



# MICROBIX PRODUCT CATALOGUE

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Proudly serving the global infectious disease diagnostics industry since 1985

February 2023 – Issue 2

# Table of Contents

<b>1.0 About Microbix</b>	<b>3</b>
1.1 Our History	4
1.2 Core Competency	14
1.3 Facilities	15
1.4 Quality Systems	16
1.4.1 Certifications	17
<b>2.0 Antigen Products</b>	<b>20</b>
2.1 About Our Antigens	21
2.2 ToRCH Antigens	22
2.3 Respiratory Antigens	25
2.4 Childhood Disease Antigens	27
2.5 STI Antigens	29
2.6 Dengue Antigens	31
2.7 Other Antigens	32
<b>Infectious Disease External Quality Controls</b>	<b>33</b>
3.1 Background	34
3.2 Our Relationship with Copan	35
3.3 Products	36
3.3.1 COVID-19 Products	37
3.3.2 Other Respiratory Products	42
3.3.3 Sexual Transmitted Infections (STI) Products	49
3.3.4 Human Papillomavirus Products	55
3.3.5 Gastrointestinal Products	61
3.3.6 Genital Ulcer Disease (GUD) Products	64
3.4 ONBOARDx™ Kits	68
<b>4.0 Proficiency Test Products</b>	<b>71</b>
4.1 About Our Proficiency Test Products	72
<b>5.0 DxTM™ Viral Transport Medium</b>	<b>73</b>
6.0 Distributors	75

# 1.0 About Microbix

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# 1.1 Our History

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## 1980s

Microbix's founder William J. Gastle develops the first product at his home in Ontario, Canada. The company was originally called Animal Health Laboratories Inc.

## 1984

William J. Gastle changes the name to Microbix Biosystems Inc.



Microbix  
Biosystems Inc.



## 1990s

Microbix occupies three sites in Toronto:

341 Bering Avenue, 109 Judge Road and 111 Judge Road.

## 1990

Microbix goes public on the Toronto Stock Exchange.



## 1995

### Our Focus on Innovation

- Microbix uses the antigen business to financially support large market opportunities.
- Microbix develops BioBlox, a new education product.
- Microbix develops ThromboClear™, a biosimilar thrombolytic drug. In 2008, Microbix acquired the NDA of the original, approved version of this drug now known by the name Kinylytic®.





## 2000s

- Microbix develops and patents VirusMax, an influenza vaccine productivity innovation.
- Microbix partners with Genpharm (the Canadian generics division of Merck KGaA) to advance Thromboclear (the original product was Abbokinase made by Abbott Laboratories), eventually replaced by Kinlytic.
- Microbix develops and patents LumiSort (a cell sorting technology to separate X and Y chromosome bearing sperm cells for dairy and other industries).

## 2006

Microbix creates pandemic kits to help combat H1N1 influenza, commonly-known at the time as 'bird flu'.



2008

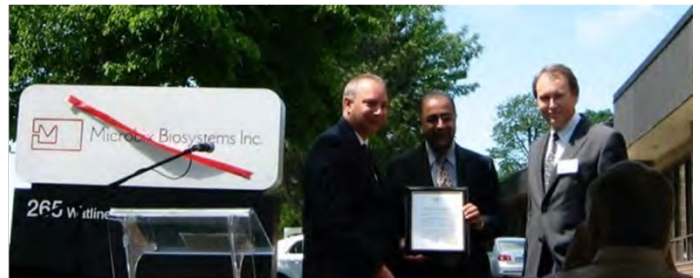


PTQ™

Microbix starts supplying PT samples, an important step towards QAPs™. Microbix offers a range of products to proficiency organizations for use in their clinical laboratory certification programs.

2009

Microbix purchases 265 Watline Avenue and develops the site creating a state of the art, CL2+ facility to produce live pathogens. A formal opening ceremony was led by world-renowned Mayor of Mississauga, Hazel McCallion.



## 2010s



### 2012

Microbix appoints Vaughn Embro-Pantalony as the new CEO & President.

Mr. Embro-Pantalony previously held senior executive positions in large biopharmaceutical and agriculture companies, including VP, Finance & CFO at Novopharm Limited, VP, Information Technology & CIO at Bayer Inc., VP, Finance & Administration at Bayer Healthcare, and General Manager of Terra International.

### 2015

Microbix signs its first Molecular Diagnostics Agreement with Microbiologics Inc. The partnership combines the companies' expertise in biomaterial development, preservation, and distribution to create highly stable viral controls for molecular testing.



### 2016

Microbix confirms its production ramp-up, with a 500% increase in bioreactor capacity and other processing upgrades to improve the efficiency, capacity and reliability of its rubella products.





## 2017

Microbix appoints Meridian Life Science, Inc. (a wholly-owned company of Meridian Bioscience, Inc.) as exclusive distributor in Asia-Pacific.

Meridian receives exclusive distribution rights to Microbix antigen products for China, Hong Kong, Taiwan and Macau.



Cameron Groome is appointed the new CEO of Microbix.

Before joining Microbix, he was the CEO of a company listed on the TSX Venture Exchange and EVP of a TSX-listed company, both in life sciences. Before his operational roles, he headed the healthcare activities of two national investment dealers. He has more than 25 years of experience as a leader, executive, equity analyst, investment banker, and corporate advisor. He has also been a member of the Life Sciences Advisory Group of Global Affairs Canada, and a director of public and private companies.

## 2018

Microbix launches its new Quality Assessment products (QAPs™), manufactured from native pathogens or synthetic whole genome of pathogens – to represent a very close facsimile of patient samples.

Microbix adds the PROCEED™ line to its quality assessment offerings, for use in research, assay development, validation/verification of instruments, troubleshooting, and operator training.



**PROCEED™**

## 2018 Business Innovation Award

Presented by



Microbix wins the 2018 Business Innovation Award in recognition of innovations relating to manufacturing, development, and international commercialization of biological products for the diagnostics industry.

## 2019

Microbix expands its new Quality Assessment products (QAPs™). All QAPs™ are manufactured from native pathogens or synthetic whole genome of pathogens, representing very close facsimiles to patient samples.

Microbix adds the REDx™ controls line to its portfolio, intended to evaluate laboratory testing performance, procedures, and workflow in nucleic acid and/or antigen-based assays that detect infectious disease pathogens in patient samples.

REDx™ Controls are designed to control the diagnostic process by detecting deviations from desired assay performance. All REDx™ controls are manufactured under ISO 13485: 2016 standard, FDA 21 CFR Part 820 Regulations and CE-marked under EU regulations. They are available for purchase in Canada, USA, Europe, UK and Australia.



**REDx**™ controls



In order to effectively support its QAPs™ programs, Microbix announces a long term lease of an additional office, production, and warehousing space at 235 Watline Avenue in Mississauga.

The newly-leased space further provides 10,300 square feet of space adjacent to its fully-owned 14,000 square foot production site at 265 Watline Avenue.

## 2020s

2020

Microbix and Copan Italia S.p.A. (Copan®), the global leader in specimen collection technologies, announce the execution of a strategic agreement with Microbix's quality assessment products (QAPs™) and Copan's flocced devices (FLOQ®).

This combines Copan's well-known FLOQ® brand with Microbix's emerging PROCEEDx™ (RUO) and REDx™ (IVD) brands – to create PROCEEDx™FLOQ® and REDx™FLOQ® as worldwide branding for active co-marketing of leading-edge FLOQSwab-formatted QAPs™ by Microbix and Copan.



Microbix's receives a grant of \$1.45 million from the Ontario Together Fund to cover 50% of the cost to scale-up production of two emerging Microbix product lines – Viral Transport Medium (now branded as DxTM™), and Quality Assessment Products (QAPs™) to assist in managing the pandemic across Canada, Australia, the EU, Scandinavia, the UK, and the US.

**Copan**  
innovating together



**REDx FLOQ PROCEEDx FLOQ**

William J. Gastle, Microbix's founder, and former CEO and Chairman of the Board, retires.



2021

Microbix receives a \$4.25 million order for its viral transport medium (generically known as “VTM” and branded as “DxTM™” by Microbix).

DxTM is a test sample-collection device that is essential for PCR-testing for the virus causing COVID-19 disease.



Microbix announces collaboration with SpeeDx Pty. Ltd (SpeeDx), under which Microbix will be exclusive developer of Quality Assessment Products (QAPs™) to facilitate the registration and commercialization of SpeeDx diagnostic assays.



Microbix secures a third manufacturing site in Mississauga, Ontario, a long-term lease agreement for a property adjacent to its two current sites. This site is reconfigured and equipped to support additional business activities, including implementation of further scale-up, full automation of production processes for its DxTM™ branded viral transport medium (generically known as “VTM”), and commissioning of additional space for other fully-automated production processes, including vial-formatted or FLOQSwab®-formatted quality assessment products (QAPs™).

## 2022

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Microbix launches their first podcast titled “Diagnostics: Beyond the Lab”, featuring industry leaders in the scientific and health community discussing discoveries, challenges, and the future of their fields. Collaborations included guests from Copan, Beckton Dickinson, Newfoundland Memorial Hospital, Government of Ontario and SpeedX.



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Microbix upgrades its mission-critical QMS and ERP systems to MasterControl® and NetSuite®, respectively. MasterControl has been a market leader for over 25 years, is active in over 50 countries and has a distinct Medtech focus – with over 750 client companies in that field. NetSuite has over 29,000 unique clients, with over 1,000 in the Medtech/Pharma fields. Its ERP integrates seamlessly with MasterControl eQMS to provide Microbix with a complete and scalable digital solution.

## 1.2 Core Competency

Microbix Biosystems Inc. develops and commercializes proprietary biological and technological solutions for human health and well-being. We manufacture a wide range of biological materials for the global diagnostics industry, notably antigens used in immunoassays and Quality Assessment Products (QAPs™). In 2021 we launched our first Viral Transport Medium, branded as DxTM™.

Microbix's business of producing high-quality viral and bacterial preparations stems from over three decades of experience in the field, including strain selection, reliable and efficient organism culture at scale, purification, and pathogen inactivation. As a result of Microbix's expertise, its products have received widespread and longstanding customer acceptance, with continuing growth in demand. Microbix's current catalogue of biological preparations cover a range of pathogens that are implicated in maternal, pediatric, respiratory, sexually transmitted, and insect-borne diseases.

Microbix also applies its biological expertise to develop other innovative and proprietary technologies and products. Our development project pipeline currently includes Kinlytic® Urokinase, a biologic thrombolytic drug used to treat blood clots.

**All Microbix products are manufactured under our strict Quality Management System certified to requirements of ISO:9001, ISO:13485 standards**



## 1.3 Facilities

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Microbix has 3 buildings with a total of 34,000 square feet on its campus. Each building houses a mixture of warehousing, office, and manufacturing space. Microbix is located close to Toronto International Airport, which facilitates communications, easy access to international visitors, shipment of finished products, and supply of raw materials.



### **265 Watline Avenue**

Our building is a wholly-owned 14,000 square foot office, manufacturing, and testing facility, with specific manufacturing space designed to meet CL2+ standards. It is purpose-built to safely and efficiently produce and inactivate viral and bacterial pathogens at an industrial scale while implementing a Quality Management System that adheres to ISO:9001 and ISO:13485 standards. We have built-in redundancy that ensures continuity of supply, with proprietary seed and cell banks kept at multiple sites. We also have continuous operation during any power outage through a custom UPS-natural gas generator system that ensures all equipment is operationally ready.

### **235 Watline Avenue**

Our second building is a 10,000 square foot facility primarily focused on the production of our non-infectious liquid and swab-based Quality Assessment Products (QAPs™). This facility contains three new, purpose-built laboratories in addition to fill, finish, and packaging space to support Manufacturing, Quality Control, and R&D needs.

### **275 Watline Avenue**

Our newly acquired third facility (also 10,000 square feet) will be operational in early 2022, with its primary focus on large-scale production of Viral Transport Medium (DxTM™), development of new product lines in this area, and substantial warehousing support.

## 1.4 Quality Systems

Quality is a process that ensures customers receive products that meet or exceed their needs and expectations. Microbix takes pride in providing customers with high-quality products. Our manufacturing starts from qualified master and working cell and seed banks.


As part of Microbix's Quality Management System, our manufacturing operations take place in a cleanroom environment protection, with a strict cleaning regime and environmental management. Furthermore, Microbix takes pride in hiring employees that are highly experienced in cell and tissue culture to develop and commercialize high-quality products. Our manufacturing site is certified to the most current and applicable ISO standards (ISO 13485:2016, ISO 9001:2015).





# 1.4.1 Certifications

## Health Canada


 Health Canada / Santé Canada
 id: 154100

Licence Number: 12336      Numéro de la licence: 12336

**Medical Device Establishment Licence**      **Licence d'établissement pour les instruments médicaux**

**MICROBIX BIOSYSTEMS INC**

SITE #1, 285 WATLINE AVENUE  
 MISSISSAUGA, ONTARIO  
 CANADA  
 L4Z 1P3

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This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

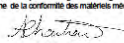
	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	No / Non	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

**Attestation made :**      **Attestations faites :**

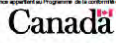
The establishment has documented procedures in place in respect of: <ul style="list-style-type: none"> <li>distribution records</li> <li>complaint handling</li> <li>recalls</li> <li>mandatory problem reporting</li> <li>handling, storage, delivery</li> <li>installation</li> <li>corrective action</li> <li>servicing</li> </ul>	[Y] [Y] [Y] [Y] [N] [N] [N] [N]	L'établissement a mis en oeuvre une procédure écrite concernant: <ul style="list-style-type: none"> <li>les registres de distribution</li> <li>les plaintes</li> <li>les rappels</li> <li>rapports d'incident obligatoires</li> <li>la manutention, le stockage, la livraison</li> <li>l'installation</li> <li>les mesures correctives</li> <li>l'entretien</li> </ul>
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*Site listing begins on the back of this page*      *Liste des sites commence au verso de cette page*

Issue Date, date de délivrance: 2020-04-21

Minister of Health Ministère de la santé	Counterigned: Director, Medical Device Compliance Program or delegated authority Contresigné par: Directeur, Programme de la conformité des matériels médicaux ou autorité déléguée   Anik Michelle Chartrand
---------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

This licence is the property of the Medical Device Compliance Program and must be returned upon demand.  
 Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.


Page 1 of 2

## ISO Certifications




### Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Microbix Biosystems Inc.  
 285 Watline Avenue  
 Mississauga  
 Ontario  
 L4Z 1P3  
 Canada

Holds Certificate No: **FM 552929**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Development and manufacture of infectious disease antigens.

For and on behalf of BSI:

  
 Carlos Ribeiro, Chief Operating Officer - Assurance - Americas

Original Registration Date: 2009-09-04      Effective Date: 2021-01-04  
 Latest Revision Date: 2021-07-16      Expiry Date: 2024-09-03

Page: 1 of 2




making excellence a habit™

The certificate holder has provided all the information required for the registration of the certificate. The certificate holder is responsible for ensuring that the certificate holder complies with the requirements of the standard. The certificate holder is responsible for ensuring that the certificate holder complies with the requirements of the standard.




### Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Microbix Biosystems Inc.  
 285 Watline Avenue  
 Mississauga  
 Ontario  
 L4Z 1P3  
 Canada

Holds Certificate No: **FM 660560**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development and manufacture of sample transport media, Quality Assessment Products (QAP) for proficiency testing, validation and verification panel and critical quality control.

For and on behalf of BSI:

  
 Gary E. Stack, Senior Vice President - Medical Devices

Original Registration Date: 2018-12-21      Effective Date: 2021-01-04  
 Latest Revision Date: 2021-07-16      Expiry Date: 2024-09-03

Page: 1 of 2




making excellence a habit™

The certificate holder has provided all the information required for the registration of the certificate. The certificate holder is responsible for ensuring that the certificate holder complies with the requirements of the standard. The certificate holder is responsible for ensuring that the certificate holder complies with the requirements of the standard.



