



MICROBIOLOGY CONTROL PRODUCTS

MOLECULAR QC MICROORGANISMS



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CUSTOMER INFORMATION

WORLDWIDE DISTRIBUTION

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

INTERNATIONAL CUSTOMERS

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

U.S. CUSTOMERS

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

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

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

PRODUCT WARRANTY

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

END USER REGISTRATION

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

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



BLOOD CULTURE IDENTIFICATION

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



Blood Culture Identification Control Panel (43 Targets) – Catalog #8254

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

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

Positive Control 1 (Six pellets/kit)

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

Positive Control 2 (Six pellets/kit)

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

Negative Control (Six pellets/kit)

- Blank pellet

BLOOD CULTURE IDENTIFICATION PANELS



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



BLOOD CULTURE IDENTIFICATION PANELS

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* (CTX-M)

Pool 5 (Five pellets/kit)

- *Klebsiella pneumoniae* (KPC)
- *Citrobacter freundii*
- *Escherichia coli* (IMP)
- *Klebsiella pneumoniae*
(CTX-M, NDM)
- *Klebsiella pneumoniae* (VIM)

Pool 6 (Five pellets/kit)

- *Klebsiella oxytoca*
- *Klebsiella pneumoniae* (OXA)
- *Proteus vulgaris*



GASTROINTESTINAL (GI)

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



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 MAX™ Enteric Parasite Panel.

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

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

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
- Not CE Marked

- *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 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*





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
- Astrovirus surrogate
- Norovirus GII surrogate
- Rotavirus
- Sapovirus 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.
-
- *Salmonella enterica* subsp. *enterica* serovar Typhimurium
 - *Shigella sonnei*
 - *Escherichia coli* (STEC)
 - *Campylobacter jejuni*
 - *Plesiomonas shigelloides*
 - *Yersinia enterocolitica*
 - *Escherichia coli* (ETEC)
 - *Vibrio parahaemolyticus*



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* subsp. *enterica* serovar Typhimurium
 - *Shigella sonnei*
 - *Escherichia coli* (STEC)
 - *Campylobacter jejuni*
 - *Plesiomonas shigelloides*
 - *Yersinia enterocolitica*
 - *Escherichia coli* (ETEC)
 - *Vibrio parahaemolyticus*



GASTROINTESTINAL PANELS

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

Negative Control (Twelve pellets/kit)

- Blank pellets





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 water for rehydration.

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

Norovirus GI.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

Assayed *C. difficile*/Epi Control Panel – 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*



Assayed 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*

Assayed 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 KWIK-STIKs 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)

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

Negative Control (Six swabs/kit):

- *Escherichia coli* derived from NCTC 11954



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 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



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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

Assayed Respiratory Control Panel – 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

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



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

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 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 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 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 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 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.





**Inactivated SARS-CoV-2 B.1.1.7 Whole Virus (Pellet)
– Catalog #HE0071N**

Contains five individually packaged lyophilized pellets made with whole inactivated SARS-CoV-2 virus (Isolate SARS-CoV-2 USA/CA_CDC_5574/2020 Lineage B.1.1.7) 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
- Not CE Marked

SARS-CoV-2 B.1.1.7 (Alpha) Whole Virus can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular applications.



Inactivated SARS-CoV-2 B.1.1.7 Whole Virus (Swab) – Catalog #HE0072NS

Contains six individually packaged lyophilized swabs made with whole inactivated SARS-CoV-2 virus (Isolate SARS-CoV-2 USA/CA_CDC_5574/2020 Lineage B.1.1.7) and inactivated human lung epithelial cells.

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

SARS-CoV-2 B.1.1.7 (Alpha) Whole Virus can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular applications.

Inactivated SARS-CoV-2 B.1.351 Whole Virus (Pellet) – Catalog #HE0073N

Contains five individually packaged lyophilized pellets made with whole inactivated SARS-CoV-2 virus (Isolate SARS-CoV-2 South Africa/KRISP-EC-K005321/2020 Lineage B.1.351) 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
- Not CE Marked



SARS-CoV-2 B.1.351 (Beta) Whole Virus can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular applications.

