Microbiologics

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)	9
Healthcare-Associated Infections (HAIs)	16
Respiratory Pathogens	21
Women's Health and Sexually Transmitted Infections (STI)	30
Emerging Diseases and Other Pathogens	37
All Products	
Inactivated Helix Elite™ Molecular Standards	40
Negative Cellularity Controls	40
Synthetic Helix Elite™ Molecular Standards	43
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 <u>microbiologics.com</u>. 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		
Hours	7:30 a.m 5 p.m. (CST)	
Phone	1.320.253.1640	
US Toll Free	800.599.2847	
Fax	320.253.6250	
Email	info@microbiologics.com	

Contact Technical Support		
Hours	8:00 a.m 5 p.m. (CST)	
Phone	1.320.229.7045	
US Toll Free	866.286.6691	
Fax	320.253.6250	
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 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 <u>microbiologics.com</u>.

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 +1 320.253.1640.

US 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 1.320.253.1640 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.



- Acinetobacter baumannii
- Candida albicans
- Candida glabrata
- Candida krusei
- Candida parapsilosis
- Candida tropicalis
- Enterobacter cloacae
- Enterococcus faecalis (vanB)
- Escherichia coli
- Haemophilus influenzae
- Klebsiella oxytoca

Blood Culture Identification (BCID) Control Panel (Inactivated) - Catalog #8215

Contains six inactivated, pre-pooled pellets comprised of the microorganisms listed below. Also included is six blank negative control pellets.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
 - Klebsiella pneumoniae (KPC)
 - Listeria monocytogenes serovar 7
 - Neisseria meningitidis
 - Proteus vulgaris
 - Pseudomonas aeruginosa
 - Serratia marcescens
 - Staphylococcus aureus (MRSA)
 - Staphylococcus epidermidis (MSSE)
 - Streptococcus agalactiae
 - Streptococcus pneumoniae
 - Streptococcus pyogenes

Blood Culture Identification (BCID) Verification Panel (Inactivated) - Catalog #8201

Contains one inactivated, pre-pooled microorganism pellet of each pool listed below (three vials total) and three vials of molecular hydration buffer. Once rehydrated, each vial contains enough material for five uses and can be used for up to 72 hours when refrigerated.

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

Pool 1 (One pellet/kit)

- Candida albicans
- Candida krusei
- Neisseria meningitidis
- Pseudomonas aeruginosa
- Staphylococcus aureus (MRSA)
- Streptococcus agalactiae
- Streptococcus pyogenes

Pool 2 (One pellet/kit)

- Acinetobacter baumannii
- Candida glabrata
- Candida tropicalis
- Enterobacter cloacae
- Enterococcus faecalis (vanB)
- Escherichia coli
- Klebsiella oxytoca
- Listeria monocytogenes serovar 7
- Staphylococcus epidermidis (MSSE)

Pool 3 (One pellet/kit)

- Candida parapsilosis
- Haemophilus influenzae
- Klebsiella pneumoniae (KPC)
- Proteus vulgaris
- Serratia marcescens
- Streptococcus pneumoniae

Blood Culture Identification (BCID) Verification Panel (Live Culture) – Catalog #5229P

Contains two KWIK-STIKs of each strain listed below (44 KWIK-STIKs total).



- 0443 Candida albicans derived from ATCC® 10231™*
- 0737 Candida glabrata derived from ATCC® 15126™*
- 0809 Candida krusei derived from ATCC® 14243™*
- 0726 Candida parapsilosis derived from ATCC® 22019™*
- 01036 Candida tropicalis derived from ATCC® 1369™*
- 0323 Enterobacter cloacae subsp. cloacae derived from ATCC® 13047™*
- 0959 Enterococcus faecalis derived from ATCC® 51299™* (vanB positive, resistant to vancomycin)
- 0681 Escherichia coli derived from ATCC® 11229™*
- 0441 Haemophilus influenzae derived from ATCC® 10211^{TM*} (type b and beta lactamase negative)
- 0530 Klebsiella oxytoca derived from ATCC® 13182™*
- 01005 Klebsiella pneumoniae derived from ATCC® BAA-1705™*
- 0277 Listeria monocytogenes derived from ATCC® 19111™* (serotype 1)
- 0453 Neisseria meningitidis derived from ATCC® 13077™* (serogroup A)
- 0944 Proteus mirabilis derived from ATCC® 35659™*
- 0353 Pseudomonas aeruginosa derived from ATCC® 27853™*
- 0247 Serratia marcescens derived from ATCC® 13880™*
- 0496 Staphylococcus aureus subsp. aureus derived from ATCC® 33591™* (methicillin resistant)
- 0371 Staphylococcus epidermidis derived from ATCC® 12228™*
- 0439 Streptococcus agalactiae derived from ATCC® 12386™* (group B)
- 0865 Streptococcus pneumoniae derived from ATCC® 10015™*
- 0385 Streptococcus pyogenes derived from ATCC® 19615™* (group A)



BRO19 Rev D

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Blood Culture Identification 2 (BCID2) Verification Panel (Live Culture) – Catalog #5258P

Contains two KWIK-STIKs of each strain listed below (70 KWIK-STIKs total).

