MICROBIOLOGY CONTROL PRODUCTS

Microbiologics®

Microorganisms And Nucleic Acids For PCR

HARDY DIAGNOSTICS
A Culture of Service™

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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	
Hours	7:30 a.m. - 5 p.m. (CST)
Phone	1.320.253.1640
US Toll Free	800.599.BUGS (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

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 +1 320.253.1640.

USA 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 kep 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. A royalty fee will be charged on behalf of the culture collection.

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.

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)
- 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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Microbiologics

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.

Safe, simple, stable controls

- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test-ready formats save you time and money
- Easy and economical storage, no freezing required
- Certificate of Analysis provides detailed strain information
- Technical Support experts available for guidance

Syndrome-Specific Panels for BCID Testing

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

Contains 6 inactivated, pre-pooled pellets comprised of the microorganisms listed below.

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

- *Acinetobacter baumannii*
- *Candida albicans*
- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*
- *Enterobacter cloacae*
- *Enterococcus faecalis (vanB)*
- *Escherichia coli*
- *Haemophilus influenzae*
- *Klebsiella oxytoca*
- *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 1 individually packaged vial containing inactivated microorganism material of each pool listed below (3 vials total) and 3 vials of molecular hydration buffer. Once rehydrated, each vial contains enough material for 5 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 (1 vial/pellet)
Candida albicans
Candida krusei
Neisseria meningitidis
Pseudomonas aeruginosa
Staphylococcus aureus (MRSA)
Streptococcus agalactiae
Streptococcus pyogenes

Pool 2 (1 vial/pellet)
Acinetobacter baumannii
Candida glabrata
Candida tropicalis
Enterobacter cloacae
Enterococcus faecalis (vanB)
Escherichia coli
Klebsiella oxytoca
Listeria monocytogenes serovar 7
Staphylococcus epidermidis (MSSE)

Pool 3 (1 vial/pellet)
Candida parapsilosis
Haemophilus influenzae
Klebsiella pneumoniae (KPC)
Proteus vulgaris
Serratia marcescens
Streptococcus pneumoniae

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

Contains 2 KWIK-STIKs of each strain listed below (44 KWIK-STIKs total).

- 0357 *Acinetobacter baumannii* derived from ATCC® 19606™*
- 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 En*terobacter cloacae* subsp. *cloacae* derived from ATCC® 13047™*
- 0959 *Enterococcus faecalis* derived from ATCC® 51299™* (vanB positive, resistant to vancomycin and high level aminoglycosides)
- 0681 *Escherichia coli* derived from ATCC® 11229™*
- 0441 *Haemophilus influenzae* derived from ATCC® 10211™* (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)

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Syndrome-Specific Panels for BCID Testing

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

Contains 5 inactivated microorganism pellets of each pool listed below (15 vials/pellets total).

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

Pool 4 (5 vials/pellets)
Acinetobacter baumannii
Pseudomonas aeruginosa
Enterobacter cloacae (CTX-M)

Pool 5 (5 vials/pellets)
Klebsiella pneumoniae (KPC)
Citrobacter freundii
Escherichia coli
Klebsiella pneumoniae (CTX-M, NDM)
Klebsiella pneumoniae (VIM)

Pool 6 (5 vials/pellets)
Klebsiella oxytoca
Klebsiella pneumoniae (OXA)
Proteus vulgaris

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

Contains 2 KWIK-STIKs of each strain listed below (24 KWIK-STIKs total).

- 0599 *Acinetobacter baumannii* derived from NCIMB 12457
- 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

Syndrome-Specific Panels for BCID Testing

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

Contains 5 inactivated microorganism pellets of each pool listed below (15 vials/pellets total).

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

Pool 1 (5 vials/pellets)
Enterococcus faecium (vanA)
Listeria monocytogenes
Staphylococcus epidermidis
Staphylococcus lugdunensis

Pool 2 (5 vials/pellets)
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus pyogenes

Pool 3 (5 vials/pellets)
Staphylococcus aureus (mecA)
Enterococcus faecalis (vanB)
Streptococcus pneumoniae

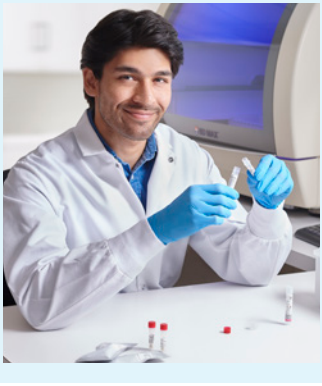
Gram-Positive Blood Culture Control Panel (Live Culture) - Catalog #5225P

Contains 2 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

GASTROINTESTINAL (GI) PATHOGENS

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.



Safe, simple, stable controls

- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test-ready formats save you time and money
- Easy and economical storage, no freezing required
- Certificate of Analysis provides detailed strain information
- Technical Support experts available for guidance

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 vials/pellets total).

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 6 inactivated, pre-pooled microorganism pellets comprised of the organisms recommended by the manufacturer for QC listed below (6 vials/pellets total).

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

- *Cryptosporidium parvum*
- *Giardia lamblia*
- *Entamoeba histolytica surrogate*

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

Contains 2 KWIK-STIKs of each strain listed below (42 KWIK-STIKs total).

Export license required for shipping outside the U.S.

- 0357 *Acinetobacter baumannii* derived from ATCC® 19606™*
- 01023 *Campylobacter coli* derived from ATCC® 33559™*
- 0121 *Campylobacter coli* derived from ATCC® 43478™*
- 0325 *Campylobacter jejuni* subsp. *jejuni* derived from ATCC® 29428™*
- 0111 *Campylobacter jejuni* subsp. *jejuni* derived from ATCC® 33560™*
- 0525 *Campylobacter jejuni* subsp. *jejuni* derived from ATCC® 43430™*
- 01101 *Escherichia coli* serotype O103:H11 derived from CDC 06-3008 (STEC)
- 01104 *Escherichia coli* serotype O104:H4 derived from ATCC® BAA-2326™* (STEC)
- 01102 *Escherichia coli* serotype O111:H8 derived from CDC 2010C-3114 (STEC)
- 01097 *Escherichia coli* serotype O145:NM derived from CDC 99-3311 (STEC)
- 0617 *Escherichia coli* serotype O157:H7 derived from ATCC® 35150™* (STEC)
- 0595 *Salmonella bongori* derived from ATCC® 43975™*
- 0901 *Salmonella enterica* subsp. *arizonae* derived from ATCC® 13314™*
- 01045 *Salmonella enterica* subsp. *diarizonae* derived from ATCC® 29934™*
- 0345 *Salmonella enterica* subsp. *enterica* serovar Enteritidis derived from ATCC® 13076™*
- 0363 *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 14028™*
- 0349 *Shigella boydii* derived from ATCC® 9207™*
- 0356 *Shigella flexneri* (2b) derived from ATCC® 12022™*
- 0348 *Shigella flexneri* derived from ATCC® 9199™*
- 0303 *Shigella sonnei* derived from ATCC® 25931™*
- 0350 *Shigella sonnei* derived from ATCC® 29930™*

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Enteric Parasite Verification Panel (Synthetic) - Catalog #8182

Contains 5 vials of dried synthetic consensus sequence DNA, 1 vial of molecular standar water for rehydration and a Certificate of Analysis. 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

Syndrome-Specific Panels for GI Testing

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

Contains 5 inactivated microorganism pellets of each pool listed below (10 vials/pellets total).

