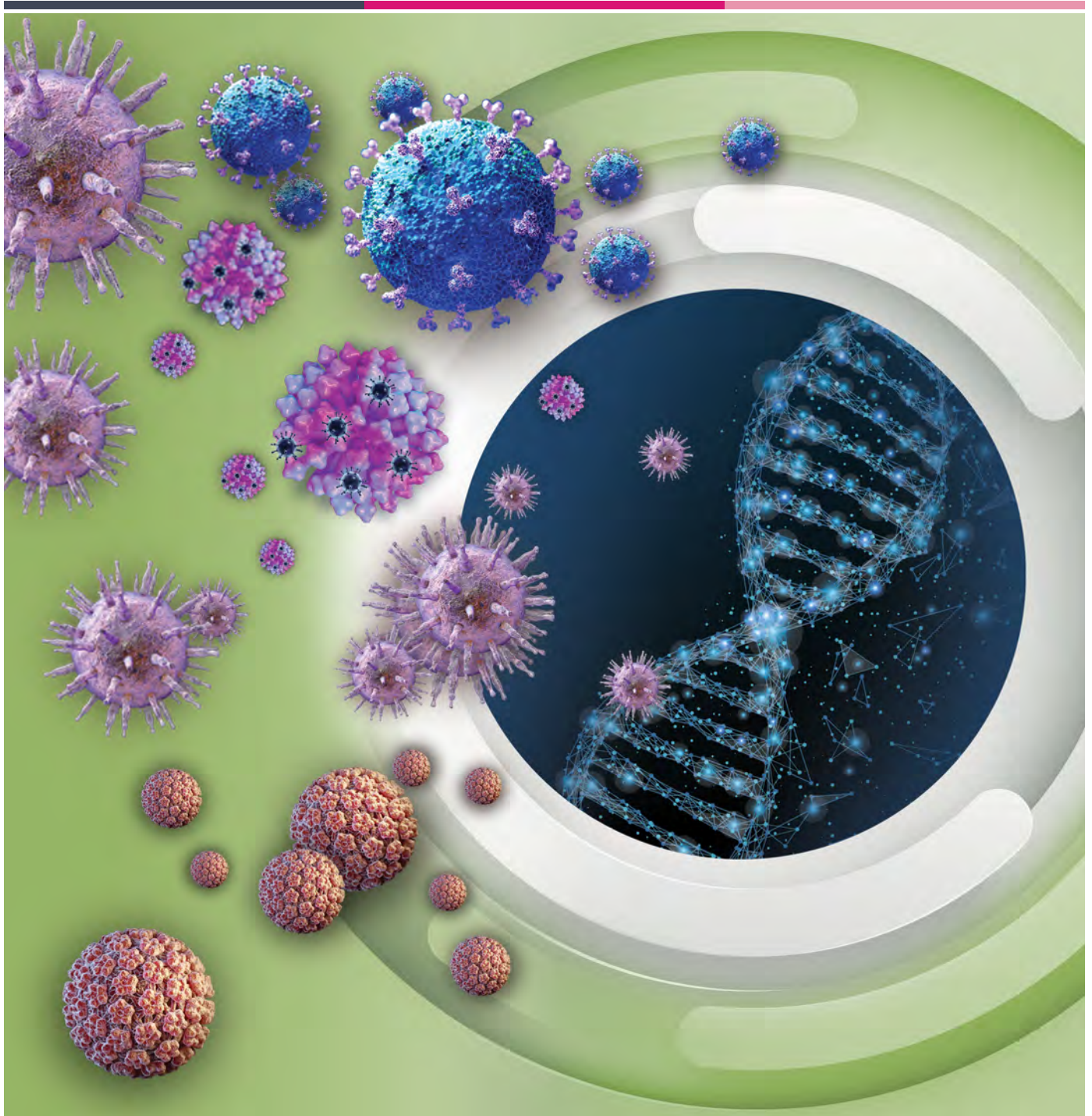


# Exact Diagnostics Quality Controls and Panels

Setting a new standard in molecular lab performance. Together.



## Setting A New Standard In Molecular Lab Performance. Together.

With our expertise designing molecular standards and quality controls, and the power of data management, we are helping you to advance the field of molecular diagnostics by driving quality and care.

You represent a fast-growing, rapidly adapting segment in the diagnostics area that is driving modern molecular medicine.

We understand that maintaining quality is your top priority and it can be challenging and time consuming. That's why we are partnering with you to elevate your understanding, bolster your progress, and help you do even more groundbreaking work.

**Together, we have the ability for quality control, data management, and the advanced science of molecular diagnostics to drive confidence and exceptional quality to patient care.**



Molecular Diagnostics



Quality Control



QC Data Management

# Exact Diagnostics Quality Controls and Panels for Infectious Disease



**Patient-like Commutability**  
with simulation of patient specimens through extractable & inactivated whole organisms in high-quality matrices



**Standardization of Results**  
across laboratories through calibration to WHO International Standards (where applicable)



**Independent Monitoring**  
of assay performance through long shelf-lives overlapping multiple assay reagent lots & assay-independent manufacturing



**Consistency**  
through lot-to-lot reproducibility & concentration trueness using absolute quantification by droplet digital PCR (ddPCR)



**Unity QC Data Management Ecosystem**  
for automated real-time result monitoring, QC rules customization & peer-grouping comparison

## Ensuring Reliable Patient Results

## Molecular Quality Controls and Panels

Elevating performance by delivering traceability, commutability, and absolute quantification by droplet digital PCR (ddPCR) to high-impact molecular testing.