# 1.4.1 Certifications

## TGA Certifications

### MANUFACTURER'S DECLARATION OF CONFORMITY AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 (relating to the devices listed in the attached Schedule)

**Reference:** See Schedule  
**Manufacturer's Name:** Microbia Biosystems Inc.  
**Business Address:** 265 Watline Ave  
Mississauga Ontario L4Z 1P3  
CANADA  
**IVD Medical Device(s) Classification:** See Schedule  
Class of Device covered by this Declaration Class 2 IVD  
**GMDN Code and Term:** CT355 Viral Infection Disease  
**Scope of Application:** All batches  
*<For Class 1 and Class 2 IVDs:>*  
Each kind of IVD medical device complies with the applicable classification rules and essential principles before being supplied.  
*<For Class 3 IVDs:>*  
For each kind of medical device to which the Declaration of Conformity (not requiring assessment by Secretary) procedures have been applied, the Production Quality Assurance procedures set out in Part 4 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 have also been applied.  
This declaration is being made on the basis of the following certificate:  
**Production Quality Management System Certificate:**  
**Assessment Body and Certificate Number:**  
**Overseas Certification:**  
ISO 13485:2016 certificate  
HSI Group America Inc.  
No. PM 000500  
**Conformity Assessment Standards Applied:**  
A standard referenced in a listed Device Standard Order

**Authorized Signatory:**  
  
**Dr. Helen, Director QA & Compliance:** 04 July 2022  
**Name, Position:** Date

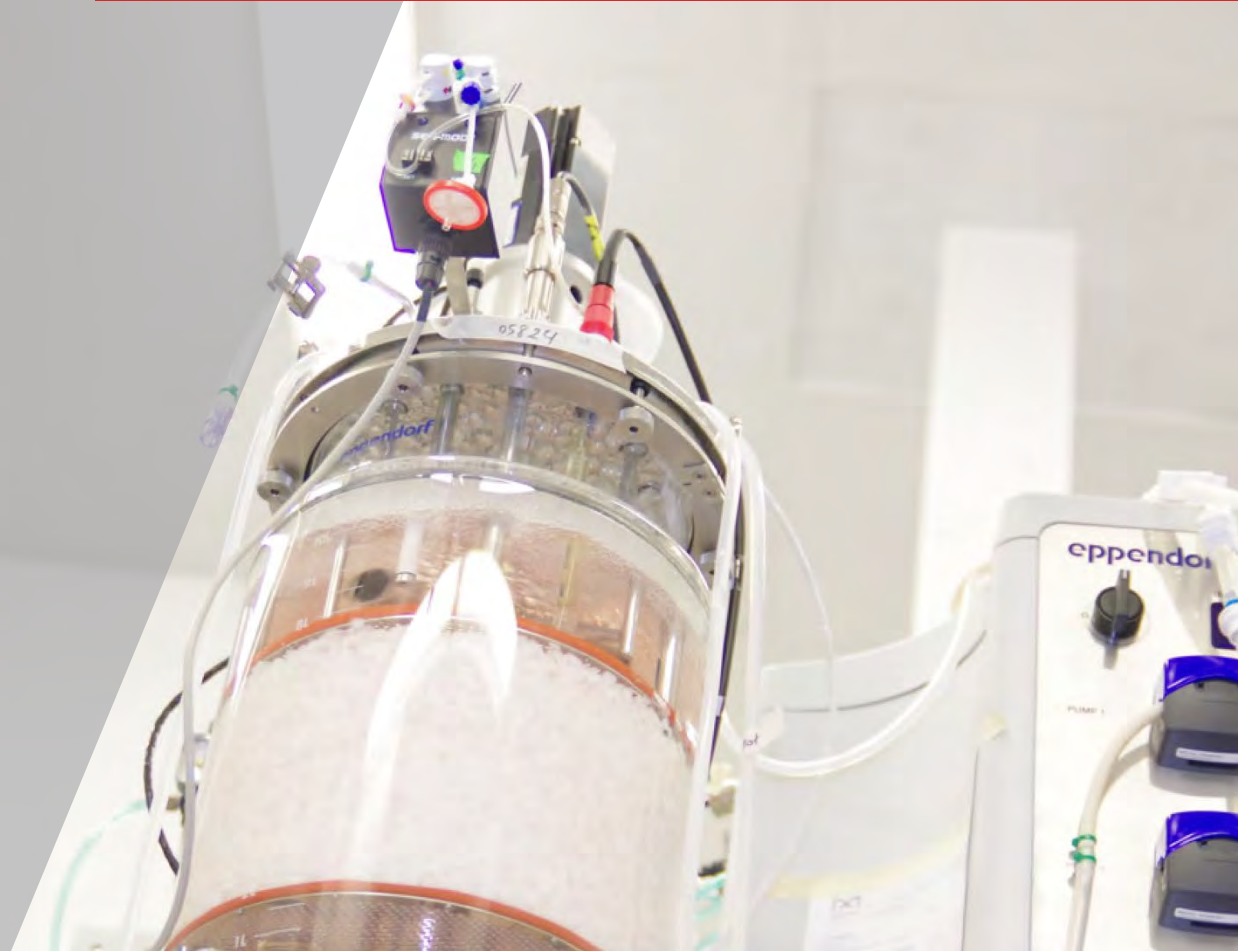
### MANUFACTURER'S DECLARATION OF CONFORMITY AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

#### SCHEDULE

HPV:  
REDx™ HPV 16 Positive (liquid control)  
REDx™ HPV 18 Positive (liquid control)  
REDx™ HPV 45 Positive (liquid control)  
REDx™ HPV Negative  
REDx™ HPV 31 Positive Control  
REDx™ HPV 33 Positive Control  
REDx™ HPV 39 Positive Control  
REDx™ HPV 51 Positive Control  
REDx™ HPV 52 Positive Control  
REDx™ HPV 66 Positive Control  
REDx™ HPV Negative Control  
REDx™ HPV 16/18/45 Positive Control  
REDx™ HPV 31/33/66 Positive Control  
REDx™ HPV 39/51/52 Positive Control  
  
Mycoplasma genitalium:  
REDx™ FLOQ®M genitalium A2058G Swab Positive Control  
REDx™ FLOQ®M genitalium A2059G Swab Positive Control  
REDx™ FLOQ®M genitalium A2059C Swab Positive Control  
REDx™ FLOQ®M genitalium A2059C Swab Positive Control  
REDx™ FLOQ®M genitalium A2058T Swab Positive Control  
  
HSV1&2/VZV/Treponema pallidum:  
REDx™ FLOQ®HSV1&2/VZV/Syphilis Swab Positive Control  
  
SARS-CoV-2:  
REDx™ SARS-CoV-2 Negative Control  
REDx™ SARS-CoV-2 Positive Control  
REDx™ FLOQ®SARS-CoV-2 Swab Negative Control  
REDx™ FLOQ®SARS-CoV-2 Swab Positive Control  
REDx™ FLOQ®SARS-CoV-2/Flu A&B/RSV Swab Positive Control  
  
SARS-CoV-2 Variant of Concern (VOC)  
REDx™ FLOQ®SARS-CoV-2 B.1.1.7 Swab Positive Control  
REDx™ FLOQ®SARS-CoV-2 B.1.351 Swab Positive Control  
REDx™ FLOQ®SARS-CoV-2 P.1 Swab Positive Control  
REDx™ FLOQ®SARS-CoV-2 B.1.1.617 Swab Positive Control  
REDx™ FLOQ®SARS-CoV-2 B.1.1.529 Swab Positive Control

## 2.0 Antigen Products

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## 2.1 About Our Antigens

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Microbix produces one of the largest ranges of infectious disease antigens at a commercial scale. These viral, bacterial, and parasitic products are used in Immunodiagnostic assays including ELISA, chemiluminescent automated immunoassays, immunohistochemistry, immunofluorescence, latex agglutination, rapid tests, and flow cytometry. They are also used as controls for diagnostic assays, basic and applied research in virology, microbiology, cell biology, immunology, and pathology, and for vaccine and antiviral research and development.

### For IVD Manufacturers:

- ToRCH Antigens
- Respiratory Antigens
- Childhood Disease Antigens
- Sexually Transmitted Infections Antigens
- Dengue Antigens
- Other Antigens



## 2.2 ToRCH Antigens

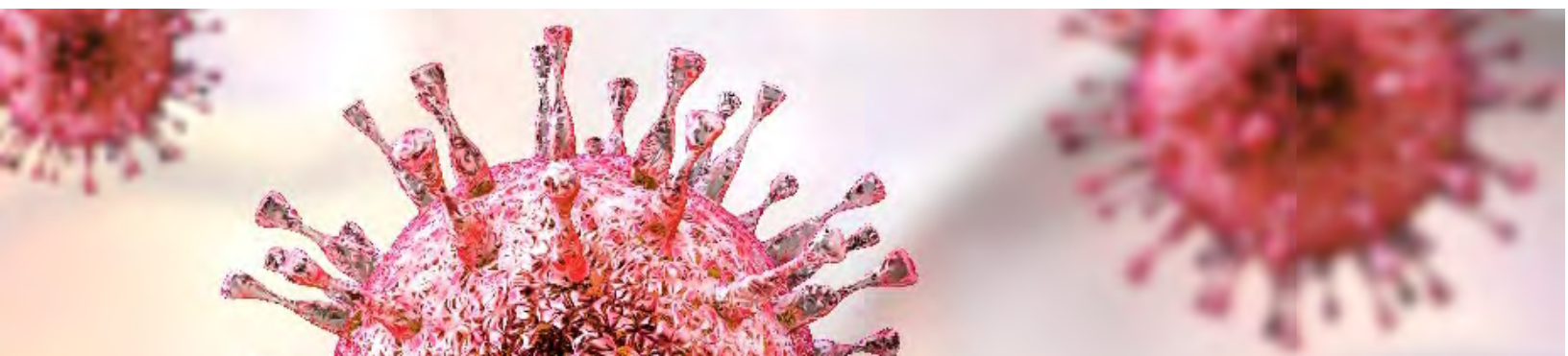
**ToRCH** infections, including **T**oxoplasmosis, **O**ther (Varicella Zoster virus, Syphilis, and Parvovirus B19), **R**ubella Virus, **C**ytomegalovirus, and **H**erpes Simplex Virus), are common etiologic agents of congenital abnormalities. These pathogens are transmitted across the placenta during pregnancy, which can give rise to serious fetal complications. Routine screening for ToRCH infections is common practice in pregnant women to rapidly detect disease and initiate proper monitoring of both the mother and fetus and avoid adverse outcomes. As a result, high-quality diagnostics are critical for proper infection management. Microbix has been a commercial leader in producing native ToRCH antigens for over 20 years. Our highly sensitive, specific, and stable native antigens are derived from cell culture-produced whole viruses that are purified and inactivated. Our trusted antigens are used by diagnostic companies worldwide to design a variety of immunoassays used in ToRCH screening.



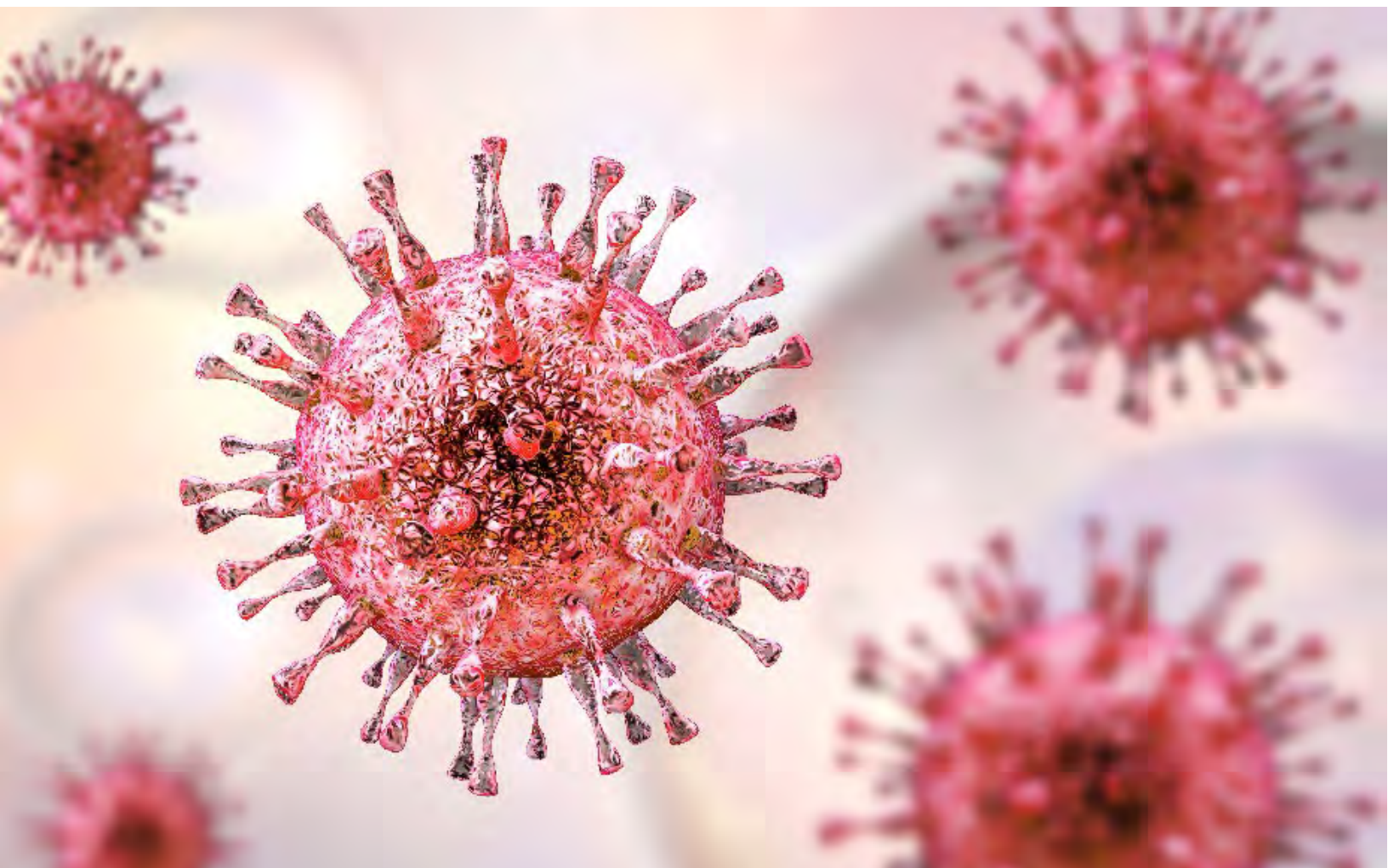
## 2.2 ToRCH Antigens

### Infectious Disease Antigens: ToRCH Antigens Products

Product Name	EL Catalogue Number	Product Description
Toxoplasma gondii, Grade IgG	EL-18-07	<b>Description:</b> Native Toxoplasma gondii antigens are obtained by extracting and subsequently centrifuging Toxoplasma tachyzoites from infected cell cultures. <b>Strain:</b> RH <b>Buffer:</b> 1% Triton x-100, Phosphate Buffered Saline pH 7.4
Toxoplasma gondii, Grade IgM	EL-18-08	<b>Description:</b> Toxoplasma Antigen, IgM Grade is produced by subjecting Toxoplasma tachyzoites to membrane fractionation, which allows for surface antigen isolation, specifically Toxoplasma p30. <b>Strain:</b> RH <b>Buffer:</b> 2% N-octyl--D-glucopyranoside (OGP) in Phosphate Buffered Saline pH 7.4
Rubella BR2S	EL-05-15	<b>Description:</b> The predominant form of the antigen is whole virions suspended in NTE with sucrose. The preparation is free of detergent. Residual non-viral protein may come from host tissue and culture medium. <b>Strain:</b> HPV-77 <b>Buffer:</b> NTE buffer (Sodium chloride, TRIS, and EDTA)
Cytomegalovirus, Grade 2	EL-01-02	<b>Description:</b> This preparation contains CMV antigens from all parts of the virus cycle of replication including early and late antigens, nuclear antigen, cytoplasmic antigen, structural and non-structural proteins. The antigen is in GBS without detergent or preservative. This preparation contains residual host cellular material. <b>Strain:</b> AD-169 <b>Buffer:</b> Glycine buffered saline (GBS) pH 9.5
Herpes Simplex 1, Grade 2	EL-02-02	<b>Description:</b> Herpes Simplex 1 Grade 2 antigen contains a high concentration of virus particles and components in a tissue culture medium containing a low concentration of bovine serum. The preparation contains no preservative or detergent. Some residual host cellular material is present. <b>Strain:</b> MacIntyre <b>Buffer:</b> Tissue culture medium
Varicella-Zoster, Grade 2	EL-03-02	<b>Description:</b> The resulting antigen preparation contains a high concentration of virus and viral components as well as some cellular material suspended in EMEM with some serum proteins. <b>Strain:</b> VZ-10 <b>Buffer:</b> EMEM



EBV Viral Capsid Ag, Purified	EL-16-06	<p><b>Description:</b> This preparation contains more than 90% virus-specific protein. The predominant form of the antigen is purified protein suspended in 20mM Tris-HCl with 3M MgCl<sub>2</sub>; pH 7.4. The preparation is free of detergent. Any residual non-viral protein comes from the host tissue and culture medium. The protein concentration is nominally 0.030 mg/ml.</p> <p><b>Strain:</b> P3H3 cells infected with EBV</p> <p><b>Buffer:</b> 20mM Tris-HCl with 3M MgCl<sub>2</sub>; pH 7.4</p>
EBV Viral Capsid Concentrate	EL-16-07	<p><b>Description:</b> This preparation contains more than 90% virus-specific protein. The predominant form of the antigen is purified protein suspended in 20mM Tris-HCl with 3M MgCl<sub>2</sub>; pH 7.4. The preparation is free of detergent. Residual non-viral protein comes from host tissue and culture medium. This preparation is a more concentrated form of EL-16-06 with a protein concentration is nominally 0.10 mg/ml.</p> <p><b>Strain:</b> P3H3 cells infected with EBV</p> <p><b>Buffer:</b> 20mM Tris-HCl with 3M MgCl<sub>2</sub>; pH 7.4</p>





## 2.3 Respiratory Antigens

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Sensitive and accurate diagnostic tests are at the forefront of respiratory disease detection and epidemiological management. Diagnostic companies are continuously improving the speed and technology underlying their tests, and thus are heavily reliant on high-quality antigens for test innovation and development. All antigens are inactivated for infectivity, not antigenicity, to ensure utmost user safety.



