

FAST, ACCURATE QC MICROORGANISMS

Reliable Biological Controls for
Clinical Laboratories

Microbiologics®

The logo for Microbiologics, featuring the brand name in a bold, sans-serif font. To the right of the text is a stylized graphic consisting of a series of blue dots arranged in a curved, spiral pattern that suggests a DNA helix or a microbial growth curve.

Distributed by

 **HARDY**
DIAGNOSTICS

The Hardy Diagnostics logo features a stylized blue circular icon composed of horizontal lines of varying lengths, creating a sense of motion or a globe. To the right of this icon, the word "HARDY" is written in a large, bold, blue sans-serif font, with "DIAGNOSTICS" in a smaller, blue sans-serif font directly below it.

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RELIABLE CONTROLS FOR CLINICAL LABORATORIES



- User-friendly design with a lyophilized microorganism pellet, ampoule of hydrating fluid and inoculating swab – all in one device
- Over 900 strains available
- Available in packs of 2 or 6



LYFO•DISK™

- Easy-to-use lyophilized microorganism pellets; simply re-hydrate the pellet and inoculate
- Over 900 strains available
- Available in vials of 6 pellets



Microbiologics

QC SETS AND PANELS

QC Sets and Panels contain the manufacturer recommended quality control strains for a particular instrument or test in an easy-to-use format. QC Sets and Panels are also available for CLSI® antimicrobial susceptibility testing and many other common quality control tests.

- One simple catalog number for fast, easy ordering
- Traceable to reference culture
- Available in KWIK-STIK™ 2 pack (2 STIKs of each microorganism) and Inactivated Helix Elite™ formats



QC Sets and Panels are available for these commonly used assays and more:

- Respiratory Pathogens (e.g. Influenza A/B, RSV, and SARS-CoV-2)
- Blood Culture Identification (e.g. GP and GN)
- Enteric/Gastrointestinal Pathogens (e.g. Norovirus, *Cryptosporidium*, *Giardia*)
- Sexual Health/Women's Health Testing (e.g. CT/NG, HPV, GBS)
- Hospital and Community Acquired Infections (e.g. *C. difficile*, MRSA, CRE)
- Transplant/Viral Load Testing [COMING SOON] (e.g. CMV, BK)

QC MICROBIOLOGY SLIDES

- Contain droplets of an air-dried, fixed preserved organism, or a smear containing a designated organism population
- Wide variety of controls for instant access to uncommon specimens
- Ready-to-use out of the box
- Each box contains 10 slides



PARASITE SUSPENSIONS

- Parasite Suspensions can be used for a variety of applications including: QC of diagnostic kits and methods, Microscopic examinations, Acid-fast staining procedures, Proficiency programs, and Educational purposes
- Room temperature storage
- Ready-to-use 1 mL suspension



HELIX|ELITE™ MOLECULAR STANDARDS

Safe, Simple, Stable Molecular Controls

Helix Elite™ Molecular Standards, available in synthetic nucleic acid and inactivated formats, are non-hazardous controls designed for use with molecular assays.

- Compatible with a variety of instruments, kits and applications
- Convenient test-ready formats save you time and money
- Easy and economical room temperature storage
- FDA listed and CE Marked as an In-Vitro Diagnostic (IVD) Medical Device, except where noted



Inactivated Helix Elite Molecular Standards

Inactivated Helix Elite Molecular Standards are fully intact, non-viable process controls that can be used for every step of the molecular testing process: from extraction through detection.

Synthetic Helix Elite Molecular Standards

Synthetic Helix Elite Molecular Standards are specially designed synthetic RNA and DNA sequences for use as amplification and detection controls in clinical assays.



Test Methods	Microbiologics® Product Format					
	KWIK-STIK™	LYFO DISK™	Microbiology Slides	Parasite Suspensions	QC Sets and Panels	Helix Elite™ Molecular Standards
Identification Tests / Traditional Methods	•	•	•	•	•	
Identification Tests / Automated Commercial Instruments	•	•			•	•
Identification Tests / Molecular Methods / Rapid Methods	•	•			•	•
Antimicrobial Susceptibility Tests	•	•			•	
Screening Tests for Diagnostically Relevant Genes of Interest						•
Validation / Verification	•	•			•	•
Education	•	•	•	•	•	•
Proficiency Testing	•	•	•			•



EZ-PRODUCT REFERENCE GUIDE

Qualitative Products*, QC Microbiology Slides, Parasite Suspensions, Molecular Standards & Reagents

