



# MICROBIOLOGY CONTROL PRODUCTS

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MOLECULAR QC MICROORGANISMS

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# 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 PANELS



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

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

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

- *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*

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

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

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

### Pool 1 (One pellet/kit)

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

### Pool 2 (One pellet/kit)

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

### Pool 3 (One pellet/kit)

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

# BLOOD CULTURE IDENTIFICATION PANELS

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

Contains two 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 *Enterobacter cloacae* subsp. *cloacae* derived from ATCC® 13047™\*
- 0959 *Enterococcus faecalis* derived from ATCC® 51299™\* (vanB positive, resistant to vancomycin)
- 0681 *Escherichia coli* derived from ATCC® 11229™\*
- 0441 *Haemophilus influenzae* derived from ATCC® 10211™\* (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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# BLOOD CULTURE IDENTIFICATION PANELS

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

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

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



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# 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*

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## 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*

### Pool 5 (Five pellets/kit)

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

### Pool 6 (Five pellets/kit)

- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Proteus vulgaris*

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

Contains two 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







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

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## BD MAX™ Enteric Parasite Control Panel – Catalog #8204

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

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



# GASTROINTESTINAL PANELS

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

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

- Export license required for shipping outside the U.S.
  - UN2814 Hazardous
- 0356 *Shigella flexneri* derived from ATCC® 12022™\*
  - 0363 *Salmonella enterica* subsp. *enterica* serovar *Typhimurium* derived from ATCC® 14028™
  - 0446 *Shigella sonnei* derived from ATCC® 9290™\*
  - 0481 *Campylobacter jejuni* subsp. *jejuni* derived from ATCC® 33291™\*
  - 0595 *Salmonella bongori* derived from ATCC® 43975™\*
  - 01023 *Campylobacter coli* derived from ATCC® 33559™\*
  - 01102 *Escherichia coli* serotype O111:H8 derived from CDC 2010C-3114 (STEC)
  - 01204 *Escherichia coli* (O157:H7) derived from ATCC® 43890™\* (STEC)



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## Enteric Parasite Verification Panel (Synthetic) – Catalog #8182

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

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

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

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

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

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





## 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
- Recombinant Norovirus GII.4

### 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
- Recombinant Astrovirus
- Recombinant Norovirus GI
- Rotavirus
- Recombinant Sapovirus



## 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
- Recombinant Astrovirus
- Recombinant Norovirus GI
- 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 pellets/kit total).

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

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

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

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

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

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



# 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):

- Recombinant Norovirus GI.1 (ORF1-ORF2)
- Recombinant Norovirus GI.4 (ORF1-ORF2)

Negative Control (Six swabs/kit):

- Rotavirus

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

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

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

Positive Control 1 (Six pellets/kit)

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

Positive Control 2 (Six pellets/kit)

- *Salmonella Typhimurium*
- *Vibrio cholerae*
- *Escherichia coli* (EPEC)
- *Escherichia coli* (ETEC)
- *Cyclospora cayetanensis* surrogate
- *Entamoeba histolytica* surrogate
- *Giardia lamblia*
- Astrovirus surrogate
- Norovirus GI surrogate
- Norovirus GI.4 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

- Room temperature storage
- Medium-high titer
- For *in vitro* diagnostic use
- 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 (approximately 100 reactions), and one vial of molecular standard water for rehydration.

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



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

Contains six positive and six negative inactivated control swabs (12 swabs total) comprised of the organisms recommended by the manufacturer for QC. For use with 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*



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## Cepheid Xpert® MRSA NxG Control Panel – Catalog #8195

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

Positive Control (Six swabs):

- Methicillin-resistant *Staphylococcus aureus*

Negative Control (Six swabs):

- *Staphylococcus epidermidis*

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

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

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

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*

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

# 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.

Positive Control (Six swabs/kit):  
- *Clostridioides difficile*

Negative Control (Six swabs/kit):  
- *Clostridium sordellii*

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



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

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



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# SYNDROME-SPECIFIC PANELS FOR HAI TESTING