## 2.3 Respiratory Antigen

### Infectious Disease Antigens: Respiratory Antigen Products

Product Name	EL Catalogue Number	Product Description
Adenovirus, Grade 2	EL-15-02	<b>Description:</b> Native adenovirus antigen preparation contains a high concentration of virus and viral components as well as some cellular material in MEM. <b>Strain:</b> Adenoid 6 <b>Buffer:</b> MEM
RSV	EL-07-03	<b>Description:</b> The native RSV antigen preparation contains a high concentration of virus and viral components as well as some cellular material in HEPES + Magnesium Sulphate. <b>Strain:</b> Long <b>Buffer:</b> HEPES + Magnesium Sulphate
Parainfluenza 2, Grade 2	EL-09-02	<b>Description:</b> Native Parainfluenza 2 virus antigen preparation contains a high concentration of virus and virus components as well as some cellular material suspended in Tissue Culture Media. <b>Strain:</b> Greer <b>Buffer:</b> Tissue Culture Media
Parainfluenza 3, Grade 2	EL-10-02	<b>Description:</b> The resulting antigen preparation contains a high concentration of virus and virus components as well as some cellular material suspended in Tissue Culture Media. <b>Strain:</b> C243 <b>Buffer:</b> Tissue Culture Media
<i>Mycoplasma pneumoniae</i> , Grade 2	EL-11-02	<b>Description:</b> Native <i>mycoplasma pneumoniae</i> antigen preparation contains soluble Mycoplasma components in PBS. <b>Strain:</b> FH <b>Buffer:</b> PBS
Influenza A, Grade 2	EL-13-02	<b>Description:</b> Native influenza A virus preparation contains a high concentration of viral antigens as well as some egg proteins (allantoic fluid). <b>Strain:</b> Influenza A/New Caledonia/20/99 (/H1N1) <b>Buffer:</b> PBS
Influenza A H3N2	EL-13-03	<b>Description:</b> Native influenza A virus preparation contains a high concentration of viral antigens as well as some egg proteins (allantoic fluid). <b>Strain:</b> H3N2 Subtype <b>Buffer:</b> PBS
Influenza B	EL-14-03	<b>Description:</b> Influenza B native antigen is derived from semi-purified cell culture lysate with a high titre of Influenza B particles. Cells were infected with the Influenza B/Hong Kong 5/72 strain. <b>Strain:</b> Hong Kong 5/72 <b>Buffer:</b> EMEM
<i>Chlamydomphila (Chlamydia) pneumoniae</i>	EL-46-02	<b>Description:</b> Native <i>C. (Chlamydia) pneumoniae</i> preparation contains a high concentration of bacteria suspended in SPG buffer. <b>Strain:</b> CWL-029 <b>Buffer:</b> SPG buffer



## 2.4 Childhood Disease Antigens

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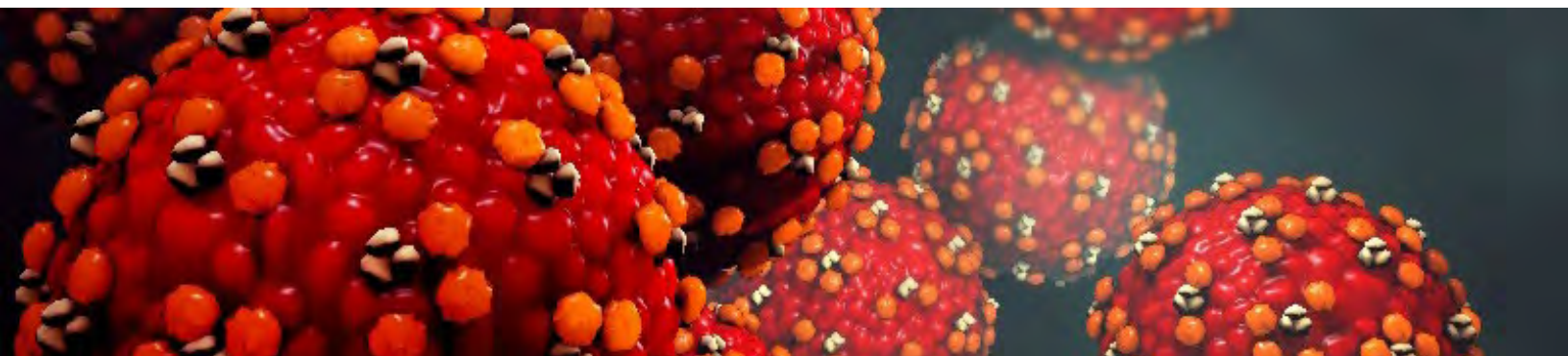
Children are exposed to a variety of communicable diseases, such as Measles, Mumps, Rubella, Epstein-Barr Virus, and Varicella Zoster. Adults can also develop symptoms and further transmit childhood viruses. To minimize the spread of disease, high-quality diagnostics, and early onset detection are required. Microbix continues to be at the leading edge of manufacturing native antigens for IVD industry leaders that specialize in childhood disease immunological test development. Our native antigens are purified and inactivated for infectivity, not antigenicity, to ensure utmost safety and satisfaction for end-users.



## 2.4 Childhood Disease Antigens

### Infectious Disease Antigens: Childhood Disease Antigens Products

Product Name	EL Catalogue Number	Product Description
Rubella BR2S	EL-05-15	<b>Description:</b> The predominant form of the native antigen is whole virions suspended in NTE with sucrose. The preparation is free of detergent. Residual non-viral protein may come from host tissue and culture medium. <b>Strain:</b> HPV-77 <b>Buffer:</b> NTE buffer (Sodium chloride, TRIS, and EDTA)
Varicella-Zoster, Grade 2	EL-03-02	<b>Description:</b> The resulting native antigen preparation contains a high concentration of virus and viral components as well as some cellular material suspended in EMEM with some serum proteins. <b>Strain:</b> VZ-10 <b>Buffer:</b> EMEM
P3H3 Cell Extract	EL-16-03	<b>Description:</b> P3H3 Cell Extract contains a high concentration of native Epstein-Barr Virus antigens, including VCA, EBNA, EA-D, and EA-R. <b>Strain:</b> P3H3 Human Burkitt's Lymphoma cells <b>Buffer:</b> Tris with NP40, sodium deoxycholate, and PMSF
EBV Viral Capsid Ag, Purified	EL-16-06	<b>Description:</b> This preparation contains more than 90% virus specific protein. The predominant form of the native antigen is purified protein suspended in 20mM Tris-HCl with 3M MgCl <sub>2</sub> ; pH 7.4. The preparation is free of detergent. Any residual non-viral protein comes from host tissue and culture medium. <b>Strain:</b> P3H3 cells infected with EBV <b>Buffer:</b> 20mM Tris-HCl with 3M MgCl <sub>2</sub> ; pH 7.4
EBV Viral Capsid Concentrate	EL-16-07	<b>Description:</b> This preparation contains more than 90% virus specific protein. The predominant form of the antigen is purified protein suspended in 20mM Tris-HCl with 3M MgCl <sub>2</sub> ; pH 7.4. The preparation is free of detergent. Residual non-viral protein comes from host tissue and culture medium. <b>Strain:</b> P3H3 cells infected with EBV <b>Buffer:</b> 20mM Tris-HCl with 3M MgCl <sub>2</sub> ; pH 7.4
Measles, Grade 2	EL-04-02	<b>Description:</b> The resulting native antigen preparation contains a high concentration of virus and viral components as well as some cellular material suspended in MEM. <b>Strain:</b> Edmonston <b>Buffer:</b> MEM
Mumps, Grade 2	EL-06-02	<b>Description:</b> The resulting native antigen preparation contains a high concentration of virus and viral components as well as some cellular material suspended in 1969B. <b>Strain:</b> Enders <b>Buffer:</b> 1969B



## 2.5 STI Antigens

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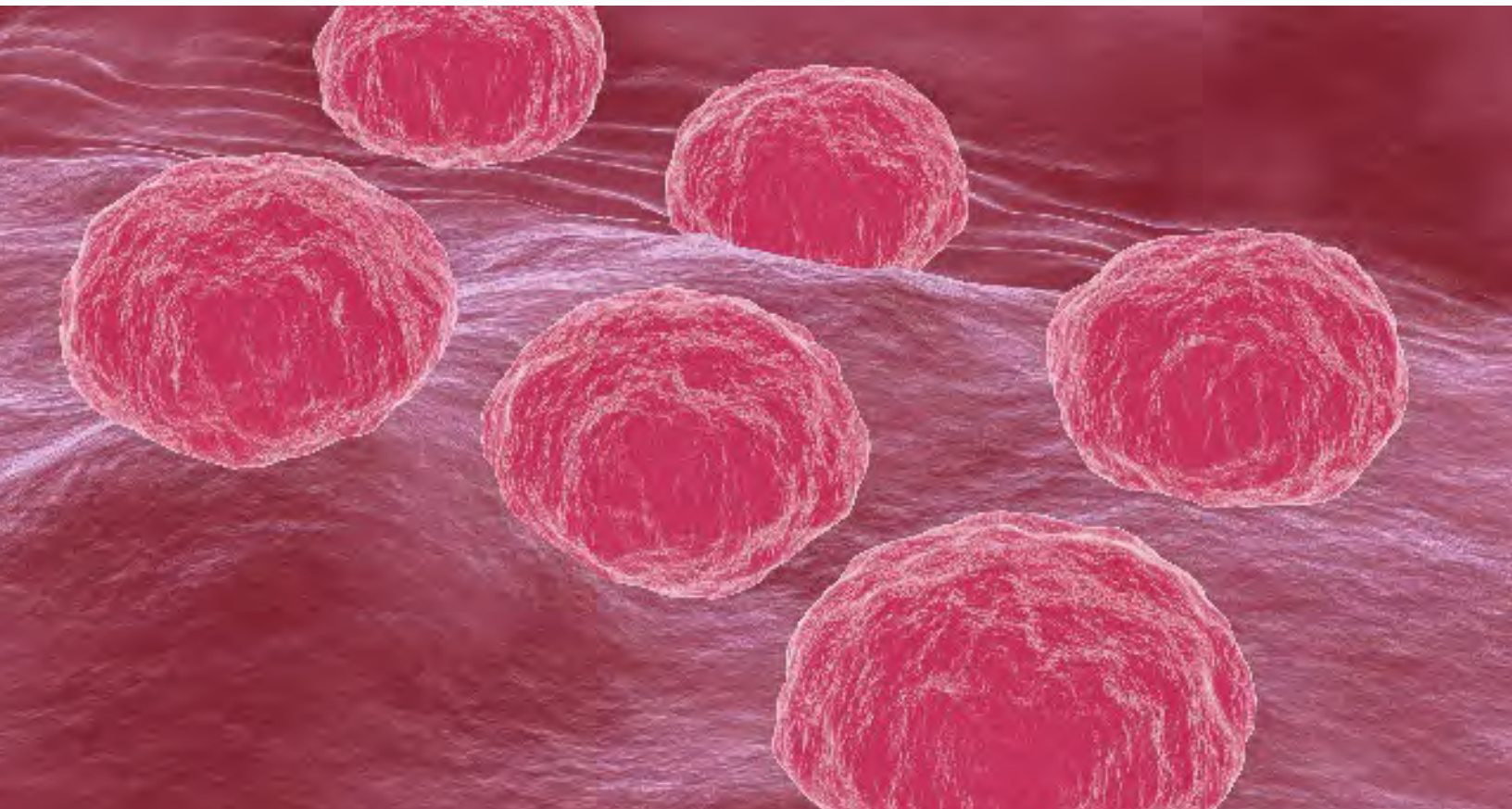
Sexually transmitted infections (STIs) are classified as infections transmitted via sexual contact. Such infections can have profound effects on an individual's sexual, reproductive, and overall health. That said, proper diagnosis is essential for infection management and the prevention of adverse health outcomes. All antigens are purified and inactivated for infectivity, not antigenicity, to ensure utmost safety and satisfaction for end-users.



