



MICROBIOLOGY CONTROL PRODUCTS

Molecular QC Microorganisms



TABLE OF CONTENTS

About Microbiologics 1

Customer Information..... 2

Products by Molecular Syndromic Testing

Blood Culture Identification (BCID) 3

Gastrointestinal (GI) 7

Healthcare-Associated Infections (HAIs)..... 14

Respiratory Pathogens..... 20

Women’s Health and Sexually Transmitted Infections (STI) 28

Emerging Diseases and Other Pathogens..... 39

All Products

Inactivated Helix Elite™ Molecular Standards 40

Negative Cellularity Controls 41

Synthetic Helix Elite™ Molecular Standards..... 44

QC Sets and Panels 45

Assay-Specific QC Sets and Panels 46

Syndrome-Specific QC Sets and Panels 47

Payment and Shipping Information 49

ABOUT MICROBIOLOGICS

Microbiologics.com

In support of our commitment to quality service, we have designed our website to be a helpful, easy-to-use resource for customers. The website is updated regularly and is the best place to obtain the most current information. Listed below are examples of the resources available:

- Digital catalog
- Product descriptions and applications
- End user registration
- Certificates of Analysis and Certificates of Performance
- Online ordering
- Contact Us form
- Instructions for Use (multiple translations)
- Locate a distributor by country
- Safety Data Sheets (multiple translations)
- Customer & Technical Support documents
- Easy-to-use product and document search
- Frequently asked questions (FAQs)
- Order management

Customer Service

We take pride in providing you with exceptional customer service. Customer calls are answered by a team of experts ready to assist you with everything from account set up to placing an order.

All international customers should contact an authorized distributor for ordering information. Locate a distributor in your area by visiting microbiologics.com. If an authorized distributor is not listed in your country, please contact Microbiologics Customer Service.

Technical Support

Our team of experienced Technical Support experts are always eager to help customers use our product successfully. They can provide guidance for selecting the right strains and product formats for your unique testing needs, and help problem solve when issues arise in your lab.

Contact Customer Service		Contact Technical Support	
Hours	7:30 a.m. - 5 p.m. (CST)	Hours	8:00 a.m. - 5 p.m. (CST)
Phone	1.320.253.7400	Phone	1.320.229.7045
US Toll Free	1.800.599.2847	US Toll Free	1.866.286.6691
Fax	320.253.6250	Fax	320.253.6250
Email	info@microbiologics.com	Email	techsupport@microbiologics.com

Safe, Simple, Stable Controls

Microbiologics products are compatible with a variety of instruments, kits and applications. Our independent external controls provide accurate, reliable results with convenient test-ready formats that save you time and money. Our controls offer easy and economical storage with no freezing required.

CUSTOMER INFORMATION

Worldwide Distribution

Our extensive distribution network allows us to reach every corner of the world, from Afghanistan to Zambia. We select distributors that are customer focused and demonstrate a commitment to our mission of providing the highest quality biomaterials for a safer, healthier world. Locate a distributor in your area by visiting microbiologics.com.

International Customers

All international customers must contact an authorized distributor within their country to place an order. To search for distributors by country, visit microbiologics.com. If an authorized distributor is not listed in your country, please contact Microbiologics Customer Service at info@microbiologics.com or +1 320.253.7400.

U.S. Customers

Customers located in the United States may purchase Microbiologics products directly or through an authorized distributor. Visit microbiologics.com to search for distributors in the United States. Orders can be placed online at microbiologics.com or by contacting Customer Service. Be prepared to provide the following information with your order:

- Customer account number
- Registration number
- Billing address
- Telephone number
- Email address
- Fax number
- Shipping address
- Purchase order number
- Credit card information
- Tax exemption information (certified exemption form must be kept on file)
- Quantities
- Microbiologics catalog number or reference culture numbers

Online orders can be placed at microbiologics.com by signing in on the homepage or clicking "Register" to create an account.

Product Warranty

Microbiologics guarantees results when the product is stored, handled and used as directed (as per the expiration date, Microbiologics Recommended Growth Requirements, Illustrated Instructions and Instructions for Use). Please report concerns to Microbiologics Technical Support immediately. For more information, see the document titled *Product Warranty and Product Replacement* located at microbiologics.com.

End User Registration

An authorized representative from your organization must agree to the terms of the End User Agreement in order to receive Microbiologics biological materials.

Registration can be completed at microbiologics.com. Contact Customer Service at 1.320.253.7400 or info@microbiologics.com with questions about the End User Agreement.



BLOOD CULTURE IDENTIFICATION

Diagnosing sepsis and bloodstream infections requires fast, accurate laboratory results for swift and proper treatment. To help clinical labs ensure their blood culture identification (BCID) instruments and assays are consistently producing reliable results, we offer a variety of verification and quality control panels designed for efficiency and usability.

BLOOD CULTURE IDENTIFICATION

#8254 - Blood Culture Identification Control Panel (43 Targets)

Contains six inactivated pre-pooled positive control 1 pellets, six inactivated pre-pooled positive control 2 pellets, and 6 inactivated negative control pellets (18 pellets/kit). The negative control pellets are blank and do not contain microorganisms.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control 1 (Six pellets/kit)

Bacteroides fragilis
Klebsiella aerogenes
Salmonella Typhimurium
Stenotrophomonas maltophilia
Enterococcus faecium (vanA/B)
Staphylococcus lugdunensis
Candida auris
Cryptococcus neoformans
Klebsiella pneumoniae (OXA-48)
Escherichia coli (NDM, CTX-M)
Klebsiella pneumoniae (VIM-1)
Escherichia coli (mcr-1, ESBL)

Negative Control (Six pellets/kit)

Blank pellet

Positive Control 2 (Six pellets/kit)

Candida albicans
Candida krusei
Neisseria meningitidis
Pseudomonas aeruginosa
Staphylococcus aureus (MRSA)
Streptococcus agalactiae (Group B)
Streptococcus pyogenes
Acinetobacter baumannii
Candida glabrata
Candida tropicalis
Enterobacter cloacae (CTX-M)
Enterococcus faecalis (vanB)
Escherichia coli (IMP)
Klebsiella oxytoca
Listeria monocytogenes
Staphylococcus epidermidis
Candida parapsilosis
Haemophilus influenzae
Klebsiella pneumoniae (KPC)
Proteus vulgaris
Serratia marcescens
Streptococcus pneumoniae

BLOOD CULTURE IDENTIFICATION

#8180 - Gram-Positive Blood Culture Control Panel (Inactivated Pellet)

Contains six inactivated pre-pooled positive control 1 pellets, six inactivated pre-pooled positive control 2 pellets, and 6 inactivated negative control pellets (18 pellets/kit). The negative control pellets are blank and do not contain microorganisms.

