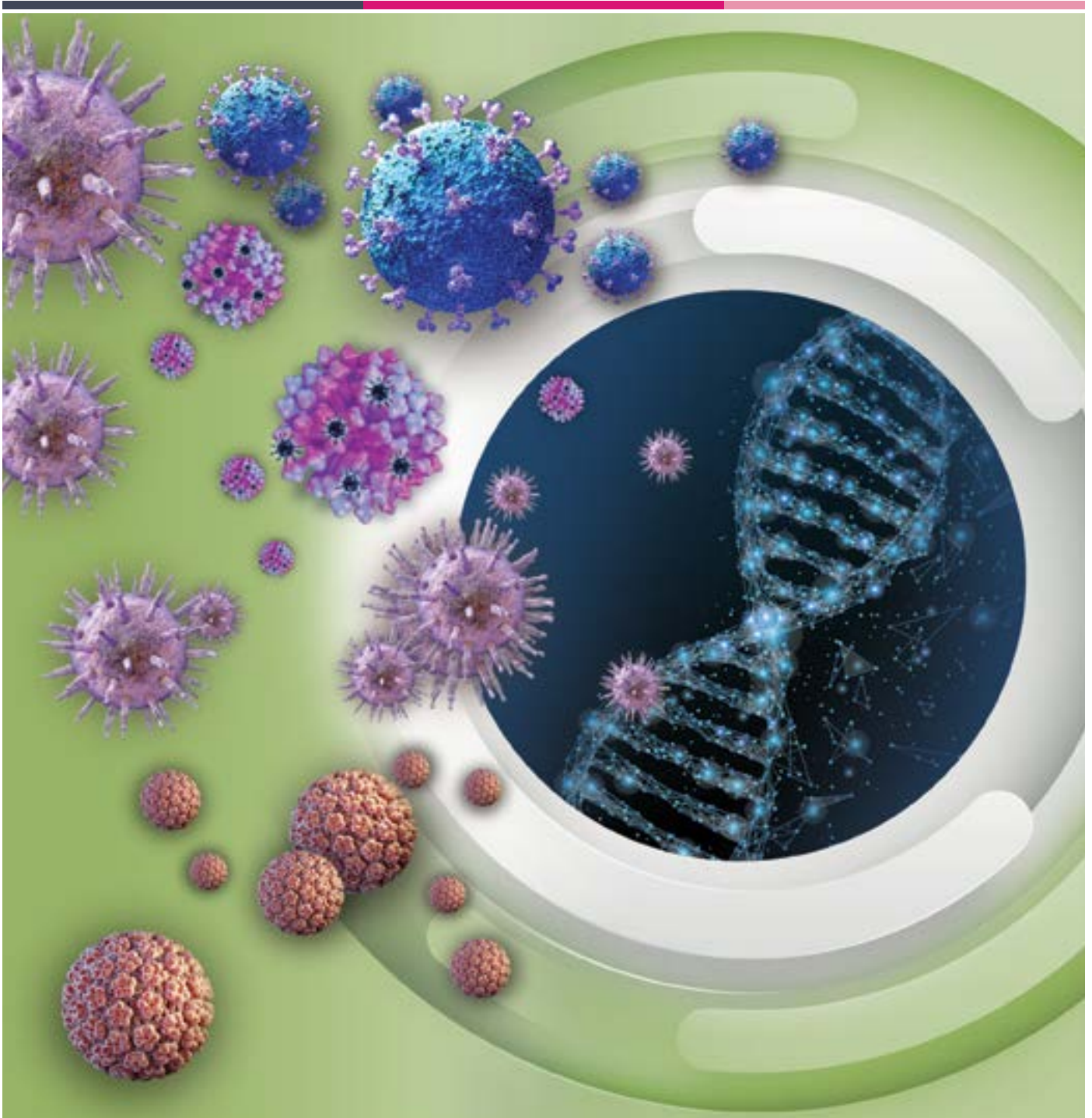


Molecular Quality Controls and Standards

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 Standards for Infectious Disease



Traceable to international standards where applicable



Commutability with high-quality matrix



Lot-to-lot reproducibility and consistency with standards manufactured under ISO 17511



Absolute quantification with digital droplet PCR





Monitor and compare results with peer groups using integrated Unity data management software

Ensuring Reliable Patient Results

Molecular Quality Controls and Standards

Elevating performance by delivering traceability, commutability, and absolute quantification to high-impact molecular testing.