## 2.5 STI Antigens

### Infectious Disease Antigens: STI Antigens Products

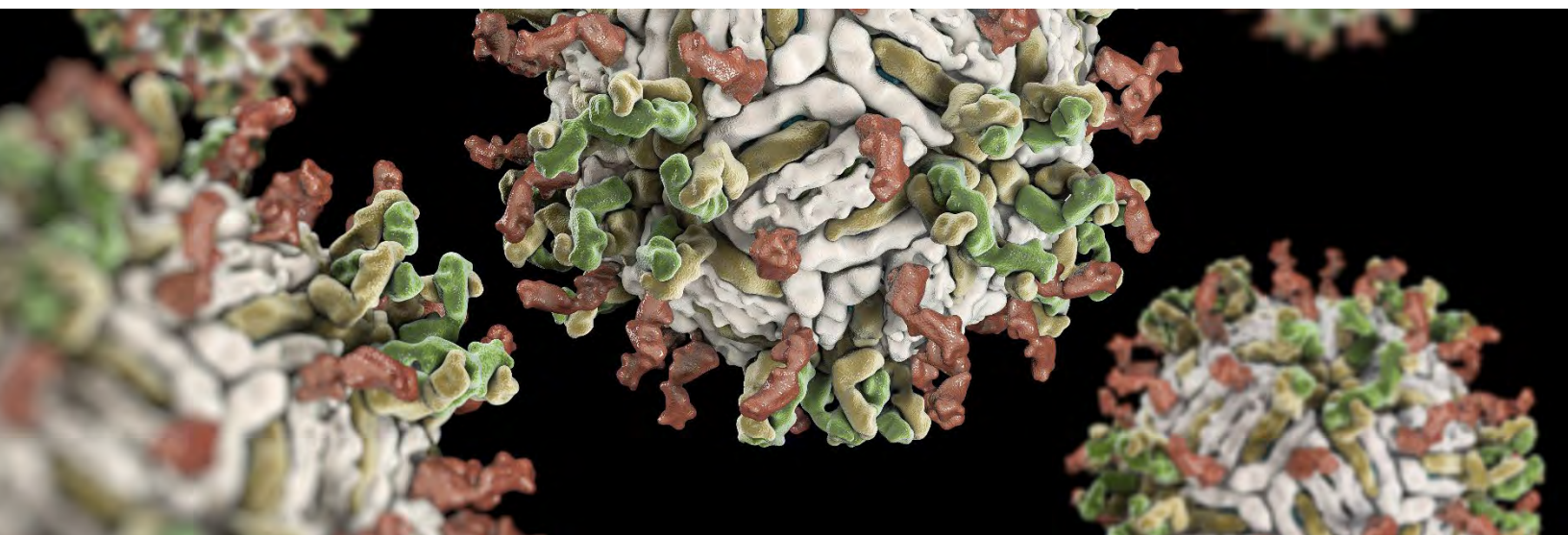
Product Name	EL Catalogue Number	Product Description
<i>Chlamydomphila</i> ( <i>Chlamydia</i> ) <i>trachomatis</i> , Grade 2	EL-12-02	<b>Description:</b> <i>C. trachomatis</i> grade 2 antigen contains a high concentration of elementary bodies and chlamydial components in PBS. The preparation contains no preservative or detergent. Residual host cellular material is present. <b>Strain:</b> <i>C. trachomatis</i> LGV type II strain 434 <b>Buffer:</b> Phosphate buffered saline pH 7.2
Herpes Simplex 1, Grade 2	EL-02-02	<b>Description:</b> HSV-1 Grade 2 antigen contains a high concentration of virus particles and components in tissue culture medium containing a low concentration of bovine serum. The preparation contains no preservative or detergent. Some residual host cellular material is present. <b>Strain:</b> MacIntyre <b>Buffer:</b> Tissue culture medium
Herpes Simplex 2, Grade 2	EL-23-02	<b>Description:</b> HSV-2 Grade 2 antigen contains a high concentration of virus particles and components in tissue culture medium containing a low concentration of bovine serum. The preparation contains no preservative or detergent. Some residual host cellular material is present. <b>Strain:</b> MS <b>Buffer:</b> Tissue culture medium



## 2.6 Dengue Antigens

### Infectious Disease Antigens: Dengue Antigens Products

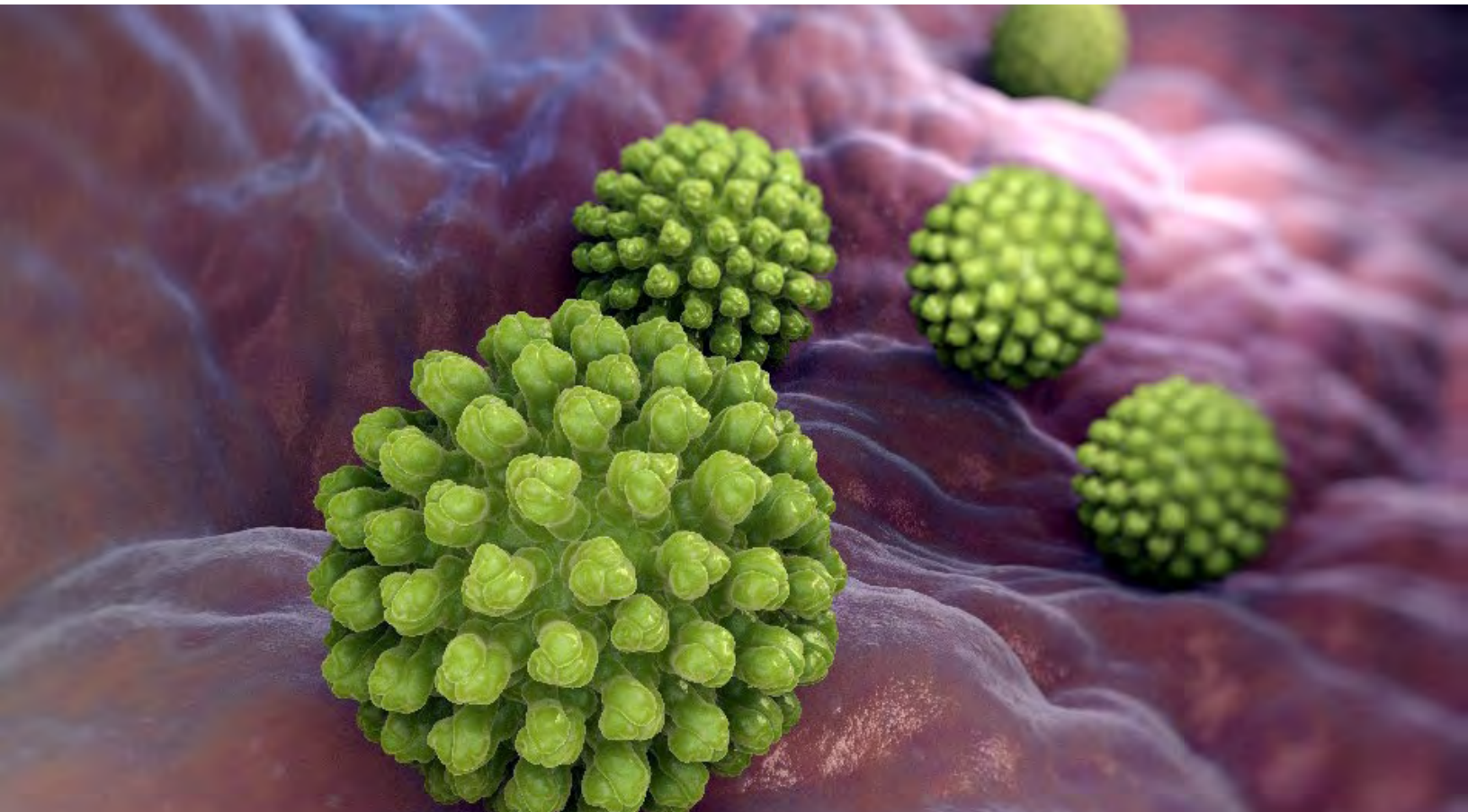
Product Name	EL Catalogue Number	Product Description
Dengue Type 1	EL-52-02	<b>Description:</b> A purified preparation of native Dengue 1 virus particles suitable for use in assays for detection of the presence of antibodies against Dengue 1 virus, and as a positive control for the presence of the Dengue 1 virus antigens in a sample. The product is formulated in a buffer that should not interfere with conjugation chemistries that are typically used in immunoassay development. <b>Strain:</b> West Pacific 74 <b>Buffer:</b> Potassium phosphate-based buffer, pH 7.2
Dengue Type 2	EL-22-02	<b>Description:</b> A purified preparation of native Dengue 2 virus particles suitable for use in assays for detection of presence of antibodies against Dengue 2 virus, and as a positive control for the presence of the Dengue 2 virus antigens in a sample. The product is formulated in a buffer that should not interfere with conjugation chemistries that are typically used in immunoassay development. <b>Strain:</b> 16681 <b>Buffer:</b> Medium 199
Dengue Type 3	EL-53-02	<b>Description:</b> A purified preparation of native Dengue 3 virus particles suitable for use in assays for detection of the presence of antibodies against Dengue 3 virus, and as a positive control for the presence of the Dengue 3 virus antigens in a sample. The product is formulated in a buffer that should not interfere with conjugation chemistries that are typically used in immunoassay development. <b>Strain:</b> CH53489 <b>Buffer:</b> Potassium phosphate-based buffer, pH 7.2
Dengue Type 4	EL-54-02	<b>Description:</b> A purified preparation of native Dengue 4 virus particles suitable for use in assays for detection of the presence of antibodies against Dengue virus and as a positive control for the presence of the Dengue virus antigens in a sample. The product is formulated in a buffer that should not interfere with conjugation chemistries that are typically used in immunoassay development. <b>Strain:</b> TVP-360 <b>Buffer:</b> Potassium phosphate-based buffer, pH 7.2



## 2.7 Other Antigens

### Infectious Disease Antigens: Gastrointestinal and Other Antigens Products

Product Name	EL Catalogue Number	Product Description
<i>Borrelia burgdorferi</i>	EL-24-02	<b>Description:</b> <i>Borrelia Burgdorferi</i> native antigen is isolated from the B31 strain cultured in BSK 11 medium. <b>Strain:</b> B31 <b>Buffer:</b> PBS with magnesium
Rotavirus Grade 3	EL-35-03	<b>Description:</b> Rotavirus native antigen is isolated from cultured MA104 cells that were infected with the Simian rotavirus SA11 strain. <b>Strain:</b> Simian rotavirusSA11, ICW 00.060.0.03.001.00.201.001 <b>Buffer:</b> MA104 cells





# 3.0 Infectious Disease External Quality Controls Quality Assessment Products (QAPs™)

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# 3.1 Background

## Why choose Microbix Quality Assessment Products?

- Derived from inactivated native pathogens or whole-genome synthetic constructs
- Simulates patient specimens
- Products are inactivated and non-hazardous
- Available in liquid and swab (Copan FLOQSwab®) formats
- Stored at 2-8°C (liquid vial) or 2-30°C (Copan FLOQSwab®)
- Commutable and cross-platform compatible
- Compatible with molecular and immunoassays
- Confirmed performance on leading IVD assays

RED <sup>TM</sup> controls	PROCEED <sup>TM</sup>	ONBOARD <sup>TM</sup> kit
<i>Quality Control</i>	<i>Verification/Validation</i>	<i>Verification/Validation Starter Kit</i>
		
<p>RED<sup>TM</sup> products are unassayed controls used for evaluating laboratory testing performance, procedures, and workflows            Certifications: ISO 13485, IVD, CE</p>	<p>PROCEED<sup>TM</sup> products are used for assay verification/validation, training, and R&amp;D purposes. Products are for RESEARCH USE ONLY!            Certifications: ISO 9001, ISO 13485</p>	<p>ONBOARD<sup>TM</sup> are all-encompassing sample kits for assay verification/validation, instrument qualification and operator training. Kits contain positive and negative samples from the PROCEED<sup>TM</sup> product line. Products are for RESEARCH USE ONLY!            Certifications: ISO 9001, ISO 13485</p>

## 3.2 Our Relationship with Copan

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### The Microbix-Copan Collaboration



Copan's "FLOQ®" swab is recognized globally as the gold standard swab used for sample collection. Copan and Microbix have had a long relationship where for years, Microbix has provided Copan with inactivated pathogens and has purchased their FLOQSwabs®. In 2019 the companies began discussing a collaboration whereby Microbix was given exclusive access to Copan's intellectual property rights, enabling us to manufacture controls and other quality assessment products (QAPs™) on Copan's FLOQSwabs®. In 2020, the relationship was formalized with a long-term agreement.

Copan's FLOQ® Swab is meticulously engineered. Its properties include a precise and consistent surface area from swab to swab across every lot produced ensuring our control material is desiccated onto and eluted from each swab in an extremely repeatable and predictable manner. This is a critical attribute for controls since clinical laboratories track and trend the performance data of controls over extended periods.

The companies agreed to co-brand the QAPs™ swab product lines as "REDx™FLOQ®Controls" and "PROCEEDx™FLOQ®". Today, Microbix provides QAPs™ desiccated on FLOQ® Swabs for use by diagnostic labs, External Quality Assessment providers, Original Equipment Manufacturers, and more.



**MICROBIX**  
THE FLOQ® SWAB QUALITY CONTROL COMPANY



# 3.3 Products



## 3.3.1 COVID-19 Products

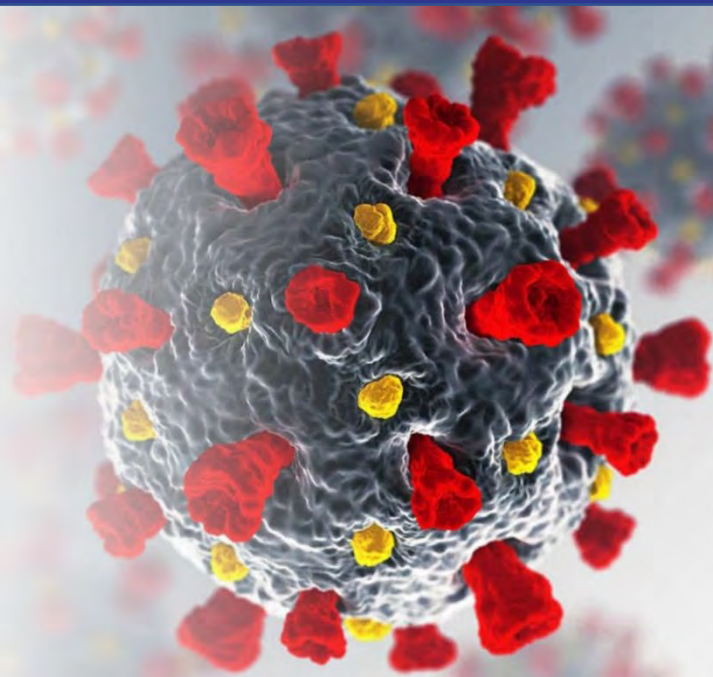
### **SARS COMPLETE™**

#### *QAPs™ for SARS-CoV-2 Molecular Diagnostics*

- Formulated with SARS-CoV-2 whole genome (cDNA) and human cells
- Whole-process samples (including extraction)
- Liquid samples (alcohol-based Sample Transport Medium) are stable for 1 year when stored at 2-8°C; 0.5 mL volume
- Copan FLOQSwab® samples are stable for 2 years when stored at 2-30°C
- SARS-CoV-2 variants of concern are available on Copan FLOQSwab® (B.1.1.7, B.1.351, P.1, B.1.617, and B.1.1.529 with all clade-specific SNPs, deletions, and insertions present)
- Inactivated to meet clinical laboratory biosafety requirements
- Commutable and cross-platform compatible

#### *QAPs™ for SARS-CoV-2 Immunoassay Diagnostics*

- Formulated with SARS-CoV-2 nucleocapsid protein
- Desiccated on Copan FLOQSwab® - stable for 2 years when stored at 2-30°C
- Compatible with most immunological tests detecting SARS-CoV-2 N protein
- Commutable and cross-platform compatible
- Meets clinical laboratory biosafety requirements



## 3.3.1 COVID-19 Products

### COVID-19 Panel

Product Name	RED <sup>controls</sup> (IVD) Catalogue Number	PROCEED <sup>RUO</sup> (RUO) Catalogue Number	Product Description
<b>Single Analyte Products</b>			
SARS-CoV-2 Positive	RED-19-01	VP-19-01	<p>These products are formulated with inactivated whole SARS-CoV-2 cDNA genome and human fibroblast cells, suspended in ThinPrep<sup>®</sup> PreservCyt<sup>®</sup>. Microbix SARS-CoV-2-Positive External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert<sup>®</sup> Xpress SARS-CoV-2 Assay, Cepheid Xpert<sup>®</sup> Xpress SARS-CoV-2/ Flu/RSV Assay, BD MAX<sup>™</sup> SARS-CoV-2 Assay, Seegene Allplex<sup>™</sup> 2019-nCoV Assay, and GenMark ePlex<sup>®</sup> SARS-CoV-2 Assay</p> <p><b>Format:</b> Vial; 0.5 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
SARS-CoV-2 MDx WT Positive Swab	RED-S-19-01	VP-S-19-01	<p>These products are formulated with inactivated whole SARS-CoV-2 cDNA genome and human fibroblast cells, desiccated on a Copan FLOQSwab<sup>®</sup>. Microbix SARS-CoV-2-Positive External Quality Controls have verified performance on some of the following IVD assays: Abbott ID NOW<sup>™</sup> COVID-19 Assay, BD Max<sup>™</sup> SARS-CoV-2 Assay, Cepheid Xpert<sup>®</sup> Xpress SARS-CoV-2 assay, Cepheid Xpert<sup>®</sup> Xpress SARS-CoV-2/ Flu/RSV Assay, and Seegene Allplex<sup>™</sup> 2019-nCoV Assay</p> <p><b>Format:</b> Copan FLOQSwab<sup>®</sup>  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>
SARS-CoV-2 Antigen Positive Swab	RED-S-19-02	VP-S-19-02	<p>These products are formulated with SARS-CoV-2 nucleocapsid (N) protein, desiccated on a Copan FLOQSwab<sup>®</sup>. Microbix SARS-CoV-2- Ag Positive External Quality Controls have verified performance on some of the following IVD assays: BD Veritor<sup>™</sup> COVID-19 Rapid Antigen Test, Quidel Sofia 2 Flu + SARS Antigen FIA, Abbott BinaxNOW<sup>®</sup> COVID-19 Ag Card, and Roche Elecsys<sup>®</sup> SARS-CoV-2 Antigen Assay</p> <p><b>Format:</b> Copan FLOQSwab<sup>®</sup>  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> Immuno</p>

