

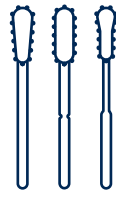
*Clinical applications*

Respiratory infections

*Respiratory infections*

# Breathtaking preanalytics tools

Better diagnostics begins  
with a better sample collection.



Collection



Transport



Processing



Artificial Intelligence

**Our comprehensive approach to preanalytics**

#### *Background*

### **Public enemy number 3**

According to the WHO<sup>1</sup>, **respiratory tract infections are among the most common disorders affecting today's population**, representing the first leading cause of death in low economic status countries and the third in the whole world. From the common cold to pneumonia, their clinical spectrum ranges from generally mild upper airway symptoms to severe lower airway pathology.

### **What's the Copan solution for respiratory infections?**

- ***Nucleic acid and antigen preservation.  
For NAAT and/or Ag testing***  
UTM® - Lollisponge™ - Mswab™ - eSwab®
- ***Nucleic acid preservation and microbial /  
viral viability inactivation. For NAAT testing***  
eNat®
- ***Microbial and viral viability preservation.  
For culture testing***  
eSwab® - Mswab™ - UTM®
- ***Sample fluidification***  
SLsolution™
- ***Mycobacteria collection and transport***  
MycotB™
- ***Molecular testing sample preparation***  
UniVerse™

### *Etiology*

## A complicated affair

Most respiratory infections are caused by viruses, but also bacteria and viral-bacterial coinfections may be involved. A complicating factor when talking about respiratory infections is that any syndrome may be caused by several different microorganisms and, similarly, any pathogen may cause a variety of distinct clinical syndromes.

On top of that, Hospital Acquired Infections, Multi-Drug Resistant bacteria, and spillover infections – as SARS-CoV-2 – are putting a **huge strain on today's clinicians' and researchers' activity.**



### *Diagnostics advancements*

## Modern tools and traditional methods

Luckily, modern molecular techniques offer unpaired sensitivity and specificity. PCR, RT-PCR, and multiplex RT-PCR panels became common in clinical laboratories, opening the possibility to assaying simultaneously several pathogens in less than 24 hours.

These tests – which joined immunodiagnostic and culture techniques – must be interpreted carefully because of their high sensitivity; it's also essential to avoid sample contamination during collection in the first place, to **obtain a biological specimen best suited for these analyses.**

That's why **for a proper diagnosis, proper sampling is necessary.**

Among the upper respiratory sampling methods<sup>2</sup>, Copan FLOQSwabs<sup>®</sup> efficiency has been proven equivalent to more invasive procedures, with a reduced patient discomfort<sup>3</sup>.

## The swab that reinvented sample collection

Unlike the structure of other swabs, FLOQSwabs® patented tip ensures a **quick, capillarity-driven sample uptake and a superior elution** of the biological specimen.

### *Shafts and tips*

## Cut out for everyone

Our anatomically designed FLOQSwabs® offer variable shaft sizes, diameters, and tip shapes to fit plenty of applications. All this made FLOQSwabs® a well-tolerated alternative to painful and costly collection procedures<sup>4,5</sup>.



### *Collection sites*

## The easiest way

Upper respiratory tract sampling represents a non-invasive way to obtain respiratory tract specimens and diagnose upper and - in some cases<sup>6</sup> - even lower respiratory tract infections.

Compared to invasive procedures – such as thoracentesis and needle aspiration – upper respiratory tract sampling can be performed repetitively and exploited for screening purposes.



**1. Nasal**

**2. Nasopharyngeal**

**3. Oral/Saliva**

**4. Throat**



## For culture, antigen detection, and molecular biology

While the diagnosis of viral infections relies mainly on molecular biology techniques, the gold standard for diagnosing bacterial infections remains culture — although new techniques have been developed over the past years<sup>7</sup>. Maintaining microbial viability is an excellent choice for keeping any testing options open: from culture to enzymatic assays, antigen detection, and molecular biology techniques.