- Refrigerated storage
- For in vitro diagnostic use
- International restrictions may apply



Pool 1 (Five pellets/kit)

Enterococcus faecium
Listeria monocytogenes
Staphylococcus epidermidis
Staphylococcus lugdunensis

Pool 2 (Five pellets/kit)

Streptococcus agalactiae
Streptococcus anginosus
Streptococcus pyogenes

Pool 3 (Five pellets/kit)

Staphylococcus aureus
Enterococcus faecalis
Streptococcus pneumoniae

#5225P - Gram-Positive Blood Culture Control Panel (Live Culture)

Contains two KWIK-STIKs of each strain listed below (20 KWIK-STIKs total).

0714 *Enterococcus faecalis* derived from NCTC 13379
01143 *Enterococcus faecium* derived from NCTC 12204
0783 *Listeria monocytogenes* derived from NCTC 10890
01065 *Staphylococcus aureus* derived from NCTC 12493
0571 *Staphylococcus epidermidis* derived from NCIMB 8853
01150 *Staphylococcus lugdunensis* derived from NCTC 7990
0480 *Streptococcus agalactiae* derived from NCTC 8017
0389 *Streptococcus anginosus* derived from NCTC 10713
0469 *Streptococcus pneumoniae* derived from NCIMB 13286
0314 *Streptococcus pyogenes* derived from NCIMB 13285



BLOOD CULTURE IDENTIFICATION

#8181 - Gram-Negative Blood Culture Control Panel (Inactivated Pellet)

Contains five inactivated microorganism pellets of each pool listed below (15 pellets/kit total).

- Refrigerated storage
- For in vitro diagnostic use
- International restrictions may apply

Pool 4 (Five pellets/kit)

Acinetobacter baumannii

Pseudomonas aeruginosa

Enterobacter cloacae (CTX-M)

Pool 5 (Five pellets/kit)

Klebsiella pneumoniae (KPC)

Citrobacter freundii

Escherichia coli (IMP)

Klebsiella pneumoniae (CTX-M, NDM)

Klebsiella pneumoniae (VIM)

Pool 6 (Five pellets/kit)

Klebsiella oxytoca

Klebsiella pneumoniae (OXA)

Proteus vulgaris





GASTROINTESTINAL (GI)

With the broad array of viruses, bacteria, and parasites that can cause gastrointestinal (GI) infections, diagnosis can sometimes feel like a guessing game. Microbiologics offers easy-to-use verification and control panels for rapid diagnostic instruments and multiplex assays designed for detecting gastrointestinal pathogens. Because QC testing shouldn't be another mystery.

ASSAY-SPECIFIC PANELS FOR GI TESTING

#8202 - BD MAX™ Enteric Parasite 20-Day QC Panel

Contains 20 inactivated, pre-pooled microorganism pellets comprised of the organisms recommended by the manufacturer for QC listed below (20 pellets/ kit total). For use with the BD MAX™ Enteric Parasite Panel.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Cryptosporidium parvum

Giardia lamblia

Entamoeba histolytica surrogate



#8204 - BD MAX™ Enteric Parasite Control Panel

Contains six inactivated, pre-pooled microorganism pellets comprised of the organisms recommended by the manufacturer for QC listed below (six pellets/ kit total). For use with the BD MAX™ Enteric Parasite Panel.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Cryptosporidium parvum

Giardia lamblia

Entamoeba histolytica surrogate



GASTROINTESTINAL PANELS

#8179 - Enteric Bacterial Organism Set (Live Culture)

Contains two KWIK-STIKs of each strain listed below
(16 KWIK-STIKs total).

- Export license required for shipping outside the U.S.
- UN2814 Hazardous



0356 *Shigella flexneri* derived from ATCC® 12022™*

0363 *Salmonella enterica* subsp. *enterica* serovar *Typhimurium* derived from ATCC® 14028™*

0446 *Shigella sonnei* derived from ATCC® 9290™*

0481 *Campylobacter jejuni* subsp. *jejuni* derived from ATCC® 33291™*

0595 *Salmonella bongori* derived from ATCC® 43975™*

01023 *Campylobacter coli* derived from ATCC® 33559™*

01102 *Escherichia coli* serotype O111:H8 derived from CDC 2010C-3114 (STEC)

01204 *Escherichia coli* (O157:H7) derived from ATCC® 43890™* (STEC)



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Work Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiology, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

#8230 - Enteric Parasite Control Panel (Inactivated Pellet)

Contains six inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (six pellets/kit total).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Cryptosporidium parvum

Giardia lamblia

Entamoeba histolytica surrogate

GASTROINTESTINAL PANELS

#8184 - Enteric Pathogens Control Panel (Inactivated Pellet)

Contains five inactivated microorganism pellets of each pool listed below (10 pellets/kit total).

- Refrigerated storage
- For in vitro diagnostic use
- Export license required for shipping outside the U.S.

Pool 7/Positive Control (Five pellets/kit)

Campylobacter jejuni

Shigella sonnei

Yersinia enterocolitica

Salmonella enterica subsp. *enterica* serovar *Typhimurium*

Vibrio parahaemolyticus

Escherichia coli (Shiga toxin 1, Shiga toxin 2)

Rotavirus SA11

Norovirus GII.4 surrogate

Pool 8/Negative Control (Five pellets/kit)

Clostridioides difficile (NAP1)



#8210 - Enteric Viral Verification Panel

Contains 20 inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (20 pellets/kit total).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

Adenovirus 40

Astrovirus surrogate

Norovirus GII surrogate

Rotavirus

Sapovirus surrogate



GASTROINTESTINAL PANELS

#8211 - Enteric Viral Control Panel

Contains six inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (six pellets/kit total).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

Adenovirus 40
Astrovirus surrogate

Rotavirus
Sapovirus surrogate



Norovirus GII surrogate

#8191 - Extended Enteric Bacterial Verification Panel (Inactivated Pellet)

Contains 21 inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (21 pellets/kit total).