Refrigerated storage | *For in vitro diagnostic use* | *International restrictions may apply*

Pool 7/Positive Control (5 vials/pellets)
Campylobacter jejuni
Shigella sonnei
Yersinia enterocolitica
Salmonella enterica subsp. *enterica* Typhimurium
Vibrio parahaemolyticus
Escherichia coli (shiga toxin 1, shiga toxin 2)
Rotavirus SA11
Recombinant Norovirus GII.4

Pool 8/Negative Control (5 vials/pellets)
Clostridium difficile NAP1

Enteric Viral Control Panel - Catalog #8211

Contains 6 inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (6 vials/pellets total).

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

- Adenovirus 40
- Recombinant Astrovirus
- Recombinant Norovirus GII
- Rotavirus
- Recombinant Sapovirus

Enteric Viral Verification Panel - Catalog #8210

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

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

- Adenovirus 40
- Recombinant Astrovirus
- Recombinant Norovirus GII
- Rotavirus
- Recombinant Sapovirus

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

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

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

- *Campylobacter jejuni* subsp. *jejuni*
- *Escherichia coli* serotype O111:H8 (STEC, eae positive, stx 1 and/or stx 2 positive)
- *Escherichia coli* serovar O159:H34 (ETEC)
- *Plesiomonas shigelloides*
- *Salmonella enterica* subsp. *enterica* serovar Typhimurium
- *Shigella sonnei*
- *Vibrio parahaemolyticus* (VP81, serotype O3:K6)
- *Yersinia enterocolitica* (biotype 2, serotype 9)

Norovirus Control Panel (Inactivated Swab) - Catalog #8205

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total) comprised of the strains listed below, and a Certificate of Analysis.

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

Positive Control (6 swabs):
- Recombinant Norovirus GI.1 (ORF1-ORF2)
- Recombinant Norovirus GII.4 (ORF1-ORF2)

Negative Control (6 swabs): Rotavirus

Helix Elite™ Molecular Standards for GI Testing

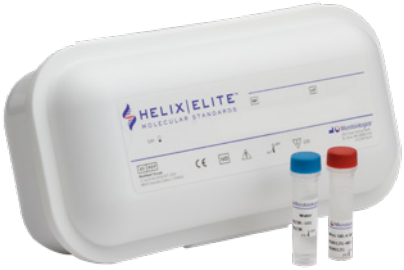
Inactivated Helix Elite Molecular Standards

Full process controls for use in molecular testing. Each kit contains 5 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

- *Room temperature storage*
- *Medium-high titer*
- *For in vitro diagnostic use*



Synthetic Helix Elite Molecular Standards

For use as a positive control in molecular applications. Each kit contains 1 vial of dried synthetic consensus sequence DNA or RNA (approximately 100 reactions), 1 vial of molecular standard water for rehydration and a Certificate of Analysis.

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

Norovirus GI.1 Synthetic RNA - Catalog #HE0013S

- *Room temperature storage*
- *ORF1-ORF2 Junction of Norovirus GI.1*
- *Dried RNA Preserved with Biomatrica RNAstable®*
- *For in vitro diagnostic use*

Norovirus GII.4 Synthetic RNA - Catalog #HE0012S

- *Room temperature storage*
- *ORF1-ORF2 Junction of Norovirus GII.4*
- *Dried RNA Preserved with Biomatrica RNAstable®*
- *For in vitro diagnostic use*

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 so you can be certain your testing procedures and materials are working properly.

Safe, simple, stable controls

- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test-ready formats save you time and money
- Easy and economical storage, no freezing required
- Certificate of Analysis provides detailed strain information
- Technical Support experts available for guidance

Cepheid Xpert® C. difficile Control Panel (Inactivated Swab) - Catalog #8200

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC. For use with Xpert® *C. difficile*/Epi assay

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

Positive Control (6 swabs): *Clostridium difficile*
Negative Control (6 swabs): *Clostridium sordellii*

Cepheid Xpert® MRSA/MRSA NxG Control Panel - Catalog #8195

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC. For use with Xpert® MRSA NxG assay.

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

Positive Control (6 swabs): Methicillin Resistant *Staphylococcus aureus*
Negative Control (6 swabs): *Staphylococcus epidermidis*

Cepheid Xpert® MRSA/SA Control Panel - Catalog #8196

Contains 12 positive control swabs and 6 negative control swabs (18 swabs total) comprised of the organisms recommended by the manufacturer for QC. For use with Xpert® SA Nasal Complete assay.

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

Positive Control 1 (6 swabs): Methicillin Resistant *Staphylococcus aureus*
Positive Control 2 (6 swabs): *Staphylococcus aureus*
Negative Control (6 swabs): *Staphylococcus epidermidis*

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

Contains 2 KWIK-STIKs of a positive control and negative control (4 KWIK-STIKs total).

Positive Control (2 KWIK-STIKs):
Clostridioides difficile derived from ATCC® 9689™*
(tcdA positive, tcdB positive)

Negative Control (2 KWIK-STIKs):
Clostridioides difficile derived from ATCC® 700057™*
(tcdA negative, tcdB negative; nontoxigenic)

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

Contains 6 pre-pooled positive control swabs and 6 negative control swabs (12 swabs total) comprised of the organisms listed below, and a Certificate of Analysis.

