**Clinical applications** 

Molecular Biology

# Molecular Biology Amplify your testing possibilities

Better diagnostics begins with a better sample collection.







Transport



Processing



Artificial Intelligence

Our comprehensive approach to preanalytics

#### Background

# **Going molecular**

Over the last four decades, significant advancements in molecular biology have stimulated research and progress in almost all the disciplines of life science, allowing things unimaginable until a short while ago, such as retrieving and amplifying Nucleic Acids from a single cell or bacteria, recognizing single nucleotide mutations, or performing population-wide genomic studies. As these technologies became available, molecular biology led to new opportunities and challenges for clinicians, including microbiologists.

# What's the Copan solution for Molecular Biology?

• Collection devices

LolliSponge<sup>™</sup>, Self-UriSponge<sup>™</sup>, hDNAfree FLOQSwabs<sup>®</sup>, FLOQSwabs<sup>®</sup>

• Media

eNAT<sup>®</sup>, MSwab<sup>®</sup>, UTM<sup>®</sup>, FecalSwab<sup>®</sup>

• Sample preparation

UniVerse®



#### **Evolution**

# From PCR to Next-Gen Sequencing

Molecular biology has had a tremendous impact on life sciences<sup>1</sup>. From the rise of DNA sequencing methods in the 1980s – sparked by the invention of the Polymerase Chain Reaction by the Nobel prize-winner Kary Mullins in 1983 – **new** technologies proliferated, improving existing techniques or developing new approaches which allowed to generate information more quickly and precisely compared to existing methods.

After these pioneer years, molecular diagnostics now entered adulthood, **expanding from specific fields or reference centers to virtually every lab** in every environment. RT-PCR, Next-Gen-Sequencing, cloning, mutagenesis, and gene therapy are just some of the most notorious methodologies available today to clinicians and researchers to discover primeval biological mechanisms or help humanity to fight future health threats.



#### Sample collection

# The importance of a proper sample collection

Even the most advanced molecular biology analyses are preceded – and thus affected – by sample collection and preparation. Since accuracy is crucial when performing these methodologies due to their extreme sensitivity and high throughput, it is shocking that while molecular biology has made great strides in the last decades, many laboratories still rely on unstandardized sample collection methods or process samples manually. Copan gives to molecular biology the sample collection and processing it deserves.



#### eNAT®

## Nucleic acid collection and preservation medium

eNAT<sup>®</sup> is our medium designed for **viral and bacterial nucleic acids collection and preservation**. Containing guanidine-thiocyanate, eNAT<sup>®</sup> **lyses cells and virus particles, removing the sample's infectivity and bacterial proliferation and preserving RNA and DNA integrity**<sup>2-11</sup>. eNAT<sup>®</sup> allows long-term sample storage for up to four weeks at RT or six months at -20°C by denaturing proteins - including nucleases - in only 30 minutes. It is the media of choice of many diagnostics kits, fully validated and included in their IFU.

Virus and bacteria infectivity Inactivation within 30 minutes

Preserves nucleic acids 4 weeks RT or 6 month at -20 °C



#### MSwab®

# Specimen Collection and Preservation Optimized for Molecular and Culture Applications

MSwab<sup>®</sup> offers the possibility of **collecting, transporting, and eluting the sample in the same tube without further manipulation**; it is suitable for crude rapid direct nucleic acid heat extraction and culture backup of viruses and selected bacteria. In addition, MSwab<sup>®</sup> represents a **non-flammable alternative to alcohol-based media**<sup>12</sup>, safe to transport, and economically convenient. A true all-around pre-analytical device designed for **optimized compatibility with molecular platforms**<sup>13-17</sup> MSwab<sup>®</sup> is available in bulk, paired with FLOQSwabs<sup>®</sup>, or as a 500ml bottle for use with UniVerse<sup>®</sup>.

Suitable for direct amplification and culture of virus and selected bacteria

Preserves nucleic acids up to 14 days at RT or 21 day refrigerated



#### FecalSwab<sup>®</sup>

# Collection, Transport & Preservation System of Feces and Rectal Swabs for Enteric Pathogens

If you are investigating gastrointestinal tract pathogens, FecalSwab<sup>®</sup> is the product to use. **Compatible with both stool and rectal swabs**, FecalSwab<sup>®</sup> showed better preserving properties at different storage conditions than traditional media and dry containers<sup>18,19</sup>. Moreover, it is **validated for bacterial culture and molecular-based assays<sup>20\*</sup>**, and if you are a lucky WASP<sup>®</sup> owner, you can process FecalSwab<sup>®</sup> samples with it<sup>21</sup>.