<p>SARS-CoV-2 B.1.1.7 Variant Positive Swab</p>	<p>RED-S-19-03</p>	<p>VP-S-19-03</p>	<p>These products are formulated with inactivated whole SARS-CoV-2 B.1.1.7 cDNA genome and human fibroblast cells, desiccated on a Copan FLOQSwab®. Microbix SARS-CoV-2 B.1.1.7 Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Abbott Alinity m SARS-CoV-2 Assay, Quidel Lyra SARS-CoV-2 Assay, BD Max™ SARS-CoV-2 Assay, Cepheid Xpert® Xpress SARS-CoV-2 assay, Cepheid Xpert® Xpress SARS-CoV-2/ Flu/RSV Assay, Seegene Allplex™ SARS-CoV-2 Variants I Assay, and EliTech Group SARS-CoV-2 ELITE Plus MGB® Assay.</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>
<p>SARS-CoV-2 B.1.351 Variant Positive Swab</p>	<p>RED-S-19-04</p>	<p>VP-S-19-04</p>	<p>These products are formulated with inactivated whole SARS-CoV-2 B.1.351 cDNA genome and human fibroblast cells, desiccated on a Copan FLOQSwab®. Microbix SARS-CoV-2 B.1.351 Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Abbott Alinity m SARS-CoV-2 Assay, Quidel Lyra SARS-CoV-2 Assay, BD Max™ SARS-CoV-2 Assay, Cepheid Xpert® Xpress SARS-CoV-2 assay, Cepheid Xpert® Xpress SARS-CoV-2/ Flu/RSV Assay, Seegene Allplex™ SARS-CoV-2 Variants I Assay, and EliTech Group SARS-CoV-2 ELITE Plus MGB® Assay.</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>
<p>SARS-CoV-2 P.1 Variant Positive Swab</p>	<p>RED-S-19-05</p>	<p>VP-S-19-05</p>	<p>These products are formulated with inactivated whole SARS-CoV-2 P.1 cDNA genome and human fibroblast cells, desiccated on a Copan FLOQSwab®. Microbix SARS-CoV-2 P.1 Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress® SARS-CoV-2/ Flu/RSV Assay, Seegene Allplex™ SARS-CoV-2 Variants I Assay and EliTech Group SARS-CoV-2 ELITE Plus MGB® Assay</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>

<p>SARS-CoV-2 B.1.617 Variant Positive Swab</p>	<p>RED-S-19-06</p>	<p>VP-S-19-06</p>	<p>These products are formulated with inactivated whole SARS-CoV-2 B.1.617 cDNA genome and human fibroblast cells, desiccated on a Copan FLOQSwab®. Microbix SARS-CoV-2 B.1.617 Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay, and EliTech Group SARS-CoV-2 Extended ELITE MGB® Assay.</p> <p><b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx</p>
<p>SARS-CoV-2 B.1.1.529 Variant Positive Swab</p>	<p>RED-S-19-07</p>	<p>VP-S-19-07</p>	<p>These products are formulated with inactivated whole SARS-CoV-2 B.1.1.529 cDNA genome and human fibroblast cells, desiccated on a Copan FLOQSwab®. Microbix SARS-CoV-2 B.1.1.529 Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay, Seegene Allplex™ 2019-nCov Assay, Seegene Allplex™ SARS-CoV-2 Master Assay, and ELITEch Group SARS-CoV-2 Extended ELITE MGB® Assay</p> <p><b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx</p>
<b>Multiple Analyte Products</b>			
<p>SAR CoV-2 Positive/Flu A/ Flu B/ RSV Positive Swab</p>	<p>RED-S-19- M1</p>	<p>VP-S-19-M1</p>	<p>These products are formulated with inactivated whole-genome SARS-CoV-2 cDNA and inactivated native Influenza A, Influenza B, and Respiratory Syncytial Virus, desiccated on a Copan FLOQSwab®. Microbix SARS-CoV-2/FluA&amp;B/RSV Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay, BioFire® Respiratory Panel 2.1, Seegene Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay, Quidel Savanna™ RVP4 Assay, Thermo Fisher TaqMan™ SARS-CoV-2, FluA/B, RSV Assay, and OHC GeneFinder™ COVID 19/Flu A&amp;B RealAmp Assay</p> <p><b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx</p>



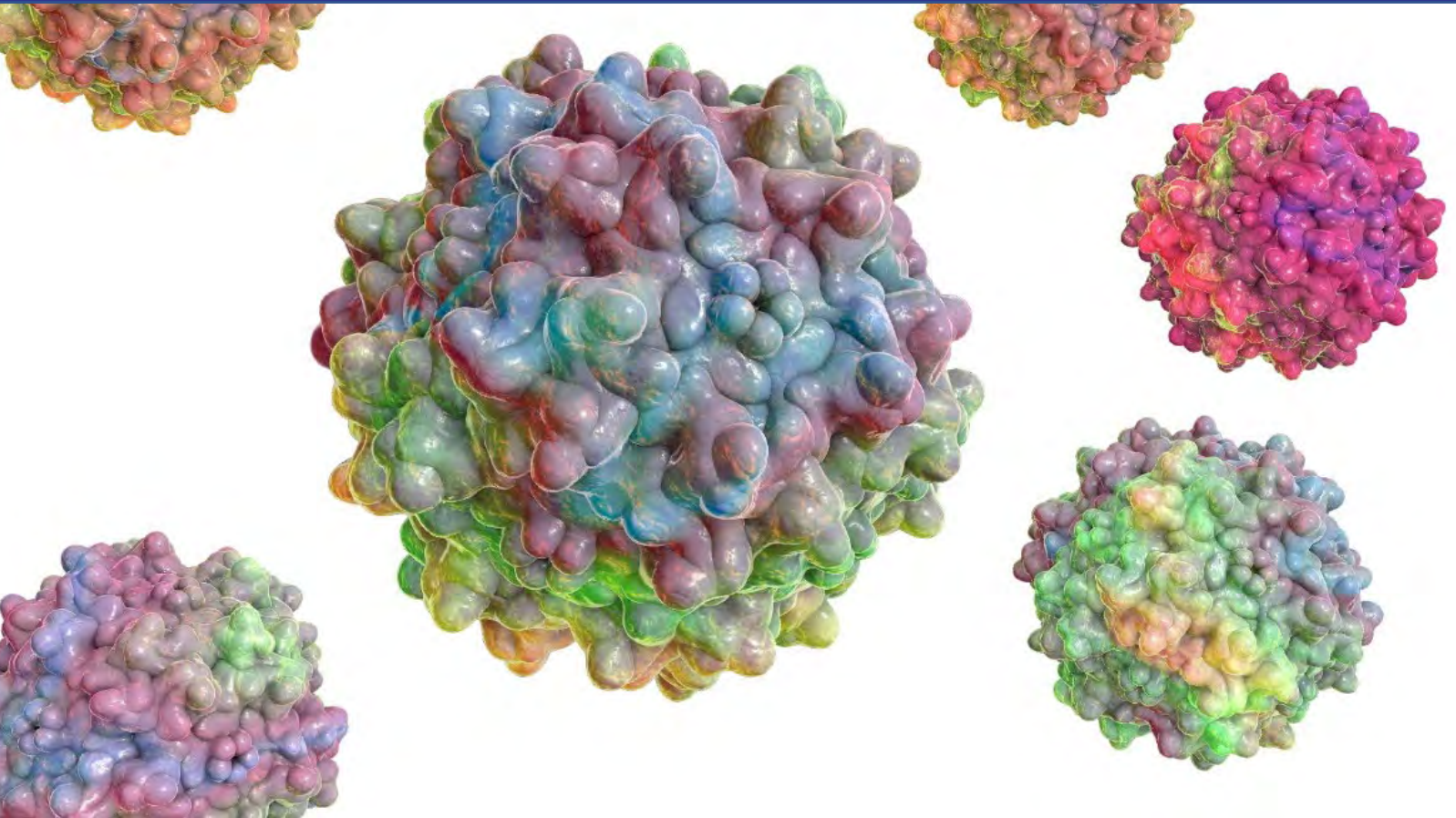
Negative Analyte Products			
SARS-CoV-2 Negative	RED-99-M3	VP-99-M3	<p>These products are formulated with human fibroblast cells, suspended in ThinPrep® PreservCyt®.</p> <p><b>Format:</b> Vial; 0.5 mL</p> <p><b>Storage Conditions:</b> 2-8°C</p> <p><b>Assay Compatibility:</b> MDx</p>
SARS-CoV-2 Negative Swab	RED-S-99-M4	VP-S-99-M4	<p>These products are formulated with human fibroblast cells, desiccated on Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx</p>
Respiratory Negative Swab	RED-S-99-01	VP-S-99-01	<p>The product formulation does not contain any infectious disease diagnostic targets.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> Immuno</p>

## 3.3.2 Other Respiratory Products

### SWAB & LIQUID FORMULATIONS

#### *QAPs™ for Respiratory Molecular and Immunoassay Diagnostics*

- Formulated with the target pathogen's whole genome
- Whole workflow controls (including extraction)
- Inactivated to meet clinical laboratory biosafety requirements
- Commutable and cross-platform compatible
- Liquid formulations are stable for 26 weeks to 2 years when stored at 2-8oC; 1mL volume
- Copan FLOQSwab® formulations are stable for 2 years when stored at 2-30oC.
- Samples can be eluted in your choice of media
- Verified performance on leading IVD platforms



## 3.3.2 Other Respiratory Products

### Respiratory Panel

Product Name	RED <sup>controls</sup> (IVD) Catalogue Number	PROCEED <sup>RUO</sup> (RUO) Catalogue Number	Product Description
<b>Single Analyte Products</b>			
Adenovirus Positive	Coming soon	VP-15-01	<p>These products are formulated with inactivated native Adenovirus suspended in a proprietary buffer. Microbix Adenovirus Positive External Quality Controls have verified performance on various IVD assays, such as SA Scientific SAS™ Adeno Test.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno</p> <p><i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p>
Parainfluenza 3 Positive	Coming soon	VP-10-M1	<p>These products are formulated with inactivated native Parainfluenza virus type 3 and human fibroblast cells suspended in a proprietary buffer. Microbix Parainfluenza 3 Positive External Quality Controls have verified performance on various IVD assays, such as Luminex NxTAG® Respiratory Pathogen Panel.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
RSV Positive	RED-07-01	VP-07-01	<p>These products are formulated with inactivated native Respiratory Syncytial Virus (RSV), suspended in a proprietary buffer. Microbix RSV Positive External Quality Controls have verified performance on some of the following IVD platforms: BD Veritor™ System, Abbott BinaxNOW®, Quidel Sofia 2 FIA, Cepheid GeneXpert®, Roche cobas® LIAT system, and Abbott ID NOW</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno</p> <p><i>*REDx™ products are only for sale in Canada and United States</i></p>

RSV Positive Swab	RED-S-07-01	VP-S-07-01	<p>These products are formulated with inactivated native Respiratory Syncytial Virus (RSV), desiccated on a Copan FLOQSwab®. Microbix RSV Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay and Abbott BinaxNOW® RSV Card</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*REDx™ products are only for sale in Canada and United States</i></p>
Respiratory NAAT RSV Positive Swab	Coming soon	Coming Soon	<p>These products are formulated with inactivated native Respiratory Syncytial Virus and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>
Influenza A Positive	RED-13-01	VP-13-01	<p>These products are formulated with inactivated native Influenza A virus suspended in a proprietary buffer. Microbix Influenza A Positive External Quality Controls have verified performance on some of the following IVD platforms: BD Veritor™ System, Abbott BinaxNOW®, Quidel Sofia 2 FIA, Cepheid GeneXpert®, Roche cobas® LIAT system, and Abbott ID NOW</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*RED products are only for sale in Canada and United States</i></p>
Influenza A Positive Swab	RED-S-13-01	VP-S-13-01	<p>These products are formulated with inactivated native Influenza A virus, desiccated on a Copan FLOQSwab®. Microbix Influenza A Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay, Sekisui Silaris™ Influenza A&amp;B assay, Quidel Sofia 2 SARS + Flu FIA, and Abbott BinaxNOW® Influenza A+B Card.</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*RED products are only for sale in Canada and United States</i></p>

<p>Respiratory NAAT Influenza A Positive Swab</p>	<p>Coming soon</p>	<p>Coming Soon</p>	<p>These products are formulated with inactivated native Influenza A virus and human fibroblast cells, desiccated on a Copan FLOQSwab®. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx</p>
<p>Influenza B Positive</p>	<p>RED-14-01</p>	<p>VP-14-01</p>	<p>These products are formulated with inactivated native Influenza B virus suspended in a proprietary buffer. Microbix Influenza B Positive External Quality Controls have verified performance on some of the following IVD platforms: BD Veritor™ System, Abbott BinaxNOW®, Quidel Sofia 2 FIA, Cepheid GeneXpert®, Roche cobas® LIAT system, and Abbott ID NOW <b>Format:</b> Vial; 1.0 mL <b>Storage Conditions:</b> 2-8°C <b>Assay Compatibility:</b> MDx, Immuno <i>*REDx™ products are only for sale in Canada and United States</i></p>
<p>Influenza B Positive Swab</p>	<p>RED-S-14-01</p>	<p>VP-S-14-01</p>	<p>These products are formulated with inactivated native Influenza B virus, desiccated on a Copan FLOQSwab®. Microbix Influenza B Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay, Sekisui Silaris™ Influenza A&amp;B assay, Quidel Sofia 2 SARS + Flu FIA, and Abbott BinaxNOW® Influenza A+B Card. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx, Immuno <i>*REDx™ products are only for sale in Canada and United States</i></p>
<p>Respiratory NAAT Influenza B Positive Swab</p>	<p>Coming soon</p>	<p>Coming Soon</p>	<p>These products are formulated with inactivated native Influenza B virus and human fibroblast cells, desiccated on a Copan FLOQSwab®. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx</p>

Multiple Analyte Products			
Influenza A + B Positive	RED-13-02	VP-13-02	<p>These products are formulated with inactivated native Influenza A virus and Influenza B virus, suspended in a proprietary buffer. Microbix Influenza A and Influenza B Positive External Quality Controls have verified performance on some of the following IVD assays: Abbott BinaxNOW® Flu A&amp;B Card, Quidel QuickVue Influenza A+B Test, Quidel Sofia Influenza A&amp;B FIA, and Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*REDx™ products are only for sale in Canada and United States</i></p>
Influenza A + RSV Positive	Coming soon	VP-13-03	<p>Microbix Influenza A+RSV Positive External Quality Controls are unassayed, whole-workflow samples that simulate clinical specimens. These products are formulated with inactivated native Influenza A virus and Respiratory Syncytial Virus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno</p>
Influenza A + Rotavirus Positive	Coming soon	VP-13-05	<p>These products are formulated with inactivated native Influenza A virus and Rotavirus suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p>
Influenza B + RSV Positive	Coming soon	VP-14-02	<p>These products are formulated with inactivated native Influenza B virus and Respiratory Syncytial Virus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno</p>

Adenovirus + RSV Positive	Coming soon	VP-07-02	<p>These products are formulated with inactivated native Adenovirus and Respiratory Syncytial Virus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p>
Influenza B + Adenovirus Positive	Coming soon	VP-14-03	<p>These products are formulated with inactivated native Influenza B virus and Adenovirus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p>
RSV + Rotavirus Positive	Coming soon	VP-07-03	<p>These products are formulated with inactivated native Respiratory Syncytial Virus and Rotavirus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p>
Influenza B + Rotavirus Positive	Coming soon	VP-14-04	<p>These products are formulated with inactivated native Influenza B virus and Rotavirus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno</p>
Adenovirus + Rotavirus Positive	Coming soon	VP-15-02	<p>These products are formulated with inactivated native Adenovirus and Rotavirus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p>