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

Positive Control (6 swabs):
- *Escherichia coli* (IMP-type)
- *Klebsiella pneumoniae* (VIM-1, Metallo-beta-lactamase positive)
- *Klebsiella pneumoniae* (NDM-1 positive, New Delhi metallo-beta-lactamase)
- *Klebsiella pneumoniae* (produces carbapenemase KPC-3)
- *Klebsiella pneumoniae* (OXA-48)

Negative Control (6 swabs): *Escherichia coli*

MRSA Organism Set (Live Culture) - Catalog #8174

Contains 2 KWIK-STIKs of 9 Staphylococcus aureus strains and 1 Staphylococcus epidermidis strain (20 KWIK-STIKs total).

- 01065 Staphylococcus aureus derived from NCTC 12493
- 0485 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*
- 0365 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 29213™*
- 0496 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 33591™*
- 0352 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 33862™*
- 0852 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 43300™*
- 01022 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 700698™*
- 0158 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 700699™*
- 0713 *Staphylococcus aureus* subsp. *aureus* derived from NCTC 12973
- 01068 *Staphylococcus epidermidis* derived from ATCC® 51625™*

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Syndrome-Specific Panels for HAI Testing

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)
- 2 strains/KWIK-STIKs: Methicillin Sensitive *Staphylococcus aureus* (MSSA)
- 1 strain/KWIK-STIKs: Methicillin Sensitive *Staphylococcus epidermidis* (MSSE)

Live Culture Staphylococcus Controls

Each kit contains 2 KWIK-STIKs at E4 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**

Strep B Organism (Live Culture) - Catalog #8173

Contains 4 KWIK-STIKs of each strain listed below (40 KWIK-STIKs total).
- 0439 *Streptococcus agalactiae* (B) derived from ATCC® 12386™*
- 0436 *Streptococcus agalactiae* (B) derived from ATCC® 27956™*
- 0710 *Streptococcus agalactiae* (B) derived from NCTC 9993
- 0104 *Streptococcus agalactiae* (B, III) derived from ATCC® 12403™*
- 0389 *Streptococcus anginosus* (G) derived from NCTC 10713
- 0603 *Streptococcus dysgalactiae* subsp. *equisimilis* (C) derived from ATCC® 12388™*
- 0373 *Streptococcus dysgalactiae* subsp. *equisimilis* (C) derived from NCTC 8543
- 0385 *Streptococcus pyogenes* (A) derived from ATCC® 19615™*
- 0978 *Streptococcus* spp. (F,2) derived from ATCC® 12392™*
- 0864 *Streptococcus* spp. (B, Ib) derived from ATCC® 12401™*

ATCC Licensed Derivative®

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

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total) comprised of the strains listed below, and a Certificate of Analysis.

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

Positive Control (6 swabs): *Enterococcus faecium* (vanA-type glycopeptide resistance and Vancomycin resistant)

Negative Control (6 swabs): *Enterococcus faecalis*

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.

Safe, simple, stable controls

- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test-ready formats save you time and money
- Easy and economical storage, no freezing required
- Certificate of Analysis provides detailed strain information
- Technical Support experts available for guidance

Assay-Specific Panels for Respiratory Testing

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

Contains 6 positive control swabs (pre-pooled) and 6 negative control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC listed below. For use with Xpert® Flu and Xpert® Flu/RSV XC assays.

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

Positive Control (6 swabs):
- Influenza A (H1N1) Virus
- Influenza A (H3H2) Virus
- Influenza B Virus
- Respiratory Syncytial Virus A

Negative Control (6 swabs): Coxsackievirus B1

Syndrome-Specific Panels for Respiratory Testing

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

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total), and a Certificate of Analysis.

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

Positive Control (6 swabs): Coxsackievirus B1
Negative Control (6 swabs): Rhinovirus 1B

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

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total), and a Certificate of Analysis.

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

Positive Control (6 swabs): *Streptococcus pyogenes*
Negative Control (6 swabs): *Streptococcus dysgalactiae*

Syndrome-Specific Panels for Respiratory Testing

Respiratory (21 Targets) Control Panel - Catalog #8217

Contains 6 inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (6 vials/pellets total).

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

- Adenovirus Type 6
- *Bordetella parapertussis*
- *Bordetella pertussis*
- *Chlamydia pneumoniae*
- Coronavirus 229E
- Recombinant Coronavirus HKU1
- Recombinant Coronavirus NL63
- Recombinant Coronavirus OC43 Strain 1 and Recombinant Coronavirus OC43 Strain 2
- Recombinant Human Metapneumovirus
- 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
- Recombinant Parainfluenza Virus 4a
- Respiratory Syncytial Virus

Respiratory Pathogens (16 Strains) Control Panel (Inactivated Pellet) - Catalog #8198

Contains 5 inactivated microorganism pellets of each pool listed below (15 vials/pellets total).

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

Positive Pool 1 (5 vials/pellets)
Adenovirus (Adenoid 6)
Bordetella holmesii
Bordetella pertussis
Parainfluenza 1 (VP1)
Parainfluenza 2 (Greer)
Parainfluenza 3 (C243)
Recombinant Human Metapneumovirus
Recombinant Parainfluenza 4
Recombinant Rhinovirus

Positive Pool 2 (5 vials/pellets)
Bordetella parapertussis
Influenza A (H1N1)
Influenza A (H3N2)
Influenza B (Hong Kong/5/72)
Recombinant RSV B
RSV A (Long)

Negative Pool (5 vials/pellets)
Coronavirus

Inactivated Helix Elite Molecular Standards

Full process controls for use in molecular testing. Each kit contains 5 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 Adenovirus 2 - Catalog #HE0026N

- Strain Adenoid 6

Inactivated Chlamydia pneumoniae - Catalog #HE0034N

- Strain CWL-029
- Not availabe for shipment to Europe

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

Each pellet contains:
- Influenza A (H1N1) Virus
- IInfluenza B Virus, Strain Hong Kong/5/72
- Respiratory Syncytial Virus (RSV) A, Strain Long

Inactivated Influenza A (H1N1) Virus - Catalog #HE0029N

- Strain subtype H1N1

Inactivated Influenza A (H3N2) Virus - Catalog #HE0043N

- Strain subtype H3N2

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 Parainfluenza Virus 3 - Catalog #HE0033N

- Strain C243

Inactivated Varicella Zoster Virus - Catalog #HE0038N

- Strain VZ-10

Microbiologics

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, pre-pooling of strains when applicable,and formats that mimic patient sample processing for ease of use.

Safe, simple, stable controls

- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test-ready formats save you time and money
- Easy and economical storage, no freezing required
- Certificate of Analysis provides detailed strain information
- Technical Support experts available for guidance

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 6 positive control swabs (pre-pooled) and 6 negative control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC listed below.
For use with Xpert® CT/NG assay.