	Verification Panels	Daily Run Controls
Use	<p>Used to establish performance characteristics</p> <ul style="list-style-type: none"> Dynamic Range Limit of Detection Specificity Limit of Quantification 	<p>Used to monitor performance</p> <ul style="list-style-type: none"> Precision: day-to-day, lot-to-lot, instrument-to-instrument and operator-to-operator
Consists of	Multiple Levels	High and Low Controls
Uses	Quantitative Assays	Qualitative and Quantitative Assays
 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
- 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. Do not dilute

Dynamic Range

ADVP100 200 cp/mL-2,000,000 cp/mL

Ordering Information

Catalog #	Description	
ADVP100	Verification Panel	5 x 1.0 mL
ADVL101	Low Run Control	5 x 1.0 mL
ADVH102	High Run Control	5 x 1.0 mL

Analyte

Inactivated Adenovirus

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
- 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. Do not dilute

Dynamic Range

BKVP100 200 IU/mL-2,000,000 IU/mL

Ordering Information

Catalog #	Description	
BKVP100	Verification Panel	6 x 1.0 mL
BKVL101	Low Run Control	5 x 1.0 mL
BKVP200	Verification Panel*	6 x 1.4 mL
BKVH102	High Run Control	5 x 1.0 mL
BKVB201	Verification Bundle*	
	BKVP200 Verification Panel	4 Kits
	1E3IU/mL Precision	2 kits (18 vials)
	5E5IU/mL Precision	2 kits (18 vials)
	BKVL0D	2 kits (20 vials)
	BKV Urine LOD	2 kits (20 vials)

*Available in the United States only

Analyte

Inactivated BKV

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
- 24 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. Do not dilute

Dynamic Range

B19P100 500 IU/mL-5,000,000 IU/mL

Ordering Information

Catalog #	Description	
B19P100	Verification Panel	5 x 1.0 mL
B19L101	Low Run Control	5 x 1.0 mL
B19H102	High Run Control	5 x 1.0 mL

Analyte

Inactivated Parvovirus B19

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
- 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. Do not dilute

Dynamic Ranges

CMVP100 . . . 400 IU/mL-4,000,000 IU/mL

CMVP200 . . . 200 IU/mL-4,000,000 IU/mL

Ordering Information

Catalog #	Description	
CMVP100	Verification Panel*	5 x 1.0 mL
CMVP200	Verification Panel*	6 x 1.4 mL
CMVL101	Low Run Control	5 x 1.0 mL
CMVH102	High Run Control	5 x 1.0 mL
CMVB200	Verification Bundle*	
	CMVP200 Verification Panel	4 Kits
	1E3 IU/mL Precision	2 Kits (18 Vials)
	5E5 IU/mL Precision	2 Kits (18 Vials)
	CMV LOD	2 Kits (20 Vials)

*Available in the United States only

Analyte

Inactivated CMV

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
- 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. Do not dilute

Dynamic Range

EBVP100 . . . 500 IU/mL-5,000,000 IU/mL

Ordering Information

Catalog #	Description	
EBVP100	Verification Panel	5 x 1.0 mL
EBVP200	Verification Panel*	7 x 1.4 mL
EBVL101	Low Run Control	5 x 1.0 mL
EBVH102	High Run Control	5 x 1.0 mL
EBVB200	Verification Bundle (4 of EBVP200)*	
	1E3IU/mL Precision	2 Kits (18 Vials)
	5E5IU/mL Precision	2 Kits (18 Vials)
	EBV LOD	2 Kits (20 Vials)

*Available in the United States only

Analyte

Inactivated EBV

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
- 24 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. Do not dilute