#### Designed for enteric pathogens

Improves fecal sample collection, transport, and processing



#### **UTM**®

#### Collection, transport, and virus storage medium

UTM<sup>®</sup> is our Universal collection and Transport Medium **suitable for collecting, transporting, and long-term freeze storage of viruses, chlamydia, mycoplasma, and ureaplasma.** Preserving viability for 48 hours at room temperature, **UTM<sup>®</sup> is compatible with viral culture, antigen detection, and molecular assays**<sup>22-25</sup>. This versatility made UTM<sup>®</sup> one of our most popular products. Like eNAT<sup>®</sup>, UTM<sup>®</sup> is the media of choice of many diagnostics kits – from respiratory to STI - fully validated and included in their IFU.

#### The gold standard for viruses

Choose by the major IVD manufacturer for respiratory assays



#### LolliSponge™

### The sponge-made device for saliva collection

LolliSponge<sup>™</sup> 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**. Conceived during the COVID-19 pandemic, LolliSponge<sup>™</sup> allowed the surveillance and the early detection of SARS-CoV-2 by RT-PCR<sup>26</sup>.

Non invasive device for pure saliva collection

Sample preservation for up to 3 days at room temperature



#### Self-UriSponge™

#### Innovative sponge system for urine self-collection

Self-UriSponge<sup>™</sup> redefines urine self-collection, offering **unpaired handling** easiness and downstream assay performance. The sponge absorbs the correct amount of first-void urine sample without risk and discomfort<sup>27</sup>, while the leak-proof tube ensures safe handling and shipment. In addition, thanks to the preservatives and its dry formula, Self UriSponge<sup>™</sup> allows the shipment of urine samples from remote areas without aecting the results<sup>27,28</sup>. Fitting the main molecular platforms, the performance of the UriSponge<sup>™</sup> is comparable with the testing of neat first-catch urine specimens<sup>28</sup>.

Compact and leak-proof device for safe and cost-effective shipment

DNA stability up to 1 week at RT or 3 weeks refrigerated



#### hDNAfreeFLOQSwabs®

# Non-invasive, Safe, and Painless DNA collection devices for Genetic applications

hDNAfreeFLOQSwabs<sup>®</sup> is a product line dedicated to DNA collection for genetic applications<sup>29,30</sup>, which **brings FLOQSwabs<sup>®</sup> advantages into the genetics field**. Free of amplifiable human DNA and detectable DNase and RNase, hDNAFLOQSwabs<sup>®</sup> are non-invasive, painless, and cost-effective alternatives to blood samples collected using hypodermic needles<sup>31</sup>. **In selected product codes, the active drying system dries the sample inside the tube, enabling 12 months of DNA stability at room temperature**, and their easiness to use improves the adoption percentage for genetic screenings, such as HLA typing, food intolerances, and ancestry testing.

Free of amplifiable human DNA, DNase and RNase free

FLOQSwabs<sup>®</sup> average DNA yield is five times higher than Rayon swabs





# The perfect match FLOQSwabs<sup>®</sup> Inside

Combining any transport media with our patented FLOQSwabs<sup>®</sup> expands testing possibilities by ensuring an unmatched specimen collection in many anatomical sites. Discover why we call them "the perfect collection device" on the dedicated brochure.

# The answer to lab challenges and bottlenecks

UniVerse® is our flexible solution for sample preparation, of which any minor improvement is the quickest and easiest way to optimize the efficiency and reliability of every methodology. Designed to streamline sample handling, elution, and preanalytic manipulation before any molecular biology analysis, UniVerse® is compatible with our Liquid-Based Microbiology collection and transport devices. Moreover, a rapidly expanding set of modules guarantees compatibility with third-party tubes and various downstream molecular platforms.

#### Expedite your workflow

# Flexible and open solution for molecular testing sample preparation

UniVerse® completely automates samples' preparation for molecular testing, such as **tube decapping and recapping, the addition of an elution media, 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.



