- Room temperature storage
- For in vitro diagnostic use
- Export license required for shipping outside the U.S.

Shigella sonnei

Escherichia coli (STEC)

Plesiomonas shigelloides

Yersinia enterocolitica

Salmonella enterica subsp.
enterica serovar *Typhimurium*

Vibrio parahaemolyticus



Campylobacter jejuni
Escherichia coli (ETEC)

#8231 - Comprehensive Enteric Bacterial Control Panel (Inactivated Pellet)

Contains six inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (six pellets/kit total).

- Room temperature storage
- For in vitro diagnostic use
- Export license required for shipping outside the U.S.

Shigella sonnei

Escherichia coli (STEC)

Plesiomonas shigelloides

Yersinia enterocolitica

Salmonella enterica subsp.
enterica serovar *Typhimurium*

Vibrio parahaemolyticus



Campylobacter jejuni
Escherichia coli (ETEC)

GASTROINTESTINAL PANELS

#8205 - Norovirus Control Panel (Inactivated Swab)

Contains six positive and six negative inactivated control swabs (12 swabs total) comprised of the strains listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Norovirus GI.1 (ORF1-ORF2) surrogate
Norovirus GII.4 (ORF1-ORF2) surrogate

Negative Control (Six swabs/kit)

Rotavirus

#8236 - Gastrointestinal (22 Targets) Control Panel (Inactivated Pellet)

Contains six pellets of Positive Control 1, six pellets of Positive Control 2, and 12 negative control pellets (24 pellets/kit total). The negative control pellets are blank and do not contain microorganisms.

- Room temperature storage
- For in vitro diagnostic use
- Export license required for shipping outside the U.S.



Positive Control 1 (Six pellets/kit)

Campylobacter jejuni
Clostridioides (Clostridium) difficile
Plesiomonas shigelloides
Yersinia enterocolitica
Escherichia coli (STEC)
Escherichia coli (EAEC) surrogate
Escherichia coli (O157)
Shigella sonnei
Cryptosporidium parvum
Adenovirus
Sapovirus surrogate

Positive Control 2 (Six pellets/kit)

Salmonella enterica subsp. *enterica* serovar *Typhimurium*
Vibrio cholerae
Escherichia coli (EPEC)
Escherichia coli (ETEC)
Cyclospora cayetanensis surrogate
Entamoeba histolytica surrogate
Giardia lamblia
Astrovirus surrogate
Norovirus GI surrogate
Norovirus GII surrogate
Rotavirus A

Negative Control (Twelve pellets/kit)

Blank pellets

HELIX ELITE™ MOLECULAR STANDARDS FOR (GI) TESTING

Inactivated Helix Elite Molecular Standards

Full process controls for use in molecular testing. Each kit contains five unassayed inactivated microorganism pellets packaged in individual vials for ease-of-use and to avoid cross contamination.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Synthetic Helix Elite Molecular Standards

For use as a positive control in molecular applications. Each kit contains one vial of dried synthetic DNA or RNA (up to 100 reactions), and one vial of molecular water for rehydration.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Dried RNA Preserved with Biomatrix RNASTABLE®



#HE0013S - Norovirus GI.1 Synthetic RNA

ORF1-ORF2 Junction of Norovirus GI.1

#HE0012S - Norovirus GII.4 Synthetic RNA

ORF1-ORF2 Junction of Norovirus GII.4

#HE0027N - Inactivated Rotavirus

Medium-high titer

Strain Simian Rotavirus SA11



HEALTHCARE-ASSOCIATED INFECTIONS (HAIs)

When it comes to detecting and identifying healthcare-associated infections (HAIs), there is no room for error. Microbiologics offers simple, reliable controls for HAI testing in clinical laboratories to ensure procedures and materials are working properly.

ASSAY-SPECIFIC PANELS FOR HAI TESTING

#8200 - Assayed *C. difficile*/Epi Control Panel

Contains six positive and six negative inactivated control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC. For use with Cepheid Xpert® *C. difficile*/Epi assay.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked



Positive Control (Six swabs/kit)

Clostridium difficile (NAP1/027)

Negative Control (Six swabs/kit)

Clostridium sordellii

#8195 - Assayed MRSA NxG Control Panel

Contains six positive and six negative inactivated control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC. For use with Cepheid Xpert® MRSA NxG assay.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Positive Control (Six swabs/kit)

Methicillin-resistant *Staphylococcus aureus*

Negative Control (Six swabs/kit)

Staphylococcus epidermidis

#8196 - Assayed SA Nasal Complete Control Panel

Contains 12 positive and six negative inactivated control swabs (18 swabs total) comprised of the organisms recommended by the manufacturer for QC. For use with Cepheid Xpert® SA Nasal Complete assay.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Positive Control 1 (Six swabs/kit)

Methicillin-resistant *Staphylococcus aureus*

Positive Control 2 (Six swabs/kit)

Staphylococcus aureus

Negative Control (Six swabs/kit)

Staphylococcus epidermidis

SYNDROME-SPECIFIC PANELS FOR HAI TESTING

#8243 - *C. difficile* Verification Panel (Live Culture)

Contains two KWIK-STIKs of each strain listed below
(four KWIK-STIKs total).

0527 *Clostridioides difficile* ATCC® 700057™*

0329 *Clostridioides difficile* ATCC® 9689™*



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Work Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiology, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

#8227 - *C. difficile* Control Panel (Inactivated Swab)

Contains six positive and six negative inactivated
control swabs.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)
Clostridioides difficile

Negative Control (Six swabs/kit)
Clostridium sordellii

#8171 - *C. difficile* QC Set (Live Culture)

Contains one KWIK-STIK™ unit of *Clostridioides
difficile* derived from ATCC® 9689™* and one
KWIK-STIK™ unit of *Clostridioides difficile* derived
from ATCC® 700057™* (two KWIK-STIKs total).



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Work Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiology, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

SYNDROME-SPECIFIC PANELS FOR HAI TESTING

#8187 - Carbapenem-resistant Enterobacteriaceae (CRE) Control Panel (Inactivated Swab)

Contains six pre-pooled positive and six negative inactivated control swabs (12 swabs total) comprised of the organisms listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Escherichia coli derived from NCTC 13476 (IMP-type)

Klebsiella pneumoniae derived from NCTC 13440 (VIM-1, Metallo-beta-lactamase positive)

Klebsiella pneumoniae derived from NCTC 13443 (DM-1 positive, New Delhi metallo-beta-lactamase)

Klebsiella pneumoniae derived from NCTC 13438 (Produces carbapenemase KPC-3)

Klebsiella pneumoniae derived from NCTC 13442 (OXA-48)

Negative Control (Six swabs/kit)

Escherichia coli derived from NCTC 11954

#8174 - MRSA Organism Set (Live Culture)

Contains four KWIK-STIK™ units of each microorganism listed below.