### SLSolution™

#### Sputum-liquefying device

The most accepted sample to diagnose bacterial respiratory infections is sputum, but its laborious processing represents a significant limitation. Our SLSolution is the answer to this processing problem, as its mucolytic activity **rapidly liquefies sputum without affecting the vitality and the morphology of bacteria and fungi**. Easy and ready-to-use for a reduced risk of cross-contamination, SLSolution™ is suitable for manual and automatic processing with WASP®.



### eSwab®

#### For traditional bacteriology culture and molecular assays

If you plan to perform other assays on the specimen besides culture, you should opt for eSwab®. eSwab® medium preserves the viability of aerobes, anaerobes, fastidious bacteria from swab specimens for bacterial culture purposes and can be used for the preservation of bacterial, viral or Chlamydial antigens and nucleic acids from swab specimens<sup>8,9,10,11,12</sup>. There is no need to say: also eSwab® is compatible with WASP® automated processing.



### MSwab®

#### Specimen Collection and Preservation Optimized for Molecular and Culture Applications

MSwab® offers the possibility to **collect, transport, and lyse the sample in the same tube without the need for further manipulation**. A true all-around pre-analytical device designed for optimized compatibility with molecular platforms, MSwab® enables a rapid direct nucleic acid heat extraction and allows backup culturing of bacteria and viruses.



UTM®

### Collection, transport, and virus storage medium

UTM® is our Universal collection and Transport Medium suitable for **collection, transport, and long-term freeze storage of viruses, chlamydia, mycoplasma, and ureaplasma**. Preserving viability for 48 hours at room temperature, UTM® is compatible with viral culture, antigen detection, and molecular assays<sup>13</sup>. This versatility made UTM® one of our most popular products, elected by CDC as the product of choice for COVID19 screening<sup>14</sup> using PCR<sup>15</sup> and viral culture<sup>16</sup>.

Microbial inactivation

### Preserve nucleic acids and ensure safety

For an errorless molecular biology analysis, RNA and DNA must be preserved with a proper specimen collection and transport method. Moreover, microbial inactivation can be a desired feature when working with dangerous pathogens.



eNAT®

### Nucleic acid collection and preservation medium

eNat® is our medium designed for viral and bacterial nucleic acids collection and preservation<sup>17</sup>. Containing guanidine-thiocyanate, eNat® **lyses cells and virus particles, preventing bacterial proliferation and preserving RNA and DNA integrity**. eNat® allows long-term storage of the sample for up to four weeks at RT or six months at -20°C by denaturing proteins - including nucleases - in only 30 minutes.

Broths

### Enrich or select

For bacterial culture purposes, we offer a wide range of enrichment and selective broths:

- BHI
- TSB
- CAT
- Thiol
- TSB Salt
- eMRSA
- Fungi
- GN
- LIM
- Selenite

## Deceitful sampling: solved

Tuberculosis (TB) is one of the main global healthcare threats. In 2019, an estimated 10 million people fell ill with TB worldwide, and a tenth of them died<sup>18</sup>. **A fast diagnosis is essential to prevent TB severe symptoms and the spread to other individuals;** nowadays, sputum culture and Nucleic Acid Amplification are the tests of choice to diagnose a mycobacteria infection. Mycobacteria collection trickiest aspect is the contamination of most samples – as sputum and bronchial lavage – by rapidly growing flora or other bacteria. To avoid the interference of these contaminants with the results, each specimen must then be processed before the analysis.



MycoTB™

### Respiratory samples processing system for mycobacteria detection

We designed our MycoTB™ specifically for this purpose. With it, you can take care of all the steps needed for mycobacteria detection in the respiratory tract and extra-pulmonary specimens<sup>19,20</sup> with a safe, easy, and ready-to-use kit.