- 0217 Staphylococcus lugdunensis derived from ATCC® 49576™*
- 0247 Serratia marcescens derived from ATCC® 13880™*
- 0277 Listeria monocytogenes derived from ATCC® 19111™*
- 0320 Bacteroides fragilis derived from ATCC® 25285™*
- 0323 Enterobacter cloacae subsp. cloacae derived from ATCC® 13047™*
- 0353 Pseudomonas aeruginosa derived from ATCC® 27853™*
- 0357 Acinetobacter baumannii derived from ATCC® 19606™*
- 0371 Staphylococcus epidermidis derived from ATCC® 12228™*
- 0385 Streptococcus pyogenes derived from ATCC® 19615™*
- 0399 Klebsiella aerogenes derived from ATCC® 35029™*
- 0439 Streptococcus agalactiae derived from ATCC® 12386™*
- 0441 Haemophilus influenzae derived from ATCC® 10211™*
- 0443 Candida albicans derived from ATCC® 10231™*
- 0453 Neisseria meningitidis derived from ATCC® 13077™*
- 0496 Staphylococcus aureus subsp. aureus derived from ATCC® 33591™*
- 0530 Klebsiella oxytoca derived from ATCC® 13182™*
- 0726 Candida parapsilosis derived from ATCC® 22019™*
- 0737 Candida glabrata derived from ATCC® 15126™*
- 0759 Stenotrophomonas maltophilia derived from ATCC® 17666™*
- 0809 Candida krusei derived from ATCC® 14243™*
- 0865 Streptococcus pneumoniae derived from ATCC® 10015™*
- 0901 Salmonella enterica subsp. arizonae derived from ATCC® 13314™*
- 0944 Proteus mirabilis derived from ATCC® 35659TM*
- 0959 Enterococcus faecalis derived from ATCC® 51299™*
- 0985 Cryptococcus neoformans derived from ATCC® 66031™*
- 01005 Klebsiella pneumoniae derived from ATCC® BAA-1705™*
- 01036 Candida tropicalis derived from ATCC® 1369™*
- 01051 Cryptococcus gattii derived from ATCC® MYA-4560™*
- 01112 Klebsiella pneumoniae derived from NCTC 13440
- 01136 Escherichia coli derived from NCTC 13476
- 01143 Enterococcus faecium derived from NCTC 12204
- 01145 Klebsiella pneumoniae derived from NCTC 13443
- 01241 Klebsiella pneumoniae derived from CDC AR-0039
- 01256 Candida auris derived from CDC B11903
- 01259 Escherichia coli derived from CDC AR-0346



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

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 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

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

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





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

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

Pool 5 (Five pellets/kit)

- Klebsiella pneumoniae
- Citrobacter freundii
- Escherichia coli
- Klebsiella pneumoniae
- Klebsiella pneumoniae

Pool 6 (Five pellets/kit)

- Klebsiella oxytoca
- Klebsiella pneumoniae
- Proteus vulgaris

Gram-Negative Blood Culture Control Panel (Live Culture) – Catalog #5226P

Contains two KWIK-STIKs of each strain listed below (24 KWIK-STIKs total).



- 0574 Citrobacter freundii derived from NCTC 9750
- 01105 Enterobacter cloacae derived from NCTC 13464
- 01136 Escherichia coli derived from NCTC 13476
- 01117 Klebsiella pneumoniae derived from NCTC 13438
- 01148 Klebsiella pneumoniae derived from NCTC 13442
- 01145 Klebsiella pneumoniae derived from NCTC 13443
- 01112 Klebsiella pneumoniae derived from NCTC 13440
- 01147 Klebsiella oxytoca derived from NCTC 11686
- 0393 Proteus vulgaris derived from NCTC 4636
- 0830 Pseudomonas aeruginosa derived from NCTC 10662
- 01146 Serratia marcescens derived from NCTC 9743





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



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

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 MAXTM Enteric Parasite Panel

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Cryptosporidium parvum
- Giardia lamblia
- Entamoeba histolytica surrogate

BD MAX™ Enteric Parasite Control Panel – Catalog #8204

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
- Cryptosporidium parvum
- Giardia lamblia
- Entamoeba histolytica surrogate



GASTROINTESTINAL PANELS

Enteric Bacterial Organism Set (Live Culture) – Catalog #8179

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)



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Enteric Parasite Verification Panel (Synthetic) – Catalog #8182

Contains five vials of dried synthetic DNA and one vial of molecular standard water for rehydration. Each vial is comprised of pooled *Cryptosporidium* spp., *Entamoeba histolytica* and *Giardia lamblia* synthetic DNA. No additional mixing or dilution required.