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

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

### Positive Control (Six swabs/kit):

- *Escherichia coli* derived from NCTC 13476 (IMP-type)
- *Klebsiella pneumoniae* derived from NCTC 13440 (VIM-1, Metallo-beta-lactamase positive)
- *Klebsiella pneumoniae* derived from NCTC 13443 (DM-1 positive, New Delhi metallo-beta-lactamase)
- *Klebsiella pneumoniae* derived from NCTC 13438 (Produces carbapenemase KPC-3)
- *Klebsiella pneumoniae* derived from NCTC 13442 (OXA-48)

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

### Negative Control (Six swabs/kit):

- *Escherichia coli* derived from NCTC 11954



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## 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



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

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

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

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

Negative Control (Six swabs/kit): *Enterococcus faecalis*



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

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

Room temperature storage | International restrictions may apply

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

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

Room temperature storage | International restrictions may apply

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

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

Room temperature storage | International restrictions may apply





# RESPIRATORY PATHOGENS

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

# ASSAY-SPECIFIC PANELS FOR RESPIRATORY TESTING

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

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

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

Positive Control (Six swabs/kit):

- Influenza A (H1N1) Virus
- Influenza A (H3H2) Virus
- Influenza B Virus
- Respiratory Syncytial Virus A

Negative Control (Six swabs/kit): Coxsackievirus B1



# SYNDROME-SPECIFIC PANELS FOR RESPIRATORY TESTING

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

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

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

Positive Control (Six swabs/kit): Coxsackievirus B1

Negative Control (Six swabs/kit): Rhinovirus 1B



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

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

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

Positive Control (Six swabs/kit): *Streptococcus pyogenes*

Negative Control (Six swabs/kit): *Streptococcus dysgalactiae*



## Respiratory (21 Targets) Control Panel – Catalog #8217

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

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

- Adenovirus Type 6
- *Bordetella parapertussis*
- *Bordetella pertussis*
- *Chlamydia pneumoniae*
- Coronavirus 229E
- 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

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## Respiratory (4 Targets) Control Panel (Inactivated Swab) – Catalog #8233

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

### Negative Control (Six swabs/kit):

- Coxsackievirus B1



## 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 Enterovirus D68 – Catalog #HE0050N



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

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

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

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

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### 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. Each kit also contains five vials of molecular standard water for rehydration.

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

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





### SARS-CoV-2 Process Control (Pellet) – Catalog #HE00625

Contains five individually packaged lyophilized pellets made with RNA transcripts containing diagnostically relevant targets (CDC and WHO consensus sequences) encapsulated in a phage protein and human lung epithelial cells. See website for complete list of targets. Each kit also contains five vials of molecular standard water for rehydration.

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

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

### SARS-CoV-2 Process Control (Swab) – Catalog #HE00635

Contains five individually packaged inactivated lyophilized swabs made with RNA transcripts containing diagnostically relevant targets (CDC and WHO consensus sequences) encapsulated in a phage protein and human lung epithelial cells. See website for complete list of targets.

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

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





## Synthetic Helix Elite Molecular Standards

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

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

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

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

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

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



# WOMEN'S HEALTH AND STI

Your laboratory is committed to elevating the standard of care for women's health and sexually transmitted infections (STIs) with advanced diagnostic technologies. When it comes to QC testing your rapid diagnostic assays, you should expect the same level of quality. Microbiologics offers a variety of controls for women's health and STI testing featuring room temperature storage, 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

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

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

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

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## Cepheid Xpert® GBS LB Control Panel – Catalog #8194