	Verification Panels and Bundles	Daily Run Controls
<b>Applications</b>	<p>Used to establish or verify performance characteristics</p> <ul style="list-style-type: none"> <li>Reportable Range</li> <li>Limit of Detection</li> <li>Limits of Quantification</li> <li>Precision</li> <li>Cut-off</li> <li>Carry-over</li> </ul> <p>Used to construct calibration curves</p> <p>Used to train and to determine proficiency of laboratory operators</p>	<p>Used to monitor intra- and inter-run performance</p> <ul style="list-style-type: none"> <li>Run-to-run, day-to-day, lot-to-lot, instrument-to-instrument and operator-to-operator</li> </ul>
<b>Consists of</b>	Multiple Levels	High, Low and Negative Controls
<b>Uses</b>	Qualitative and Quantitative Assays	
<b>Assay Type</b>	IVD and LDT	

Verification & Validation

Quality Control



## Exact Diagnostics Adenovirus



- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
ADVL101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
ADVH102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panel</b>			
ADVP100	Verification Panel . . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analyte

Inactivated Adenovirus

### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)

See Page 13 for Bulk Urine Negative Control (Cat# 12019386)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5
ADVP100	200 cp/mL	2,000 cp/mL	20,000 cp/mL	200,000 cp/mL	2,000,000 cp/mL

## Exact Diagnostics BKV



- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- Calibrated against the 1st WHO International Standard for BK Virus
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
BKVL101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
BKVH102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b>			
BKVP100	Verification Panel . . . . .	6 x 1.0 mL	IVD, CE-IVD
BKVP200	Verification Panel . . . . .	.6 x 1.4 mL	IVD
BKVL201	1E3 IU/mL Precision . . . . .	.9 x 1.4 mL	IVD
BKVH202	5E5 IU/mL Precision . . . . .	.9 x 1.4 mL	IVD
BKVL0D	BKV LOD . . . . .	10 x 1.0 mL	IVD
BKVUL0D	BKV Urine LOD . . . . .	10 x 1.4 mL	IVD
<b>Verification Bundle</b>			
BKVB201	Verification Bundle . . . . .	BKVP200 (4 kits), BKVL201 (2 kits), BKVH202 (2 kits), BKVL0D (2 kits), BKVUL0D (2 kits)	

### Analyte

Inactivated BKV

### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)

See Page 13 for Bulk Urine Negative Control (Cat# 12019386)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5	Panel Member 6
BKVP100	200 IU/mL	2,000 IU/mL	20,000 IU/mL	200,000 IU/mL	2000,000 IU/mL	20,000,000 IU/mL
BKVP200	100 IU/mL	2,000 IU/mL	20,000 IU/mL	200,000 IU/mL	2000,000 IU/mL	20,000,000 IU/mL

Refer to myelinserts.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.

## Exact Diagnostics Parvovirus B19



- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- Calibrated against the 3rd WHO International Standard for Parvovirus B19 (12/208)
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 2 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
B19L101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
B19H102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panel</b>			
B19P100	Verification Panel . . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analyte

Inactivated Parvovirus B19

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5
B19P100	500 IU/mL	5,000 IU/mL	50,000 IU/mL	500,000 IU/mL	5,000,000 IU/mL

## Exact Diagnostics CMV



- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- Calibrated against the 1st WHO International Standard for Cytomegalovirus (09/162)
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
CMVL101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
CMVH102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b>			
CMVP100	Verification Panel . . . . .	.6 x 1.4 mL	IVD
CMVP200	Verification Panel . . . . .	.6 x 1.4 mL	IVD
CMVL201	1E3 IU/mL Precision . . . . .	.9 x 1.4 mL	IVD
CMVH202	5E5 IU/mL Precision . . . . .	.9 x 1.4 mL	IVD
CMVLOD	CMV LOD . . . . .	10 x 1.0 mL	IVD
<b>Verification Bundle</b>			
CMVB200	Verification Bundle . . .	CMVP200 (4 kits), CMVL201 (2 kits), CMVH202 (2 kits), CMVLOD (2 kits)	

### Analyte

Inactivated CMV

### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)  
See Page 13 for Bulk Urine Negative Control (Cat# 12019386)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5	Panel Member 6
CMVP100	400 IU/mL	4,000 IU/mL	40,000 IU/mL	400,000 IU/mL	4,000,000 IU/mL	N/A
CMVP200	200 IU/mL	400 IU/mL	4,000 IU/mL	40,000 IU/mL	400,000 IU/mL	4,000,000 IU/mL

## Exact Diagnostics EBV



- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- Calibrated against the 1st WHO International Standard for Epstein-Barr virus (09/260)
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
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#### Run Controls

EBVL101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
EBVH102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD

#### Panels

EBVP100	Verification Panel . . . . .	5 x 1.0 mL	IVD, CE-IVD
EBVP200	Verification Panel . . . . .	7 x 1.4 mL	IVD
EBVL201	1E3 IU/mL Precision . . . . .	9 x 1.4 mL	IVD
EBVH202	5E5 IU/mL Precision . . . . .	9 x 1.4 mL	IVD
EBVL0D	EBV LOD . . . . .	10 x 1.0 mL	IVD

#### Verification Bundle

EBVB200	Verification Bundle . . .	EBVP200 (4 kits), EBVL201 (2 kits), EBVH202 (2 kits), EBVL0D (2 kits)	
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### Analyte

Inactivated EBV

#### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5	Panel Member 6	Panel Member 7
EBVP100	500 IU/mL	5,000 IU/mL	50,000 IU/mL	500,000 IU/mL	5,000,000 IU/mL		
EBVP100	100 IU/mL	500 IU/mL	5,000 IU/mL	50,000 IU/mL	500,000 IU/mL	5,000,000 IU/mL	50,000,000 IU/mL

## Exact Diagnostics HHV-6



- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- Calibrated against the 1st WHO International Standard for HHV-6B (15/266)
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 2 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
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#### Run Controls

HV6L101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
HV6H102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD

#### Panels

HV6AP100	Verification Panel	5 x 1.0 mL	IVD, CE-IVD
HV6BP100	Verification Panel	5 x 1.0 mL	IVD, CE-IVD

### Analytes

Inactivated HHV-6A

Inactivated HHV-6B

#### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5
HV6AP100	500 cp/mL	5,000 cp/mL	50,000 cp/mL	500,000 cp/mL	5,000,000 cp/mL
HV6BP100	500 cp/mL	5,000 cp/mL	50,000 cp/mL	500,000 cp/mL	5,000,000 cp/mL

Refer to myInserTs.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.