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

Enteric Parasite Control Panel (Inactivated Pellet) – Catalog #8230

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
- Entamoeba histolytica surrogate
- Giardia lamblia



GASTROINTESTINAL PANELS



Enteric Pathogens Control Panel (Inactivated Pellet) – Catalog #8184

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)



Enteric Viral Verification Panel - Catalog #8210

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

- Rotavirus
- Astrovirus surrogate
- Sapovirus surrogate
- Norovirus GII surrogate



Enteric Viral Control Panel – Catalog #8211

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
- Norovirus GII surrogate
- Rotavirus
- Sapovirus surrogate

GASTROINTESTINAL PANELS

Extended Enteric Bacterial Verification Panel (Inactivated Pellet) – Catalog #8191

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 derived from NCTC 12984
- Escherichia coli derived from CDC 2010C-3114 (STEC, serotype O111:H8, eae positive, stx 1 and/or stx 2 positive)
- Campylobacter jejuni derived from NCTC 11322
- Plesiomonas shigelloides derived from NCTC 10363
- Yersinia enterocolitica derived from NCTC 11174 (biotype 2, serotype 9)
- Escherichia coli derived from NCTC 11602 (ETEC, serovar o159:h34)
- Vibrio parahaemolyticus derived from NCTC 13209 (VP81, serotype O3:K6)

Comprehensive Enteric Bacterial Control Panel (Inactivated Pellet) – Catalog #8231

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.
- Salmonella enterica serovar Typhimurium derived from NCTC 74
- Shigella sonnei derived from NCTC 12984
- Escherichia coli derived from CDC 2010C-3114 (STEC, serotype O111:H8, eae positive, stx 1 and/or stx 2 positive)
- Campylobacter jejuni derived from NCTC 11322
- Plesiomonas shigelloides derived from NCTC 10363
- Yersinia enterocolitica derived from NCTC 11174 (biotype 2, serotype 9)
- Escherichia coli derived from NCTC 11602 (ETEC, serovar o159:h34)
- Vibrio parahaemolyticus derived from NCTC 13209 (VP81, serotype O3:K6)





Norovirus Control Panel (Inactivated Swab) – Catalog #8205

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



Gastrointestinal (22 Targets) Control Panel (Inactivated Pellet) – Catalog #8236

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 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

Inactivated Rotavirus - Catalog #HE0027N

- Medium-high titer
- Strain Simian Rotavirus SA11



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 standard water for rehydration.

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

Norovirus Gl.1 Synthetic RNA – Catalog #HE0013S

• ORF1-ORF2 Junction of Norovirus GI.1

Norovirus GII.4 Synthetic RNA – Catalog #HE0012S

ORF1-ORF2 Junction of Norovirus GII.4



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

Cepheid Xpert® C. difficile/Epi Control Panel (Inactivated Swab) – Catalog #8200

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



Cepheid Xpert® MRSA NxG Control Panel - Catalog #8195

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):

- Methicillin-resistant Staphylococcus aureus

Negative Control (Six swabs):

- Staphylococcus epidermidis

Cepheid Xpert® SA Nasal Complete Control Panel – Catalog #8196

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



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

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

- 0527 Clostridioides difficile ATCC® 700057™*
- 0329 Clostridioides difficile ATCC® 9689™*

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

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





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

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 total.

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SYNDROME-SPECIFIC PANELS FOR HAI TESTING

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

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

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

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



MRSA Organism Set (Live Culture) - Catalog #8174

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™*



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SA Organism Set (Live Culture) – Catalog #8178

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

- 11 strains/KWIK-STIKs: Methicillin-Resistant Staphylococcus aureus (MRSA)
- Two strains/KWIK-STIKs: Methicillin-Sensitive Staphylococcus aureus (MSSA)
- One strain/KWIK-STIKs: Methicillin-Sensitive Staphylococcus epidermidis (MSSE)

SYNDROME-SPECIFIC PANELS FOR HAI TESTING

Live Culture Staphylococcus Controls

Each kit contains two KWIK-STIKs at F4 concentration.