Dynamic Ranges

HV6AP100 . . . 500 cp/mL-5,000,000 cp/mL

HV6BP100 . . . 500 cp/mL-5,000,000 cp/mL

Ordering Information

Catalog #	Description	
HV6AP100	HHV-6A Verification Panel	5 x 1.0 mL
HV6BP100	HHV-6B Verification Panel	5 x 1.0 mL
HV6L101	Low Run Control	5 x 1.0 mL
HV6H102	High Run Control	5 x 1.0 mL

Analytes

Inactivated HHV-6A

Inactivated HHV-6B

Transplantation

Exact Diagnostics HSV-1



- Verification Panel offers a wide dynamic range
- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic CSF matrix
- 24 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. Do not dilute

Dynamic Range
HSV1P100 . . . 200 cp/mL-2,000,000 cp/mL

Ordering Information

Catalog #	Description	
HSV1P100	Verification Panel	5 x 1.0 mL
HSV1L101	Low Run Control	5 x 1.0 mL
HSV1H102	High Run Control	5 x 1.0 mL
HSVB200	Verification Bundle	5 kits
- HSV-1	3x, 5x, 10x LOD
- HSV-2	3x, 5x, 10x LOD
- HSV-1/HSV-2	3x, 5x, 10x LOD

Analyte

Inactivated HSV-1

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
- 24 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. Do not dilute

Dynamic Range
HSV2P100 . . . 200 cp/mL-2,000,000 cp/mL

Ordering Information

Catalog #	Description	
HSV2P100	Verification Panel	5 x 1.0 mL
HSV2L101	Low Run Control	5 x 1.0 mL
HSV2H102	High Run Control	5 x 1.0 mL
HSVB200	Verification Bundle5 kits
HSV-1	3x, 5x, 10x LOD
HSV-2	3x, 5x, 10x LOD
HSV-1/HSV-2	3x, 5x, 10x LOD

Analyte

Inactivated HSV-2

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
- 24 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. Do not dilute

Dynamic Range
JCVP100 200 IU/mL-20,000,000 IU/mL

Ordering Information

Catalog #	Description	
JCVP100	Verification Panel	6 x 1.0 mL
JCVL101	Low Run Control	5 x 1.0 mL
JCVH102	High Run Control	5 x 1.0 mL

Analytes

Inactivated JCV

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
- 24 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. Do not dilute

Dynamic Range
VZVP100 500cp/mL-2,000,000cp/mL

Ordering Information

Catalog #	Description	
VZVP100	Verification Panel	5 x 1.0 mL
VZVL101	Low Run Control	5 x 1.0 mL
VZVH102	High Run Control	5 x 1.0 mL

Analyte

Inactivated Varicella Zoster Virus (VZV)

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

Exact Diagnostics HBV



- Calibrated against the 3rd WHO International Standard for Hepatitis B (10/264)
- Verification Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 24 hour stability when stored at 2-8°C

Dynamic Ranges

HBVP100 100 IU/mL-100,000,000 IU/mL

HBVP200 100 IU/mL-100,000,000 IU/mL

Ordering Information

Catalog #	Description	
HBVP100	Verification Panel*	7 x 1.0 mL
HBVP200	Verification Panel*	7 x 1.4 mL
HBVL101	Low Run Control	5 x 1.0 mL
HBVH102	High Run Control	5 x 1.0 mL
HBVB200	Verification Panels Bundle (4 of HBVP200)*	
	1E3 IU/mL Precision	2 Kits (18 vials)
	1E6 IU/mL Precision	2 Kits (18 vials)
	HBV LOD2 Kits (20 Vials)

*Available in the United States only

Analytes

Inactivated HBV

Exact Diagnostics HCV



- Calibrated against the 4th WHO International Standard for Hepatitis C (06/102)
- Verification Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 24 hour stability when stored at 2-8°C