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

Positive Control (6 swabs):
- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- Human cells

Negative Control (6 swabs): Human cells

Cepheid Xpert® GBS LB Control Panel - Catalog #8194

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC listed below. For use with Xpert® GBS LB assay.

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

Positive Control (6 swabs): *Streptococcus agalactiae*
Negative Control (6 swabs): *Lactobacillus acidophilus*

GBS QC Set (Live Culture) - Catalog #8164

Contains 4 KWIK-STIKs: 3 KWIK-STIKs of *Streptococcus* species (low, medium, and high levels) and 1 KWIK-STIK of *Lactobacillus acidophilus* (negative control).

- **Low:** *Streptococcus* spp. (Group B, Ib) derived from ATCC® 12401™*
- **Medium:** *Streptococcus* spp. (Group B, Ib) derived from ATCC® 12401™*
- **High:** *Streptococcus* spp. (Group B, Ib) derived from ATCC® 12401™*
- **Negative Control:** *Lactobacillus acidophilus* derived from ATCC® 4356™*

ATCC Licensed Derivative®

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Human Papillomavirus (HPV) Control Panel - Catalog #8214

Contains 6 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

- Recombinant HPV 16
- Recombinant HPV 18
- Recombinant HPV 45

Human Papillomavirus (HPV) Verification Panel - Catalog #8216

Contains 20 inactivated, pre-pooled microorganism pellets each comprised of the organisms listed below.

Room temperature storage | For in vitro diagnostic use | Does not contain human beta globin | International restrictions may apply

- Recombinant HPV 16
- Recombinant HPV 18
- Recombinant HPV 45

Trichomonas vaginalis (TV) Control Panel - Catalog #8189

Contains 6 positive control swabs and 6 negative control swabs (12 swabs total) comprised of the strains listed below, and a Certificate of Analysis.

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

Positive Control (6 swabs):
- *Trichomonas vaginalis*
- Human cells

Negative Control (6 swabs):
- *Neisseria gonorrhoeae*
- Human cells

Vaginal Control Panel - Catalog #8209

Contains 2 pools of 6 inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (12 pellets/vial total).

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

Pool 1 (6 vials/pellet)
- *Lactobacillus crispatus*

Pool 2 (6 vials/pellets)
- *Atopobium vaginae*
- *Candida albicans*
- *Candida glabrata*
- *Candida krusei*
- *Gardnerella vaginalis*
- Recombinant BVAB2
- *Trichomonas vaginalis*

Vaginal Verification Panel - Catalog #8208

Includes 2 boxes containing 20 individually packaged inactivated microorganism pellets of each pool listed below (120 vials/pellets total).

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

Pool 1 (20 vials/pellets)
- *Lactobacillus crispatus*

Pool 2 (20 vials/pellets)
- *Gardnerella vaginalis*

Pool 3 (20 vials/pellets)
- *Atopobium vaginae*
- *Candida albicans*
- *Gardnerella vaginalis*
- Recombinant BVAB2

Pool 4 (20 vials/pellets)
- *Atopobium vaginae*
- *Gardnerella vaginalis*
- Recombinant BVAB2
- *Trichomonas vaginalis*

Pool 5 (20 vials/pellets)
- *Atopobium vaginae*
- *Candida glabrata*
- *Gardnerella vaginalis*
- *Lactobacillus crispatus*

Pool 6 (20 vials/pellets)
- *Atopobium vaginae*
- *Candida krusei*
- *Gardnerella vaginalis*
- *Lactobacillus crispatus*

Inactivated Helix Elite Molecular Standards

Full process controls for use in molecular testing. Each kit contains 5 unassayed lyophilized 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 *Chlamydia trachomatis* - Catalog #HE0035N

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

Inactivated Herpes Simplex Virus 1 - Catalog #HE0036N

Inactivated Herpes Simplex Virus 2 - Catalog #HE0037N

Inactivated *Neisseria gonorrhoeae* - Catalog #HE0041N

Inactivated *Trichomonas vaginalis* - Catalog #HE0042N

Synthetic Helix Elite Molecular Standards

For use as a positive control in molecular applications. Kits contain: 1 vial of dried synthetic consensus sequence DNA or RNA (approximately 100 reactions), 1 vial of molecular standard water for rehydration and a Certificate of Analysis.

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

Human papillomavirus 16 Synthetic DNA - Catalog #HE0046S
Fragments of E6,E7 and L1 genes | Dried DNA Preserved with Biomatrica DNAstable®

Human papillomavirus 18 Synthetic DNA - Catalog #HE0048S
Fragments of E6, E7 and L1 genes | Dried DNA Preserved with Biomatrica DNAstable®

Treponema pallidum Synthetic DNA - Catalog #HE0047S
Fragments of 47 kDa protein and DNA Polymerase I genes | Dried DNA Preserved with Biomatrica DNAstable®

Microbiologics

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 when applicable. From parasitology to patient/donor screening and testing, Microbiologics has your control needs covered.

Safe, simple, stable controls

- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test-ready formats save you time and money
- Easy and economical storage, no freezing required
- Certificate of Analysis provides detailed strain information
- Technical Support experts available for guidance

Inactivated Helix Elite Molecular Standards

Full process controls for use in molecular testing. Each kit contains 5 unassayed lyophilized 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 Cytomegalovirus High Control - Catalog #HE0040N
AD-169

Inactivated Cytomegalovirus Low Control - Catalog #HE0039N
AD-169

Synthetic Helix Elite Molecular Standards

For use as a positive control in molecular applications. Kits contain: 1 vial of dried synthetic consensus sequence DNA or RNA (approximately 100 reactions), 1 vial of molecular standard water for rehydration and a Certificate of Analysis.

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 cayetanensis | 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
Fragments from the NSP3 gene, the capsid protein gene, and the E2 glycoprotein gene | Dried DNA Preserved with Biomatrica DNAstable® | Export license required for shipping outside U.S.

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®

Synthetic Helix Elite Molecular Standards

For use as a positive control in molecular applications. Kits contain: 1 vial of dried synthetic consensus sequence DNA or RNA (approximately 100 reactions), 1 vial of molecular standard water for rehydration and a Certificate of Analysis.