- Staphylococcus aureus subsp. aureus derived from ATCC® 25923™*
 (MSSA Live Culture Positive Control) Catalog #0360MSSA
- Staphylococcus aureus subsp. aureus derived from ATCC® 700699™* (MRSA Live Culture Positive Control) - Catalog #0158MRSA
- Staphylococcus epidermidis derived from ATCC® 12228™* (MSSE Live Culture Positive Control) - Catalog #0371MSSE





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

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



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

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

Room temperature storage | International restrictions may apply

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

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

Room temperature storage | International restrictions may apply

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

Contains six individually packaged inactivated control swabs containing Methicillin-Susceptible Staphylococcus epidermidis (MSSE)

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

Cepheid Xpert® Respiratory Control Panel (Inactivated Swab) - Catalog #8199

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

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

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



Group A Streptococcus (GAS) Control Panel (Inactivated Swab) – Catalog #8219

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



Respiratory Control Panel (22 Targets) – Catalog #8247

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
- Not CE Marked

- 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

Respiratory (21 Targets) Control Panel – Catalog #8217

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

SYNDROME-SPECIFIC PANELS FOR RESPIRATORY TESTING

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

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 (H3N2) 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



SYNDROME-SPECIFIC PANELS FOR RESPIRATORY TESTING

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

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)





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

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

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



Inactivated Adenovirus 2 – Catalog #HE0026N

- Strain Adenoid 6

Inactivated Respiratory Syncytial Virus A – Catalog #HE0028N

- Strain Long

Inactivated Influenza A (H1N1) Virus - Catalog #HE0029N

- Strain subtype H1N1

Inactivated Influenza B Virus – Catalog #HE0030N

- Strain Hong Kong/5/72

Inactivated Parainfluenza Virus 1 – Catalog #HE0031N

- Strain VP1

Inactivated Parainfluenza Virus 2 – Catalog #HE0032N

- Strain Greer

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

Inactivated Parainfluenza Virus 3 – Catalog #HE0033N

- Strain C243

Inactivated Chlamydia pneumoniae – Catalog #HE0034N

Inactivated Varicella Zoster Virus – Catalog #HE0038N

- Strain VZ-10

Inactivated Influenza A (H3N2) Virus – Catalog #HE0043N

- Strain subtype H3N2

Inactivated Influenza A/B and Respiratory Syncytial Virus – Catalog #HE0044N

Each pellet contains:

- Influenza A (H1N1) Virus
- Influenza B Virus, Strain Hong Kong/5/72
- Respiratory Syncytial Virus (RSV) A, Strain Long

Inactivated Enterovirus D68 – Catalog #HE0050N



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

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 standard 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.

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

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.





SARS-CoV-2 Process Control (Pellet) - Catalog #HE0062S

Contains five individually packaged inactivated lyophilized pellets made with RNA transcripts containing diagnostically relevant targets (CDC and WHO consensus sequences: Orf1ab/RdRP/S/E/ORF8/M/N) encapsulated in a phage protein and human lung epithelial cells. See website for positions of each gene targets. Each kit also contains five vials of molecular standard water for rehydration.

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

SARS-CoV-2 Process Control can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular applications

SARS-CoV-2 Process Control (Swab) - Catalog #HE0063S

Contains five individually packaged inactivated lyophilized swabs made with RNA transcripts containing diagnostically relevant targets (CDC and WHO consensus sequences: Orf1ab/RdRP/S/E/ORF8/M/N) encapsulated in a phage protein and human lung epithelial cells. See website for positions of each gene target.

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

SARS-CoV-2 Process Control can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular applications





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 standard water for rehydration.

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

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

Contains one vial of dried synthetic RNA and one vial of molecular standard 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.

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

Contains one vial of dried synthetic RNA and one vial of molecular standard 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 rapid diagnostic assays, you should expect the same level of quality. Microbiologics offers a variety of controls for women's health and STI testing featuring room temperature storage, prepooling of strains, and formats that mimic patient sample processing for ease of use.



BD MAX™ CT/GC/TV 20-Day QC Panel – Catalog #8193

Contains 20 inactivated, pre-pooled microorganism pellets each comprised of the organisms recommended by the manufacturer for QC listed below. For use with BD MAX™ CT/GC/TV assay.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas vaginalis

Cepheid Xpert® CT/NG Control Panel - Catalog #8188

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



Product image applies to both CAT #8188 and CAT #8194

Cepheid Xpert® GBS LB Control Panel – Catalog #8194

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

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

Positive Control (Six swabs): Streptococcus agalactiae Negative Control (Six swabs): Lactobacillus acidophilus

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

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



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Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) Control Panel (Inactivated Swab) – Catalog #8229

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

GBS Verification Panel (Live Culture) - Catalog #8173

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™*

ATCC Licensed Derivative

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

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



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



GBS QC Set (Live Culture) - Catalog #8164

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, lb) derived from ATCC® 12401™*
- Medium: Streptococcus agalactiae (Group B, lb) derived from ATCC® 12401™*
- High: Streptococcus agalactiae (Group B, lb) derived from ATCC® 12401™*
- Negative Control: Lactobacillus acidophilus derived from ATCC® 4356™*



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Human Papillomavirus (HPV) Verification Panel – Catalog #8216

Contains 20 inactivated, pre-pooled microorganism pellets each comprised of the organisms listed below. Control includes DNA sequences for E6/E7 amplification of HPV 16, 18 and 45 types.