Inactivated SARS-CoV-2 B.1.351 Whole Virus (Swab) – Catalog #HE0074NS

Contains six individually packaged lyophilized swabs made with whole inactivated SARS-CoV-2 virus (Isolate SARS-CoV-2 South Africa/KRISP-EC-K005321/2020 Lineage B.1.351) and inactivated human lung epithelial cells.

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



SARS-CoV-2 B.1.351 (Beta) Whole Virus 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 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 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 water for rehydration. See website for complete list of targets.



WOMEN'S HEALTH AND STI

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

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
- Not CE Marked

- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Trichomonas vaginalis*

Assayed 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

Assayed 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/kit): *Streptococcus agalactiae*

Negative Control (Six swabs/kit): *Lactobacillus acidophilus*

Bacterial vaginosis (BV) Control Panel - Catalog #8249

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

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

Positive Control (Six pellets/kit):

- *Atopobium vaginae*
- *Gardnerella vaginalis*

Negative Control (Six pellets/kit):

- *Lactobacillus crispatus*



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

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

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

Positive Control 1 (Six pellets/kit):

- *Candida albicans*
- *Candida glabrata*

Positive Control 2 (Six pellets/kit):

- *Trichomonas vaginalis*

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*



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™*



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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*





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



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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 (20 pellets/kit). 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 surrogate, gene target E6/E7
 - HPV 18 surrogate, gene target E6/E7
 - HPV 45 surrogate, gene target E6/E7

Human Papillomavirus (HPV) Control Panel – Catalog #8214



Contains six inactivated, pre-pooled microorganism pellets comprised of the organisms listed below (six pellets/kit). 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 surrogate, gene target E6/E7
 - HPV 18 surrogate, gene target E6/E7
 - HPV 45 surrogate, gene target E6/E7



Multiplex Vaginal Verification Panel – Catalog #8245

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

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

Positive Control 1 (Two swabs/kit):

- *Atopobium vaginae*
- BVAB2 surrogate

Positive Control 2 (Two swabs/kit):

- *Candida albicans*

Positive Control 3 (Two swabs/kit):

- *Candida glabrata*

Positive Control 4 (Two swabs/kit):

- *Trichomonas vaginalis*

Negative Control (Two swabs/kit):

- *Lactobacillus acidophilus*



Multiplex Vaginal Control Panel – Catalog #8255

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

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

Positive Control (Six swabs/kit):

- *Atopobium vaginae*
- BVAB2 surrogate
- *Candida albicans*
- *Candida glabrata*
- *Trichomonas vaginalis*

Negative Control (Six swabs/kit):

- *Lactobacillus acidophilus*

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



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



Rapid Group B Streptococcus (GBS) Control Panel – Catalog #8242

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

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

Positive Control (Six swabs/kit):
 - Group B Streptococcus (*Streptococcus agalactiae*)

Negative Control (Six swabs/kit):
 - *Lactobacillus acidophilus*
 - *Escherichia coli* surrogate for sample adequacy control



Rapid Group B Streptococcus (GBS) Verification Panel – Catalog #8258

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

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

Positive Control (10 swabs/kit):

- Group B Streptococcus (*Streptococcus agalactiae*)

Negative Control (10 swabs/kit):

- *Lactobacillus acidophilus*
- *Escherichia coli* surrogate for sample adequacy control



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*

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 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* – Catalog #HE0035N

- Strain LGV-2-434

Inactivated Herpes Simplex Virus 1 – Catalog #HE0036N

- Strain MacIntyre

Inactivated Herpes Simplex Virus 2 – Catalog #HE0037N

- Strain MS

Inactivated *Neisseria gonorrhoeae* – Catalog #HE0041N

- Strain GL0071

Inactivated *Trichomonas vaginalis* – Catalog #HE0042N

- Strain GL0028

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

- *Chlamydia trachomatis* Strain LGV-2-434

- *Neisseria gonorrhoeae* Strain GL0071

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

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



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

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



Package Details:

Products contain the following:

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

Product Highlights:

