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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 eas 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)

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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



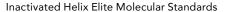


Safe, Simple, Stable Molecular Controls

Helix Elite $^{\text{TM}}$ 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



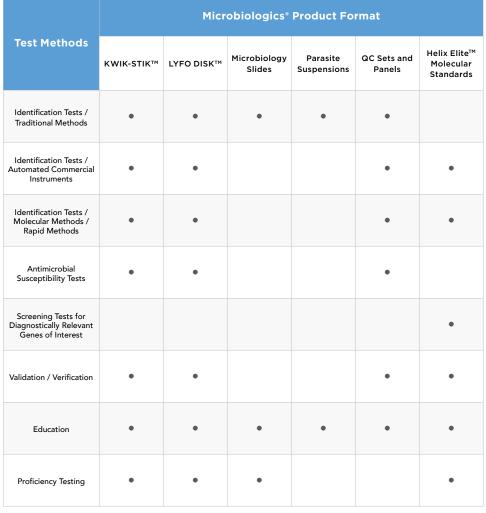
Inactivated Helix Elite Molecular Standards are fully intact, nonviable process controls that can be used for every step of the molecular testing process: from extraction through detection.

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.









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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	Culture Purposes					
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	Culture Purposes					
LYFO DISK™	Vial of six microorganism pellets.	Non-Enumerated	Culture Purposes					
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	 Validation of New Methods or Instruments QC of Research ISO 17025 Laboratories One Passage 100% Traceable Certificate of Analysis 					
UV-BioTAG™	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. UV-BioTAG Vial: Six microorganism pellets in vials. Packaged in a canister.	Non-Enumerated	 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	Microscopic Examinations					
Parasite Suspensions	Vial containing 1 ml of a parasite species, packaged in a canister.	Non-Enumerated	QC & Proficiency of Diagnostic Medical Parasitology Testing Teaching Purposes in Education Settings					
Helix Elite™	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	 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 					
Molecular Standards	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	 Amplification/Detection Control Sensitivity Specificity Validation & Verification Assay Optimization Training Proficiency Testing Lot-to-Lot Testing Molecular Instruments and Assays QC 					
	KWIK-STIK™: Self-contained unit including a microorganism pellet, hydrating fluid and swab. Packaged in a foil pouch and a box.	Non-Enumerated	Culture Purposes					
QC Sets & Panels	Helix EliteTM : 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	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	 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.

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 $^{^{\}dagger}$ 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	 Applications Requiring a Specific CFU Range Microbial Detection & Enumeration Verification & Validation Bioburden Determination Minimum Lethal Concentration 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	ISO 17025 Laboratories Applications Requiring a Specific CFU Range Microbial Detection & Enumeration					
	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	Growth Promotion Testing Microbial Limits Testing Microbial Enumeration Testing Validations Instant Dissolve No Dilution Hour Stability 50 Tests per Kit					
EZ-Accu Shot™	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	Growth Promotion Testing Microbial Limits Testing Microbial Enumeration Testing 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	 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	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	 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	Antimicrobial Effectiveness & Preservative Efficacy Testing					
EZ-SPORE™	Vial of ten microorganism pellets in a plastic canister.	10⁴ CFU per pellet	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	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.

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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	Refe	ified rence erial	Molecular			Reagent
	KWIK-STIK"	KWIK-STIK" Plus	LYFO DISK"	Parasite Suspensions	QC Sets and Panels KWIK-STIK™	UV-BioTAG"	Enumerated Mycoplamsa	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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