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

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

Positive Control (Six swabs): *Streptococcus agalactiae*

Negative Control (Six swabs): *Lactobacillus acidophilus*

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

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

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

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



**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™\*



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

**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™\*



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



### Human Papillomavirus (HPV) Verification Panel – Catalog #8216

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

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

- HPV 16 gene target E6/E7
- HPV 18 gene target E6/E7
- HPV 45 gene target E6/E7



### Human Papillomavirus (HPV) Control Panel – Catalog #8214

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

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

- HPV 16 gene target E6/E7
- HPV 18 gene target E6/E7
- HPV 45 gene target E6/E7



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

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

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

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



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

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

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

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



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

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

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

Positive Control (Six pellets/kit):  
- *Mycoplasma genitalium*

Negative Control (Six pellets/kit):  
- Blank pellet



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

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

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

Positive Control (Six swabs/kit):

- *Trichomonas vaginalis*
- Human cells

Negative Control (Six swabs/kit):

- *Neisseria gonorrhoeae*
- Human cells



**Vaginal Verification Panel – Catalog #8208**

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

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

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

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

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

Pool 4 (20 pellets/kit)  
- *Atopobium vaginae*  
- *Gardnerella vaginalis*  
- Recombinant BVAB2  
- *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*  
- Recombinant BVAB2  
- *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 Neisseria gonorrhoeae – Catalog #HE0041N

- Strain GL0071

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

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

- Chlamydia trachomatis Strain LGV-2-434

- Neisseria gonorrhoeae Strain GL0071

### Inactivated Herpes Simplex Virus 2 – Catalog #HE0037N

- Strain MS

### Inactivated Trichomonas vaginalis – Catalog #HE0042N

- Strain GL0028

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

### Negative Cellularity Control (Inactivated Pellet) – Catalog #HE0058N

- A549 lung epithelial cells



## Synthetic Helix Elite Molecular Standards

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

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

### Human papillomavirus 16 Synthetic DNA – Catalog #HE0046S

- Fragments of E6, E7 and L1 genes

### Human papillomavirus 18 Synthetic DNA – Catalog #HE0048S

- Fragments of E6, E7 and L1 genes

### Treponema pallidum Synthetic DNA – Catalog #HE0047S

- Fragments of 47 kDa protein and DNA Polymerase I genes



# EMERGING DISEASES AND OTHER PATHOGENS

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



## Inactivated Helix Elite Molecular Standards

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

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

### Inactivated Cytomegalovirus High Control – Catalog #HE0040N

- AD-169

### Inactivated Cytomegalovirus Low Control – Catalog #HE0039N

- AD-169

### Inactivated Cryptosporidium and Giardia – Catalog #HE0049N

- *Giardia lamblia* (Strain H3)

- *Cryptosporidium parvum* (Strain Iowa)

### Inactivated *Borrelia burgdorferi* – Catalog #HE0052N



## Synthetic Helix Elite Molecular Standards

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

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

### *Cryptosporidium hominis* Synthetic DNA – Catalog #HE0001S

- 18S rRNA gene of *Cryptosporidium hominis* | Dried DNA Preserved with Biomatrix DNASTable®

### *Cryptosporidium parvum* Synthetic DNA – Catalog #HE0002S

- 18S rRNA gene of *Cryptosporidium parvum* | Dried DNA Preserved with Biomatrix DNASTable®

### *Cyclospora cayentanensis* Synthetic DNA – Catalog #HE0025S

- 18S rRNA gene of *Cyclospora cayentanensis* | Dried DNA Preserved with Biomatrix DNASTable®

### *Dientamoeba fragilis* Synthetic DNA – Catalog #HE0015S

- 18S rRNA gene of *Dientamoeba fragilis* | Dried DNA Preserved with Biomatrix DNASTable®

### Eastern Equine Encephalitis Virus Synthetic RNA – Catalog #HE0016S

- Fragments from the NSP3 gene, the capsid protein gene, and the E2 glycoprotein gene | Dried RNA Preserved with Biomatrix RNASTable® | Export license required for shipping outside U.S.