- Fully intact, non-viable process controls
- Used for every step of the molecular testing process: from extraction through detection
- Quick-dissolve lyophilized pellets and lyophilized swabs may be reconstituted in buffer or transport medium and processed using the same protocols as the patient sample
- Independent external controls provide accurate, reliable results
- Test-ready format saves you time and money
- Easy and economical room temperature storage
- FDA listed and CE Marked as an *In Vitro* Diagnostic (IVD) Medical Device, except where noted
- Technical Support Experts available for guidance

NEGATIVE CELLULARITY CONTROLS

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 23
HE0052N	Inactivated <i>Borrelia burgdoferi</i>	See page 39
HE0034N	Inactivated <i>Chlamydia pneumoniae</i>	See page 23
HE0035N	Inactivated <i>Chlamydia trachomatis</i>	See page 37
HE0045N	Inactivated <i>Chlamydia trachomatis/Neisseria gonorrhoeae</i> (CT/NG)	See page 37
HE0040N	Inactivated Cytomegalovirus High Control	See page 39
HE0039N	Inactivated Cytomegalovirus Low Control	See page 39
HE0036N	Inactivated Herpes Simplex Virus 1	See page 37
HE0037N	Inactivated Herpes Simplex Virus 2	See page 37
HE0056N	Inactivated Human Papillomavirus 16 (HPV) Cellularity Control	See page 37
HE0057N	Inactivated Human Papillomavirus 18 (HPV) Cellularity Control	See page 37
HE0044N	Inactivated Influenza A/B and Respiratory Syncytial Virus	See page 23
HE0029N	Inactivated Influenza A (H1N1) Virus	See page 23
HE0043N	Inactivated Influenza A (H3N2) Virus	See page 23
HE0030N	Inactivated Influenza B Virus	See page 23
HE0041N	Inactivated <i>Neisseria gonorrhoeae</i>	See page 37
HE0031N	Inactivated Parainfluenza Virus 1	See page 23
HE0032N	Inactivated Parainfluenza Virus 2	See page 23
HE0033N	Inactivated Parainfluenza Virus 3	See page 23
HE0028N	Inactivated Respiratory Syncytial Virus A	See page 23
HE0027N	Inactivated Rotavirus	See page 13
HE0071N	Inactivated SARS-CoV-2 B.1.1.7 Whole Virus (Pellet)	See page 25
HE0072NS	Inactivated SARS-CoV-2 B.1.1.7 Whole Virus (Swab)	See page 26
HE0073N	Inactivated SARS-CoV-2 B.1.351 Whole Virus (Pellet)	See page 26

INACTIVATED HELIX ELITE™ CONTINUED

Catalog Number	Product Description	Full Product Details
HE0074NS	Inactivated SARS-CoV-2 B.1.351 Whole Virus (Swab)	See page 26
HE0065N	Inactivated SARS-CoV-2 Whole Virus (Pellet)	See page 24
HE0066NS	Inactivated SARS-CoV-2 Whole Virus (Swab)	See Page 24
HE0042N	Inactivated <i>Trichomonas vaginalis</i>	See page 37
HE0038N	Inactivated Varicella Zoster Virus	See page 23
HE0059N	Inactivated Zika Virus	See page 39
HE0053NS	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Inactivated Swab	See page 18
HE0054NS	Methicillin-Susceptible <i>Staphylococcus aureus</i> (MSSA) Inactivated Swab	See page 18
HE0055NS	Methicillin-Susceptible <i>Staphylococcus epidermidis</i> (MSSE) Inactivated Swab	See page 18
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 (approximately 100 reactions)
- One vial of molecular 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, except where noted
- Technical Support Experts available for guidance

SYNTHETIC HELIX ELITE™

Catalog Number	Product Description	Full Product Details
HE0013S	Norovirus GI.1 Synthetic RNA	See page 13
HE0012S	Norovirus GII.4 Synthetic RNA	See page 13
HE0060S	SARS-CoV-2 Synthetic RNA (N Gene Targets)	See page 27
HE0061S	SARS-CoV-2 Synthetic RNA (N/E/RdRp/S Gene Targets)	See page 27

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 QC 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 29
8202	BD MAX™ Enteric Parasite 20-Day QC Panel	See page 8
8204	BD MAX™ Enteric Parasite Control Panel	See page 8
8200	Assayed <i>C. difficile</i> /Epi Control Panel	See page 15
8188	Assayed CT/NG Control Panel	See page 29
8194	Assayed GBS LB Control Panel	See page 29
8195	Assayed MRSA NxG Control Panel	See page 15
8196	Assayed SA Nasal Complete Control Panel	See page 15
8199	Assayed Respiratory Control Panel	See page 20