Labelling

Recapping

Aliquoting

Decapping

ing Vo

Vortexing

Media dispensing ID scan

#### Conclusions and future

## Diagnostics of the near future

Combining any transport media with our patented FLOQSwabs<sup>®</sup> expands testing possibilities by ensuring an unmatched specimen Molecular biology enabled the development of breakthrough solutions that significantly improved the life quality of countless individuals, **revolutionizing diagnosis, treatment, drug design, and research.** However, this is just the beginning: although **molecular diagnostics is already an integral part of traditional laboratories in many fields**, its broader spread in novel clinical applications will provide better testing for old and new diseases.

# **Scientific references**

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

- Tabery, James, Monika Piotrowska, and Lindley Darden, "Molecular Biology", The Stanford Encyclopedia of Philosophy (Spring 2021 Edition), Edward N. Zalta (ed.)
- Roy C, Robert D, Bénéjat L, et al. Performance Evaluation of the Novodiag Bacterial GE+ Multiplex PCR Assay. J Clin Microbiol. 2020 Sep 22;58(10):e01033-20.
- 3. Thomas PPM, Yadav J, Kant R, et al. Sexually Transmitted Infections and Behavioral Determinants of Sexual and Reproductive Health in the Allahabad District (India) Based on Data from the ChlamIndia Study. Microorganisms. 2019 Nov 12;7(11):557.
- 4. Falaschi Z, Danna PSC, Arioli R, et al. Chest CT accuracy in diagnosing COVID-19 during the peak of the Italian epidemic: A retrospective correlation with RT-PCR testing and analysis of discordant cases. Eur J Radiol. 2020 Sep;130:109192.
- Welch SR, Davies KA, Buczkowski H, et al. Analysis of Inactivation of SARS-CoV-2 by Specimen Transport Media, Nucleic Acid Extraction Reagents, Detergents, and Fixatives. J Clin Microbiol. 2020 Oct 21;58(11):e01713-20.
- Narchi H, George JV, Al-Hamad SM, et al. Nasopharyngeal Isolates from a Cohort of Medical Students with or without Pharyngitis. Sultan Qaboos Univ Med J. 2020;20(3):e287-e294.
- 7. Nagel A, Dimitrakopoulou E, Teig N, et al. Characterization of a universal screening approach for congenital CMV infection based on a highly-sensitive, quantitative, multiplex real-time PCR assay. PLoS One. 2020 Jan 9;15(1):e0227143.
- 8. Lee YM, Kim DY, Park KH, et al. Monitoring environmental contamination caused by SARS-CoV-2 in a healthcare facility by using adenosine triphosphate testing. Am J Infect Control. 2020;48(10):1280-1281.
- 9. van Pamelen J, van Olst L, Budding AE; BIA Study Group, de Vries HE, Visser LH. Alterations of Gut Microbiota and the Brain-Immune-Intestine Axis in Patients With Relapsing-Remitting Multiple Sclerosis After Treatment With Oral Cladribine: Protocol for a Prospective Observational Study. JMIR Res Protoc. 2020 Jul 29;9(7):e16162.
- 10. Ciardiello, T, Pinto, D, Marotta, L, et al. E, ects of Fermented Oils on Alpha-Biodiversity and Relative Abundance of Cheek Resident Skin Microbiota. Cosmetics 2020, 7, 34.
- Cieplik F, Wiedenhofer AM, Pietsch V, et al. Oral Health, Oral Microbiota, and Incidence of Stroke-Associated Pneumonia-A Prospective Observational Study. Front Neurol. 2020 Nov 6;11:528056.
- 12. Badman SG, Vallely AJ, Pardo C, et al. A comparison of ThinPrep against four non-volatile transport media for HPV testing at or near the point of care. Pathology. 2021 Feb;53(2):264-266.
- 13. Schnee SV, Pfeil J, Ihling CM, et al. Performance of the Alere i RSV assay for point-of-care detection of respiratory syncytial virus in children. BMC Infect Dis. 2017 Dec 13;17(1):767
- 14. 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 Aug;51(8):2696-701.