## Synthetic Helix Elite Molecular Standards

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

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

### **Encephalitozoon intestinalis Synthetic DNA – Catalog #HE0004S**

- 18S rRNA gene of *Encephalitozoon intestinalis* | Dried DNA Preserved with Biomatrix DNASTable®

### **Entamoeba dispar Synthetic DNA – Catalog #HE0007S**

-18S rRNA gene of *Entamoeba dispar* | Dried DNA Preserved with Biomatrix DNASTable®

### **Entamoeba histolytica Synthetic DNA – Catalog #HE0006S**

- 18S rRNA gene of *Entamoeba histolytica* | Dried DNA Preserved with Biomatrix DNASTable®

### **Enterocytozoon bieneusi Synthetic DNA – Catalog #HE0003S**

- 18S rRNA gene of *Enterocytozoon bieneusi* | Dried DNA Preserved with Biomatrix DNASTable®

### **Giardia lamblia Synthetic DNA – Catalog #HE0005S**

- 18S rRNA gene of *Giardia lamblia* | Dried DNA Preserved with Biomatrix DNASTable®

### **Plasmodium malariae Synthetic DNA – Catalog #HE0011S**

- 18S rRNA A-type gene of *Plasmodium malariae* | Dried DNA Preserved with Biomatrix DNASTable®

### **Plasmodium ovale Synthetic DNA – Catalog #HE0010S**

- 18S rRNA gene of asexual *Plasmodium ovale* | Dried DNA Preserved with Biomatrix DNASTable®

### **Plasmodium falciparum Synthetic DNA – Catalog #HE0008S**

- 18S rRNA gene of asexual *Plasmodium falciparum* | Dried DNA Preserved with Biomatrix DNASTable®

### **Plasmodium vivax Synthetic DNA – Catalog #HE0009S**

- 18S rRNA gene of asexual *Plasmodium vivax* | Dried DNA Preserved with Biomatrix DNASTable®

### **West Nile Virus Synthetic RNA – Catalog #HE0014S**

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

# HELIX|ELITE™

MOLECULAR STANDARDS

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. Inactivated, Full Process Controls for Molecular Assays



## Package Details:

Products contain the following:

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

## 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 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

## INACTIVATED HELIX ELITE™

Catalog Number	Product Description	Full Product Details
HE0026N	Inactivated Adenovirus 2	See page 25
HE0052N	Inactivated <i>Borrelia burgdorferi</i>	See page 37
HE0034N	Inactivated <i>Chlamydia pneumoniae</i>	See page 25
HE0035N	Inactivated <i>Chlamydia trachomatis</i>	See page 35
HE0045N	Inactivated <i>Chlamydia trachomatis/Neisseria gonorrhoeae</i> (CT/NG)	See page 35
HE0049N	Inactivated <i>Cryptosporidium</i> and <i>Giardia</i>	See page 37
HE0040N	Inactivated Cytomegalovirus High Control	See page 37
HE0039N	Inactivated Cytomegalovirus Low Control	See page 37
HE0050N	Inactivated Enterovirus D68	See page 25
HE0036N	Inactivated Herpes Simplex Virus 1	See page 35
HE0037N	Inactivated Herpes Simplex Virus 2	See page 35
HE0056N	Inactivated Human Papillomavirus 16 (HPV) Cellularity Control	See page 35
HE0057N	Inactivated Human Papillomavirus 18 (HPV) Cellularity Control	See page 35
HE0044N	Inactivated Influenza A/B and Respiratory Syncytial Virus	See page 25
HE0029N	Inactivated Influenza A (H1N1) Virus	See page 25
HE0043N	Inactivated Influenza A (H3N2) Virus	See page 25
HE0030N	Inactivated Influenza B Virus	See page 25
HE0058N	Inactivated Negative Cellularity Control	See page 35
HE0041N	Inactivated <i>Neisseria gonorrhoeae</i>	See page 35
HE0031N	Inactivated Parainfluenza Virus 1	See page 25
HE0032N	Inactivated Parainfluenza Virus 2	See page 25
HE0033N	Inactivated Parainfluenza Virus 3	See page 25
HE0028N	Inactivated Respiratory Syncytial Virus A	See page 25
HE0027N	Inactivated Rotavirus	See page 15
HE0065N	Inactivated SARS-CoV-2 Whole Virus (Pellet)	See page 26