## How it works



Mix



Incubate



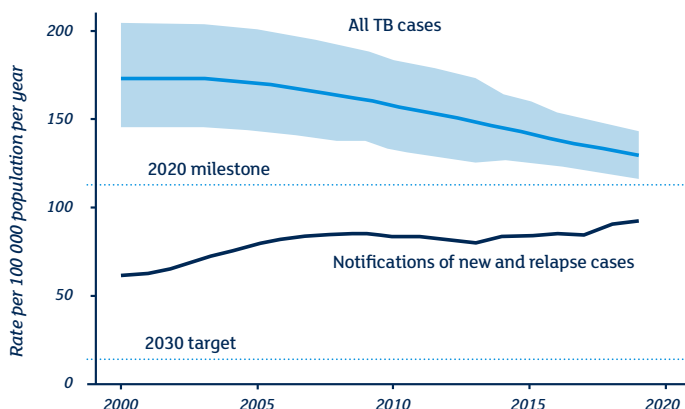
Neutralize



Centrifuge



Resuspend



Global TB incidence rate

### Progresses and milestones

Globally, the TB incidence rate is falling, but not fast enough to reach the first milestone of the End TB Strategy; that is, a 20% reduction between 2015 and 2020. Worldwide, the cumulative reduction from 2015 to 2019 was 9% (Global tuberculosis report 2020, WHO).



## From the pandemic and beyond

In 2020 the Covid-19 pandemic caused a global surge in viral collection systems demand, and put us into the spotlight the leading producers of microbiology collection and transport devices.

We faced this challenge head-on: on top of rethinking and expanding our production chain across the globe, **we exploited our innovative thinking to conceive new products that helped the fight against the virus.**

### *Global guidelines*

## A quest for quality

Covid-19 pandemic stressed more than ever the crucial role of sample quality in preanalytics and diagnostics. This global search for quality made UTM® and FLOQSwabs®, our products for viral collection and transport, to be declared by WHO and the CDC the products of choice for the sample collection from suspected cases of coronavirus disease.



### *LoliSponge™*

## The sponge-made device for saliva collection

LoliSponge™ can be used to collect saliva when professional assistance is not available. Its key feature is the **easy sampling, performed just by keeping the dry sponge stick in the mouth for a few minutes.** After collection, the sponge is placed in the tube and transported to the lab, where it can be centrifuged and tested with molecular diagnostic assays.

UniVerse™

## The answer to lab challenges and bottlenecks

UniVerse™ is the symbol of Copan's drive to share Laboratories challenges. It has been **developed to answer some of the most critical needs faced by laboratories during the Covid-19 pandemic**: the massive increase of sample numbers – especially hazardous ones – the variability of tube and transport media types, the risk of cross-contamination, and fragmented workflows and traceability errors caused by the lab overload.