SYNDROME-SPECIFIC QC SETS AND PANELS

Catalog Number	Product Description	Full Product Details
8249	Bacterial vaginosis (BV) Control Panel	See page 30
8254	Blood Culture Identification Control Panel (43 Targets)	See page 4
8227	<i>C. difficile</i> Control Panel (Inactivated Swab)	See page 16
8171	<i>C. difficile</i> QC Set (Live Culture)	See page 16
8243	<i>C. difficile</i> Verification Panel (Live Culture)	See page 16
8250	<i>Candida vaginitis/Trichomonas vaginalis</i> (CV/TV) Control Panel	See page 30
8187	Carbapenem-resistant <i>Enterobacteriaceae</i> (CRE) Control Panel (Inactivated Swab)	See page 17
8229	<i>Chlamydia trachomatis/Neisseria gonorrhoeae</i> (CT/NG) Control Panel (Inactivated Swab)	See page 31
8228	CT/GC/TV Control Panel (Inactivated Pellet)	See page 31
8231	Comprehensive Enteric Bacterial Control Panel (Inactivated Pellet)	See page 11
8179	Enteric Bacterial Organism Set (Live Culture)	See page 9
8230	Enteric Parasite Control Panel (Inactivated Pellet)	See page 9
8184	Enteric Pathogens Control Panel (Inactivated Pellet)	See page 10
8211	Enteric Viral Control Panel	See page 10
8210	Enteric Viral Verification Panel	See page 10
8190	Enterovirus (EV) Control Panel (Inactivated Swab)	See page 20
8191	Extended Enteric Bacterial Verification Panel (Inactivated Pellet)	See page 11
8246	Flu/RSV/SARS-CoV-2 Control Panel (Inactivated Swab)	See page 21
8236	Gastrointestinal (22 Targets) Control Panel (Inactivated Pellet)	See page 12
8219	Group A <i>Streptococcus</i> (GAS) Control Panel (Inactivated Swab)	See page 20
8232	Group B <i>Streptococcus</i> (GBS) Control Panel (Inactivated Swab)	See page 31
8164	GBS QC Set (Live Culture)	See page 32
8181	Gram-Negative Blood Culture Control Panel (Inactivated Pellet)	See page 6
8180	Gram-Positive Blood Culture Control Panel (Inactivated Pellet)	See page 5

SYNDROME-SPECIFIC QC SETS AND PANELS CONTINUED

Catalog Number	Product Description	Full Product Details
8214	Human Papillomavirus (HPV) Control Panel	See page 32
8216	Human Papillomavirus (HPV) Verification Panel	See page 32
8245	Multiplex Vaginal Verification Panel	See page 33
8255	Multiplex Vaginal Control Panel	See page 33
8174	MRSA Organism Set (Live Culture)	See page 17
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
8242	Rapid Group B <i>Streptococcus</i> (GBS) Control Panel	See page 34
8258	Rapid Group B <i>Streptococcus</i> (GBS) Verification Panel	See page 35
8205	Norovirus Control Panel (Inactivated Swab)	See page 12
8178	SA Organism Set (Live Culture)	See page 17
	Live Culture Staphylococcus Controls	See page 18
8247	Respiratory Control Panel (22 Targets)	See page 21
8238	Rifampicin-Resistant <i>Mycobacterium tuberculosis</i> Negative Control (Inactivated Pellet)	See page 22
8206	Rifampicin-Resistant <i>Mycobacterium tuberculosis</i> Positive Control Panel (Inactivated Pellet)	See page 22
8173	GBS Verification Panel (Live Culture)	See page 31
8189	<i>Trichomonas vaginalis</i> (TV) Control Panel (Inactivated Swab)	See page 35
8209	Vaginal Control Panel	See page 36
8208	Vaginal Verification Panel	See page 36
8203	Vancomycin Resistant <i>Enterococcus</i> (VRE) Control Panel (Inactivated Swab)	See page 18

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