Influenza A + Adenovirus Positive	Coming soon	VP-13-04	<p>These products are formulated with inactivated native Influenza A virus and Adenovirus, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL</p> <p><b>Storage Conditions:</b> 2-8°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p> <p><i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p>
SARS-CoV-2/FluA&B/RSV Positive Swab	RED-S-19-M1	VP-S-19-M1	<p>These products are formulated with inactivated whole-genome SARS-CoV-2 cDNA and inactivated native Influenza A, Influenza B, and Respiratory Syncytial Virus, desiccated on a Copan FLOQSwab®. Microbix SARS-CoV-2/FluA&amp;B/RSV Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay, BioFire® Respiratory Panel 2.1, Seegene Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay, Quidel Savanna™ RVP4 Assay, Thermo Fisher TaqMan™ SARS-CoV-2, FluA/B, RSV Assay, and OHC GeneFinder™ COVID 19/Flu A&amp;B RealAmp Assay</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx</p>
<b>Negative Analyte Products</b>			
Respiratory Negative Swab (REDxTMFLOQ®) Negative Swab (PTDxTM & PROCEEDxTMFLOQ®)	RED-S-99-01	VP-S-99-01	<p>The product formulation does not contain any infectious disease diagnostic targets.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> Immuno</p>
Respiratory Negative	Coming soon	VP-99-01	<p>These products do not contain any infectious disease diagnostic targets.</p> <p><b>Format:</b> Vial, 1.0 mL</p> <p><b>Storage Conditions:</b> 2-8°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p>



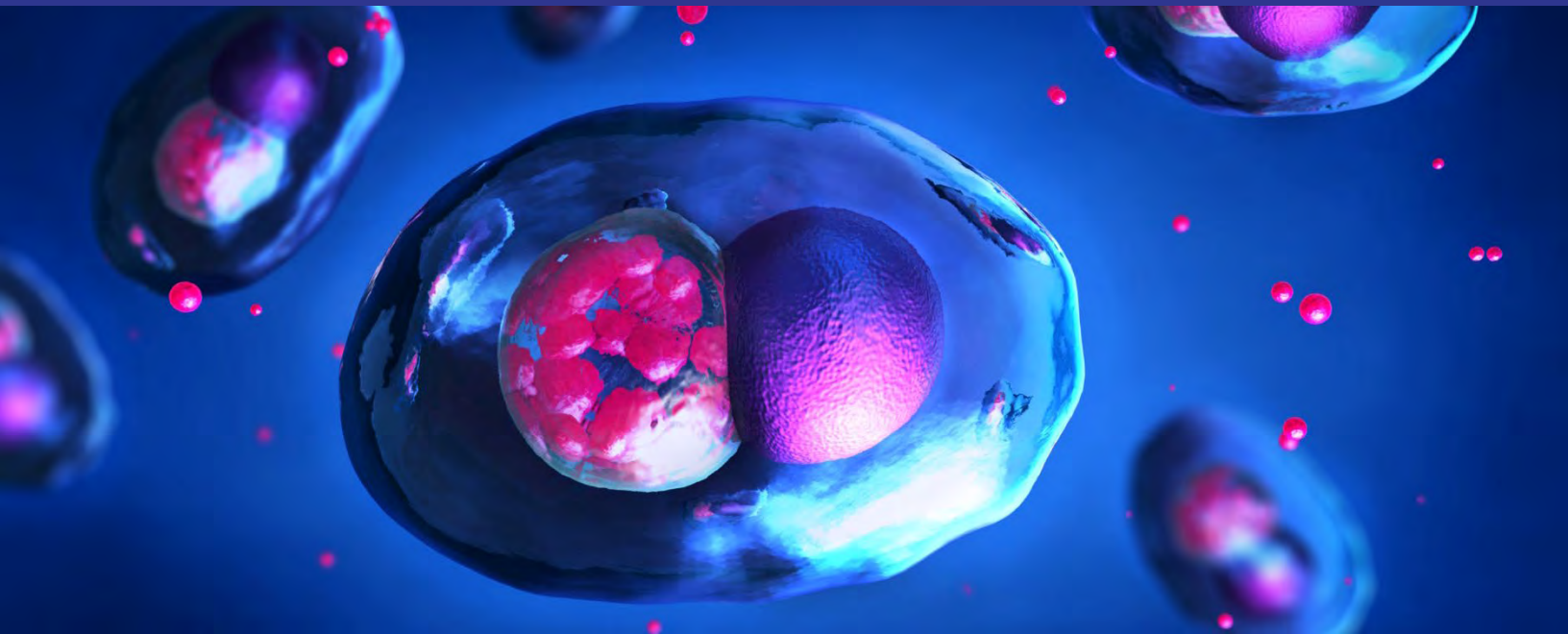
### 3.3.3 Sexual Transmitted Infections (STI) Products

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#### LIQUID FORMULATIONS

##### *QAPs™ for STI Molecular and Immunoassay Diagnostics*

- Formulated with the target pathogen's whole genome
- Whole-workflow controls (including extraction)
- Inactivated to meet clinical laboratory biosafety requirements
- Commutable and cross-platform compatible
- Liquid formulations are stable for 24 weeks to 2 years when stored at 2-8°C; 1mL volumes
- Copan FLOQSwab® formulations are stable for 2 years when stored at 2-30°C
- Verified performance on leading IVD platforms



### 3.3.3 Sexual Transmitted Infections (STI) Products

#### Sexual Transmitted Infections Panel

Product Name	RED <sup>controls</sup> (IVD) Catalogue Number	PROCEED <sup>controls</sup> (RUO) Catalogue Number	Product Description
<b>Single Analyte Products</b>			
<i>Chlamydia trachomatis</i> Positive (MDx)	RED-12-M1	VP-12-M1	<p>These products are formulated with inactivated native <i>Chlamydia trachomatis</i> and human fibroblast cells suspended in ThinPrep<sup>®</sup> PreservCyt<sup>®</sup>. Microbix <i>Chlamydia trachomatis</i> Positive External Quality Controls have verified performance on some of the following IVD platforms: BD Max<sup>™</sup> System, BD Viper<sup>™</sup>, Cepheid GeneXpert<sup>®</sup>, Hologic Aptima<sup>®</sup>, and Roche cobas<sup>®</sup> 6800/8800.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx  <i>*REDx<sup>™</sup> products are only for sale in Canada and United States</i></p>
<i>Chlamydia trachomatis</i> Positive	RED-12-01	VP-12-01	<p>These products are formulated with inactivated native <i>Chlamydia trachomatis</i> suspended in a proprietary buffer. Microbix <i>Chlamydia trachomatis</i> Positive External Quality Controls have verified performance on some of the following IVD platforms: Cepheid GeneXpert<sup>®</sup>, Quidel Quickvue<sup>®</sup>, and Sekisui OSOM<sup>®</sup>.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*REDx<sup>™</sup> products are only for sale in Canada and United States</i></p>

<p><i>Neisseria gonorrhoea</i> Positive</p>	<p>RED-17-M1</p>	<p>VP-17-M1</p>	<p>These products are formulated with inactivated native <i>Neisseria gonorrhoeae</i> and human fibroblast cells suspended in ThinPrep® PreservCyt®. Microbix <i>Neisseria gonorrhoeae</i> Positive External Quality Controls have verified performance on some of the following IVD platforms: BD Max™ System, BD Viper™, Cepheid GeneXpert®, Hologic Aptima®, and Roche cobas® 6800/8800.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx  <i>*REDx™ products are only for sale in Canada and United States</i></p>
<p><i>Trichomonas vaginalis</i> Positive</p>	<p>RED-61-01</p>	<p>VP-61-01</p>	<p>These products are formulated with inactivated native <i>Trichomonas vaginalis</i>, and human fibroblast cells suspended in a proprietary buffer. Microbix <i>Trichomonas vaginalis</i> Positive External Quality Controls have verified performance on some of the following IVD platforms: Cepheid GeneXpert®, Hologic Aptima®, Hologic Panther®, Quidel Solana, and Sekisui OSOM®.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*REDx™ products are only for sale in Canada and United States</i></p>
<p><i>Trichomonas vaginalis</i> Positive</p>	<p>Coming soon</p>	<p>VP-61-02</p>	<p>These products are formulated with inactivated native <i>Trichomonas vaginalis</i>, and human fibroblast cells suspended in a proprietary buffer. Microbix <i>Trichomonas vaginalis</i> Positive External Quality Controls have verified performance on various IVD platforms such as the Cepheid GeneXpert®.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>

<p><i>Mycoplasma genitalium</i> Positive</p>	<p>RED-63-01</p>	<p>VP-63-01</p>	<p>These products are formulated with inactivated cells that contain whole genome <i>Mycoplasma genitalium</i> and human fibroblast cells suspended in ThinPrep® PreservCyt®. Microbix M. genitalium Positive External Quality Controls have verified performance on some of the following IVD assays: Roche cobas® TV/MG assay, Hologic Aptima® <i>Mycoplasma genitalium</i> Assay, Speedx ResistancePlus® MG Assay, EliTechGroup STI PLUS ELITE MGB® Assay, and Diagenode S-DiaMGTV™ Assay.</p> <p><b>Format:</b> Vial: 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p><i>Mycoplasma genitalium</i> A2059G Positive Swab</p>	<p>RED-S-63-02</p>	<p>VP-S-63-02</p>	<p>These products are formulated with inactivated <i>Mycoplasma genitalium</i> whole genome with A2059G point mutation in the 23S rRNA gene and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>
<p><i>Mycoplasma genitalium</i> A2058G Positive Swab</p>	<p>RED-S-63-03</p>	<p>VP-S-63-03</p>	<p>These products are formulated with inactivated <i>Mycoplasma genitalium</i> whole genome with A2058G point mutation in the 23S rRNA gene and human fibroblast cells, desiccated on a Copan FLOQSwab®. Microbix M.genitalium A2058G Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Speedx ResistancePlus® MG Assay, EliTechGroup Macrolide –R/MG ELITE MGB® Assay and Seegene Allplex™ MG &amp; AziR Assay.</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>
<p><i>Mycoplasma genitalium</i> A2059C Positive Swab</p>	<p>RED-S-63-04</p>	<p>VP-S-63-04</p>	<p>These products are formulated with inactivated <i>Mycoplasma genitalium</i> whole genome with A2059C point mutation in the 23S rRNA gene and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p>Format: Copan FLOQSwab®  Storage Conditions: 2-30°C  Assay Compatibility: MDx</p>

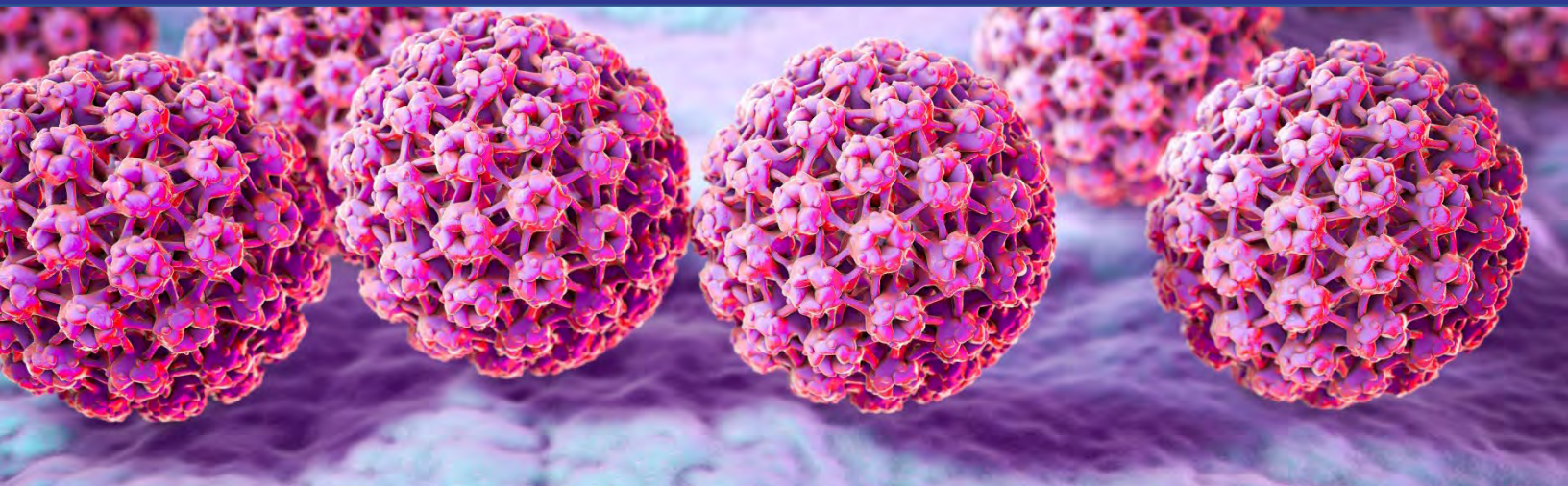
<i>Mycoplasma genitalium</i> A2058T Positive Swab	RED-S-63-05	VP-S-63-05	These products are formulated with inactivated <i>Mycoplasma genitalium</i> whole genome with A2058T point mutation in the 23S rRNA gene and human fibroblast cells, desiccated on a Copan FLOQSwab®. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx
<i>Mycoplasma genitalium</i> A2058C Positive Swab	RED-S-63-06	VP-S-63-06	These products are formulated with inactivated <i>Mycoplasma genitalium</i> whole genome with A2058C point mutation in the 23S rRNA gene and human fibroblast cells, desiccated on a Copan FLOQSwab®. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx
<b>Multiple Analyte Products</b>			
<i>Chlamydia trachomatis</i> + <i>Neisseria gonorrhoea</i> Positive	RED-12-M2	VP-12-M2	These products are formulated with inactivated native <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> and human fibroblast cells suspended in ThinPrep® PreservCyt®. Microbix <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> Positive External Quality Controls have verified performance on some of the following IVD platforms: Abbott RealTime System, Hologic Aptima®, BD Max™ System, BD Viper™, Cepheid GeneXpert® and Roche cobas® 4800. <b>Format:</b> Vial; 1.0 mL <b>Storage Conditions:</b> 2-8°C <b>Assay Compatibility:</b> MDx <i>*REDx™ products are only for sale in Canada and United States</i>
CT/NG/TV/MG Positive Swab	Coming soon	VP-S-12-M3	These products are formulated with inactivated cells that contain whole genome <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Trichomonas vaginalis</i> , <i>Mycoplasma genitalium</i> and human fibroblast cells, desiccated on a Copan FLOQSwab®. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx

Multiple Analyte Products			
STI Negative	RED-99-M1	VP-99-M1	<p>These products are formulated with human fibroblast cells suspended in ThinPrep® PreservCyt®.</p> <p><b>Format:</b> Vial;1.0 mL</p> <p><b>Storage Conditions:</b> 2-8°C</p> <p><b>Assay Compatibility:</b> MDx</p>

## 3.3.4 Human Papillomavirus Products

### LIQUID FORMULATIONS

- Formulated with inactivated whole-genome samples that contain all common assay targets (E1, E6, E7, L1), episomal and integrated viral DNA, viral RNA, proteins, and human DNA
- Prepared in HOLOGIC® ThinPrep® PreservCyt®
- Commutable and cross-platform compatible (verified with laboratory developed and IVD tests)
- Liquid formulations are stable for 2 years when stored at 2-8°C; 1mL volume
- Copan FLOQSwab® formulations are coming soon! Samples will be stable for 2 years when stored at 2-30°C
- Whole-workflows controls (including extraction)
- Inactivated to meet clinical laboratory biosafety requirements
- Dedicated low risk/non-oncogenic HPV 67 Positive sample to evaluate test specificity and rule out cross-reactivity
- Verified performance on leading IVD platforms