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

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 malariae Synthetic DNA - Catalog #HE0011S
18S rRNA A-type gene of Plasmodium malariae | 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 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 DNA Preserved with Biomatrica DNAstable®

HELIX | ELITE™
MOLECULAR STANDARDS

Inactivated, Full Process Controls for Molecular Assays

Highlights:

- Fully intact, non-viable process controls
- Used for every step of the molecular testing process: from extraction through detection
- Quick-dissolve lyophilized pellets 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

Applications:

- Multiple targets available for gastrointestinal, respiratory, sexual health and transplant assays
- Sensitivity and Specificity
- Verification and Validation
- Assay Optimization
- Training
- Proficiency Testing
- Lot-to-Lot Testing of Assay
- External Assay QC

Package Details:

- 5 qualitative lyophilized microorganism pellets packaged in individual vials
- Instructions for Use
- Certificate of Analysis

HELIX | ELITE™
MOLECULAR STANDARDS

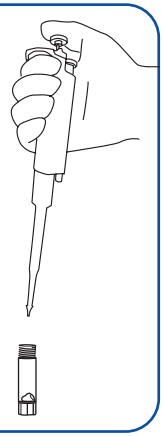
ILLUSTRATED INSTRUCTIONS

1

Open the foil pouch and ensure the pellet is at the bottom of the vial before opening.

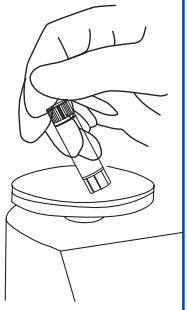
2

Rehydrate the lyophilized pellet with the appropriate buffer. A minimum volume of 100 µl is recommended.



3

Vortex briefly to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.



4

Use the appropriate volume for the assay being performed and follow labratory protocols or manufacturer instructions for processing a sample.

Note: Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material is not recommended.

Inactivated Helix Elite™

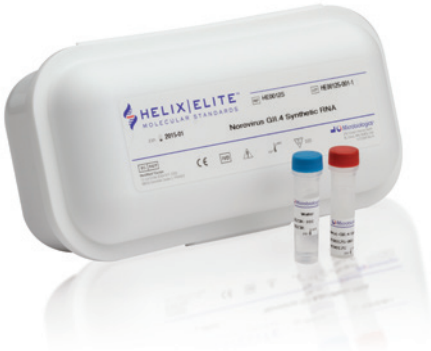
Catalog Number	Product Description	Comments
HE0026N	Inactivated Adenovirus 2	Strain Adenoid 6; IVD
HE0034N	Inactivated *Chlamydia pneumoniae*	Strain CWL-029; IVD; not available for shipment to Europe
HE0035N	Inactivated *Chlamydia trachomatis*	Strain LGV-2-434; IVD; not available for shipment to Europe
HE0045N	Inactivated *Chlamydia trachomatis*/ *Neisseria gonorrhoeae* (CT/NG)	Chlamydia trachomatis Strain LGV-2-434; Neisseria gonorrhoeae Strain GL0071; IVD; not available for shipment to Europe
HE0040N	Inactivated Cytomegalovirus High Control	Strain AD-169; IVD; not available for shipment to Europe
HE0039N	Inactivated Cytomegalovirus Low Control	Strain AD-169; IVD; not available for shipment to Europe
HE0050N	Inactivated Enterovirus D68	IVD
HE0036N	Inactivated Herpes Simplex Virus 1	Strain MacIntyre; IVD
HE0037N	Inactivated Herpes Simplex Virus 2	Strain MS; IVD
HE0044N	Inactivated Influenza A/B and Respiratory Syncytial Virus	Influenza A (H1N1) Virus; Influenza B Virus, Strain Hong Kong/5/72; Respiratory Syncytial Virus (RSV) A, Strain Long; IVD
HE0029N	Inactivated Influenza A (H1N1) Virus	Strain Subtype H1N1; IVD
HE0043N	Inactivated Influenza A (H3N2) Virus	Strain Subtype H3N2; IVD
HE0030N	Inactivated Influenza B Virus	Strain Hong Kong/5/72; IVD
HE0041N	Inactivated *Neisseria gonorrhoeae*	Strain GL0071; IVD
HE0031N	Inactivated Parainfluenza Virus 1	Strain VP1; IVD
HE0032N	Inactivated Parainfluenza Virus 2	Strain Greer; IVD
HE0033N	Inactivated Parainfluenza Virus 3	Strain C243; IVD
HE0028N	Inactivated Respiratory Syncytial Virus A	Strain Long; IVD

Inactivated Helix Elite™

Catalog Number	Product Description	Comments
HE0027N	Inactivated Rotavirus	Strain Simian rotavirus SA11; IVD; medium-high titer
HE0042N	Inactivated *Trichomonas vaginalis*	Strain GL0028; IVD
HE0038N	Inactivated Varicella Zoster Virus	Strain VZ-10; IVD

HELIX | ELITE™
MOLECULAR STANDARDS

Synthetic Nucleic Acid RNA and DNA Sequences for Use as Amplification and Detection Controls in Molecular Assays



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

Applications:

- Sensitivity and Specificity
- Verification and Validation
- Assay Optimization
- Training
- Proficiency Testing
- Lot-to-Lot Testing

Package Details:

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

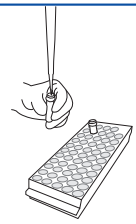
HELIX | ELITE™
MOLECULAR STANDARDS

ILLUSTRATED INSTRUCTIONS

1 Rehydration

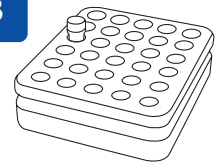
Open the foil pouch and then centrifuge the synthetic Helix Elite Molecular Standard tube before opening the tube to avoid loss of the dried material.

2



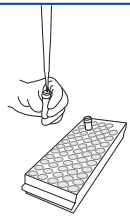
Add 55 µl Helix Elite molecular standard water to the Helix Elite Molecular Standard tube.

3



Incubate the Helix Elite Molecular Standard tube at 2°C-8°C for 15 minutes to allow for complete rehydration.

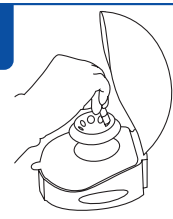
4



Mix the hydrated Helix Elite Molecular Standard by gently pipetting up and down several times.

Do not vortex as this may damage the nucleic acids.

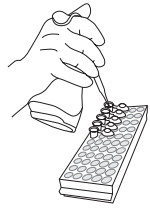
5



Briefly centrifuge to ensure all liquid is in the bottom of the tube.

6

Aliquot 10 µl of the rehydrated synthetic Helix Elite Molecular Standard into 5 new, labeled microcentrifuge tubes.



Store aliquots at or below -20°C. These tubes are concentrated stock tubes that must be diluted further for use in molecular assays.