Dynamic Ranges

HCVP100 100 IU/mL-30,000,000 IU/mL

HCVP200 100 IU/mL-30,000,000 IU/mL

Ordering Information

Catalog #	Description	
HCVP100	Verification Panel*	7 x 1.0 mL
HCVP200	Verification Panel*	7 x 1.4 mL
HCVL101	Low Run Control	5 x 1.0 mL
HCVH102	High Run Control	5 x 1.0 mL
HCVB200	Verification Panels Bundle (4 of HCVP200)*	
	1E3IU/mL Precision2 Kits (18 Vials)
	1E6IU/mL Precision2 Kits (18 Vials)
	HCV LOD2 Kits (20 Vials)
HCVGTP	Genotype Panel**	6 x 1.0 mL
	(HCVGT 1a, HCVGT 1b, HCVGT 2, HCVGT 3, HCVGT 4, HCVGT 5)	

*Available in the United States only

**For Research Use Only. Not for use in diagnostic procedures.

Analytes

Recombinant HCV

Exact Diagnostics HIV-1



- Calibrated against the 3rd WHO International Standard for HIV-1 (10/152)
- Verification Panel offers a wide dynamic range
- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- 24 hour stability when stored at 2-8°C

Dynamic Ranges

HIVP100 100 cp/mL-6,000,000 cp/mL

HIVP200 100 cp/mL-6,000,000 cp/mL

Ordering Information

Catalog #	Description	
HIVP100	Verification Panel*	7 x 1.0 mL
HIVP200	Verification Panel*	7 x 1.4 mL
HIVL101	Low Run Control	5 x 1.0 mL
HIVH102	High Run Control	5 x 1.0 mL
HIVB200	Verification Bundle (4 of HIVP200)*	
	1E3 cp/mL Precision2 Kits (18 Vials)
	1E5 cp/mL Precision2 Kits (18 Vials)
	HIV-1 LOD2 Kits (20 Vials)

*Available in the United States only

Analytes

Inactivated HIV-1

Exact Diagnostics Analytical Measurement Range Bundle



- 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)
- True EDTA plasma matrix

Ordering Information

Catalog #	Description	Quantity
AMRP100	HBVAMR, HCVAMR, HIVAMR panels*	1 each

*Available in the United States only

Analytes

Inactivated HBV
Recombinant HCV
Inactivated HIV-1

Exact Diagnostics HBV Analytical Measurement Range Panel



- Calibrated against the 3rd WHO International Standard for Hepatitis B (10/264)
- 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
- 36 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

Ordering Information

Catalog #	Description	Quantity
HBVAMR	Panels*	3 x 1.0 mL

*Available in the United States only

Analytes

Inactivated HBV

Exact Diagnostics HCV Analytical Measurement Range Panel



- Calibrated against the 4th WHO International Standard for Hepatitis C (06/102)
- 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
- 36 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

Ordering Information

Catalog #	Description	Quantity
HCVAMR	Panels*	3 x 1.0 mL

*Available in the United States only

Analytes

Recombinant HCV

Exact Diagnostics HIV-1 Analytical Measurement Range Panel



- 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
- 36 month shelf life from date of manufacture
- 24 hour stability when stored at 2-8°C

Ordering Information

Catalog #	Description	Quantity
HIVAMR	Panels*	3 x 1.0 mL

*Available in the United States only

Analytes

Inactivated HIV-1

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

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
- Controls can be frozen and reused a maximum of four (4) times. Do not dilute
- 18 month shelf life when stored at -20°C
- 24 hour stability when stored at 2-8°C

Ordering Information

Catalog #	Description	Quantity
HBVSCREEN	HBV DNA Screen Control*	10 x 1.4 mL
HCVSCREEN	HCV RNA Screen Control*	10 x 1.4 mL
HIVSCREEN	HIV-1 RNA Screen Control*	10 x 1.4 mL
VIRSCREEN	HIV-1, HCV, HBV Screen Control*	10 x 1.4 mL