- Room temperature storage
- For in vitro diagnostic use
- Does not contain human beta globin
- International restrictions may apply
- HPV 16 gene target E6/E7
- HPV 18 gene target E6/E7
- HPV 45 gene target E6/E7



Human Papillomavirus (HPV) Control Panel – Catalog #8214

Contains six inactivated, pre-pooled microorganism pellets comprised of the organisms listed below. Control includes DNA sequences for E6/E7 amplification of HPV 16, 18 and 45 types.

- Room temperature storage
- For in vitro diagnostic use
- Does not contain human beta globin
- International restrictions may apply
- HPV 16 gene target E6/E7
- HPV 18 gene target E6/E7
- HPV 45 gene target E6/E7

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

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 gene target E6/E7 and L1
- HPV 18 gene target E6/E7 and L1
- HPV 31 gene target E6/E7 and L1
- HPV 45 gene target E6/E7 and L1
- HPV 68 gene target E6/E7 and L1
- Human Cells



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

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 gene target E6/E7 and L1
- HPV 18 gene target E6/E7 and L1
- HPV 31 gene target E6/E7 and L1
- HPV 45 gene target E6/E7 and L1
- HPV 68 gene target E6/E7 and L1
- Human Cells



Mycoplasma genitalium Control Panel (Inactivated Pellet) – Catalog #8240

Contains six inactivated, pre-pooled pellets comprised of the microorganisms listed below each control listed below (12 pellets/kit).

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

Positive Control (Six pellets/kit):

- Mycoplasma genitalium

Negative Control (Six pellets/kit):

- Blank pellet



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

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
- Human cells

Negative Control (Six swabs/kit):

- Neisseria gonorrhoeae
- Human cells





Vaginal Verification Panel - Catalog #8208

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

Vaginal Control Panel - Catalog #8209

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



Inactivated Chlamydia trachomatis – Catalog #HE0035N

- Strain LGV-2-434

Inactivated Herpes Simplex Virus 1 – Catalog #HE0036N

- Strain MacIntyre

Inactivated Neisseria gonorrhoeae – Catalog #HE0041N

- Strain GL0071

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

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

Inactivated Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) – Catalog #HE0045N

- Chlamydia trachomatis Strain LGV-2-434
- Neisseria gonorrhoeae Strain GL0071

Inactivated Herpes Simplex Virus 2 – Catalog #HE0037N

- Strain MS

Inactivated Trichomonas vaginalis – Catalog #HE0042N

- Strain GL0028

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



Synthetic Helix Elite Molecular Standards

For use as a positive control in molecular applications. Kits contain: one vial of dried synthetic DNA or RNA (approximately 100 reactions), and one vial of molecular standard water for rehydration.

- Room temperature storage
- For in vitro diagnostic use
- International restrictions may apply
- Dried DNA Preserved with Biomatrica DNAstable®

Human papillomavirus 16 Synthetic DNA – Catalog #HE0046S

- Fragments of E6,E7 and L1 genes

Human papillomavirus 18 Synthetic DNA – Catalog #HE0048S

- Fragments of E6, E7 and L1 genes

Treponema pallidum Synthetic DNA – Catalog #HE0047S

- Fragments of 47 kDa protein and DNA Polymerase I genes



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.



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

Inactivated Cytomegalovirus High Control - Catalog #HE0040N

- AD-169

Inactivated Cytomegalovirus Low Control - Catalog #HE0039N

- AD-169

Inactivated Cryptosporidium and Giardia - Catalog #HE0049N

- Giardia lamblia (Strain H3)
- Cryptosporidium parvum (Strain Iowa)

Inactivated Borrelia burgdorferi - Catalog #HE0052N



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 (approximately 100 reactions), and one vial of molecular standard water for rehydration.

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

Cryptosporidium hominis Synthetic DNA – Catalog #HE0001S

- 18S rRNA gene of Cryptosporidium hominis | Dried DNA Preserved with Biomatrica DNAstable®

Cryptosporidium parvum Synthetic DNA - Catalog #HE0002S

- 18S rRNA gene of Cryptosporidium parvum | Dried DNA Preserved with Biomatrica DNAstable®

Cyclospora cayetanensis Synthetic DNA – Catalog #HE0025S

- 18S rRNA gene of Cyclospora cayentanensis | Dried DNA Preserved with Biomatrica DNAstable®

Dientamoeba fragilis Synthetic DNA - Catalog #HE0015S

- 18S rRNA gene of Dientamoeba fragilis | Dried DNA Preserved with Biomatrica DNAstable®

Eastern Equine Encephalitis Virus Synthetic RNA - Catalog #HE0016S



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 standard water for rehydration.