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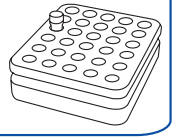
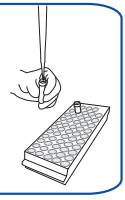
1 Dilution & Use

Obtain an aliquot of the rehydrated Helix Elite Molecular Standard. If needed, thaw the aliquot at 2°C-8°C for 15 minutes and centrifuge briefly.



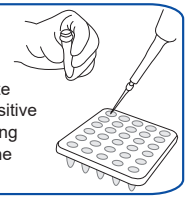
2

Add 90 µl Helix Elite molecular standard water into the tube containing 10 µl of the rehydrated Helix Elite Molecular Standard. Gently mix by pipetting up and down several times.



3

Use 5 µl of the diluted Helix Elite Molecular Standard for each positive control reaction and run according to the protocol appropriate for the molecular assay being used.



4

The remaining 95 µl of diluted Helix Elite Molecular Standard should be further aliquoted into single-use volumes to avoid freeze-thaw of the material. Store all aliquots of diluted Helix Elite Molecular Standard tubes at or below -20°C. These tubes are fully diluted and ready to use in molecular assays.

Synthetic Helix Elite™

Catalog Number	Product Description	Comments
HE0001S	*Cryptosporidium hominis* Synthetic DNA	18S rRNA gene of *Cryptosporidium hominis*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0002S	*Cryptosporidium parvum* Synthetic DNA	18S rRNA gene of *Cryptosporidium parvum*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0025S	*Cyclospora cayetanensis* Synthetic DNA	18S rRNA gene of *Cyclospora cayetanensis*; Dried DNA preserved with Biomatrica DNAstable®; IVD
HE0015S	*Dientamoeba fragilis* Synthetic DNA	18S rRNA gene of *Dientamoeba fragilis*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0016S	Eastern Equine Encephalitis Virus Synthetic RNA	Fragments from the NSP3 gene, the capsid protein gene, and the E2 glycoprotein gene; Dried RNA Preserved with Biomatrica RNAstable®; Export license required for shipping this product outside the US; IVD
HE0004S	*Encephalitozoon intestinalis* Synthetic DNA	18S rRNA gene of *Encephalitozoon intestinalis*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0007S	*Entamoeba dispar* Synthetic DNA	18S rRNA gene of *Entamoeba dispar*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0006S	*Entamoeba histolytica* Synthetic DNA	18S rRNA gene of *Entamoeba histolytica*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0003S	*Enterocytozoon bieneusi* Synthetic DNA	18S rRNA gene of *Enterocytozoon bieneusi*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0005S	*Giardia lamblia* Synthetic DNA	18S rRNA of *Giardia lamblia*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0046S	Human papillomavirus 16 Synthetic DNA	Fragments of E6, E7 and L1 genes; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0048S	Human papillomavirus 18 Synthetic DNA	Fragments of E6,E7 and L1 genes; Dried DNA Preserved with Biomatrica DNAstable®; IVD

Synthetic Helix Elite™

Catalog Number	Product Description	Comments
HE0013S	Norovirus GI.1 Synthetic RNA	ORF1-ORF2 Junction of Norovirus GI.1; Dried RNA Preserved with Biomatrica RNAstable®; IVD
HE0012S	Norovirus GII.4 Synthetic RNA	ORF1-ORF2 Junction of Norovirus GII.4; Dried RNA Preserved with Biomatrica RNAstable®; IVD
HE0024S	Pan Mycoplasma Synthetic DNA	Consensus sequence of the 16S rRNA gene; Dried DNA preserved with Biomatrica DNAstable®; Non-IVD (not intended for clinical use)
HE0008S	*Plasmodium falciparum* Synthetic DNA	18S rRNA gene of asexual *Plasmodium falciparum*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0011S	*Plasmodium malariae* Synthetic DNA	18S rRNA A-type gene of *Plasmodium malariae*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0010S	*Plasmodium ovale* Synthetic DNA	18S rRNA gene of asexual *Plasmodium ovale*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0009S	Plasmodium vivax Synthetic DNA	18S rRNA gene of asexual *Plasmodium vivax*; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0047S	*Treponema pallidum* Synthetic DNA	Fragments of 47 kDa protein and DNA Polymerase I genes; Dried DNA Preserved with Biomatrica DNAstable®; IVD
HE0014S	West Nile Virus Synthetic RNA	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®; IVD

Microbiologics
QC SETS AND PANELS

Bundled Sets and Panels of Microorganism Strains for QC and Verification of Assays and Test Kits

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

Applications:

- SQC of microbial identification and detection instruments and commercial diagnostic assays including biochemical, PCR and molecular technologies
- Verification and Validation
- Routine quality control

Package Details:

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

Assay-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8193	**BD MAX™ CT/GC/TV 20-Day QC Panel** - *Chlamydia trachomatis* - *Neisseria gonorrhoeae* - *Trichomonas vaginalis*	See page 24
8202	**BD MAX™ Enteric Parasite 20-Day QC Panel** - *Cryptosporidium parvum* - *Entamoeba histolytica* surrogate - *Giardia lamblia*	See page 10
8204	**BD MAX™ Enteric Parasite Control Panel** - *Cryptosporidium parvum* - *Entamoeba histolytica* surrogate - *Giardia lamblia*	See page 10
8200	**Cepheid Xpert® *C. difficile* Control Panel (Inactivated Swab)** **Positive Control:** *Clostridium difficile* (NAP1/027) **Negative Control:** *Clostridium sordellii*	See page 16
8188	**Cepheid Xpert® CT/NG Control Panel (Inactivated Swab)** **Positive Control:** - *Chlamydia trachomatis* Strain LGV-2-434 - *Neisseria gonorrhoeae* - Human cells **Negative Control:** Human cells	See page 24
8194	**Cepheid Xpert® GBS LB Control Panel (Inactivated Swab)** **Positive Control:** *Streptococcus agalactiae* **Negative Control:** *Lactobacillus acidophilus*	See page 24
8195	**Cepheid Xpert® MRSA/MRSA NxG Control Panel (Inactivated Swab)** **Positive Control:** Methicillin resistant *Staphylococcus aureus* **Negative Control:** *Staphylococcus epidermidis*	See page 16
8196	**Cepheid Xpert® MRSA/SA Control Panel (Inactivated Swab)** **Positive Control 1:** Methicillin resistant *Staphylococcus aureus* **Positive Control 2:** *Staphylococcus aureus* **Negative Control:** *Staphylococcus epidermidis*	See page 16
8199	**Cepheid Xpert® Respiratory Control Panel (Inactivated Swab)** **Positive Control:** - Influenza A (H1N1) Virus - Influenza A (H3H2) Virus - Influenza B Virus - Respiratory Syncytial Virus A **Negative Control:** Coxsackievirus B1	See page 20