*Available outside the United States only

Analytes

Inactivated HBV
Inactivated HCV
Inactivated HIV-1

Exact Diagnostics ZKV



- 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

Dynamic Range

ZKVP100. . . . 100 cp/mL-1,000,000 cp/mL

Ordering Information

Catalog #	Description	Quantity
ZKVP100	Verification Panel	5 x 1.0 mL
ZKVL101	Low Run Control	5 x 1.0 mL
ZKVH102	High Run Control	5 x 1.0 mL

Analytes

Inactivated Zika Virus

Exact Diagnostics Negative Control



- High quality matrix to ensure lot-to-lot reproducibility
- True EDTA plasma matrix
- Control can be frozen and reused a maximum of four (4) times
- 18 month shelf life from date of manufacture
- EDX Bulk Negative: 5 day stability when stored at 2-8°C.
- EDX Negative Run Control: 24 hour stability when stored at 2-8°C

Ordering Information

Catalog #	Description	Quantity
NEG000	Negative Control	5 x 1.0 mL
NEG050	Bulk Negative Control	1 x 50 mL

Analytes

Non-reactive for:

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

Sexually Transmitted Infections

Exact Diagnostics CT/NG



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic Matrix
- Run Control has 24 month shelf life from date of manufacture
- Run Control has 90 day stability when stored at 2-8°C

Ordering Information

Catalog #	Description	Quantity
CTNGB200	Verification Bundle (5 kits*)	9 x 1.0 mL
CTNGRC	Run Control*	1 x 6.0 mL

*Available in the United States only

Analytes

Chlamydia trachomatis (CT)
Neisseria gonorrhoeae (NG)

Exact Diagnostics HPV Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Formulated in PreservCyt
- 36 month shelf life from date of manufacture
- 10 day stability when stored at room temperature

Ordering Information

Catalog #	Description	Quantity
HPV16C	HPV Genotype 16	10 x 5.0 mL
HPV18C	HPV Genotype 18	10 x 5.0 mL
HPV68C	HPV Genotype 68	10 x 5.0 mL
HPVNEG	HPV Negative Control	10 x 5.0 mL
HPVP100	HPV Control Set	40 x 5.0 mL
	1 kit each of HPV16C, HPV18C, HPV68C & HPVNEG	
HPVP200	HPV Verification Panel*	1 kit
	- HPV 16	3X, 5X, 10X LOD
	- HPV 18	3X, 5X, 10X LOD
	- HPV 16/18/68	3X, 5X, 10X LOD
	- HPV Negative	5 kits (16 x 1.4 mL)
HPVB200	HPV Verification Bundle*	5 kits of HPVP200

*Available in the United States only

Analytes

Human Papillomavirus (HPV) Genotype 16
 Human Papillomavirus (HPV) Genotype 18

Human Papillomavirus (HPV) Genotype 68
 Human Cell Line

Amplichek STI



- Liquid, multi-analyte quality control designed to monitor the performance of *in vitro* nucleic acid test systems for sexually transmitted infections (STI)
- Convenient single use configuration to minimize contamination
- Use to monitor multiple assay steps including lysis, nucleic acid extraction and amplification
- Positive level prepared from intact, inactivated bacteria and human cell lines containing high risk HPV genotypes 16, 18 and 68
- 2-year shelf life at -20 to -70C

Ordering Information

Catalog #	Description	Quantity
12000991	Negative	10 x 0.2 mL
12000992	Positive	10 x 0.2 mL
12000993	Negative MiniPak	1 x 0.2 mL
12000994	Positive MiniPak	1 x 0.2 mL

Analytes

Chlamydia trachomatis (CT)
 Human Papillomavirus (HPV)
Neisseria gonorrhoeae (NG or GC)

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

Sexually Transmitted Infections

AmpliClear



- Unassayed, non-reactive quality control that serves as a companion to AmpliPROBE CT/GC and AmpliTrol CT/GC
- 2 year shelf life at 2–8°C
- 60 day open-vial stability at 2–8°C

Ordering Information

Catalog #	Description
00127	Single Level/Dropper Bottle 1 x 5 mL

Analytes

Non-reactive for:

- Chlamydia trachomatis* (CT)
- Neisseria gonorrhoeae* (GC)