Staphylococcus aureus derived from ATCC® 33591™*

Staphylococcus aureus derived from ATCC® 700699™*

Staphylococcus aureus derived from ATCC® 43300™*

Staphylococcus aureus derived from ATCC® 700698™*

Staphylococcus aureus derived from NCTC 12493

Staphylococcus aureus subsp. *aureus* derived from NCTC 12973

Staphylococcus aureus derived from ATCC® 6538™*

Staphylococcus aureus derived from ATCC® 29213™*

Staphylococcus aureus subsp. *aureus* derived from ATCC® 33862™*

Staphylococcus epidermidis derived from ATCC® 51625™*



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Work Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiology, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

SYNDROME-SPECIFIC PANELS FOR HAI TESTING

#8178 - SA Organism Set (Live Culture)

Contains 14 Staphylococcal strains, one KWIK-STIK of each strain (14 KWIK-STIKs total).

Eleven strains/KWIK-STIKs Methicillin-Resistant *Staphylococcus aureus* (MRSA)

Two strains/KWIK-STIKs Methicillin-Sensitive *Staphylococcus aureus* (MRSA)

One strain/KWIK-STIKs Methicillin-Sensitive *Staphylococcus epidermidis* (MSSE)

Live Culture *Staphylococcus* Controls

Each kit contains two KWIK-STIKs at E4 concentration.

#0360MSSA

Staphylococcus aureus subsp. *aureus* derived from ATCC® 25923™*
(MSSA Live Culture Positive Control)

#0158MRSA

Staphylococcus aureus subsp. *aureus* derived from ATCC® 700699™*
(MRSA Live Culture Positive Control)

#0371MSSE

Staphylococcus epidermidis derived from ATCC® 12228™*
(MSSE Live Culture Positive Control)



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Work Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiology, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

SYNDROME-SPECIFIC PANELS FOR HAI TESTING

#8203 - Vancomycin Resistant *Enterococcus* (VRE) Control Panel (Inactivated Swab)

Contains six positive and six negative inactivated control swabs (12 swabs total) comprised of the strains listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Enterococcus faecium (vanA-type glycopeptide resistance and Vancomycin resistant)

Negative Control (Six swabs/kit)

Enterococcus faecalis

#HE0053NS - Methicillin-Resistant *Staphylococcus aureus* (MRSA) Inactivated Swab

Contains six individually packaged inactivated control swabs containing Methicillin-Resistant *Staphylococcus aureus* (MRSA).

- Room temperature storage
- International restrictions may apply

#HE0054NS - Methicillin-Susceptible *Staphylococcus aureus* (MSSA) Inactivated Swab

Contains six individually packaged inactivated control swabs containing Methicillin-Susceptible *Staphylococcus aureus* (MSSA).

- Room temperature storage
- International restrictions may apply

#HE0055NS - Methicillin-Susceptible *Staphylococcus epidermidis* (MSSE) Inactivated Swab

Contains six individually packaged inactivated control swabs containing Methicillin-Susceptible *Staphylococcus aureus* (MRSA).

- Room temperature storage
- International restrictions may apply



RESPIRATORY PATHOGENS

Cold and flu season is a busy time in the laboratory. QC testing your diagnostic instruments and assays shouldn't add to the stress. Microbiologics offers accurate, test-ready controls for a variety of respiratory pathogens to help you meet laboratory standards and ensure your methods and materials are producing reliable results.

ASSAY-SPECIFIC PANELS FOR RESPIRATORY TESTING

#8199 - Assayed Respiratory Control Panel

Contains six pre-pooled positive and six negative, inactivated control swabs (12 swabs/kit) comprised of the microorganisms listed below. For use with Cepheid Xpert® Xpress Flu/RSV assay.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Positive Control (Six swabs/kit)

Influenza A (H1N1) Virus

Influenza A (H3H2) Virus

Influenza B Virus

Respiratory Syncytial Virus A

Negative Control (Six swabs/kit)

Coxsackievirus B1



SYNDROME-SPECIFIC PANELS FOR RESPIRATORY TESTING

#8190 - Enterovirus (EV) Control Panel (Inactivated Swab)

Contains six positive and six negative, inactivated control swabs (12 swabs/kit) comprised of the microorganisms listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Coxsackievirus B1

Negative Control (Six swabs/kit)

Rhinovirus 1B

#8219 - Group A *Streptococcus* (GAS) Control Panel (Inactivated Swab)

Contains six positive and six negative, inactivated control swabs (12 swabs/kit) comprised of the microorganisms listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

Positive Control (Six swabs/kit)

Streptococcus pyogenes

Negative Control (Six swabs/kit)

Streptococcus dysgalactiae

SYNDROME-SPECIFIC PANELS FOR RESPIRATORY TESTING

#8246 - Flu/RSV/SARS-CoV-2 Control Panel (Inactivated Swab)

Contains six pre-pooled positive and six negative, inactivated control swabs (12 swabs/kit) comprised of the microorganisms listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Influenza A (H1N1) Virus
Influenza A (H3H2) Virus
Influenza B Virus
Respiratory Syncytial Virus A
SARS-CoV-2 Virus
Human lung epithelial cells

Negative Control (Six swabs/kit)

Coxsackievirus B1
Human lung epithelial cells

#8247 - Respiratory Control Panel (22 Targets)

Contains six pre-pooled positive and six negative, inactivated microorganism pellets (12 pellets/kit). The negative control pellets are blank and do not contain organisms.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Adenovirus Type 6
Bordetella parapertussis
Bordetella pertussis
Chlamydia pneumoniae
Coronavirus 229E
Coronavirus HKU1 surrogate
Coronavirus NL63 surrogate
Coronavirus OC43 surrogate Strain 1 and
Coronavirus OC43 surrogate Strain 2
Human Metapneumovirus surrogate
Human Rhinovirus
Influenza A