Product	Packaging/Contents	Enumeration	Applications/Specifications
KWIK-STIK™	Self-contained unit including a microorganism pellet, hydrating fluid and swab. Packaged in a foil pouch and a box. Available in packs of two or six.	Non-Enumerated	<ul style="list-style-type: none"> • Culture Purposes • QC ID Instruments • QC Antimicrobial Susceptibility Tests
KWIK-STIK™ Plus (Two Passages)	Five KWIK-STIK units. Each self-contained unit includes a microorganism pellet, hydrating fluid and swab. Packaged in a foil pouch and a canister.	Non-Enumerated	<ul style="list-style-type: none"> • Culture Purposes • QC ID Instruments • Pharmacopeial Tests • Two Passages • Provides More Subcultures
LYFO DISK™	Vial of six microorganism pellets.	Non-Enumerated	<ul style="list-style-type: none"> • Culture Purposes • QC ID Instruments • QC Antimicrobial Susceptibility Tests
Lab-Elite™ CRM (One Passage)	One KWIK-STIK unit. A self-contained unit that includes a microorganism pellet, hydrating fluid and swab. Packaged in foil pouch and a canister.	Non-Enumerated	<ul style="list-style-type: none"> • Validation of New Methods or Instruments • QC of Research • ISO 17025 Laboratories • One Passage • 100% Traceable • Certificate of Analysis
UV-BioTAG™	<p>UV-BioTAG Swab: Six all-in-one devices including a microorganism pellet, ampoule of hydration fluid and inoculating swab. Packaged in a foil pouch and a canister.</p> <p>UV-BioTAG Vial: Six microorganism pellets in vials. Packaged in a canister.</p>	Non-Enumerated	<ul style="list-style-type: none"> • Fluoresces under UV light to distinguish QC strains from other possible contaminants • Detection Methods Demonstration of Capability (DOC) • Media QC • Validation/Verification
QC Microbiology Slides	Box of ten slides containing droplets of an air-dried, fixed and preserved organism, or a smear containing a designated organism population.	Non-Enumerated	<ul style="list-style-type: none"> • Microscopic Examinations
Parasite Suspensions	Vial containing 1 ml of a parasite species, packaged in a canister.	Non-Enumerated	<ul style="list-style-type: none"> • QC & Proficiency of Diagnostic Medical Parasitology Testing • Teaching Purposes in Education Settings
Helix Elite™ Molecular Standards	Inactivated Controls: Kit containing inactivated pellets or swabs that mimic patient sample processing. Packaged in a box. For <i>in vitro</i> diagnostic (IVD) use.	Unassayed	<ul style="list-style-type: none"> • Full Process Control Used for Extraction Through Detection • Sensitivity • Specificity • Validation & Verification • Assay Optimization • Training • Proficiency Testing • Lot-to-Lot Testing • Molecular Instruments and Assays QC
	Synthetic Nucleic Acids: Kit containing dried synthetic DNA or RNA (approximately 100 reactions) and molecular water for rehydration. Packaged in a box. For <i>in vitro</i> diagnostic (IVD) use.	Unassayed	<ul style="list-style-type: none"> • Amplification/Detection Control • Sensitivity • Specificity • Validation & Verification • Assay Optimization • Training • Proficiency Testing • Lot-to-Lot Testing • Molecular Instruments and Assays QC
QC Sets & Panels	KWIK-STIK™: Self-contained unit including a microorganism pellet, hydrating fluid and swab. Packaged in a foil pouch and a box.	Non-Enumerated	<ul style="list-style-type: none"> • Culture Purposes • QC ID Instruments • QC Antimicrobial • Susceptibility Tests
	Helix Elite™: Kits contain pellets or swabs of dried synthetic DNA/RNA or inactivated microorganisms. Packaged in a box. For <i>in vitro</i> diagnostic (IVD) use.	Unassayed	<ul style="list-style-type: none"> • Inactivated Microorganisms - Full Process Control Used for Extraction Through Detection • Synthetic DNA/RNA - Amplification/Detection Control • Sensitivity • Specificity • Validation & Verification • Assay Optimization • Training • Proficiency Testing • Lot-to-Lot Testing • Molecular Instruments and Assays QC
UNEX Buffer	Bottle contains 100 ml of guanidine thiocyanate lysis buffer.	N/A	<ul style="list-style-type: none"> • Designed for preserving samples and nucleic acid extraction (UNEX) of DNA and RNA from viruses, bacteria and parasites • Not intended to diagnose, treat or prevent disease

* Quantitative products are not intended for clinical use.

† Exceptions to 8 hour stability is Microbiologics catalog number 0488A which must be used within 30 minutes of hydration.

EZ-PRODUCT REFERENCE GUIDE

Qualitative Products*, QC Microbiology Slides, Parasite Suspensions, Molecular Standards & Reagents