AmpliPROBE CT/GC



- Unassayed quality control for nucleic acid amplification assays
- 2 year shelf life at 2–8°C
- 60 day open-vial stability at 2–8°C

Ordering Information

Cat #	Description
00138	Single Level/Dropper Bottle 1 x 5 mL

Analytes

- Chlamydia trachomatis* (CT)
- Neisseria gonorrhoeae* (GC)

AmpliTrol CT/GC



- Unassayed quality control for DNA amplification assays
- 2 year shelf life at 2–8°C
- 60 day open-vial stability at 2–8°C

Ordering Information

Cat #	Description
00126	Single Level/Dropper Bottle 1 x 5 mL

Analytes

- Chlamydia trachomatis* (CT)
- Neisseria gonorrhoeae* (GC)

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
CDFB200	Verification Bundle (5 kits) 15 x 1.0 mL

Analytes

Inactivated *C. difficile*

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
MRSAB200 Verification Bundle (5 kits) 6 x 1.0 mL

Analytes

Inactivated Methicillin-resistant *Staphylococcus aureus* (MRSA)
Inactivated Methicillin-susceptible *Staphylococcus aureus* (MSSA)

Hospital Associated Infections

Exact Diagnostics Enterovirus Control



- Manufacturing targets established using ddPCR
- High quality matrix to ensure lot-to-lot reproducibility
- Synthetic CSF Matrix
- 24 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. Do not dilute

Ordering Information

Catalog #	Description
EVRC	Control. 5 x 1.0 mL

Analyte

Inactivated Coxsackievirus A9

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

Hospital Associated Infections

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	Volume
12000201	Negative	10 x 0.2 mL
12000202	Level 1	10 x 0.2 mL
12000203	Level 2	10 x 0.2 mL
12000204	Level 3	10 x 0.2 mL
12000575	Negative MiniPak	1 x 0.2 mL
12000576	Level 1 MiniPak	1 x 0.2 mL
12000577	Level 2 MiniPak	1 x 0.2 mL
12000578	Level 3 MiniPak	1 x 0.2 mL

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> (C diff.) 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
- Once thawed, EDX RP Positive Run Control must be used immediately

Ordering Information

Catalog #	Description	Volume
RPPOS	Positive	6 x 0.3 mL
RPNEG	Negative	6 x 0.3 mL

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 Control



- 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)
- 2 year shelf life from date of manufacture
- Controls can be frozen and reused a maximum of five (5) times. Do not dilute

Ordering Information

Catalog #	Description	Quantity
COVFLU	Positive	5 x 1.0 mL
COVFLUNEG	Negative	5 x 1.0 mL

Targets

Whole Organism

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

Exact Diagnostics SARS-CoV-2



- Contains E, N, ORF1ab, RdRP and S genes
- Quantitation with digital droplet PCR
- 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

Quantitation

COV019..... 200,000 cp/mL
COV000..... 75,000 cp/mL

Ordering Information

Catalog #	Description	Quantity
COV019	Standard	5 x 0.3 mL
COV000	Negative	5 x 0.3 mL

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

CE MARKED. AVAILABLE OUTSIDE THE US ONLY.

COV019CE	Positive Run Control	5 x 0.3 mL
COV000CE	Negative Run Control	5 x 0.3 mL

Targets

SARS-CoV-2 Genes

E	RdRP
N	S
ORF1ab	

Exact Diagnostics SARS-CoV-2 S Gene Variant Controls



- Quantitation with digital droplet PCR
- Human genomic DNA (gDNA) background
- High quality matrix to ensure lot-to-lot reproducibility
- 18 month shelf life from date of manufacture when stored at -20°C
- 12 month shelf life when stored at 2-8°C

Ordering Information

Catalog #	Description	Quantity
COVA	Alpha Variant Control*	1 x 0.25 mL
COVB	Beta Variant Control*	1 x 0.25 mL
COVDK	Delta-Kappa Variant Control*	1 x 0.25 mL
COVE	Epsilon Variant Control*	1 x 0.25 mL
COVG	Gamma Variant Control*	1 x 0.25 mL

*For research use only. Not for use in diagnostic procedures.