Influenza A subtype H1
Influenza A subtype H1-2009
Influenza A subtype H3
Influenza B
Mycoplasma pneumoniae
Parainfluenza Virus 1
Parainfluenza Virus 2
Parainfluenza Virus 3
Parainfluenza Virus 4a surrogate
Respiratory Syncytial Virus
SARS-CoV-2 Virus

SYNDROME-SPECIFIC PANELS FOR RESPIRATORY TESTING

#8268 - Rapid SARS-CoV-2 Control Panel

Contains six positive, inactivated control swabs of SARS-CoV-2 Virus.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked



#8206 - Rifampicin-Resistant *Mycobacterium tuberculosis* Positive Control Panel (Inactivated Pellet)

Contains six inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (18 pellets/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control 1 (Six pellets/kit)

Mycobacterium bovis (MTB) (BCG)

Positive Control 2 (Six pellets/kit)

Mycobacterium tuberculosis (MTB/RIF) surrogate (rpoB: L511P, H526Y, S531L)

Positive Control 3 (Six pellets/kit)

Mycobacterium tuberculosis (MTB/RIF) surrogate (rpoB: D516V, S522L)

#8238 - Rifampicin-Resistant *Mycobacterium tuberculosis* Negative Control (Inactivated Pellet)

Contains six inactivated pellets of *Mycobacterium gordonae* (Six pellets/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



HELIX ELITE™ MOLECULAR STANDARDS FOR RESPIRATORY TESTING

Inactivated Helix Elite Molecular Standards

Full process controls for use in molecular testing. Each kit contains five unassayed inactivated microorganism pellets packaged in individual vials for ease-of-use.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



#HE0026N - Inactivated Adenovirus 2

Strain Adenoid 6

#HE0028N - Inactivated Respiratory Syncytial Virus A

Strain Long

#HE0029N - Inactivated Influenza A (H1N1) Virus

Strain subtype H1N1

#HE0030N - Inactivated Influenza B Virus

Strain Hong Kong/5/72

#HE0031N - Inactivated Parainfluenza Virus 1

Strain VP1

#HE0032N - Inactivated Parainfluenza Virus 2

Strain Greer

#HE0033N - Inactivated Parainfluenza Virus 3

Strain C243

#HE0034N - Inactivated *Chlamydia pneumoniae*

#HE0038N - Inactivated Varicella Zoster Virus

Strain VZ-10

#HE0043N - Inactivated Influenza A (H3N2) Virus

Strain subtype H3N2

#HE0044N - Inactivated Influenza A/B and Respiratory Syncytial Virus

Each pellet contains:

Influenza A (H1N1) Virus

Influenza B Virus, Strain Hong Kong/5/72

Respiratory Syncytial Virus (RSV) A, Strain Long

HELIX ELITE™ MOLECULAR STANDARDS FOR RESPIRATORY TESTING

#HE0065N - Inactivated SARS-CoV-2 Whole Virus (Pellet)

Contains five individually packaged lyophilized pellets made with whole inactivated SARS-CoV-2 virus (Isolate SARS-CoV-2/USA/WA1/2020) and inactivated human lung epithelial cells. Each kit also contains five vials of molecular water for rehydration.



- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

SARS-CoV-2 Whole Virus can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular applications.

#HE0066NS - Inactivated SARS-CoV-2 Whole Virus (Swab)

Contains six individually packaged lyophilized swabs made with whole inactivated SARS-CoV-2 virus (Isolate SARS-CoV-2/USA/WA1/2020) and inactivated human lung epithelial cells.



- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

SARS-CoV-2 Whole Virus can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular applications.

SYNTHETIC HELIX ELITE™ MOLECULAR STANDARDS FOR RESPIRATORY TESTING

Synthetic Helix Elite Molecular Standards

For use as a positive control in molecular applications. Each kit contains one vial of dried synthetic consensus sequence DNA or RNA (up to 100 reactions), and one vial of molecular water for rehydration.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

#HE0060S - SARS-CoV-2 Synthetic RNA (N Gene Targets)

Contains one vial of dried synthetic RNA and one vial of molecular water for rehydration. The SARS-CoV-2 synthetic RNA material is a 1044-nucleotide portion of the SARS-CoV-2 N (nucleocapsid) gene. It contains three markers N1, N2 and N3 that are commonly used in diagnostic assays.

#HE0061S - SARS-CoV-2 Synthetic RNA (N/E/RdRp/S Gene Targets)

Contains one vial of dried synthetic RNA and one vial of molecular water for rehydration. See website for complete list of targets.





WOMEN'S HEALTH AND STI

Your laboratory is committed to elevating the standard of care for women's health and sexually transmitted infections (STIs) with advanced diagnostic technologies. When it comes to QC testing your molecular methods, you should expect the same level of quality. Microbiology offers a variety of controls for women's health and STI testing featuring room temperature storage, pre-pooling of strains, and formats that mimic patient sample processing for ease of use.

ASSAY-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8188 - Assayed CT/NG Control Panel

Contains six pre-pooled positive and six negative, inactivated control swabs (12 swabs/kit) comprised of the microorganisms listed below. For use with Cepheid Xpert® CT/NG assay.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Positive Control (Six swabs/kit)

Chlamydia trachomatis (LGV-2-434)

Neisseria gonorrhoeae

Negative Control (Six swabs/kit)

Human cells



SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8249 - Bacterial vaginosis (BV) Control Panel

Contains six inactivated pre-pooled positive control pellets and six inactivated negative control pellets comprised of the organisms listed below (12 vials/pellets total).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

Positive Control (Six pellets/kit)

Atopobium vaginae
Gardnerella vaginalis

Negative Control (Six pellets/kit)

Lactobacillus crispatus



#8250 - Candida vaginitis/Trichomonas vaginalis (CV/TV) Control Panel

Contains six inactivated pre-pooled positive control 1 pellets and six inactivated pre-pooled positive control 2 pellets comprised of the organisms listed below (12 vials/pellets total).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

Positive Control 1 (Six pellets/kit)

Candida albicans
Candida glabrata

Positive Control 2 (Six pellets/kit)

Trichomonas vaginalis



SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8228 - CT/GC/TV Control Panel (Inactivated Pellet)

Contains six inactivated, pre-pooled pellets comprised of the microorganisms listed below (six pellets/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Chlamydia trachomatis

Neisseria gonorrhoeae

Trichomonas vaginalis

#8229 - *Chlamydia trachomatis*/*Neisseria gonorrhoeae* (CT/NG) Control Panel (Inactivated Swab)

Contains six pre-pooled positive and six negative, inactivated control swabs (12 swabs/kit) comprised of the microorganisms listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Chlamydia trachomatis

Neisseria gonorrhoeae

Negative Control (Six swabs/kit)

Human cells

#8173 - GBS Verification Panel (Live Culture)

Contains two KWIK-STIKs of each strain listed below (12 KWIK-STIKs total).