# Transplantation

## Exact Diagnostics JCV



- Calibrated against the 1st WHO International Standard for JC Virus (14/114)
- Manufacturing targets established using ddPCR
- Verification Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 2 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
JCVL101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
JCVH102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b>			
JCVP100	Verification Panel . . . . .	6 x 1.0 mL	IVD, CE-IVD

### Analytes

Inactivated JCV

### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)

See Page 13 for Bulk Urine Negative Control (Cat# 12019386)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5	Panel Member 6
JCVP100	200 IU/mL	2,000 IU/mL	20,000 IU/mL	200,000 IU/mL	2,000,000 IU/mL	20,000,000 IU/mL

# Sexually-Transmitted Infections

## Exact Diagnostics CT/NG



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- Run Control has 30 day open vial stability when stored at 2-8°C
- Barcoded vials compatible with automated platforms

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
CTNGPOS	Low Run Control . . . . .	6 x 1.1 mL	IVD
<b>Panels</b>			
CTNGP200	Verification Panel. . . . .	9 x 1.0 mL	IVD
<b>Verification Bundle</b>			
CTNGB200	Verification Bundle . . . . .	CTNGP200 (5 kits)	

### Analytes

*Chlamydia trachomatis* (CT)

*Neisseria gonorrhoeae* (NG)

### Complementary product:

See page 12 for STI Negative Run Control (Cat# NEGSTI)

See Page 13 for Bulk Urine Negative Control (Cat# 12019386)

Catalog #	Panel Members		
CTNGP200	CT (3X LOD)	CT (5X LOD)	CT (10X LOD)
	NG (3X LOD)	NG (5X LOD)	NG (10X LOD)
	CT/NG (3X LOD)	CT/NG (5X LOD)	CT/NG (10X LOD)

# Sexually-Transmitted Infections

## Exact Diagnostics TV/MG



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Panel</b>			
TVMGP200	Verification Panel	9 x 1.0 mL	IVD
<b>Verification Bundle</b>			
TVMGB200	Verification Bundle	. . . . . TVMGP200 (5 kits)	

Complementary product:  
See Page 13 for Bulk Urine Negative Control (Cat# 12019386)

### Analytes

*Trichomonas vaginalis*  
*Mycoplasma genitalium*

Catalog #	Panel Members		
TVMGP200	TV (3X LOD)	TV (5X LOD)	TV (10X LOD)
	MG (3X LOD)	MG (5X LOD)	MG (10X LOD)
	TV/MG (3X LOD)	TV/MG (5X LOD)	TV/MG (10X LOD)

## Exact Diagnostics HPV



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Formulated in PreservCyt
- 3 year shelf life from date of manufacture
- Controls stable for 10 days when stored at room temperature

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
HPV16C	HPV Genotype 16 Control	10 x 5.0 mL	IVD, CE-IVD
HPV18C	HPV Genotype 18 Control	10 x 5.0 mL	IVD, CE-IVD
HPV68C	HPV Genotype 68 Control	10 x 5.0 mL	IVD, CE-IVD
HPVNEG	HPV Negative Control	10 x 5.0 mL	IVD, CE-IVD
<b>Panels</b>			
HPVP100	HPV Control Set . . . . .		
	(1) HPV16C, (1) HPV18C, (1) HPV68C, (1) HPVNEG		
HPVP200	HPV Verification Panel . . . . .	16 x 1.4 mL	IVD
<b>Verification Bundle</b>			
HPVB200	Verification Bundle . . . . .	HPVP200 (5 kits)	

### Analytes

Human Papillomavirus (HPV) Genotype 16  
Human Papillomavirus (HPV) Genotype 18  
Human Papillomavirus (HPV) Genotype 68  
Human Cell Line

Catalog #	Panel Members		
HPVP200	HPV 16 (3X LOD)	HPV 16 (5X LOD)	HPV 16 (10X LOD)
	HPV 18 (3X LOD)	HPV 18 (5X LOD)	HPV 18 (10X LOD)
	3 of HPV 16/18/68 (3X LOD)	HPV 16/18/68 (5X LOD)	HPV 16/18/68 (10X LOD)

Refer to myelinserts.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.



# Sexually-Transmitted Infections

## Exact Diagnostics HSV-1



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic CSF matrix
- 2 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
HSV1L101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
HSV1H102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b>			
HSV1P100	Verification Panel	5 x 1.0 mL	IVD, CE-IVD
HSV1P200	Verification Panel	9 x 1.0 mL	IVD, CE-IVD
<b>Verification Bundle</b>			
HSV1B200	Verification Bundle . . . . .	HSV1P200 (5 kits)	

### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)

See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

### Analyte

Inactivated HSV-1

### HSV-1

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5
HSV1P100	200 cp/mL	2,000 cp/mL	20,000 cp/mL	200,000 cp/mL	2,000,000 cp/mL

### HSV-1/HSV-2

Catalog #	Panel Members		
HSVP200	HSV-1 (3X LOD)	HSV-1 (5X LOD)	HSV-1 (10X LOD)
	HSV-2 (3X LOD)	HSV-2 (5X LOD)	HSV-2 (10X LOD)
	HSV-1/HSV-2 (3X LOD)	HSV-1/HSV-2 (5X LOD)	HSV-1/HSV-2 (10X LOD)