## INACTIVATED HELIX ELITE™ CONTINUED

Catalog Number	Product Description	Full Product Details
HE0066NS	Inactivated SARS-CoV-2 Whole Virus (Swab)	See Page 26
HE0042N	Inactivated <i>Trichomonas vaginalis</i>	See page 35
HE0038N	Inactivated Varicella Zoster Virus	See page 25
HE0053NS	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Inactivated Swab	See page 20
HE0054NS	Methicillin-Susceptible <i>Staphylococcus aureus</i> (MSSA) Inactivated Swab	See page 20
HE0055NS	Methicillin-Susceptible <i>Staphylococcus epidermidis</i> (MSSE) Inactivated Swab	See page 20

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 standard water for rehydration
- Instructions for Use
- Certificate of Analysis

## Product Highlights:

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

## SYNTHETIC HELIX ELITE™

Catalog Number	Product Description	Full Product Details
HE0001S	<i>Cryptosporidium hominis</i> Synthetic DNA	See page 37
HE0002S	<i>Cryptosporidium parvum</i> Synthetic DNA	See page 37
HE0025S	<i>Cyclospora cayetanensis</i> Synthetic DNA	See page 37
HE0015S	<i>Dientamoeba fragilis</i> Synthetic DNA	See page 37
HE0016S	Eastern Equine Encephalitis Virus Synthetic RNA	See page 37
HE0004S	<i>Encephalitozoon intestinalis</i> Synthetic DNA	See page 38
HE0007S	<i>Entamoeba dispar</i> Synthetic DNA	See page 38
HE0006S	<i>Entamoeba histolytica</i> Synthetic DNA	See page 38
HE0003S	<i>Enterocytozoon bieneusi</i> Synthetic DNA	See page 38
HE0005S	<i>Giardia lamblia</i> Synthetic DNA	See page 38
HE0046S	Human papillomavirus 16 Synthetic DNA	See page 35
HE0048S	Human papillomavirus 18 Synthetic DNA	See page 35
HE0013S	Norovirus GI.1 Synthetic RNA	See page 15
HE0012S	Norovirus GII.4 Synthetic RNA	See page 15
HE0008S	<i>Plasmodium falciparum</i> Synthetic DNA	See page 38
HE0011S	<i>Plasmodium malariae</i> Synthetic DNA	See page 38
HE0010S	<i>Plasmodium ovale</i> Synthetic DNA	See page 38
HE0009S	<i>Plasmodium vivax</i> Synthetic DNA	See page 38
HE0060S	SARS-CoV-2 Synthetic RNA (N Gene Targets)	See page 28
HE0061S	SARS-CoV-2 Synthetic RNA (N/E/RdRp/S Gene Targets)	See page 28
HE0062s	SARS-CoV-2 Process Control (Pellet)	See page 27
HE0063S	SARS-CoV-2 Process Control (Swab)	See page 27
HE0047S	<i>Treponema pallidum</i> Synthetic DNA	See page 35
HE0014S	West Nile Virus Synthetic RNA	See page 38

# 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 30
8202	BD MAX™ Enteric Parasite 20-Day QC Panel	See page 10
8204	BD MAX™ Enteric Parasite Control Panel	See page 10
8200	Cepheid Xpert® C. difficile/Epi Control Panel (Inactivated Swab)	See page 17
8188	Cepheid Xpert® CT/NG Control Panel (Inactivated Swab)	See page 30
8194	Cepheid Xpert® GBS LB Control Panel (Inactivated Swab)	See page 30
8195	Cepheid Xpert® MRSA NxG Control Panel (Inactivated Swab)	See page 17
8196	Cepheid Xpert® Nasal Control Panel (Inactivated Swab)	See page 17
8199	Cepheid Xpert® Respiratory Control Panel (Inactivated Swab)	See page 22