Streptococcus agalactiae (B) derived from ATCC® 12386™*

Streptococcus agalactiae (B, III) derived from ATCC® 12403™*

Streptococcus anginosus (G) derived from NCTC 10713

Streptococcus dysgalactiae subsp. *equisimilis* (C) derived from ATCC® 12388™*

Streptococcus pyogenes (A) derived from ATCC® 19615™*

Streptococcus agalactiae (III) derived from ATCC® BAA-22™*



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Work Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiologics, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8232 - Group B Streptococcus (GBS) Control Panel (Inactivated Swab)

Contains six positive and six negative, inactivated control swabs (12 swabs/kit) comprised of the microorganisms listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Streptococcus agalactiae

Negative Control (Six swabs/kit)

Lactobacillus acidophilus

#8164 - GBS QC Set (Live Culture)

Each set contains a low, medium and high level of the same microorganism and one negative control (Four KWIK-STIKs/kit).

Low

Streptococcus agalactiae (Group B, Ib) derived from ATCC® 12401™*

Medium

Streptococcus agalactiae (Group B, Ib) derived from ATCC® 12401™*

High

Streptococcus agalactiae (Group B, Ib) derived from ATCC® 12401™*

Negative Control

Lactobacillus acidophilus derived from ATCC® 4356™*



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Work Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiology, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8245 - Multiplex Vaginal Verification Panel

Contains two inactivated positive control 1 swabs, two inactivated positive control 2 swabs, two inactivated positive control 3 swabs, two inactivated positive control 4 swabs and two inactivated negative control swabs (10 swabs/kit).



- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Positive Control 1 (Two swabs/kit)

Atopobium vaginae
BVAB2 surrogate

Positive Control 4 (Two swabs/kit)

Trichomonas vaginalis

Positive Control 2 (Two swabs/kit)

Candida albicans

Negative Control (Two swabs/kit)

Lactobacillus acidophilus

Positive Control 3 (Two swabs/kit)

Candida glabrata

#8255 - Multiplex Vaginal Control Panel

Contains six inactivated pre-pooled positive control swabs, and six inactivated negative control swabs (12 swabs/kit).



- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Not CE Marked

Positive Control (Two swabs/kit)

Atopobium vaginae
BVAB2 surrogate
Candida albicans
Candida glabrata
Trichomonas vaginalis

Negative Control (Two swabs/kit)

Lactobacillus acidophilus

SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8235 - Multi-Strain Human Papillomavirus (HPV) Verification Panel (Inactivated Pellet)

Contains 20 inactivated, pre-pooled pellets comprised of human cells and the microorganisms listed below (20 pellets/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

HPV 16 surrogate, gene target E6/E7 and L1
HPV 18 surrogate, gene target E6/E7 and L1
HPV 31 surrogate, gene target E6/E7 and L1
HPV 45 surrogate, gene target E6/E7 and L1
HPV 68 surrogate, gene target E6/E7 and L1
Human Cells



#8234 - Multi-Strain Human Papillomavirus (HPV) Control Panel (Inactivated Pellet)

Contains six inactivated, pre-pooled pellets comprised of human cells and the microorganisms listed below (six pellets/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

HPV 16 surrogate, gene target E6/E7 and L1
HPV 18 surrogate, gene target E6/E7 and L1
HPV 31 surrogate, gene target E6/E7 and L1
HPV 45 surrogate, gene target E6/E7 and L1
HPV 68 surrogate, gene target E6/E7 and L1
Human Cells



SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8242 - Rapid Group B Streptococcus (GBS) Control Panel

Contains six inactivated pre-pooled positive control swabs, and six inactivated negative control swabs (12 swabs/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Group B Streptococcus (*Streptococcus agalactiae*)

Negative Control (Ten swabs/kit)

Lactobacillus acidophilus

Escherichia coli surrogate for sample adequacy control

#8258 - Rapid Group B Streptococcus (GBS) Verification Panel

Contains 10 inactivated pre-pooled positive control swabs, and 10 inactivated negative control swabs (20 swabs/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Ten swabs/kit)

Group B Streptococcus (*Streptococcus agalactiae*)

Negative Control (Ten swabs/kit)

Lactobacillus acidophilus

Escherichia coli surrogate for sample adequacy control

SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8189 - *Trichomonas vaginalis* (TV) Control Panel (Inactivated Swab)

Contains six positive (pre-pooled) and six negative inactivated control swabs (12 swabs/kit) comprised of the strains listed below.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Positive Control (Six swabs/kit)

Trichomonas vaginalis

Negative Control (Six swabs/kit)

Neisseria gonorrhoeae

Human cells

#8208 - Vaginal Verification Panel

Includes two boxes containing 20 individually packaged inactivated microorganism pellets of each pool listed below (120 pellets/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



Pool 1 (20 pellets/kit)

Lactobacillus crispatus

Pool 2 (20 pellets/kit)

Gardnerella vaginalis

Pool 3 (20 pellets/kit)

Atopobium vaginae
Candida albicans
Gardnerella vaginalis
BVAB2 surrogate

Pool 4 (20 pellets/kit)

Atopobium vaginae
Gardnerella vaginalis
BVAB2 surrogate
Trichomonas vaginalis

Pool 5 (20 pellets/kit)

Atopobium vaginae
Candida glabrata
Gardnerella vaginalis
Lactobacillus crispatus

Pool 6 (20 pellets/kit)

Atopobium vaginae
Candida krusei
Gardnerella vaginalis
Lactobacillus crispatus

SYNDROME-SPECIFIC PANELS FOR WOMEN'S HEALTH AND STI TESTING

#8209 - Vaginal Control Panel

Contains six inactivated, pre-pooled microorganism pellets of each pool listed below (12 pellets/kit).