## Exact Diagnostics HSV-2



- Manufacturing targets established using ddPCR
- Verification Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic CSF matrix
- 2 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
HSV2L101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
HSV2H102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b>			
HSV2P100	Verification Panel	5 x 1.0 mL	IVD, CE-IVD
HSV2P200	Verification Panel	9 x 1.0 mL	IVD, CE-IVD
<b>Verification Bundle</b>			
HSV2B200	Verification Bundle . . . . .	HSV2P200 (5 kits)	

### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)

See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

### Analyte

Inactivated HSV-2

### HSV-1

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5
HSV2P100	200 cp/mL	2,000 cp/mL	20,000 cp/mL	200,000 cp/mL	2,000,000 cp/mL

### HSV-1/HSV-2

Catalog #	Panel Members		
HSVP200	HSV-1 (3X LOD)	HSV-1 (5X LOD)	HSV-1 (10X LOD)
	HSV-2 (3X LOD)	HSV-2 (5X LOD)	HSV-2 (10X LOD)
	HSV-1/HSV-2 (3X LOD)	HSV-1/HSV-2 (5X LOD)	HSV-1/HSV-2 (10X LOD)

## Exact Diagnostics HBV



- Calibrated against the 3rd WHO International Standard for Hepatitis B (10/264)
- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- Run controls stable for 5 days when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
HBVL101	HBV-1 Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
HBVH102	HBV-1 High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b>			
HBVP100	Verification Panel . . . . .	7 x 1.0 mL	IVD
HBVP200	Verification Panel . . . . .	6 x 1.4 mL	IVD
HBVL201	1E3 IU/mL Precision . . . . .	9 x 1.4 mL	IVD
HBVH202	1E6 IU/mL Precision . . . . .	9 x 1.4 mL	IVD
HBVLOD	BKV LOD . . . . .	10 x 1.0 mL	IVD
<b>Verification Bundle</b>			
HBVB200	Verification Bundle . . . . .	HBVP200 (5 kits)	

Complementary product:  
See page 13 for Negative Run Control (Cat # NEG000/NEG050)

### Analytes

Inactivated HBV

### HBV

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5	Panel Member 6	Panel Member 7
HBVP100	100 IU/mL	1,000 IU/mL	10,000 IU/mL	100,000 IU/mL	1,000,000 IU/mL	10,000,000 IU/mL	100,000,000 IU/mL
HBVP200	100 IU/mL	1,000 IU/mL	10,000 IU/mL	100,000 IU/mL	1,000,000 IU/mL	10,000,000 IU/mL	100,000,000 IU/mL

## Exact Diagnostics HCV



- Calibrated against the 4th WHO International Standard for Hepatitis C (06/102)
- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- Run controls stable for 5 days when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
HCVL101	HCV-1 Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
HCVH102	HCV-1 High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b>			
HCVP100	Verification Panel . . . . .	7 x 1.0 mL	IVD
HCVP200	HCV Verification Panel . . . . .	7 x 1.4 mL	IVD
HCVL201	1E3 IU/mL Precision . . . . .	9 x 1.4 mL	IVD
HCVH202	1E6 IU/mL Precision . . . . .	9 x 1.4 mL	IVD
HCVLOD	HCV LOD . . . . .	10 x 1.0 mL	IVD
HCVGTP*	Genotype Panel . . . . .		
HCVGT 1a, HCVGT 1b, HCVGT 2, HCVGT 3, HCVGT 4 HCVGT 5			
<b>Verification Bundle</b>			
HCVB200	Verification Bundle . . . . .	HCVP200 (4 kits), HCVL201 (2 kits), HCVH202 (2 kits), HCVLOD (2 kits)	

\*FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES

Complementary product:  
See page 13 for Negative Run Control (Cat # NEG000/NEG050)

### Analytes

Recombinant HCV

### HCV

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5	Panel Member 6	Panel Member 7
HCVP100	100 IU/mL	300 IU/mL	3,000 IU/mL	30,000 IU/mL	300,000 IU/mL	3,000,000 IU/mL	30,000,000 IU/mL
HCVP200	100 IU/mL	300 IU/mL	3,000 IU/mL	30,000 IU/mL	300,000 IU/mL	3,000,000 IU/mL	30,000,000 IU/mL

Refer to myelinserts.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.

## Exact Diagnostics HIV



- A family of unassayed external controls, verification panels and verification panel bundles used in the determination of values in the measurement of HIV-1 and HIV-2 RNA
- Verification Panel offers a wide dynamic range
- Calibrated against the 3rd WHO International Standard for HIV-1 (10/152)
- Calibrated against the 2nd WHO International Standard for HIV-2 (16/296)
- Calibrated with digital droplet PCR
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA Plasma
- Run controls stable for 5 days when stored at 2-8°C
- Controls can be frozen and reused a maximum of two (2) times

### Ordering Information

Catalog #	Description	Format	Intended Use
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#### Run Controls

HIVL101	HIV-1 Low Run Control . . .	5 x 1.0 mL	IVD, CE-IVD
HIVH102	HIV-1 High Run Control. . . . .	5 x 1.0 mL	IVD, CE-IVD

#### Panels

HIVP100	HIV-1 Verification Panel . . . . .	7 x 1.0 mL	IVD
HIVP200	HIV-1 Verification Panel . . . . .	6 x 1.4 mL	IVD
HIVL201	HIV-1 1E3 cp/mL Precision . . .	9 x 1.4 mL	IVD
HIVH202	HIV-1 1E5 cp/mL Precision . . .	9 x 1.4 mL	IVD
HIVLOD	HIV-1 LOD . . . . .	10 x 1.0 mL	IVD
HIVQP200*	HIV-1/HIV-2 Verification Panel .	9 x 1.4 mL	RUO