Product	Packaging/Contents	Enumeration	Applications/Specifications
Epower™	Vial of ten microorganism pellets in a plastic canister.	Ranging from 10 ² to 10 ⁸ CFU per pellet	<ul style="list-style-type: none"> • Applications Requiring a Specific CFU Range • Microbial Detection & Enumeration • Equipment Calibration • Verification & Validation • Bioburden Determination • Minimum Lethal Concentration • Lethality Studies • Disinfectant Testing • Internal Proficiency • Water Testing
Epower™ CRM (One Passage)	Vial of ten microorganism pellets in a plastic canister.	Ranging from 10 ² to 10 ⁷ CFU per pellet	<ul style="list-style-type: none"> • ISO 17025 Laboratories • Applications Requiring a Specific CFU Range • Microbial Detection & Enumeration • Equipment Calibration • Water Testing • Verification & Validation • Disinfectant Testing • Internal Proficiency • Bioburden Determination • Minimum Lethal Concentration • One Passage • Certificate of Analysis
EZ-Accu Shot™	EZ-Accu Shot™ : Kit containing five vials of microorganism pellets (one pellet per vial) and five vials of hydrating fluid. Packaged in a box.	Delivers 10-100 CFU per 0.1 ml	<ul style="list-style-type: none"> • Growth Promotion Testing • Microbial Limits Testing • Microbial Enumeration Testing • Validations • Instant Dissolve • No Dilution • 8 Hour Stability† • 50 Tests per Kit
	EZ-Accu Shot™ Select : Six compendial strains in one kit containing six vials of microorganism pellets (one pellet per vial) and six vials of hydrating fluid. Packaged in a box.	Delivers 10-100 CFU per 0.1 ml	<ul style="list-style-type: none"> • Growth Promotion Testing • Microbial Limits Testing • Microbial Enumeration Testing • 8 hour Stability† • Six Different Compendial Strains in One Package • Instant Dissolve • No Dilution • Ten Tests for Each Microorganism per Kit
	EZ-Accu Shot™ Starved Cells : Five vials of a single, quantitated microorganism (one pellet per vial).	Delivers 50-200 CFU per inoculum on R2A media	<ul style="list-style-type: none"> • Designed for laboratories performing the Growth Promotion Test of R2A media according to the Japanese Pharmacopeia, JP G8 Water 4.4.2 Growth Promotion Test in both required strains • 50 Test per kit
EZ-CFU™	Kit containing two vials of ten microorganism pellets and ten vials of hydrating fluid. Packaged in a box.	Delivers 10-100 CFU per 0.1 ml	<ul style="list-style-type: none"> • Growth Promotion Testing • Microbial Limits Testing • Microbial Enumeration Testing • Validations • Requires a 1:10 Dilution • 30 Minute Stability • > 900 Tests per Kit
EZ-CFU™ One Step	Kit containing two vials of ten microorganism pellets and ten vials of hydrating fluid. Packaged in a box.	Delivers 10-100 CFU per 0.1 ml	<ul style="list-style-type: none"> • Growth Promotion Testing • Microbial Limits Testing • Microbial Enumeration Testing • Validations • No Dilution • 8 Hour Stability • 190 Tests per Kit
EZ-PEC™	Kit containing two vials of ten microorganism pellets and ten vials of hydrating fluid. Packaged in a box.	Final concentration of 10 ⁵ to 10 ⁶ CFU per ml of product tested	<ul style="list-style-type: none"> • Antimicrobial Effectiveness & Preservative Efficacy Testing
EZ-SPORE™	Vial of ten microorganism pellets in a plastic canister.	10 ⁴ CFU per pellet	<ul style="list-style-type: none"> • Daily Food Process Controls to Verify Spoilage Detection Methods
Enumerated Mycoplasma	Five cryovials of 0.5 ml frozen suspension.	Delivers 10,000 – 99,000 CFU/ml	<ul style="list-style-type: none"> • Positive controls for Mycoplasma media • Growth Promotion Testing • Microbial Identification • Molecular Testing • Enumerated Mycoplasma simplifies compliance with USP <63> / Ph. Eur. 2.6.7 by eliminating the need for manual enumeration

* Quantitative products are not intended for clinical use.

† Exceptions to 8 hour stability is Microbiologics catalog number 0488A which must be used within 30 minutes of hydration.

EZ-PRODUCT REFERENCE GUIDE

Industry Reference Guide of the Largest and Most Diverse Line of QC Microorganisms

Industry	Reference Stock Cultures						Enumerated Microorganism Preparations						QC Slides	Certified Reference Material		Molecular		Reagent		
	KWIK-STIK™	KWIK-STIK™ Plus	LYFO DISK™	Parasite Suspensions	QC Sets and Panels KWIK-STIK™	UV-BioTAG™	Enumerated Mycoplasma	Epower™	EZ-Accu Shot™ Products	EZ-CFU™	EZ-CFU™ One Step	EZ-PEC™	EZ-SPORE™	QC Microbiology Slides	Epower™ CRM	Lab-Elite™ CRM	Helix Elite™ Inactivated Controls	Helix Elite™ Synthetic Nucleic Acids	QC Sets and Panels Helix Elite™	UNEX Buffer
Clinical	•		•	•	•									•			•	•	•	•
Food	•	•	•		•	•		•	•	•	•	•	•		•	•	•	•		•
Environmental/ Water	•	•	•		•			•	•	•					•	•	•	•		•
Pharmaceutical/ Personal Care	•	•	•		•		•	•	•	•	•	•			•	•				•
Educational/ Research	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•		•
Cannabis	•		•		•	•		•							•					•

Your strain. Your format. Your convenience.

We simplify environmental isolate and objectionable organism testing by providing a complete solution to help you meet FDA, USDA, USP and other regulations and guidelines. Using your environmental isolate or targeted objectionable organism, we manufacture test-ready controls quantitated for specific methods.



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