## 3.3.4 Human Papillomavirus Products

### Human Papillomavirus Panel

Product Name	RED <sup>controls</sup> (IVD) Catalogue Number	PROCEED <sup>controls</sup> (RUO) Catalogue Number	Product Description
<b>Single Analyte Products</b>			
HPV 16 Positive	RED-62-16	VP-62-16	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 16 genetic material, suspended in ThinPrep<sup>®</sup> PreservCyt<sup>®</sup>. Microbix HPV 16 External Quality Controls have verified performance on some of the following IVD assays: Abbott RealTime High Risk HPV Assay, Cepheid Xpert<sup>®</sup> HPV Assay, Hologic Aptima<sup>®</sup> HPV Assay, Roche cobas<sup>®</sup> 4800 and cobas<sup>®</sup> 6800/8800 HPV Test, BD Onclarity<sup>™</sup> HPV Assay, and Seegene Anyplex<sup>™</sup> II HPV HR Detection Assay</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
HPV 18 Positive	RED-62-18	VP-62-18	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 18 genetic material, suspended in ThinPrep<sup>®</sup> PreservCyt<sup>®</sup>. Microbix HPV 18 External Quality Controls have verified performance on some of the following IVD assays: Abbott RealTime High Risk HPV Assay, Cepheid Xpert<sup>®</sup> HPV Assay, Hologic Aptima<sup>®</sup> HPV Assay, Roche cobas<sup>®</sup> 4800 and cobas<sup>®</sup> 6800/8800 HPV Test, BD Onclarity<sup>™</sup> HPV Assay, and Seegene Anyplex<sup>™</sup> II HPV HR Detection Assay</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
HPV 31 Positive	RED-62-31	VP-62-31	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 31 genetic material, suspended in ThinPrep<sup>®</sup> PreservCyt<sup>®</sup>. Microbix HPV 31 External Quality Controls have verified performance on some of the following IVD assays: Abbott RealTime High Risk HPV Assay, Cepheid Xpert<sup>®</sup> HPV Assay, Hologic Aptima<sup>®</sup> HPV Assay, Roche cobas<sup>®</sup> 4800 and cobas<sup>®</sup> 6800/8800 HPV Test, BD Onclarity<sup>™</sup> HPV Assay, and Seegene Anyplex<sup>™</sup> II HPV HR Detection Assay</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>



<p>HPV 33 Positive</p>	<p>RED-62-33</p>	<p>VP-62-33</p>	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 33 genetic material, suspended in ThinPrep® PreservCyt®. Microbix HPV 33 External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® HPV Assay, Roche cobas® 4800 and cobas® 6800/8800 HPV Test, and BD Onclarity™ HPV Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p>HPV 39 Positive</p>	<p>RED-62-39</p>	<p>VP-62-39</p>	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 39 genetic material, suspended in ThinPrep® PreservCyt®. Microbix HPV 39 External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® HPV Assay, Roche cobas® 4800 and cobas® 6800/8800 HPV Test, and BD Onclarity™ HPV Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p>HPV 45 Positive</p>	<p>RED-62-45</p>	<p>VP-62-45</p>	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 45 genetic material, suspended in ThinPrep® PreservCyt®. Microbix HPV 45 External Quality Controls have verified performance on some of the following IVD assays: Abbott RealTime High Risk HPV Assay, Cepheid Xpert® HPV Assay, Hologic Aptima® HPV Assay, Roche cobas® 4800 and cobas® 6800/8800 HPV Test, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p>HPV 51 Positive</p>	<p>RED-62-51</p>	<p>VP-62-51</p>	<p>These products are formulated with inactivated cells that contain HPV 51 whole genome and human fibroblast cells, suspended in ThinPrep® PreservCyt®. Microbix HPV 51 External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® HPV Assay, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>

<p>HPV 52 Positive</p>	<p>RED-62-52</p>	<p>VP-62-52</p>	<p>These products are formulated with inactivated cells that contain HPV 52 whole genome and human fibroblast cells, suspended in ThinPrep® PreservCyt®. Microbix HPV 52 External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® HPV Assay, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p>HPV 66 Positive</p>	<p>RED-62-66</p>	<p>VP-62-66</p>	<p>These products are formulated with inactivated cells that contain HPV 66 whole genome and human fibroblast cells, suspended in ThinPrep® PreservCyt®. Microbix HPV 66 External Quality Controls have verified performance on some of the following IVD assays: Cepheid Xpert® HPV Assay, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p>High-risk HPV Negative (HPV 67)</p>	<p>RED-62-67</p>	<p>VP-62-67</p>	<p>These products are formulated with inactivated cells that contain HPV 67 whole genome and human fibroblast cells, suspended in ThinPrep® PreservCyt®. Microbix HPV 67 External Quality Controls have verified performance on some of the following IVD assays: Abbott RealTime High Risk HPV Assay, Cepheid Xpert® HPV Assay, Hologic Aptima® HPV Assay, Roche cobas® 4800 and cobas® 6800/8800 HPV test, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p>HPV 16 Positive Swab</p>	<p>Coming Soon</p>	<p>Coming Soon</p>	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 16 genetic material, desiccated on a Copan FLOQSwab®.  <b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>

HPV 18 Positive Swab	Coming Soon	Coming Soon	These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 18 genetic material, desiccated on a Copan FLOQSwab®. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx
HPV 45 Positive Swab	Coming Soon	Coming Soon	These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 45 genetic material, desiccated on a Copan FLOQSwab®. <b>Format:</b> Copan FLOQSwab® <b>Storage Conditions:</b> 2-30°C <b>Assay Compatibility:</b> MDx
<b>Multiple Analyte Products</b>			
HPV 16/18/45 Positive	RED-62-M1	VP-62-M1	These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 16, 18, and 45 genetic materials, suspended in ThinPrep® PreservCyt®. Microbix HPV 16/18/45 External Quality Controls have verified performance on some of the following IVD assays: Abbott Alinity m HR HPV Assay, Cepheid Xpert® HPV Assay, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay <b>Format:</b> Vial; 1.0 mL <b>Storage Conditions:</b> 2-8°C <b>Assay Compatibility:</b> MDx
HPV 31/33/66 Positive	RED-62-M2	VP-62-M2	These products are formulated with inactivated cells that contain HPV type 31, 33, and 66 whole genome and human fibroblast cells, suspended in ThinPrep® PreservCyt®. Microbix HPV 31/33/66 External Quality Controls have verified performance on some of the following IVD assays: Abbott Alinity m HR HPV Assay, Cepheid Xpert® HPV Assay, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay <b>Format:</b> Vial; 1.0 mL <b>Storage Conditions:</b> 2-8°C <b>Assay Compatibility:</b> MDx

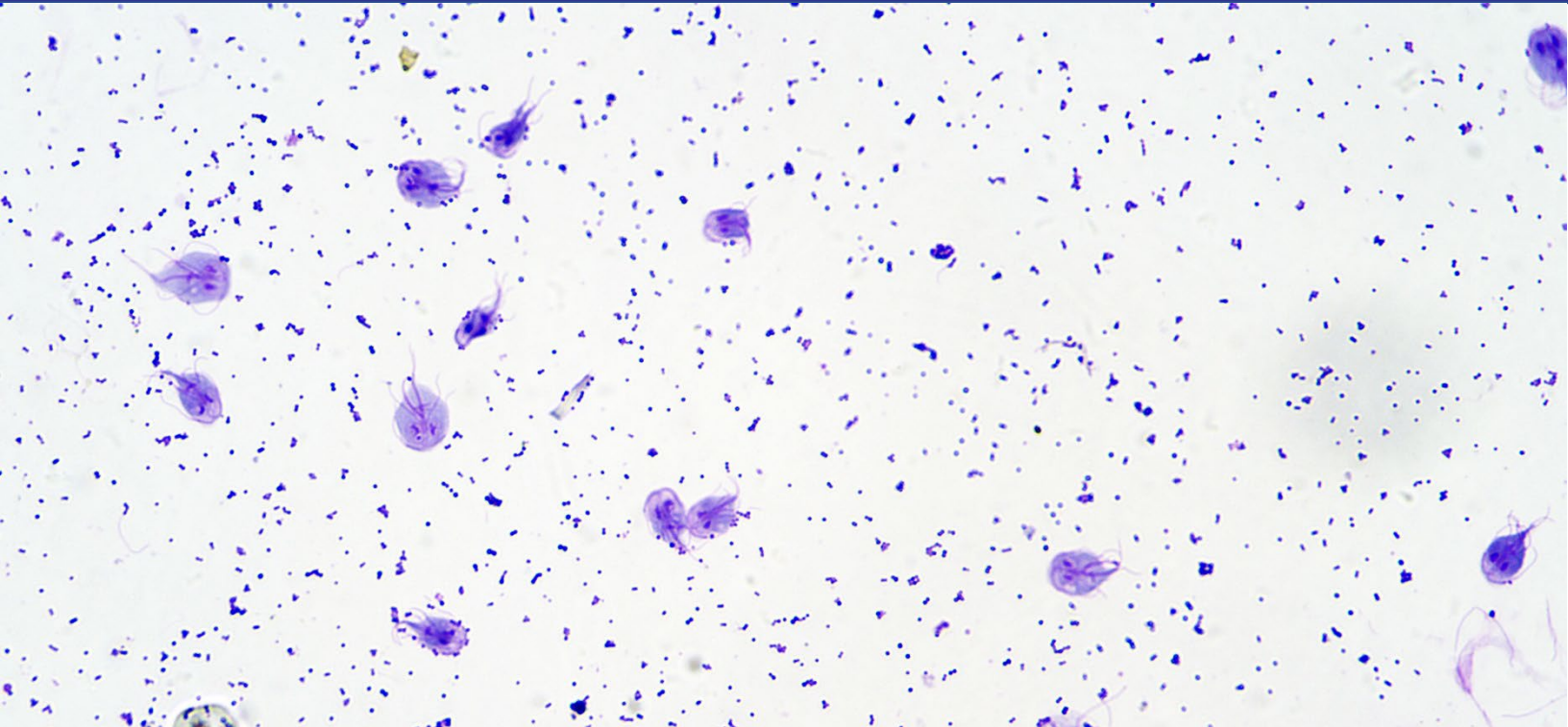
<p>HPV 39/51/52 Positive</p>	<p>RED-62-M3</p>	<p>VP-62-M3</p>	<p>These products are formulated with inactivated cells that contain HPV type 39, 51, and 52 whole genome and human fibroblast cells, suspended in ThinPrep® PreservCyt®. Microbix HPV 39/51/52 External Quality Controls have verified performance on some of the following IVD assays: Abbott Alinity m HR HPV Assay, Cepheid Xpert® HPV Assay, BD Onclarity™ HPV Assay, and Seegene Anyplex™ II HPV HR Detection Assay  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>
<p>HPV 16/18/45 Positive Swab</p>	<p>Coming Soon</p>	<p>Coming Soon</p>	<p>These products are formulated with inactivated human epithelial cells with integrated and episomal HPV 16, 18, and 45 genetic materials, desiccated on a Copan FLOQSwab®.  <b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>
<b>Negative Analyte Products</b>			
<p>STI Negative</p>	<p>RED-99-M1</p>	<p>VP-99-M1</p>	<p>These products are formulated with human fibroblast cells, suspended in ThinPrep® PreservCyt®.  <b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx</p>

## 3.3.5 Gastrointestinal Products

### LIQUID FORMULATIONS

#### *QAPs™ for Gastrointestinal and Immunoassay Diagnostics*

- Formulated with the target pathogen's whole genome
- Whole workflow controls (including extraction)
- Inactivated to meet clinical laboratory biosafety requirements
- Liquid formulations are stable for 1+ years when stored at 2-8°C; 1mL and 0.5mL volumes
- Commutable and cross-platform compatible
- Verified performance on leading IVD platforms



## 3.3.5 Gastrointestinal Products

### Gastrointestinal Panel

Product Name	RED <sup>controls</sup> (IVD) Catalogue Number	PROCEED <sup>D</sup> (RUO) Catalogue Number	Product Description
<b>Single Analyte Products</b>			
<i>Cryptosporidium parvum</i> Positive	RED-37-01	VP-37-01	<p>These products are formulated with inactivated native <i>Cryptosporidium parvum</i> suspended in a proprietary buffer. Microbix <i>Cryptosporidium parvum</i> Positive External Quality Controls have verified performance on some of the following IVD assays: Meridian Bioscience ImmunoCard STAT<sup>®</sup> Crypto/Giardia Rapid Assay, and BioFire<sup>®</sup> FilmArray<sup>®</sup> Gastrointestinal Panel</p> <p><b>Format:</b> Vial; 0.5 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno</p> <p><i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i>  <i>*REDx<sup>™</sup> products are only for sale in Canada and United States</i></p>
<i>Giardia lamblia</i> Positive	RED-38-01	VP-38-01	<p>These products are formulated with inactivated native <i>Giardia lamblia</i> suspended in a proprietary buffer. Microbix <i>Giardia lamblia</i> Positive External Quality Controls have verified performance on some of the following IVD assays: Meridian Bioscience ImmunoCard STAT<sup>®</sup> Crypto/Giardia Rapid Assay, and BioFire<sup>®</sup> FilmArray<sup>®</sup> Gastrointestinal Panel</p> <p><b>Format: Vial:</b> 0.5 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno</p> <p><i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i>  <i>*REDx<sup>™</sup> products are only for sale in Canada and United States</i></p>

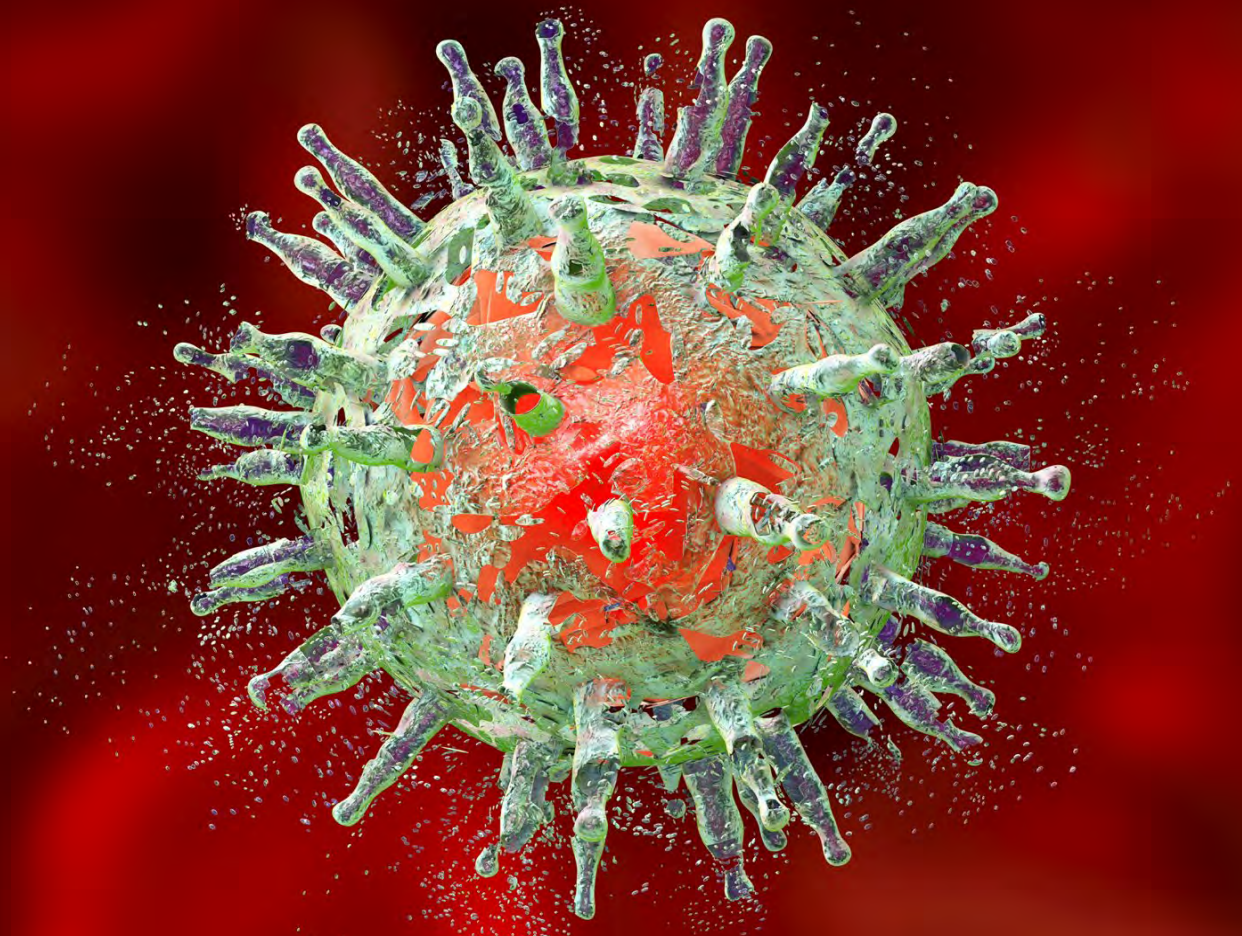
Rotavirus Positive	RED-35-01	VP-35-01	<p>These products are formulated with inactivated native Rotavirus suspended in a proprietary buffer. Microbix Rotavirus Positive External Quality Controls have verified performance on some of the following IVD assays: Meridian Bioscience™ Immunocard STAT® Rotavirus Assay, SA Scientific SAS™ Rota Test, Remel™ Xpect™ Rotavirus Control Assay, and Fisher Healthcare™ Sure-Vue™ Rota Test assay</p> <p><b>Format:</b> Vial; 1.0 mL</p> <p><b>Storage Conditions:</b> 2-8°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p> <p><i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p> <p><i>*REDx™ products are only for sale in Canada and United States</i></p>
<b>Multiple Analyte Products</b>			
<i>Cryptosporidium parvum + Giardia lamblia</i> Mixed Positive	RED-37-01	VP-37-02	<p>These products are formulated with inactivated native <i>Cryptosporidium parvum</i> and <i>Giardia lamblia</i> suspended in a proprietary buffer. Microbix <i>Cryptosporidium parvum</i> and <i>Giardia lamblia</i> Positive External Quality Controls have verified performance on some of the following IVD assays: Meridian Bioscience™ Immunocard STAT® Crypto/Giardia Rapid Assay, and Fisher Healthcare™ Sure-Vue™ Signature Test Kit Assay – Cryptosporidium/Giardia</p> <p><b>Format:</b> Vial; 0.5 mL</p> <p><b>Storage Conditions:</b> 2-8°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p> <p><i>*Products are QC-released with immunoassays but are also compatible with molecular assays</i></p> <p><i>*REDx™ products are only for sale in Canada and United States</i></p>
<b>Negative Analyte Products</b>			
Negative Sample	Coming soon	VP-99-01	<p>These products do not contain any infectious disease diagnostic targets.</p> <p><b>Format:</b> Vial, 1.0 mL</p> <p><b>Storage Conditions:</b> 2-8°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p>