#### Verification Bundles

HIVB200	HIV-1 Verification Bundle...HIVP200 (4 kits), HIVL201 (2 kits), HIVH202 (2 kits), HIVLOD (2 kits)		
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HIVQB200*	HIV-1/HIV-2 Verification Bundle . . . . .	HIVQP200 (5 kits)	
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\*FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES

### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)

### Analyte

Inactivated HIV-1      Inactivated HIV-2

#### HIV-1

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5	Panel Member 6	Panel Member 7
HIVP100	100 cp/mL	600 cp/mL	6,000 cp/mL	60,000 cp/mL	600,000 cp/mL	2,000,000 cp/mL	6,000,000 cp/mL
HIVP200	100 cp/mL	600 cp/mL	6,000 cp/mL	60,000 cp/mL	600,000 cp/mL	2,000,000 cp/mL	6,000,000 cp/mL

#### HIV-1/HIV-2

Catalog #	Panel Members		
HIVQP200	HIV-1 (3X LOD)	HIV-1 (5X LOD)	HIV-1 (10X LOD)
	HIV-2 (3X LOD)	HIV-2 (5X LOD)	HIV-2 (10X LOD)
	HIV-1/HIV-2 (2.5X LOD)	HIV-1/HIV-2 (5X LOD)	HIV-1/HIV-2 (10X LOD)

## Exact Diagnostics HBV, HCV and HIV Analytical Measurement Range



- HBV: Calibrated against the 3rd WHO International Standard for Hepatitis B (10/264)
- HCV: Calibrated against the 4th WHO International Standard for Hepatitis C (06/102)
- HIV: Calibrated against the 3rd WHO International Standard for HIV-1 (10/152)
- Manufacturing targets established using ddPCR
- AMR Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
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#### Panels

HBVAMR	HBV Analytical Measuring Range Pane .	3 x 1.0 mL	IVD
HCVAMR	HCV Analytical Measuring Range Panel .	3 x 1.0 mL	IVD
HIVAMR	HIV Analytical Measuring Range Panel . .	3 x 1.0 mL	IVD

#### AMR Bundle

AMRP100	Analytical Measuring Range Bundle . . . .	HBVAMR (1 kit), HCVAMR (1 kit), HIVAMR (1 kit)	
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### Analytes

Inactivated HBV      Recombinant HCV      Inactivated HIV-1

### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3
HBVAMR	100 IU/mL	100,000 IU/mL	10,000,000 IU/mL
HCVAMR	500 IU/mL	50,000 IU/mL	5,000,000 IU/mL
HIVAMR	600 IU/mL	60,000 IU/mL	6,000,000 IU/mL

Refer to myInsersts.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.

# Negative Controls

## Exact Diagnostics STI Negative Run Control



- Screened negative for 2 molecular targets
- High quality synthetic matrix to ensure lot-to-lot reproducibility
- 18 month shelf life from date of manufacture when stored at 2-8°C
- 30 day open vial stability when stored at 2-8°C
- Barcoded vials compatible with automated platforms

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
NEGSTI	STI Negative Run Control . . . .	6 x 1.1 mL	IVD

### Analytes

#### Non-reactive for:

*Chlamydia trachomatis* (CT)  
*Neisseria gonorrhoeae* (NG)

## Exact Diagnostics Synthetic Negative Run Control



- Screened negative for 9 molecular targets
- High quality synthetic matrix to ensure lot-to-lot reproducibility
- 2 year shelf life from date of manufacture when stored at -20°C or below
- 5 day stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
NEGSYN	Synthetic Negative Run Control	5 x 1.0 mL	IVD, CE-IVD

### Analytes

#### Non-reactive for:

<i>Anaplasma phagocytophilum</i>	Enterovirus (EV) Coxsackievirus A9
<i>Babesia microti</i>	Herpes Simplex Virus-1 (HSV-1)
<i>Bartonella quintana</i>	Herpes Simplex Virus-2 (HSV-2)
<i>Borrelia burgdorferi</i>	Varicella Zoster Virus (VZV)
<i>Ehrlichia chaffeensis</i>	

## Exact Diagnostics HAI Negative Run Control



- Screened negative for 3 molecular targets
- High quality synthetic matrix to ensure lot-to-lot reproducibility
- 2 year shelf life from date of manufacture when stored at -20°C or below
- 5 day stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
NEGHA1	HAI Negative Run Control . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analytes

#### Non-reactive for:

*Clostridium difficile* (*C. difficile*)  
Methicillin-resistant *Staphylococcus aureus* (MRSA)  
Methicillin-susceptible *Staphylococcus aureus* (MSSA)

Refer to myelInserts.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.

# Negative Controls

## Exact Diagnostics Negative Control



- Screened negative for 16 molecular targets
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 3 year shelf life from date of manufacture
- 5 day stability when stored at 2-8°C
- Control can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
NEG000	Negative Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
NEG050	Bulk Negative Control . . . . .	1 x 50 mL	IVD, CE-IVD

### Analytes

#### Non-reactive for:

Adenovirus DNA	HBsAg	HHV-6 DNA	JC Virus DNA
BKV DNA	HBV DNA	HIV-1/2 Antibodies	VZV DNA
CMV DNA	HCV Antibodies	HIV-1 RNA	Zika Virus RNA
EBV DNA	HCV RNA	HSV-1/2 DNA	

## NEW | Exact Diagnostics Bulk CSF Negative Control



- Screened negative for 9 molecular targets
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic CSF matrix
- 3 year shelf life from date of manufacture
- 5 day stability when stored at 2-8°C
- Control can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
12019432	Bulk CSF Negative . . . . .	1 x 50 mL	IVD

