVID-19 medical devices that are not yet licensed in Canada. COVID-19 related uses for existing devices licensed under the Medical Devices Regulations or Interim Order No.

# What are MDL and MDEL?

The MDL (approval licence) is an approval of the device, while the MDEL (factory license) is a permit given to the manufacturer/distributor/importer company.

The foreign medical device (class I) manufacturer who intends to sell their medical devices directly to the user in Canada must obtain an MDEL. The manufacturer who intends to sell to the importer on-site must obtain it if he/she is not already in possession of it.

Class II, III and IV medical device manufacturers will also need to prove that they have a certified ISO 13485 quality management system under the Medical Device Single Audit Program (MDSAP).

# FDA/EUA (United States)

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.



# About Emergency Use Authorizations (EUAs)

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when the Secretary of HHS declares that an emergency use authorization is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.

The HHS declaration to support such use must be based on one of four types of determinations of threats or potential threats by the Secretary of HHS, Homeland Security, or Defense.



# About CE marking

Many products require CE marking before they can be sold in the EU. CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.

# When is CE marking mandatory?

CE marking is only obligatory for products for which EU specifications exist and require the affixing of CE marking.

Some products are subject to several EU requirements at the same time. You must make sure that your product complies with all the relevant requirements before affixing the CE marking to it. It is forbidden to affix the CE marking to products for which EU specifications do not exist or do not require the affixing of CE marking.

# Gene Bio Medical Innovative Diagnostics Solutions

With our professionalism and innovation, we aim to establish as a comprehensive, advanced, and reliable service provider for the diversified biomedical industry in the world and become a leader in the biomedical industry.



Our brands

This brochure is intended for the Canadian Market and may not cover all our products. For clients in other locations, please contact us for more information regarding products available for your region.



# CONTACT US

Tel: (604) 370-0166

Email: sales@genebiomedical.com

www.genebiomedical.com