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

Encephalitozoon intestinalis Synthetic DNA - Catalog #HE0004S

- 18S rRNA gene of Encephalitozoon intestinalis | Dried DNA Preserved with Biomatrica DNAstable®

Entamoeba dispar Synthetic DNA - Catalog #HE0007S

-18S rRNA gene of Entamoeba dispar | Dried DNA Preserved with Biomatrica DNAstable®

Entamoeba histolytica Synthetic DNA - Catalog #HE0006S

- 18S rRNA gene of Entamoeba histolytica | Dried DNA Preserved with Biomatrica DNAstable®

Enterocytozoon bieneusi Synthetic DNA – Catalog #HE0003S

- 18S rRNA gene of Enterocytozoon bieneusi | Dried DNA Preserved with Biomatrica DNAstable®

Giardia lamblia Synthetic DNA - Catalog #HE0005S

- 18S rRNA gene of Giardia lamblia | Dried DNA Preserved with Biomatrica DNAstable®

Plasmodium falciparum Synthetic DNA - Catalog #HE0008S

- 18S rRNA gene of asexual Plasmodium falciparum | Dried DNA Preserved with Biomatrica DNAstable®

Plasmodium ovale Synthetic DNA – Catalog #HE0010S

- 18S rRNA gene of asexual Plasmodium ovale | Dried DNA Preserved with Biomatrica DNAstable®

Plasmodium malariae Synthetic DNA - Catalog #HE0011S

- 18S rRNA A-type gene of Plasmodium malariae | Dried DNA Preserved with Biomatrica DNAstable®

Plasmodium vivax Synthetic DNA – Catalog #HE0009S

- 18S rRNA gene of asexual Plasmodium vivax | Dried DNA Preserved with Biomatrica DNAstable®

West Nile Virus Synthetic RNA - Catalog #HE0014S

- Fragments from the 5'UTR region, anchored capsid protein C gene, capsid protein C gene, membrane glycoprotein precursor prM gene, envelope protein E gene, nonstructural protein NS1, NS2A, NS3, and NS5 genes, and the 3' UTR region of the West Nile Virus genome | Dried RNA Preserved with Biomatrica RNAstable®



Helix EliteTM 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. Inactivated, Full Process Controls for Molecular Assays



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:

- 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
- Technical Support Experts available for guidance

NEGATIVE CELLULARITY CONTROLS

Negative Cellularity Control (Inactivated Pellet) - Catalog #HE0058N

- Human lung epithelial cells

Negative Cellularity Control (Inactivated Swab) - Catalog #HE0067NS

- Human lung epithelial cells

INACTIVATED HELIX ELITE™

Catalog Number	Product Description	Full Product Details
HE0026N	Inactivated Adenovirus 2	See page 26
HE0052N	Inactivated Borrelia burgdoferi	See page 38
HE0034N	Inactivated Chlamydia pneumoniae	See page 26
HE0035N	Inactivated Chlamydia trachomatis	See page 36
HE0045N	Inactivated Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG)	See page 36
HE0049N	Inactivated Cryptosporidium and Giarda	See page 38
HE0040N	Inactivated Cytomegalovirus High Control	See page 38
HE0039N	Inactivated Cytomegalovirus Low Control	See page 38
HE0050N	Inactivated Enterovirus D68	See page 26
HE0036N	Inactivated Herpes Simplex Virus 1	See page 36
HE0037N	Inactivated Herpes Simplex Virus 2	See page 36
HE0056N	Inactivated Human Papillomavirus 16 (HPV) Cellularity Control	See page 36
HE0057N	Inactivated Human Papillomavirus 18 (HPV) Cellularity Control	See page 36
HE0044N	Inactivated Influenza A/B and Respiratory Syncytial Virus	See page 26
HE0029N	Inactivated Influenza A (H1N1) Virus	See page 26
HE0043N	Inactivated Influenza A (H3N2) Virus	See page 26
HE0030N	Inactivated Influenza B Virus	See page 26
HE0041N	Inactivated Neisseria gonorrhoeae	See page 36
HE0031N	Inactivated Parainfluenza Virus 1	See page 26
HE0032N	Inactivated Parainfluenza Virus 2	See page 26
HE0033N	Inactivated Parainfluenza Virus 3	See page 26
HE0028N	Inactivated Respiratory Syncytial Virus A	See page 26
HE0027N	Inactivated Rotavirus	See page 15
HE0065N	Inactivated SARS-CoV-2 Whole Virus (Pellet)	See page 27
HE0066NS	Inactivated SARS-CoV-2 Whole Virus (Swab)	See Page 27