*ID scan*



*Vortexing*



*Decapping*



*Aliquoting*



*Recapping*



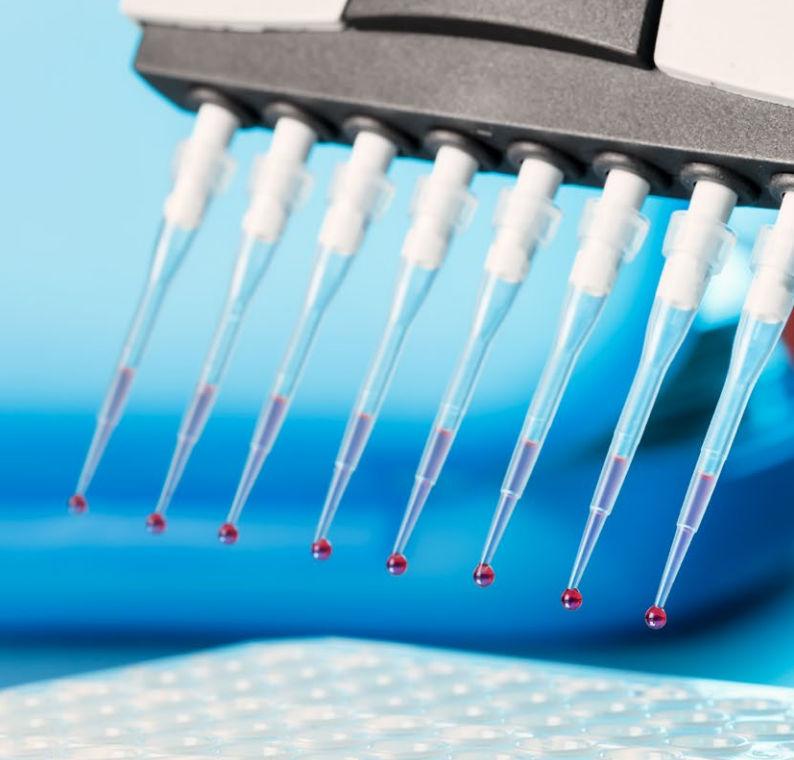
*Labelling*

*Expedite your workflow*

## Flexible and open solution for molecular testing sample preparation

UniVerse completely automates samples' preparation for molecular testing, as tube decapping and recapping, barcode identification, and liquid transfer to secondary tubes or 96-well plates.

With its four operational modes and three independent robotic arms, UniVerse™ handles 130 tubes/hour or 220 96-well plate samples/hour, integrating impeccably into your molecular biology lab's workflow.



#### *Downstream Applications*

### **Designed with diagnostic assays in mind**

Our liquid-based media offer excellent performances for many respiratory disease downstream diagnostic assays, from traditional culture to the most advanced molecular platforms. Discover below some examples!

#### ***Bacterial culture***

Bacterial culture is eSwab® proper application. For example, this study exploits eSwab® to determine the prevalence of *S. aureus* in microbiology and non-microbiology medical laboratories. Of note, the study demonstrates that eSwab® is compatible with downstream molecular testing as well<sup>21</sup>.

#### ***Viral culture***

The first isolation of SARS-CoV-2 from a Korean patient has been possible by UTM®, which allowed both culture and Next-Generation sequencing of the virus<sup>22</sup>

#### ***Mycobacterial culture***

MYCO-TB™ proved to be effective for the rapid digestion and decontamination of respiratory materials for Mycobacteria detection - by culture and molecular assays<sup>23</sup> - while eSwab® appeared to be an appropriate system for maintenance, transport, and recovery of select nontuberculous (NTM) and *Nocardia* species<sup>24</sup>.

#### ***RT-PCR***

Respiratory viruses and immunological markers can be analyzed by RT-PCR after eNat® or UTM collection and storage (RT, 4°C and -80°C<sup>25,26</sup>. Moreover, SARS-CoV-2 RNA has been detected up to 7 days at RT and 14 days at refrigerated conditions (4°C, -20°C) starting from UTM® and eSwab®-collected specimens<sup>9</sup>.

### ***LAMP***

mSwab collection and preservation is compatible with Loop-mediated isothermal amplification, ensuring a rapid specimen-to-result diagnosis of respiratory syncytial virus infection<sup>27</sup>.

*Mycoplasma pneumoniae*, leading cause of community-acquired pneumonia (CAP), can be also detectable by LAMP assay starting from respiratory samples collected in UTM<sup>28</sup>.

### ***Filmarray multiplex***

Human Adenovirus can be identified in tracheal aspirate by Filmarray multiplex PCR respiratory panel after UTM<sup>®</sup> collection and elution<sup>29</sup>.

UTM<sup>®</sup> has been used also for SARS-CoV-2 detection by rapid fully automated assay<sup>30</sup>.

### ***Gram stain***

Mucous-rich respiratory samples can be treated with SLSolution™ before Gram smear processing, culturing, and molecular tests<sup>31</sup>.

### ***DFA/IFA***

Starting from samples collected with FLOQSwabs<sup>®</sup> and eluted in UTM<sup>®</sup>, respiratory syncytial virus can be detected with Direct Immunofluorescence assay (DFA)<sup>32</sup>, while SARS-CoV-2 can be recognized by several Antigen Fluorescent Immunoassays (FIA)<sup>33,34</sup>.

### ***Immunoassay***

Nasopharyngeal and oropharyngeal specimens can be collected in UTM<sup>®</sup> for the identification of SARS-CoV-2 antigens. Of note, UTM<sup>®</sup> is compatible with several immunochromatographic rapid test<sup>35</sup>.

### ***TMA***

Respiratory viruses and bacteria can be identified using a Pan-microarray based technology as in this study, Nasopharyngeal and oropharyngeal samples obtained using FLOQSwabs<sup>®</sup> eluted in viral transport medium<sup>36</sup>.