## 3.3.6 Genital Ulcer Disease (GUD) Products

### LIQUID FORMULATIONS

#### *QAPs™ for GUD Molecular and Immunoassay Diagnostics*

- Formulated with the target pathogen's whole genome
- Whole workflow controls (including extraction)
- Inactivated to meet clinical laboratory biosafety requirements
- Commutable and cross-platform compatible
- Available in Liquid formulations; stable for 24 weeks at 2-8-∞C; 1mL volume
- Available in Copan FLOQSwab-∕E formulations; stable for 1-2 years at 2-30-∞C
- Verified performance on leading IVD platforms





### 3.3.6 Genital Ulcer Disease Panel

#### Genital Ulcer Disease Panel

Product Name	RED <sup>controls</sup> (IVD) Catalogue Number	PROCEED <sup>controls</sup> (RUO) Catalogue Number	Product Description
<b>Single Analyte Products</b>			
HSV 1 Positive	RED-02-M1	VP-02-M1	<p>These products are formulated with inactivated native Herpes Simplex Virus 1 and human fibroblast cells suspended in a proprietary buffer. Microbix HSV 1 Positive External Quality Controls have verified performance on some of the following IVD platforms: Roche cobas<sup>®</sup> 4800, Hologic Aptima<sup>®</sup>, Meridian Bioscience Alethia<sup>®</sup>, Luminex ARIES<sup>®</sup>, DiaSorin Simplexa<sup>®</sup>, Quidel Solana and Quidel AmpliVue<sup>™</sup>.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with molecular assays but are also compatible with immunoassays</i>  <i>*REDx<sup>™</sup> products are only for sale in Canada and United States</i></p>
HSV 2 Positive	RED-23-M1	VP-23-M1	<p>These products are formulated with inactivated native Herpes Simplex Virus 2 and human fibroblast cells, suspended in a proprietary buffer. Microbix HSV 2 Positive External Quality Controls have verified performance on some of the following IVD platforms: Roche cobas<sup>®</sup> 4800, Hologic Aptima<sup>®</sup>, Meridian Bioscience Alethia<sup>®</sup>, Luminex ARIES<sup>®</sup>, DiaSorin Simplexa<sup>®</sup>, Quidel Solana and Quidel AmpliVue<sup>™</sup>.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with molecular assays but are also compatible with immunoassays</i>  <i>*REDx<sup>™</sup> products are only for sale in Canada and United States</i></p>

HSV 1 Positive Swab	Coming Soon	Coming Soon	<p>These products are formulated with native Herpes Simplex Virus 1 and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p>
HSV 2 Positive Swab	Coming Soon	Coming Soon	<p>These products are formulated with inactivated native Herpes Simplex Virus 2 and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p>
<i>T. Pallidum</i> Positive Swab	Coming Soon	Coming Soon	<p>These products are formulated with inactivated cells containing <i>Treponema pallidum</i> genome and human fibroblast cells desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx</p>
Varicella Zoster Virus Positive Swab	Coming Soon	Coming Soon	<p>These products are formulated with inactivated native Varicella Zoster Virus and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx, Immuno</p>
Monkeypox Congo Basin Positive Swab	Coming Soon	Coming Soon	<p>These products are formulated with inactivated whole-genome Monkeypox virus and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx</p>
Monkeypox West African Positive Swab	Coming Soon	Coming Soon	<p>These products are formulated with inactivated whole-genome Monkeypox virus and human fibroblast cells, desiccated on a Copan FLOQSwab®.</p> <p><b>Format:</b> Copan FLOQSwab®</p> <p><b>Storage Conditions:</b> 2-30°C</p> <p><b>Assay Compatibility:</b> MDx</p>

Multiple Analyte Products			
HSV 1 & HSV 2 Positive	Coming Soon	VP-02-M2	<p>These products are formulated with inactivated native Herpes Simplex Virus 1, Herpes Simplex Virus 2, and human fibroblast cells, suspended in a proprietary buffer.</p> <p><b>Format:</b> Vial; 1.0 mL  <b>Storage Conditions:</b> 2-8°C  <b>Assay Compatibility:</b> MDx, Immuno  <i>*Products are QC-released with molecular assays but are also compatible with immunoassays</i></p>
HSV1&2/VZV/Syphilis Positive Swab	RED-S-03-M1	VP-S-03-M1	<p>These products are formulated with inactivated native Herpes Simplex Virus 1, Herpes Simplex Virus 2, Varicella Zoster Virus, and cells containing Treponema pallidum genome desiccated on a Copan FLOQSwab®. Microbix HSV1&amp;2/VZV/Syphilis Positive Swab External Quality Controls have verified performance on some of the following IVD assays: Seegene Allplex™ Genital Ulcer Assay, BioFire® FilmArray® Meningitis/ Encephalitis Panel, DiaSorin Simplexa® HSV1&amp;HSV2 Direct Assay, DiaSorin Simplexa® VZV Swab Direct Assay, and Meridian Bioscience Alethia® HSV1&amp;2 Assay.</p> <p><b>Format:</b> Copan FLOQSwab®  <b>Storage Conditions:</b> 2-30°C  <b>Assay Compatibility:</b> MDx</p>

## 3.4 ONBOARDx™ Kits

ONBOARDx™ Kits are assemblies of our PROCEEDx™ Research Use Only (RUO) products. They are helpful tools for verifying the performance of new test systems and training lab personnel. These non-infectious samples are perfect surrogates for hazardous patient samples to confirm positive and negative detection of specific analytes. ONBOARDx™ Kits are available in liquid form for refrigerated storage or at ambient temperature on Copan FLOQSwabs® and we have several versions containing a range of respiratory samples.



## 3.4 ONBOARDx™ Kits

### ONBOARDx™ Kits

Product Name	ONBOARDx™ kit PROCEEDx™ (RUO) Catalogue Number	Product Description
ONBOARDx™ FLOQ® SARS-CoV-2 Variant Swab Kit	VP-SK-CVAR-01	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2 B.1.1.7 Positive swab x 3 PROCEEDx™FLOQ® SARS-CoV-2 B.1.351 Positive swab x 3 PROCEEDx™FLOQ® SARS-CoV-2 P.1 Positive swab x 3 PROCEEDx™FLOQ® SARS-CoV-2 WT Positive swab x 3
ONBOARDx™ FLOQ® SARS-CoV-2 Variant Swab Kit	VP-SK-CVAR-02	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2 B.1.1.7 Positive swab x 3 PROCEEDx™FLOQ® SARS-CoV-2 B.1.351 Positive swab x 3 PROCEEDx™FLOQ® SARS-CoV-2 P.1 Positive swab x 3 PROCEEDx™FLOQ® SARS-CoV-2 B.1.617 Positive Swab x 3 PROCEEDx™FLOQ® SARS-CoV-2 WT Positive swab x 3
ONBOARDx™ FLU Kit	VP-SK-FLU-01	<b>Contains:</b> PROCEEDx™FLOQ® Influenza A Positive swab x 10 PROCEEDx™FLOQ® Influenza B Positive swab x 10 PROCEEDx™FLOQ® Respiratory Swab Negative Sample x 4
ONBOARDx™ FLOQ®RSV Swab Kit	VP-SK-RVP-01	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2/FluA&B/RSV Positive swab x 8 PROCEEDx™FLOQ® Respiratory Swab Negative Sample x 16
ONBOARDx™ Respiratory Kit	VP-K-RESP-01	<b>Contains:</b> PROCEEDx™ SARS-CoV-2 Positive (0.5mL) vial x 3 PROCEEDx™ Influenza A Positive (1mL) vial x 3 PROCEEDx™ Influenza B Positive (1mL) vial x 3 PROCEEDx™ RSV Positive (1mL) vial x 3
ONBOARDx™ RSV Kit	VP-SK-RSV-01	<b>Contains:</b> PROCEEDx™FLOQ® RSV Positive Swab x 10 PROCEEDx™FLOQ® Respiratory Swab Negative Sample x 2
ONBOARDx™ RSV Kit 2	VP-SK-RSV-02	<b>Contains:</b> PROCEEDx™FLOQ® RSV Positive Swab x 20 PROCEEDx™FLOQ® Respiratory Swab Negative Sample x 4
ONBOARDx™ SARS-CoV-2 Kit	VP-K-COV2-01	<b>Contains:</b> PROCEEDx™ SARS-CoV-2 Positive (0.5mL) vial x 8 PROCEEDx™ SARS-CoV-2 Negative (0.5mL) vial x 4
ONBOARDx™FLOQ® Respiratory Swab Kit	VP-SK-RESP-01	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2 Positive swab x 3 PROCEEDx™FLOQ® Influenza A Positive swab x 3 PROCEEDx™FLOQ® Influenza B Positive swab x 3 PROCEEDx™FLOQ® RSV Positive swab x 3

ONBOARDx™FLOQ® Respiratory Swab Kit	VP-SK-RESPAG-02	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2 Antigen Positive swab x 5 PROCEEDx™FLOQ® Influenza A Positive swab x 5 PROCEEDx™FLOQ® Influenza B Positive swab x 5 PROCEEDx™FLOQ® Respiratory Swab Negative Sample x 5
ONBOARDx™FLOQ® SARS-CoV-2 Antigen Swab Kit	VP-SK-COV2AG-01	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2 Antigen Positive swab x 10 PROCEEDx™FLOQ® SARS-CoV-2 Negative swab x 2
ONBOARDx™FLOQ® SARS-CoV-2 Antigen Swab Kit	VP-SK-COV2AG-02	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2 Antigen Positive swab x 15 PROCEEDx™FLOQ® SARS-CoV-2 Negative swab x 5
ONBOARDx™FLOQ® SARS-CoV-2 Swab Kit	VP-SK-COV2-01	<b>Contains:</b> PROCEEDx™FLOQ® SARS-CoV-2 Positive swab x 8 PROCEEDx™FLOQ® SARS-CoV-2 Negative swab x 4
ONBOARDx™ High-Risk HPV Kit	VP-K-HPV-02	<b>Contains:</b> PROCEEDx™ HPV 16/18/45 Positive Sample (1mL) Vial x 3 PROCEEDx™ HPV 31/33/66 Positive Sample (1mL) Vial x 3 PROCEEDx™ HPV 39/51/52 Positive Sample (1mL) Vial x 3
ONBOARDx™ HPV Positive Sample Kit	VP-K-HPV-04	<b>Contains:</b> PROCEEDx™ HPV 16 Positive Sample (1mL) Vial x 3 PROCEEDx™ HPV 18 Positive Sample (1mL) Vial x 3 PROCEEDx™ HPV 45 Positive Sample (1mL) Vial x 3 PROCEEDx™ Negative Sample (1mL) Vial x 3

# 4.0 Proficiency Test Products



## 4.1 About Our Proficiency Test Products

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### **External Quality Assessment (EQA) and Proficiency Testing (PT)**

Microbix has long provided viral and bacterial samples, for CAP-accredited and ISO 17043 certified external quality assessment and proficiency test (PT) programs. We are experts in cell culture, purification, and inactivation of infectious disease pathogens. We culture well-characterized strains that produce accurate, consistent results.

*Only available for purchase by accredited EQA program providers*



## 5.0 DxTM™ Viral Transport Medium

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## 5.0 DxTM™ Viral Transport Medium

Microbix's DxTM™ Viral Transport Medium is a Canadian-made, proprietary IVD Medical Device that is designed for use in the collection and transport of specimens containing viruses, including SARS-CoV-2. The DxTM™ formulation is designed to stabilize available viral particles within a given sample. It is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing clinical laboratory. DxTM™ is suitable for processing using standard procedures for viral nucleic acid testing.

DxTM™ is used primarily for transporting patient sample swabs or for transporting materials released into the medium from such swabs.

Manufactured under our ISO 13485 Quality Management System, DxTM™ packaging tubes contain 1 or 3 ml of the medium, with the tubes able to accommodate 80 mm and 100 mm breakpoint swabs for transportation. DxTM™ facilitates the collection and transport of samples in areas where refrigeration is not readily available, with validated ambient temperature storage and shipping (2-25°C). The advanced formulation stabilizes viral components and suppresses microbial contamination.

DxTM™ Viral Transport Medium is validated for viral nucleic acid testing. It is designed to be non-inactivating so it could also potentially be used for isolating and growing viral pathogens from patient specimens. This was performed in comparison to the Gold-Standard predicate device, where DxTM™ was shown to be equivalent to that Gold-Standard in terms of handling and extraction, thereby assuring the very highest standard of performance.



*Please contact us directly to learn more about VTM*

## 6.0 Distributors

Microbix has distribution agreements with high-quality distribution partners, skilled in infectious disease diagnostics technologies, that also supply complementary products to our QAPs™. We believe they will be able to serve you very well technically and with high-quality service. Visit our website to find your distributor.



For direct purchases and technical information, please contact [customer.service@microbix.com](mailto:customer.service@microbix.com)

For local suppliers:

You can find our distributors on the map above or contact us directly via the following:

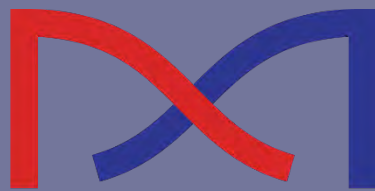
### **Customer Service**

Visit [microbix.com](http://microbix.com) on the web

p: +1 (800) 794-6694 toll-free in North America

p: +1 (905) 361-8910 worldwide

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