### Analytes

#### Non-reactive for:

<i>Anaplasma phagocytophilum</i>	Coxsackievirus A9	Enterovirus (EV)
<i>Babesia microti</i>	Herpes Simplex Virus-1 (HSV-1)	
<i>Bartonella quintana</i>	Herpes Simplex Virus-2 (HSV-2)	
<i>Borrelia burgdorferi</i>	Varicella Zoster Virus (VZV)	
<i>Ehrlichia chaffeensis</i>		

## NEW | Exact Diagnostics Bulk Urine Negative Control



- Screened negative for 10 molecular targets
- High quality matrix to ensure lot-to-lot reproducibility
- Pooled human urine
- 2 year shelf life from date of manufacture
- 5 day stability when stored at 2-8°C
- Control can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
12019386	Bulk Urine Negative. . . . .	1 x 50 mL	RUO

### Analytes

#### Non-reactive for:

Adenovirus (ADV)	John Cunningham Virus (JCV)
BK Virus (BKV)	<i>Mycoplasma genitalium</i> (MG)
<i>Candida auris</i> ( <i>C. auris</i> )	<i>Neisseria gonorrhoeae</i> (NG)
<i>Chlamydia trachomatis</i> (CT)	<i>Trichomonas vaginalis</i> (TV)
Cytomegalovirus (CMV)	Zika Virus (ZKV)



## Blood Screening

### Exact Diagnostics HBV, HCV and HIV-1 Screen Controls



- Calibrated against the 3rd WHO International Standard for HBV (10/264)
- Calibrated against the 4th WHO International Standard for HCV (06/102)
- Calibrated against the 3rd WHO International Standard for HIV-1 (10/152)
- Citrate plasma matrix
- 18 month shelf life when stored at -20°C
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

#### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
HBVSCREEN	HBV DNA Screen Control . . . . .	10 x 1.4 mL	CE-IVD
HCVSCREEN	HCV RNA Screen Control . . . . .	10 x 1.4 mL	CE-IVD
HIVSCREEN	HIV-1 RNA Screen Control . . . . .	10 x 1.4 mL	CE-IVD
VIRSCREEN	HIV-1, HCV, HBV Screen Control	10 x 1.4 mL	CE-IVD

#### Analytes

Inactivated HBV	Inactivated HCV	Inactivated HIV-1
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## Meningitis and Encephalitis

### Exact Diagnostics VZV



- Manufacturing targets established using ddPCR
- Verification Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic CSF matrix
- 2 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

#### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
VZVL101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
VZVH102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panel</b>			
VZVP200	Verification Panel . . . . .	5 x 1.0 mL	IVD, CE-IVD

#### Analyte

Inactivated Varicella Zoster Virus (VZV)

#### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)

See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5
VZVP100	500 cp/mL	2,000 cp/mL	20,000 cp/mL	200,000 cp/mL	2,000,000 cp/mL

### Exact Diagnostics Enterovirus Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 2 year shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

#### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
EVRC	Control . . . . .	5 x 1.0 mL	CE-IVD

#### Analyte

Inactivated Coxsackievirus A9

#### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)

See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

Refer to myelinserts.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.

# Hospital-Associated Infections

## Exact Diagnostics *C. difficile* Verification Bundle



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
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#### Panel

CDFP200	Verification Panel	3 x 1.0 mL	IVD, CE-IVD
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#### Verification Bundle

CDFB200	Verification Bundle	CDFP200 (5 kits)	
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### Analytes

Inactivated *C. difficile*

#### Complementary product:

See page 12 for HAI Negative Run Control (Cat # NEGHA1)

Catalog #	Panel Members		
CDFP200	<i>C. difficile</i> (3X LOD)	<i>C. difficile</i> (5X LOD)	<i>C. difficile</i> (10X LOD)

## Exact Diagnostics MRSA Verification Bundle



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
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#### Panel

MRSAP200	Verification Panel	3 x 1.0 mL	IVD, CE-IVD
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#### Verification Bundle

MRSAB200	Verification Bundle	MRSAP200 (5 kits)	
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### Analytes

Inactivated Methicillin-resistant *Staphylococcus aureus* (MRSA)

Inactivated Methicillin-susceptible *Staphylococcus aureus* (MSSA)

#### Complementary product:

See page 12 for HAI Negative Run Control (Cat # NEGHA1)

Catalog #	Panel Members		
MRSAP200	MRSA (3X LOD)	MRSA (5X LOD)	MRSA (10X LOD)
	MSSA (3X LOD)	MSSA (5X LOD)	MSSA (10X LOD)

## Amplichek II



- Liquid, multi-analyte quality control designed to monitor the performance of *in vitro* nucleic acid test systems for Healthcare Associated Infections (HAI)
- Use with multiple specimen types and sampling tools including swabs and transfer pipets
- Convenient single use configuration to minimize contamination
- Contains intact, inactivated bacteria to monitor the full NAT process from extraction to amplification and detection
- Negative, Levels 1 and 2 are suitable for Cepheid Xpert assays
- 2 year shelf life at 2-8°C

Contact your local Bio-Rad office for additional assay compatibility and Level selection information.