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply

Pool 1 (Six pellets/kit)

Lactobacillus crispatus

Pool 2 (Six pellets/kit)

Atopobium vaginae

Candida albicans

Candida glabrata

Candida krusei

Gardnerella vaginalis

BVAB2 surrogate

Trichomonas vaginalis



HELIX ELITE™ MOLECULAR STANDARDS FOR WOMEN'S HEALTH AND STI TESTING

Inactivated Helix Elite Molecular Standards

Full process controls for use in molecular testing.
Each kit contains five unassayed lyophilized pellets
packaged in individual vials for ease-of-use.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply



#HE0035N - Inactivated *Chlamydia trachomatis*

Strain LGV-2-434

#HE0036N - Inactivated Herpes Simplex Virus 1

Strain MacIntyre

#HE0037N - Inactivated Herpes Simplex Virus 2

Strain MS

#HE0041N - Inactivated *Neisseria gonorrhoeae*

Strain GL0071

#HE0042N - Inactivated *Trichomonas vaginalis*

Strain GL0028

#HE0045N - Inactivated *Chlamydia trachomatis*/*Neisseria gonorrhoeae* (CT/NG)

Chlamydia trachomatis Strain LGV-2-434

Neisseria gonorrhoeae Strain GL0071

#HE0056N - Human Papillomavirus 16 (HPV 16) Cellularity Control (Inactivated Pellet)

#HE0057N - Human Papillomavirus 18 (HPV 18) Cellularity Control (Inactivated Pellet)



EMERGING DISEASES AND OTHER PATHOGENS

With emerging diseases comes expanded pathogen testing and quality control needs. Microbiologics provides a variety of controls with features designed to simplify verification and QC including room temperature storage and pre-pooling of strains. From parasitology to patient/donor screening and testing, Microbiologics has your control needs covered.

114

Full process controls for use in molecular testing. Each kit contains five unassayed lyophilized pellets packaged in individual vials for ease-of-use.

- ### #HE0040N - Inactivated Cytomegalovirus High Control

#HE0039N - Inactivated Cytomegalovirus Low Control

#HE0052N - Inactivated *Borrelia burgdorferi*

#HE0059N - Inactivated Zika Virus



Helix Elite™ Inactivated Molecular Standards contain multiple targets available for gastrointestinal, respiratory, sexual health and transplant assays. These controls can be applied to: Sensitivity and specificity testing, verification and validation, assay optimization, and training. Other applications include: Proficiency testing, lot-to-lot assay testing, and external assay QC.



Package Details

Products contain the following:

- Pellet format contains five qualitative lyophilized microorganism pellets packaged in individual vials and Instructions for Use
- Swab format contains six individually packaged lyophilized swabs and Instructions for Use

Product Highlights

Products contain the following:

- Fully intact, non-viable process controls
- Used for every step of the molecular testing process: from extraction through detection
- Quick-dissolve lyophilized pellets and lyophilized swabs may be reconstituted in buffer or transport medium and processed using the same protocols as the patient sample
- Independent external controls provide accurate, reliable results
- Test-ready format saves 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
- Technical Support Experts available for guidance

NEGATIVE CELLULARITY CONTROLS

#HE0058N - Negative Cellularity Control (Inactivated Pellet)

Human lung epithelial cells

#HE0067NS - Negative Cellularity Control (Inactivated Swab)

Human lung epithelial cells

Inactivated Helix Elite™

Catalog Number	Product Description	Full Product Details
HE0026N	Inactivated Adenovirus 2	See page 25
HE0052N	Inactivated <i>Borrelia burgdoferi</i>	See page 40
HE0034N	Inactivated <i>Chlamydia pneumoniae</i>	See page 25
HE0035N	Inactivated <i>Chlamydia trachomatis</i>	See page 38
HE0045N	Inactivated <i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoeae</i> (CT/NG)	See page 38
HE0040N	Inactivated Cytomegalovirus High Control	See page 40
HE0039N	Inactivated Cytomegalovirus Low Control	See page 40
HE0036N	Inactivated Herpes Simplex Virus 1	See page 38
HE0037N	Inactivated Herpes Simplex Virus 2	See page 38
HE0056N	Inactivated Human Papillomavirus 16 (HPV) Cellularity Control	See page 38
HE0057N	Inactivated Human Papillomavirus 18 (HPV) Cellularity Control	See page 38
HE0029N	Inactivated Influenza A (H1N1) Virus	See page 25
HE0043N	Inactivated Influenza A (H3N2) Virus	See page 25
HE0044N	Inactivated Influenza A/B and Respiratory Syncytial Virus	See page 25
HE0030N	Inactivated Influenza B Virus	See page 25
HE0041N	Inactivated <i>Neisseria gonorrhoeae</i>	See page 38
HE0031N	Inactivated Parainfluenza Virus 1	See page 25
HE0032N	Inactivated Parainfluenza Virus 2	See page 25
HE0033N	Inactivated Parainfluenza Virus 3	See page 25
HE0028N	Inactivated Respiratory Syncytial Virus A	See page 25
HE0027N	Inactivated Rotavirus	See page 13
HE0065N	Inactivated SARS-CoV-2 Whole Virus (Pellet)	See page 26
HE0066NS	Inactivated SARS-CoV-2 Whole Virus (Swab)	See page 26
HE0042N	Inactivated <i>Trichomonas vaginalis</i>	See page 38

Inactivated Helix Elite™ Continued

Catalog Number	Product Description	Full Product Details
HE0038N	Inactivated Varicella Zoster Virus	See page 25
HE0059N	Inactivated Zika Virus	See page 40
HE0053NS	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Inactivated Swab	See page 19
HE0054NS	Methicillin-Susceptible <i>Staphylococcus aureus</i> (MSSA) Inactivated Swab	See page 19
HE0055NS	Methicillin-Susceptible <i>Staphylococcus epidermidis</i> (MSSE) Inactivated Swab	See page 19
HE0058N	Negative Cellularity Control (Inactivated Pellet)	See page 41
HE0067NS	Negative Cellularity Control (Inactivated Swab)	See page 41

HELIX|ELITE™

MOLECULAR STANDARDS

Helix Elite™ Synthetic Molecular Standards can be applied to a number of test and applications including but not limited to: Sensitivity and specificity testing, verification and validation, assay optimization, training, proficiency testing, and lot-to-lot assay testing. Synthetic Nucleic Acid RNA and DNA Sequences for Use as Amplification and Detection Controls in Molecular Assays.