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8215	**Blood Culture Identification (BCID) Control Panel (Inactivated)** - *Acinetobacter baumannii* - *Candida albicans* - *Candida glabrata* - *Candida krusei* - *Candida parapsilosis* - *Candida tropicalis* - *Enterobacter cloacae* - *Enterococcus faecalis* (vanB) - *Escherichia coli* - *Haemophilus influenzae* - *Klebsiella oxytoca* - *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*	See page 5
8201	**Blood Culture Identification (BCID) Verification Panel (Inactivated)** **Pool 1:** - *Candida albicans* - *Candida krusei* - *Neisseria meningitidis* - *Pseudomonas aeruginosa* - *Staphylococcus aureus* (MRSA) - *Streptococcus agalactiae* - *Streptococcus pyogenes* **Pool 2:** - *Acinetobacter baumannii* - *Candida glabrata* - *Candida tropicalis* - *Enterobacter cloacae* - *Enterococcus faecalis* (vanB) - *Escherichia coli* - *Klebsiella oxytoca* - *Listeria monocytogenes* serovar 7 - *Staphylococcus epidermidis* (MSSE) **Pool 3:** - *Candida parapsilosis* - *Haemophilus influenzae* - *Klebsiella pneumoniae* (KPC) - *Proteus vulgaris* - *Serratia marcescens* - *Streptococcus pneumoniae*	See page 5
5229P	**Blood Culture Identification (BCID) Verification Panel (Live Culture)** - *Acinetobacter baumannii* - *Candida albicans* - *Candida glabrata* - *Candida krusei* - *Candida parapsilosis* - *Candida tropicalis* - *Enterobacter cloacae* subsp. *cloacae* - *Enterococcus faecalis* - *Escherichia coli* - *Haemophilus influenzae* - *Klebsiella oxytoca* - *Klebsiella pneumoniae* - *Listeria monocytogenes* - *Neisseria meningitidis* - *Proteus mirabilis* - *Pseudomonas aeruginosa* - *Serratia marcescens* - *Staphylococcus aureus* subsp. *aureus* - *Staphylococcus epidermidis* - *Streptococcus agalactiae* - *Streptococcus pneumoniae* - *Streptococcus pyogenes*	See page 6

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8171	***C. difficile* QC Set (Live Culture)** **Positive Control:** *Clostridioides difficile* **Negative Control:** *Clostridioides difficile*	See page 17
8187	**Carbapenem-resistant Enterobacteriaceae (CRE) Control Panel (Inactivated Swab)** **Positive Control:** - *Escherichia coli* - *Klebsiella pneumoniae* (4 strains) **Negative Control:** *Escherichia coli*	See page 17
8179	**Enteric Bacterial Organism Set (Live Culture)** - *Acinetobacter baumannii* - *Campylobacter coli* (2 strains) - *Campylobacter jejuni* subsp. *jejuni* (3 strains) - *Escherichia coli* serotype O103:H11 (STEC) - *Escherichia coli* serotype O104:H4 (STEC) - *Escherichia coli* serotype O111:H8 (STEC) - *Escherichia coli* serotype O145:NM (STEC) - *Escherichia coli* serotype O157:H7 (STEC) - *Salmonella bongori* - *Salmonella enterica* subsp. *arizonae* - *Salmonella enterica* subsp. *diarizonae* - *Salmonella enterica* subsp. *enterica* serovar Enteritidis - *Salmonella enterica* subsp. *enterica* serovar Typhimurium - *Shigella boydii* - *Shigella flexneri* (2b) - *Shigella flexneri* - *Shigella sonnei* (2 strains)	See page 11
8182	**Enteric Parasite Verification Panel (Synthetic)** - *Cryptosporidium* spp. - *Entamoeba histolytica* - *Giardia lamblia*	See page 11
8184	**Enteric Pathogens Control Panel (Inactivated Pellet)** **Pool 7/Positive Control:** - *Campylobacter jejuni* - *Escherichia coli* (shiga toxin 1, shiga toxin 2) - Recombinant Norovirus GII.4 - Rotavirus SA11 - *Salmonella enterica* subsp. *enterica* Typhimurium - *Shigella sonnei* - *Vibrio parahaemolyticus* - *Yersinia enterocolitica* **Pool 8/Negative Control:** *Clostridium difficile* NAP1	See page 12

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8211	**Enteric Viral Control Panel** - Adenovirus 40 - Recombinant Astrovirus - Recombinant Norovirus GII - Rotavirus - Recombinant Sapovirus	See page 12
8210	**Enteric Viral Verification Panel** - Adenovirus 40 - Recombinant Astrovirus - Recombinant Norovirus GII - Recombinant Sapovirus - Rotavirus	See page 12
8190	**Enterovirus (EV) Control Panel (Inactivated Swab)** **Positive Control:** Coxsackievirus B1 **Negative Control:** Rhinovirus 1B	See page 20
8191	**Extended Enteric Bacterial Verification Panel (Inactivated Pellet)** - *Campylobacter jejuni subsp. jejuni* - *Escherichia coli* serotype O111:H8 (STEC) - *Escherichia coli serovar* O159:H34 (ETEC) - *Plesiomonas shigelloides* - *Salmonella enterica* subsp. *enterica* serovar Typhimurium - *Shigella sonnei* - *Vibrio parahaemolyticus* - *Yersinia enterocolitica*	See page 13
8219	**Group A Streptococcus (GAS) Control Panel (Inactivated Swab)** **Positive Control:** *Streptococcus pyogenes* **Negative Control:** *Streptococcus dysgalactiae*	See page 20
8164	**GBS QC Set (Live Culture)** **- Low:** *Streptococcus species* (Group B, Ib) **- Medium:** *Streptococcus species* (Group B, Ib) **- High:** *Streptococcus species* (Group B, Ib) **- Negative Control:** *Lactobacillus acidophilus*	See page 25