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)	

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. Do not dilute

Ordering Information

Catalog #	Description
ANARC	Anaplasma Control 5 x 1.0 mL

Analytes

Anaplasma phagocytophilum

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. Do not dilute

Ordering Information

Catalog #	Description
BABRC	Babesia Control 5 x 1.0 mL

Analytes

Babesia microti

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. Do not dilute

Ordering Information

Catalog #	Description
BRLRC	Bartonella Control 5 x 1.0 mL

Analytes

Bartonella quintana

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. Do not dilute

Ordering Information

Catalog #	Description
BORRC	Borrelia Control 5 x 1.0 mL

Analytes

Borrelia burgdorferi

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

Ordering Information

Catalog #	Description
ERLRC	Ehrlichia Control 5 x 1.0 mL

Analytes

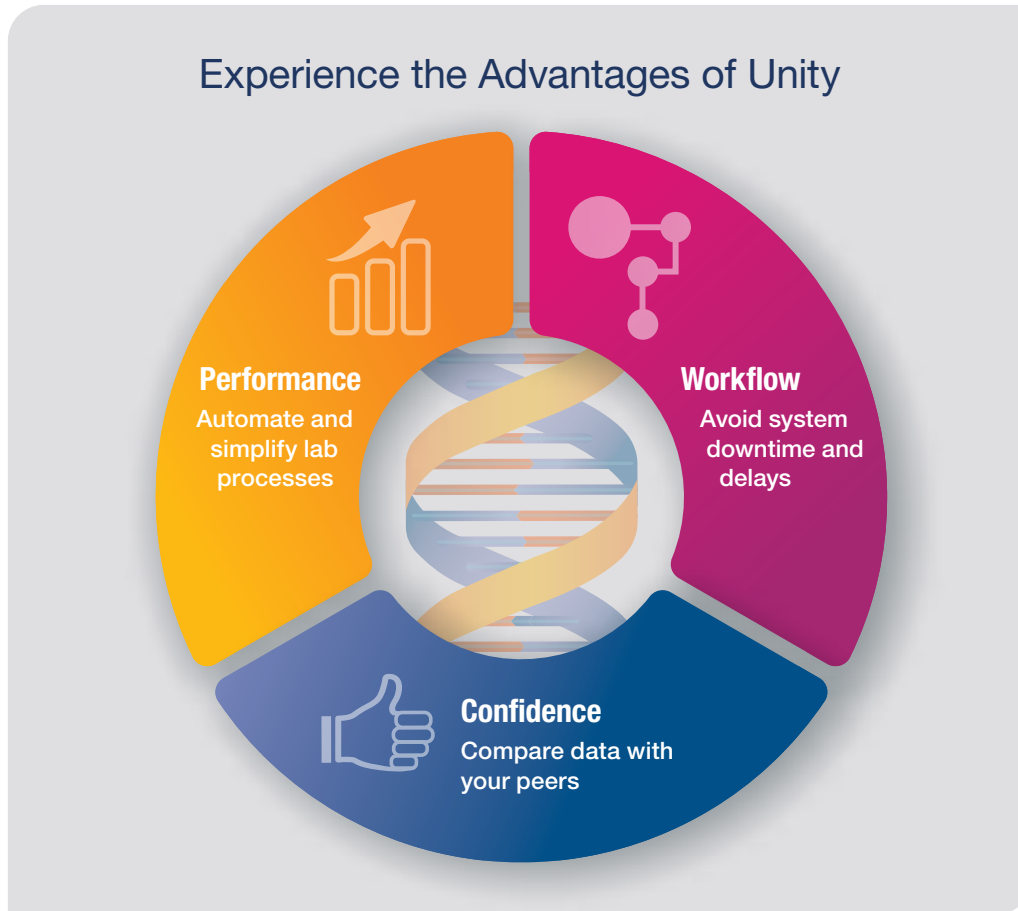
Ehrlichia chaffeensis

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