Package Details

Products contain the following:

- One vial of dried, stabilized RNA or DNA (approximately 100 reactions)
- One vial of molecular water for rehydration
- Instructions for Use

Product Highlights

Products contain the following:

- Non-hazardous positive controls for molecular diagnostic assays
- Contains consensus sequences of diagnostic regions from the target's genome, representing the known genetic diversity of the microorganism
- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test ready format saves time and money
- Room temperature storage is easy and economical
- FDA listed and CE Marked as an In Vitro Diagnostic (IVD) Medical Device, except where noted
- Technical Support Experts available for guidance

Synthetic Helix Elite™

Catalog Number	Product Description	Full Product Details
HE0013S	Norovirus GI.1 Synthetic RNA	See page 13
HE0012S	Norovirus GII.4 Synthetic RNA	See page 13

QC SETS AND PANELS

Microbiologics QC Sets and Panels offer QC of microbial identification for detection instruments and commercial diagnostic assays including biochemical, PCR, and molecular technologies. Microbiologics QC Sets and Panels can be applied to verification, validation and routine quality control testing. Bundled Sets and Panels of Microorganism Strains for QC and Verification of Assays and Test Kits.

Package Details

Products contain the following:

- Live Culture QC Sets and Panels
- Inactivated Microorganism QC Sets and Panels
- Synthetic DNA/RNA QC Sets and Panels



Product Highlights

Products contain the following:

- Each assay-specific QC set or panel contains the manufacturer recommended quality control strains for a particular assay in an easy-to-use format
- Each syndrome-specific QC set or panel contains common quality control strains for syndromic assays in an easy-to-use format
- One simple catalog number for fast, easy ordering
- Protects your reputation by providing documentation and assurance that the laboratory can consistently produce accurate results
- Ensures testing procedures and materials are working properly
- Convenient, test-ready format saves time and money
- Technical Support Experts available for guidance

Assay-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8202	BD MAX™ Enteric Parasite 20-Day QC Panel	See page 8
8204	BD MAX™ Enteric Parasite Control Panel	See page 8
8200	Assayed <i>C. difficile</i> /Epi Control Panel	See page 15
8188	Assayed CT/NG Control Panel	See page 31
8195	Assayed MRSA NxG Control Panel	See page 15
8199	Assayed Respiratory Control Panel	See page 21
8196	Assayed SA Nasal Complete Control Panel	See page 15

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8249	Bacterial vaginosis (BV) Control Panel	See page 30
8254	Blood Culture Identification Control Panel (43 Targets)	See page 4
8250	<i>Candida vaginitis</i> / <i>Trichomonas vaginalis</i> (CV/TV) Control Panel	See page 30
8187	Carbapenem-resistant <i>Enterobacteriaceae</i> (CRE) Control Panel (Inactivated Swab)	See page 17
8227	<i>C. difficile</i> Control Panel (Inactivated Swab)	See page 16
8171	<i>C. difficile</i> QC Set (Live Culture)	See page 16
8243	<i>C. difficile</i> Verification Panel (Live Culture)	See page 16
8229	<i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoeae</i> (CT/NG) Control Panel (Inactivated Swab)	See page 31
8231	Comprehensive Enteric Bacterial Control Panel (Inactivated Pellet)	See page 11
8228	CT/GC/TV Control Panel (Inactivated Pellet)	See page 31
8179	Enteric Bacterial Organism Set (Live Culture)	See page 9
8230	Enteric Parasite Control Panel (Inactivated Pellet)	See page 9
8184	Enteric Pathogens Control Panel (Inactivated Pellet)	See page 10
8211	Enteric Viral Control Panel	See page 11
8210	Enteric Viral Verification Panel	See page 10
8190	Enterovirus (EV) Control Panel (Inactivated Swab)	See page 22
8191	Extended Enteric Bacterial Verification Panel (Inactivated Pellet)	See page 11
8246	Flu/RSV/SARS-CoV-2 Control Panel (Inactivated Swab)	See page 23
8236	Gastrointestinal (22 Targets) Control Panel (Inactivated Pellet)	See page 12
8164	GBS QC Set (Live Culture)	See page 34
8173	GBS Verification Panel (Live Culture)	See page 31
8181	Gram-Negative Blood Culture Control Panel (Inactivated Pellet)	See page 6
8180	Gram-Positive Blood Culture Control Panel (Inactivated Pellet)	See page 5

Syndrome-Specific QC Sets and Panels Continued

Catalog Number	Product Description	Full Product Details
8219	Group A <i>Streptococcus</i> (GAS) Control Panel (Inactivated Swab)	See page 22
8232	Group B <i>Streptococcus</i> (GBS) Control Panel (Inactivated Swab)	See page 32
	Live Culture <i>Staphylococcus</i> Controls	See page 18
8174	MRSA Organism Set (Live Culture)	See page 17
8255	Multiplex Vaginal Control Panel	See page 33
8245	Multiplex Vaginal Verification Panel	See page 33
8234	Multi-Strain Human Papillomavirus (HPV) Control Panel (Inactivated Pellet)	See page 34
8235	Multi-Strain Human Papillomavirus (HPV) Verification Panel (Inactivated Pellet)	See page 34
8205	Norovirus Control Panel (Inactivated Swab)	See page 12
8242	Rapid Group B <i>Streptococcus</i> (GBS) Control Panel	See page 35
8258	Rapid Group B <i>Streptococcus</i> (GBS) Verification Panel	See page 35
8247	Respiratory Control Panel (22 Targets)	See page 23
8268	Rapid SARS-CoV-2 Control Panel	See page 24
8238	Rifampicin-Resistant <i>Mycobacterium tuberculosis</i> Negative Control (Inactivated Pellet)	See page 24
8206	Rifampicin-Resistant <i>Mycobacterium tuberculosis</i> Positive Control Panel (Inactivated Pellet)	See page 24
8178	SA Organism Set (Live Culture)	See page 18
8189	<i>Trichomonas vaginalis</i> (TV) Control Panel (Inactivated Swab)	See page 36
8209	Vaginal Control Panel	See page 37
8208	Vaginal Verification Panel	See page 36
8203	Vancomycin Resistant <i>Enterococcus</i> (VRE) Control Panel (Inactivated Swab)	See page 19



Hardy Diagnostics Headquarters

1430 West McCoy Lane, Santa Maria, CA 93455

Phone: 805-346-2766 or 800-266-2222

Email: sales@hardydiagnostics.com

HardyDiagnostics.com