INACTIVATED HELIX ELITE™ CONTINUED

Catalog Number	Product Description	Full Product Details
HE0042N	Inactivated Trichomonas vaginalis	See page 36
HE0038N	Inactivated Varicella Zoster Virus	See page 26
HE0053NS	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Inactivated Swab	See page 20
HE0054NS	Methicillin-Susceptible <i>Staphylococcus aureus</i> (MSSA) Inactivated Swab	See page 20
HE0055NS	Methicillin-Susceptible <i>Staphylococcus epidermidis</i> (MSSE) Inactivated Swab	See page 20
HE0058N	Negative Cellularity Control (Inactivated Pellet)	See page 40
HE0067NS	Negative Cellularity Control (Inactivated Swab)	See page 40



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 (up to 100 reactions)
- One vial of molecular standard water for rehydration
- Instructions for Use

Product Highlights:

- · 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
- · Technical Support Experts available for guidance

SYNTHETIC HELIX ELITE™

Catalog Number	Product Description	Full Product Details
HE0001S	Cryptosporidium hominis Synthetic DNA	See page 38
HE0002S	Cryptosporidium parvum Synthetic DNA	See page 38
HE0025S	Cyclospora cayetanensis Synthetic DNA	See page 38
HE0015S	Dientamoeba fragilis Synthetic DNA	See page 38
HE0016S	Eastern Equine Encephalitis Virus Synthetic RNA	See page 38
HE0004S	Encephalitozoon intestinalis Synthetic DNA	See page 39
HE0007S	Entamoeba dispar Synthetic DNA	See page 39
HE0006S	Entamoeba histolytica Synthetic DNA	See page 39
HE0003S	Enterocytozoon bieneusi Synthetic DNA	See page 39
HE0005S	Giardia lamblia Synthetic DNA	See page 39
HE0046S	Human papillomavirus 16 Synthetic DNA	See page 36
HE0048S	Human papillomavirus 18 Synthetic DNA	See page 36
HE0013S	Norovirus GI.1 Synthetic RNA	See page 15
HE0012S	Norovirus GII.4 Synthetic RNA	See page 15
HE0008S	Plasmodium falciparum Synthetic DNA	See page 39
HE0011S	Plasmodium malariae Synthetic DNA	See page 39
HE0010S	Plasmodium ovale Synthetic DNA	See page 39
HE0009S	Plasmodium vivax Synthetic DNA	See page 39
HE0060S	SARS-CoV-2 Synthetic RNA (N Gene Targets)	See page 29
HE0061S	SARS-CoV-2 Synthetic RNA (N/E/RdRp/S Gene Targets)	See page 29
HE0062S	SARS-CoV-2 Process Control (Pellet)	See page 28
HE0063S	SARS-CoV-2 Process Control (Swab)	See page 28
HE0047S	Treponema pallidum Synthetic DNA	See page 36
HE0014S	West Nile Virus Synthetic RNA	See page 39

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:

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

Product Highlights:

- 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
8193	BD MAX™ CT/GC/TV 20-Day QC Panel	See page 31
8202	BD MAX™ Enteric Parasite 20-Day QC Panel	See page 10
8204	BD MAX™ Enteric Parasite Control Panel	See page 10
8200	Cepheid Xpert® C. difficile/Epi Control Panel (Inactivated Swab)	See page 17
8188	Cepheid Xpert® CT/NG Control Panel (Inactivated Swab)	See page 31
8194	Cepheid Xpert® GBS LB Control Panel (Inactivated Swab)	See page 31
8195	Cepheid Xpert® MRSA NxG Control Panel (Inactivated Swab)	See page 17
8196	Cepheid Xpert® Nasal Control Panel (Inactivated Swab)	See page 17
8199	Cepheid Xpert® Respiratory Control Panel (Inactivated Swab)	See page 22