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8181	**Gram-Negative Blood Culture Control Panel (Inactivated Pellet)** **Pool 4:** - *Acinetobacter baumannii* - *Pseudomonas aeruginosa* - *Enterobacter cloacae* (CTX-M) **Pool 5:** - *Klebsiella pneumoniae* (KPC) - *Citrobacter freundii* - *Escherichia coli* - *Klebsiella pneumoniae* (2 strains, CTX-M, NDM, VIM) **Pool 6:** - *Klebsiella oxytoca* - *Klebsiella pneumoniae* (OXA) - *Proteus vulgaris*	See page 7
5226P	**Gram-Negative Blood Culture Control Panel (Live Culture)** - *Acinetobacter baumannii* - *Citrobacter freundii* - *Enterobacter cloacae* - *Escherichia coli* - *Klebsiella pneumoniae* (4 strains) - *Klebsiella oxytoca* - *Proteus vulgaris* - *Pseudomonas aeruginosa* - *Serratia marcescens*	See page 7
8180	**Gram-Positive Blood Culture Control Panel (Inactivated Pellet)** **Pool 1:** - *Enterococcus faecium* (vanA) - *Listeria monocytogenes* - *Staphylococcus epidermidis* - *Staphylococcus lugdunensis* **Pool 2:** - *Streptococcus agalactiae* - *Streptococcus anginosus* - *Streptococcus pyogenes* **Pool 3:** - *Staphylococcus aureus* (mecA) - *Enterococcus faecalis* (vanB) - *Streptococcus pneumoniae*	See page 8
5225P	**Gram-Positive Blood Culture Control Panel (Live Culture)** - *Enterococcus faecalis* - *Enterococcus faecium* - *Listeria monocytogenes* - *Staphylococcus aureus* - *Staphylococcus epidermidis* - *Staphylococcus lugdunensis* - *Streptococcus agalactiae* - *Streptococcus anginosus* - *Streptococcus pneumoniae* - *Streptococcus pyogenes*	See page 8
8214	**Human Papillomavirus (HPV) Control Panel** - Recombinant HPV 16 - Recombinant HPV 18 - Recombinant HPV 45	See page 25

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8216	**Human Papillomavirus (HPV) Verification Panel** - Recombinant HPV 16 - Recombinant HPV 18 - Recombinant HPV 45	See page 25
8174	**MRSA Organism Set (Live Culture)** - *Staphylococcus aureus* (9 strains) - *Staphylococcus epidermidis*	See page 17
8205	**Norovirus Control Panel (Inactivated Swab)** **Positive Control:** - Recombinant Norovirus GI.1 (ORF1-ORF2) - Recombinant Norovirus GII.4 (ORF1-ORF2) **Negative Control:** Rotavirus	See page 13
8178	**SA Organism Set (Live Culture)** - 11 strains: Methicillin Resistant *Staphylococcus aureus* (MRSA) - 2 strains: Methicillin Sensitive *Staphylococcus aureus* (MSSA) - 1 strain: Methicillin Sensitive *Staphylococcus epidermidis* (MSSE)	See page 18
	Live Culture *Staphylococcus* Controls **- Catalog #0360MSSA:** *Staphylococcus aureus* subsp. *aureus* (MSSA Live Culture Positive Control) **- Catalog #0158MRSA:** *Staphylococcus aureus* subsp. *aureus* (MRSA Live Culture Positive Control) **- Catalog #0371MSSE:** *Staphylococcus epidermidis* (MSSE Live Culture Positive Control)	See page 18
8217	**Respiratory (21 Targets) Controls Panel** - Adenovirus Type 6 - *Bordetella parapertussis* - *Bordetella pertussis* - *Chlamydia pneumoniae* - Coronavirus 229E - Recombinant Coronavirus HKU1 - Recombinant Coronavirus NL63 - Recombinant Coronavirus OC43 Strain 1 and Recombinant Coronavirus OC43 Strain 2 - Recombinant Human Metapneumovirus - 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 - Recombinant Parainfluenza Virus 4a - Respiratory Syncytial Virus	See page 21

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8198	**Respiratory Pathogens (16 Strains) Control Panel (Inactivated Pellet)** **Pool 1/Positive Control:** - Adenovirus (Adenoid 6) - *Bordetella holmesii* - *Bordetella pertussis* - Metapneumovirus - Parainfluenza 1 (VP1) - Parainfluenza 2 (Greer) - Parainfluenza 3 (C243) - Recombinant Human Metapneumovirus - Recombinant Parainfluenza 4 - Recombinant Rhinovirus **Positive 2/Positive Control:** - *Bordetella parapertussis* - Influenza A (H1N1) - Influenza A (H3N2) - Influenza B (Hong Kong/5/72) - Recombinant RSV B - RSV A (Long) **Negative Control** - Coronavirus	See page 21
8173	**Strep B Organism (Live Culture)** - 3 strains: *Streptococcus agalactiae* (B) - *Streptococcus agalactiae* (B, III) - *Streptococcus anginosus* (G) - 2 strains: *Streptococcus dysgalactiae* subsp. *equisimilis* (C) - *Streptococcus pyogenes* (A) - *Streptococcus* spp.(F,2) - *Streptococcus* spp. (B, Ib)	See page 18
8189	***Trichomonas vaginalis* (TV) Control Panel (Inactivated Swab)** **Positive Control:** - *Trichomonas vaginalis* - Human cells **Negative Control:** - *Neisseria gonorrhoeae* - Human cells	See page 26
8209	**Vaginal Control Panel** **Pool 1:** *Lactobacillus crispatus* **Pool 2:** - *Atopobium vaginae* - *Candida albicans* - *Candida glabrata* - *Candida krusei* - *Gardnerella vaginalis* - Recombinant BVAB2 - *Trichomonas vaginalis*	See page 26

Syndrome-Specific QC Sets and Panels

Catalog Number	Product Description	Full Product Details
8208	**Vaginal Verification Panel** **Pool 1:** *Lactobacillus crispatus* **Pool 2:** *Gardnerella vaginalis* **Pool 3:** - *Atopobium vaginae* - *Candida albicans* - *Gardnerella vaginalis* - Recombinant BVAB2 **Pool 4:** - *Atopobium vaginae* - *Gardnerella vaginalis* - Recombinant BVAB2 - *Trichomonas vaginalis* **Pool 5:** - *Atopobium vaginae* - *Candida glabrata* - *Gardnerella vaginalis* - *Lactobacillus crispatus* **Pool 6:** - *Atopobium vaginae* - *Candida krusei* - *Gardnerella vaginalis* - *Lactobacillus crispatus*	See page 26
8203	**Vancomycin Resistant *Enterococcus* (VRE) Control Panel (Inactivated Swab)** **Positive Control:** *Enterococcus faecium* **Negative Control:** *Enterococcus faecalis*	See page 18

Microbiologics®

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A Culture of Service™

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