### Ordering Information

Catalog #	Description	Format	Intended Use
12000201	Negative . . . . .	10 x 0.2 mL	IVD, CE-IVD
12000202	Level 1 . . . . .	10 x 0.2 mL	IVD, CE-IVD
12000203	Level 2 . . . . .	10 x 0.2 mL	IVD, CE-IVD
12000204	Level 3 . . . . .	10 x 0.2 mL	IVD, CE-IVD
12000575	Negative MiniPak . . . . .	1 x 0.2 mL	IVD, CE-IVD
12000576	Level 1 MiniPak . . . . .	1 x 0.2 mL	IVD, CE-IVD
12000577	Level 2 MiniPak . . . . .	1 x 0.2 mL	IVD, CE-IVD
12000578	Level 3 MiniPak . . . . .	1 x 0.2 mL	IVD, CE-IVD

### Analytes

*Clostridium difficile* (*C. diff.*)  
Methicillin-resistant *Staphylococcus aureus* (MRSA)  
Methicillin-sensitive *Staphylococcus aureus* (MSSA)  
Vancomycin-resistant *enterococci* (VRE or vanR)

### Product Level Selection by Analyte

- Reactive
- Non-reactive

#### Analytes

Analyte	Level	Negative* (Non-reactive)	Level 1 (MSSA)	Level 2 (Low Positive)	Level 3 (High Positive)
<i>Clostridium difficile</i> ( <i>C. diff.</i> ) genes: Toxin B, Binary Toxin, TcdC		●	●	●	●
Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) genes: SPA, SCCmec, mecA		●	●	●	●
Methicillin-Sensitive <i>Staphylococcus aureus</i> (MSSA) gene: SPA		●	●		
Vancomycin-Resistant <i>enterococci</i> (VRE or vanR) genes: vanA, vanB**		●	●	●	●

\*Contains Methicillin Sensitive *Staphylococcus epidermidis* (MSSE).  
\*\*Not available in the USA.

## Respiratory

### Exact Diagnostics RP Positive & Negative Run Controls



- 23 Analyte respiratory control
- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
RPPOS	RP Positive Control . . . . .	6 x 0.3 mL	IVD, CE-IVD
RPNEG	RP Negative Control . . . . .	6 x 0.3 mL	IVD, CE-IVD

### Analytes

Adenovirus	Coronavirus OC43	Middle Eastern Respiratory Syndrome (RNA IVT)	Respiratory Syncytial Virus (A)
<i>Bordetella parapertussis</i>	Human metapneumovirus (RNA IVT)	Parainfluenza 1	Respiratory Syncytial Virus (B)
<i>Bordetella pertussis</i>	Influenza A H1N1	Parainfluenza 2	Severe Acute Respiratory Syndrome
<i>Chlamydomphila pneumoniae</i>	Influenza A H1N1-09 (RNA IVT)	Parainfluenza 3	Coronavirus 2
Coronavirus 229E	Influenza A H3N2 (RNA IVT)	Parainfluenza 4	
Coronavirus HKU1 (RNA IVT)	Influenza B	Rhinovirus	
Coronavirus NL63 (RNA IVT)	<i>Mycoplasma pneumoniae</i>		

Refer to myelinserts.com, exactdiagnostics.com or the package insert of currently available lots for specific analyte and stability claims.

## Exact Diagnostics SARS-CoV-2, Flu, RSV Run Controls



- Whole organism SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus (A)
- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic matrix, including human genomic DNA (gDNA)
- 24 month shelf life from date of manufacture
- Controls can be frozen and reused a maximum of five (5) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Controls</b>			
COVFLU	Positive Run Control . . .	5 x 1.0 mL	IVD, CE-IVD
COVFLUNEG	Negative Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panel</b>			
COVFLUP200*	Verification Panel . . . . .	9 x 1.4 mL	RUO
<b>Verification Bundle</b>			
COVFLUB200*	SARS-CoV-2, Flu, RSV Verification Bundle . . . . .		
COVFLUP200	(5 kits)		

\*FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES

### Targets

#### Whole Organism

- SARS-CoV-2
- Influenza A-H1N1
- Influenza B
- Respiratory Syncytial Virus (A)

Catalog #	Panel Members		
COVFLUP200	Flu A (3X LOD)	Flu A (5X LOD)	Flu A (10X LOD)
	Flu B (3X LOD)	Flu B (5X LOD)	Flu B (10X LOD)
	RSV A (3X LOD)	RSV A (5X LOD)	RSV A (10X LOD)
	SARS-CoV-2 (3X LOD)	SARS-CoV-2 (5X LOD)	SARS-CoV-2 (10X LOD)
	SARS-CoV-2, Flu, RSV (3X LOD)	SARS-CoV-2, Flu, RSV (5X LOD)	SARS-CoV-2, Flu, RSV (10X LOD)

## Exact Diagnostics SARS-CoV-2 Standard and Run Controls



- Contains E, N, ORF1ab, RdRP and S genes
- Quantitation with ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic matrix, including human genomic DNA (gDNA)
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Standards</b>			
COV019*	Standard . . . . .	5 x 0.3 mL	RUO
COV000*	Negative . . . . .	5 x 0.3 mL	RUO
<b>Related Products</b>			
COV019CE	Positive Run Control . . .	5 x 0.3 mL	IVD, CE-IVD
COV000CE	Negative Run Control . . . . .	5 x 0.3 mL	IVD, CE-IVD

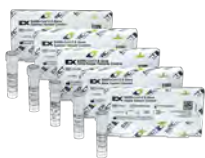
\*FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES

### Targets

#### SARS-CoV-2 Genes

- |                       |                        |
|-----------------------|------------------------|
| Envelope (E) Gene     | RdRP (RNA-dependent    |
| Nucleocapsid (N) Gene | RNA polymerase) Gene   |
| ORF1ab Gene           | Spike Protein (S) Gene |

## Exact Diagnostics SARS-CoV-2 S Gene Variant Controls



- Quantitation with ddPCR
- Human genomic DNA (gDNA) background
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic matrix, including human genomic DNA (gDNA)
- 18 month shelf life from date of manufacture when stored at -20°C
- 12 month shelf life when stored at 2-8°C
- 7 day open-vial stability when stored at 2-8°C

### Ordering Information

Catalog #	Description	Format	Intended Use
COVA	Alpha Variant Control . . . . .	1 x 0.25 mL	RUO
COVB	Beta Variant Control . . . . .	1 x 0.25 mL	RUO
COVDK	Delta-Kappa Variant Control . . . . .	1 x 0.25 mL	RUO
COVE	Epsilon Variant Control . . . . .	1 x 0.25 mL	RUO
COVG	Gamma Variant Control . . . . .	1 x 0.25 mL	RUO