## Scientific references

All the independent studies we cited in this product focus are listed here.

1. [https://www.who.int/gard/publications/The\\_Global\\_Impact\\_of\\_Respiratory\\_Disease.pdf](https://www.who.int/gard/publications/The_Global_Impact_of_Respiratory_Disease.pdf)
2. Loens K, Van Heirstraeten L, Malhotra-Kumar S, et al. Optimal sampling sites and methods for detection of pathogens possibly causing community-acquired lower respiratory tract infections. *J Clin Microbiol*. 2009
3. Zasada, A.A., Zacharczuk, K., Woznica, K. et al. The influence of a swab type on the results of point-of-care tests. *AMB Expr*, 2020
4. Speicher DJ, Luinstra K, Smith EJ, et al. Non-invasive detection of IgG antibodies from common pathogenic viruses using oral flocked swabs. *Diagn Microbiol Infect Dis*, 2020.
5. Debyle C, Bulkow L, Miernyk K, et al. Comparison of nasopharyngeal flocked swabs and nasopharyngeal wash collection methods for respiratory virus detection in hospitalized children using real-time polymerase chain reaction. *J Virol Methods*, 2012.
6. Loens K, Van Heirstraeten L, Malhotra-Kumar S, et al. Optimal sampling sites and methods for detection of pathogens possibly causing community-acquired lower respiratory tract infections. *J Clin Microbiol*, 2009
7. Noviello S, Huang DB. The Basics and the Advancements in Diagnosis of Bacterial Lower Respiratory Tract Infections. *Diagnostics (Basel)*, 2019
8. Van Horn KG, Audette CD, Sebeck D, et al. Comparison of the Copan ESwab system with two Amies agar swab transport systems for maintenance of microorganism viability. *J Clin Microbiol*, 2008
9. Rogers AA, Baumann RE, Borillo GA, et al. Evaluation of Transport Media and Specimen Transport Conditions for the Detection of SARS-CoV-2 by Use of Real-Time Reverse Transcription-PCR. *J Clin Microbiol*, 2020
10. Kanwar N, Crawford J, Ulen C, et al. Multicenter Clinical Evaluation of the Automated Aries Group A Strep PCR Assay from Throat Swabs. *J Clin Microbiol*. 2019
11. Yarbrough ML, Warren DK, Allen K, et al. Multicenter Evaluation of the Xpert MRSA NxG Assay for Detection of Methicillin-Resistant *Staphylococcus aureus* in Nasal Swabs. *J Clin Microbiol*, 2017
12. Rubin LG, Rizvi A, Baer A. Effect of swab composition and use of swabs versus swab-containing skim milk-tryptone-glucose-glycerol (STGG) on culture- or PCR-based detection of *Streptococcus pneumoniae* in simulated and clinical respiratory specimens in STGG transport medium. *J Clin Microbiol*, 2008
13. Walsh P, Overmyer CL, Pham K, et al. Comparison of respiratory virus detection rates for infants and toddlers by use of flocked swabs, saline aspirates, and saline aspirates mixed in universal transport medium for room temperature storage and shipping. *J Clin Microbiol*, 2008
14. <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>
15. Benirschke RC, McElvania E, Thomson RB Jr, et al. Clinical Impact of Rapid Point-of-Care PCR Influenza Testing in an Urgent Care Setting: a Single-Center Study. *J Clin Microbiol*, 2019
16. Park WB, Kwon NJ, Choi SJ, et al. Virus Isolation from the First Patient with SARS-CoV-2 in Korea. *J Korean Med Sci*, 2020
17. Kohmer N, Nagel A, Berger A, et al. Laboratory diagnosis of congenital CMV infection in newborns: Impact of pre-analytic factors. *J Clin Virol*, 2019
18. [https://www.who.int/health-topics/tuberculosis#tab=tab\\_1](https://www.who.int/health-topics/tuberculosis#tab=tab_1)
19. De Geyter D, Cnudde D, Van der Beken M, et al. Evaluation of the Copan Myco-TB kit for the decontamination of respiratory samples for the detection of *Mycobacteria*. *Eur J Clin Microbiol Infect Dis*, 2018.
20. Bisognin F, Lombardi G, Lombardo D, et al. Comparison of MycoPrep and the new MYCO-TB kit: rapid and efficient digestion and decontamination of respiratory specimens for the detection of *Mycobacteria*. *New Microbiol*, 2020.
21. ie X, Dai X, Ni L, et al. Molecular epidemiology and virulence characteristics of *Staphylococcus aureus* nasal colonization in medical laboratory staff: comparison between microbiological and non-microbiological laboratories. *BMC Infect Dis*, 2018.
22. Pavel STI, Yetiskin H, Aydin G, et al. Isolation and characterization of severe acute respiratory syndrome coronavirus 2 in Turkey. *PLoS One*, 2020
23. Bisognin F, Lombardi G, Lombardo D, et al. Comparison of MycoPrep and the new MYCO-TB kit: rapid and efficient digestion and decontamination of respiratory specimens for the detection of *Mycobacteria*. *New Microbiol*, 2020.
24. Gandhi B, Woods G, Mazzulli T. Recovery of Nontuberculous *Mycobacteria* and *Nocardiae* Causing Skin/Soft Tissue Infections by Use of the Copan ESwab Collection and Transport System. *J Clin Microbiol*, 24 2019.
25. Baldassarre ME, Di Mauro A, Labellarte G, et al. Resveratrol plus carboxymethyl- $\beta$ -glucan in infants with common cold: A randomized double-blind trial. *Heliyon*, 2020.