## SYNDROME-SPECIFIC QC SETS AND PANELS

Catalog Number	Product Description	Full Product Details
8215	Blood Culture Identification (BCID) Control Panel (Inactivated)	See page 4
8201	Blood Culture Identification (BCID) Verification Panel (Inactivated)	See page 4
5229P	Blood Culture Identification (BCID) Verification Panel (Live Culture)	See page 5
5258P	Blood Culture Identification 2 (BCID2) Verification Panel (Live Culture)	See page 6
8227	<i>C. difficile</i> Control Panel (Inactivated Swab)	See page 18
8171	<i>C. difficile</i> QC Set (Live Culture)	See page 18
8187	Carbapenem-resistant Enterobacteriaceae (CRE) Control Panel (Inactivated Swab)	See page 19
8229	Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) Control Panel (Inactivated Swab)	See page 31
8228	CT/GC/TV Control Panel (Inactivated Pellet)	See page 31
8231	Comprehensive Enteric Bacterial Control Panel (Inactivated Pellet)	See page 13
8179	Enteric Bacterial Organism Set (Live Culture)	See page 11
8230	Enteric Parasite Control Panel (Inactivated Pellet)	See page 11
8182	Enteric Parasite Verification Panel (Synthetic)	See page 11
8184	Enteric Pathogens Control Panel (Inactivated Pellet)	See page 12
8211	Enteric Viral Control Panel	See page 12
8210	Enteric Viral Verification Panel	See page 12
8190	Enterovirus (EV) Control Panel (Inactivated Swab)	See page 22
8191	Extended Enteric Bacterial Verification Panel (Inactivated Pellet)	See page 13
8236	Gastrointestinal (22 Targets) Control Panel (Inactivated Pellet)	See page 14
8219	Group A Streptococcus (GAS) Control Panel (Inactivated Swab)	See page 22
8232	Group B Streptococcus (GBS) Control Panel (Inactivated Swab)	See page 31
8164	GBS QC Set (Live Culture)	See page 32

## SYNDROME-SPECIFIC QC SETS AND PANELS CONTINUED

Catalog Number	Product Description	Full Product Details
8181	Gram-Negative Blood Culture Control Panel (Inactivated Pellet)	See page 7
5226P	Gram-Negative Blood Culture Control Panel (Live Culture)	See page 7
8180	Gram-Positive Blood Culture Control Panel (Inactivated Pellet)	See page 8
5225P	Gram-Positive Blood Culture Control Panel (Live Culture)	See page 8
8214	Human Papillomavirus (HPV) Control Panel	See page 32
8216	Human Papillomavirus (HPV) Verification Panel	See page 32
8174	MRSA Organism Set (Live Culture)	See page 19
8234	Multi-Strain Human Papillomavirus (HPV) Control Panel (Inactivated Pellet)	See page 33
8235	Multi-Strain Human Papillomavirus (HPV) Verification Panel (Inactivated Pellet)	See page 33
8240	Mycoplasma genitalium Control Panel (Inactivated Pellet)	See page 40
8205	Norovirus Control Panel (Inactivated Swab)	See page 14
8178	SA Organism Set (Live Culture)	See page 19
	Live Culture Staphylococcus Controls	See page 20
8217	Respiratory (21 Targets) Controls Panel	See page 23
8238	Rifampicin-Resistant Mycobacterium tuberculosis Negative Control (Inactivated Pellet)	See page 24
8206	Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet)	See page 24
8173	GBS Verification Panel (Live Culture)	See page 31
8189	Trichomonas vaginalis (TV) Control Panel (Inactivated Swab)	See page 34
8209	Vaginal Control Panel	See page 34
8208	Vaginal Verification Panel	See page 34
8203	Vancomycin Resistant Enterococcus (VRE) Control Panel (Inactivated Swab)	See page 20