SYNDROME-SPECIFIC QC SETS AND PANELS

Catalog Number	Product Description	Full Product Details
8215	Blood Culture Identification (BCID) Control Panel (Inactivated)	See page 4
8201	Blood Culture Identification (BCID) Verification Panel (Inactivated)	See page 4
5229P	Blood Culture Identification (BCID) Verification Panel (Live Culture)	See page 5
5258P	Blood Culture Identification 2 (BCID2) Verification Panel (Live Culture)	See page 6
8227	C. difficile Control Panel (Inactivated Swab)	See page 18
8171	C. difficile QC Set (Live Culture)	See page 18
8243	C. difficile Verification Panel (Live Culture)	See page 18
8187	Carbapenem-resistant Enterobacteriaceae (CRE) Control Panel (Inactivated Swab)	See page 19
8229	Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) Control Panel (Inactivated Swab)	See page 32
8228	CT/GC/TV Control Panel (Inactivated Pellet)	See page 32
8231	Comprehensive Enteric Bacterial Control Panel (Inactivated Pellet)	See page 13
8179	Enteric Bacterial Organism Set (Live Culture)	See page 11
8230	Enteric Parasite Control Panel (Inactivated Pellet)	See page 11
8182	Enteric Parasite Verification Panel (Synthetic)	See page 11
8184	Enteric Pathogens Control Panel (Inactivated Pellet)	See page 12
8211	Enteric Viral Control Panel	See page 12
8210	Enteric Viral Verification Panel	See page 12
8190	Enterovirus (EV) Control Panel (Inactivated Swab)	See page 22
8191	Extended Enteric Bacterial Verification Panel (Inactivated Pellet)	See page 13
8246	Flu/RSV/SARS-CoV-2 Control Panel (Inactivated Swab)	See page 24
8236	Gastrointestinal (22 Targets) Control Panel (Inactivated Pellet)	See page 14
8219	Group A Streptococcus (GAS) Control Panel (Inactivated Swab)	See page 22
8232	Group B Streptococcus (GBS) Control Panel (Inactivated Swab)	See page 32
8164	GBS QC Set (Live Culture)	See page 33

SYNDROME-SPECIFIC QC SETS AND PANELS CONTINUED

Catalog Number	Product Description	Full Product Details
8181	Gram-Negative Blood Culture Control Panel (Inactivated Pellet)	See page 8
5226P	Gram-Negative Blood Culture Control Panel (Live Culture)	See page 8
8180	Gram-Positive Blood Culture Control Panel (Inactivated Pellet)	See page 7
5225P	Gram-Positive Blood Culture Control Panel (Live Culture)	See page 7
8214	Human Papillomavirus (HPV) Control Panel	See page 33
8216	Human Papillomavirus (HPV) Verification Panel	See page 33
8174	MRSA Organism Set (Live Culture)	See page 19
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
8240	Mycoplasma genitalium Control Panel (Inactivated Pellet)	See page 34
8205	Norovirus Control Panel (Inactivated Swab)	See page 14
8178	SA Organism Set (Live Culture)	See page 19
	Live Culture Staphylococcus Controls	See page 20
8247	Respiratory Control Panel (22 Targets)	See page 23
8217	Respiratory (21 Targets) Control Panel	See page 23
8238	Rifampicin-Resistant <i>Mycobacterium tuberculosis</i> Negative Control (Inactivated Pellet)	See page 25
8206	Rifampicin-Resistant <i>Mycobacterium tuberculosis</i> Positive Control Panel (Inactivated Pellet)	See page 25
8173	GBS Verification Panel (Live Culture)	See page 32
8189	Trichomonas vaginalis (TV) Control Panel (Inactivated Swab)	See page 35
8209	Vaginal Control Panel	See page 35
8208	Vaginal Verification Panel	See page 35
8203	Vancomycin Resistant Enterococcus (VRE) Control Panel (Inactivated Swab)	See page 20

PAYMENT AND SHIPPING

PAYMENT OPTIONS

Microbiologics accepts payment by the following methods:

- ACH
- Check (payable to Microbiologics, Inc.)
- Credit card
- · Money order
- Wire transfer

Important: To ensure your payment is processed accurately, please note your account number and the invoice number on all correspondence and payments.

Credit Card Purchases

Microbiologics welcomes the use of VISA®, MasterCard® and American Express®.

Terms

- All invoices are payable "Net 30 Days" (with the exception of credit card payments)
- Past due accounts are subject to finance charges of 1.5% per month
- All payments are paid in United States Dollars (USD)
- A royalty fee will be charged on behalf of the culture collection.
- If not reflected on an invoice, the purchaser is responsible for all applicable State Sales and Use Taxes
- When paying by wire transfer the customer is responsible to pay all applicable transfer fees. Please email
 Microbiologics Customer Service at info@microbiologics.com to review options for wire transfer fee payments.

SHIPPING AND DELIVERY

Orders are shipped within 48 hours except when a specific shipping date is requested. All shipments are EXW (Ex Works) Saint Cloud, Minnesota, unless prior arrangements are made. Lyophilized microorganisms are identified as Biological Substance Category B or Infectious Substance and are subject to regulated packaging materials, special labeling and special shipping requirements. All shipping and handling charges will be listed as separate line items on the invoice.

Products are shipped at ambient temperature unless otherwise requested. The outside of the shipping container is identified with the notation "refrigerate upon receipt" to assure proper handling and storage upon arrival. Due to the nature of our products, we are unable to accept returns. If any product arrives in a damaged condition, the carrier must note the condition on the delivery receipt. All claims for products damaged during shipment must be made within 30 days of receipt. Microbiologics guarantees the performance of our products at all times. If at any time you are dissatisfied with our products or service, please contact our Customer Service team at 1.320.253.1640 or info@microbiologics.com for resolution.

TRADEMARKS

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