26. Tian J, Pinto JM, Li L, et al. Identification of Viruses in Patients With Postviral Olfactory Dysfunction by Multiplex Reverse-Transcription Polymerase Chain Reaction. *Laryngoscope*, 2021.
27. Mahony J, Chong S, Bulir D, et al. Development of a sensitive loop-mediated isothermal amplification assay that provides specimen-to-result diagnosis of respiratory syncytial virus infection in 30 minutes. *J Clin Microbiol*, 2013.
28. Petrone BL, Wolff BJ, DeLaney AA, Diaz MH, Winchell JM. Isothermal Detection of *Mycoplasma pneumoniae* Directly from Respiratory Clinical Specimens. *J Clin Microbiol*, 2015.
29. Azekawa S, Namkoong H, Mitamura K, Kawaoka Y, Saito F. Co-infection with SARS-CoV-2 and influenza A virus. *IDCases*, 2020.
30. Eckbo EJ, Locher K, Caza M, et al. Evaluation of the BioFire® COVID-19 test and Respiratory Panel 2.1 for rapid identification of SARS-CoV-2 in nasopharyngeal swab samples. *Diagn Microbiol Infect Dis*, 2021.30.
31. C. Fontana, M. Favaro and C. Favalli. How Liquid Based Microbiology Can Change the Workflow in the Microbiology Laboratories. *Advances in Microbiology*, 2013.
32. Sun Y, Deng J, Qian Y, et al. Laboratory Evaluation of Rapid Antigen Detection Tests for More-Sensitive Detection of Respiratory Syncytial Virus Antigen. *Jpn J Infect Dis*, 2019.
33. Porte L, Legarraga P, Iruretagoyena M, et al. Evaluation of two fluorescence immunoassays for the rapid detection of SARS-CoV-2 antigen-new tool to detect infective COVID-19 patients. *PeerJ*, 2021.
34. Bianco G, Boattini M, Barbui AM, et al. Evaluation of an antigen-based test for hospital point-of-care diagnosis of SARS-CoV-2 infection. *J Clin Virol*, 2021.
35. Corman VM, Haage VC, Bleicker T, et al. Comparison of seven commercial SARS-CoV-2 rapid point-of-care antigen tests: a single-centre laboratory evaluation study. *Lancet Microbe*, 2021.
36. Seckar T, Lin X, Bose D, et al. Detection of Microbial Agents in Oropharyngeal and Nasopharyngeal Samples of SARS-CoV-2 Patients. *Front Microbiol*, 2021.







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