- 15. Mahony J, Chong S, Bulir D, et al. Multiplex loop-mediated isothermal amplification (M-LAMP) assay for the detection of influenza A/H1, A/H3 and influenza B can provide a specimen-to-result diagnosis in 40 min with single genome copy sensitivity. J Clin Virol. 2013 Sep;58(1):127-31.
- 16. Peters RM, Schnee SV, Tabatabai J, et al. Evaluation of Alere i RSV for Rapid Detection of Respiratory Syncytial Virus in Children Hospitalized with Acute Respiratory Tract Infection. J Clin Microbiol. 2017 Apr;55(4):1032-1036.
- 17. Heers T, van Neer A, Becker A, et al. Loop-mediated isothermal amplification (LAMP) assay-A rapid detection tool for identifying red fox (Vulpes vulpes) DNA in the carcasses of harbour porpoises (Phocoena phocoena). PLoS One. 2017 Sep 1;12(9):eo184349.
- Hirvonen JJ, Kaukoranta SS. Comparison of FecalSwab and ESwab devices for storage and transportation of Diarrheagenic bacteria. J Clin Microbiol. 2014.
- Rojas HF, Lima A, Kubasek C, et al. Evaluation of Copan FecalSwab<sup>™</sup> preserved stool specimens with the BD MAX<sup>™</sup> Enteric Bacterial Panel and the BD MAX<sup>™</sup> Extended Enteric Bacterial Panel. Diagn Microbiol Infect Dis. 2020.
- 20. Suzane Silbert, Alicia Gostnell, Carly Kubasek, et al. Evaluation of the New FecalSwab to Maintain Stability of Stool Samples. Submitted for Molecular Tests, Journal of Clinical Microbiology, 2017.
- 21. Goneau LW, Mazzulli A, Trimi X, et al. Evaluating the preservation and isolation of stool pathogens using the COPAN FecalSwab<sup>™</sup> Transport System and Walk-Away Specimen Processor. Diagn Microbiol Infect Dis, 2019.
- 22. 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 Jul 23;58(8):e00708-20.
- 23. 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 Jan;131(1):158-164.
- 24. 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 Feb 27;57(3):e01281-18
- 25. Shakya S, Thingulstad S, Syversen U, et al. Prevalence of Sexually Transmitted Infections among Married Women in Rural Nepal. Infect Dis Obstet Gynecol. 2018 Aug 26;2018:4980396.
- 26. Ottaviano E, Parodi C, Borghi E, et al; LollipopStudy Group, Bianchi S. Saliva detection of SARS-CoV-2 for mitigating company outbreaks: a surveillance experience, Milan, Italy, March 2021. Epidemiol Infect. 2021 Jul 30;149:e171.
- 27. Smith KS, Kaldor JM, Hocking JS, et al. The acceptability and cost of a home-based chlamydia retesting strategy: findings from the REACT randomised controlled trial. BMC Public Health, 2016
- 28. Costa AG, Garland SM, Guy R, et al. UriSwab: an e ective transport medium for nucleic acid detection of Chlamydia trachomatis, Mycoplasma genitalium and Neisseria gonorrhoeae. Sex Health. 2017 Nov;14(6):502-506
- 29. Eipel M, Mayer F, Arent T, et al. Epigenetic age predictions based on buccal swabs are more precise in combination with cell type-specific DNA methylation signatures. Aging (Albany NY). 2016 May;8(5):1034-48.
- 30. Schöfl, G., Lang, K., Quenzel, P. et al. 2.7 million samples genotyped for HLA by next generation sequencing: lessons learned. BMC Genomics 18, 161 (2017).
- 31. Theda, C., Hwang, S.H., Czajko, A. et al. Quantitation of the cellular content of saliva and buccal swab samples. Sci Rep 8, 6944 (2018).



This document may contain product information otherwise not accessible or valid in your country. Please be aware that Copan Italia S.p.A. does take any responsibility for accessing such information which may not comply with any valid legal process, regulation, registration or usage in the country of your origin. Product clearance and availability restrictions may apply in some Countries. Please refer to Copan website (www.copangroup.com) to view and/or download the most recent version of the brochure. This document is mainly intended for marketing purposes, always consult product insert for complete information. The use of this product in association with diagnostic kits or instrumentation should be internally validated by the user. ©2021 Copan Italia. All rights reserved. The trademarks mentioned herein are property of Copan Italia S.p.A. **Code: JMKC043R00** 



**Copan Italia s.p.a.** Via Francesco Perotti 10, <u>25</u>125 Brescia, <u>I</u>taly t | f +030 2687211 @ | info@copangroup.com www.copangroup.com