### Targets

#### Synthetic RNA Transcripts

Alpha Variant (B.1.1.7)	Delta-Kappa Variants
Beta Variant (B.1.351)	(B.1.617.1, B.1.617.2 and
Epsilon Variant (B.1.427, B.1.429)	AY sublineages, B.1.617.3)
Gamma Variant (P.1)	

#### Complementary product:

See page 17 for SARS-CoV-2, Negative (Cat # COV000)

## Vector-Borne

### Exact Diagnostics Anaplasma Run Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
ANARC	Anaplasma Control . . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analytes

*Anaplasma phagocytophilum*

#### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)  
See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

### Exact Diagnostics Babesia Run Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b>			
BABRC	Babesia Control . . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analytes

*Babesia microti*

#### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)  
See Page 13 for Bulk CSF Negative Control (Cat# 12019432)



## Exact Diagnostics Bartonella Run Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b> BRTRC	Bartonella Control. . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analytes

*Bartonella quintana*

### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)  
See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

## Exact Diagnostics Borrelia Run Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b> BORRC	Borrelia Control. . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analytes

*Borrelia burgdorferi*

### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)  
See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

## Exact Diagnostics Ehrlichia Run Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- 18 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b> ERLRC	Ehrlichia Control . . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analytes

*Ehrlichia chaffeensis*

### Complementary product:

See page 12 for Synthetic Negative Run Control (Cat # NEGSYN)  
See Page 13 for Bulk CSF Negative Control (Cat# 12019432)

## Exact Diagnostics ZKV Verification Panel



- Manufacturing targets established using ddPCR
- Verification Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 36 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C
- Controls can be frozen and reused a maximum of four (4) times

### Ordering Information

Catalog #	Description	Format	Intended Use
<b>Run Control</b> ZKVL101	Low Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
ZKVH102	High Run Control . . . . .	5 x 1.0 mL	IVD, CE-IVD
<b>Panels</b> ZKVP100	Verification Panel . . . . .	5 x 1.0 mL	IVD, CE-IVD

### Analytes

Inactivated Zika Virus

### Complementary product:

See page 13 for Negative Run Control (Cat # NEG000/NEG050)  
See Page 13 for Bulk Urine Negative Control (Cat# 12019386)

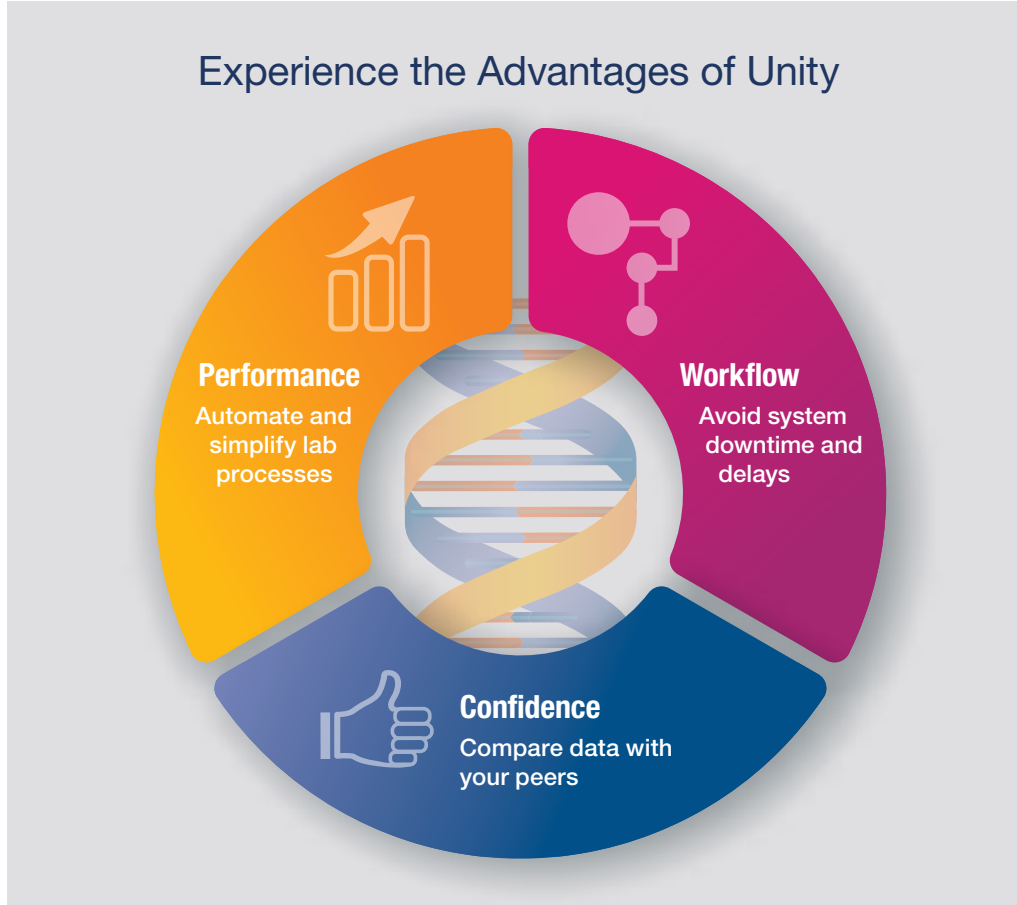
Catalog #	Panel Member 1	Panel Member 2	Panel Member 3	Panel Member 4	Panel Member 5
ZKVP100	100 cp/mL	1,000 cp/mL	10,000 cp/mL	100,000 cp/mL	1,000,000 cp/mL

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