




NEW AMPLISENS® PCR KITS

Corynebacterium diphtheriae




C. diphtheriae is the bacterium that causes the disease diphtheria. Although the geographic occurrence for the disease is worldwide, it is mainly to be found in tropical regions and underdeveloped countries. Those facing the greatest risk of contracting the disease are immunocompromised individuals, poorly immunized adults and unvaccinated children.

The portals of entry for *C. diphtheriae* are the nose, tonsils and throat. Diseased individuals may experience a sore throat, overall weakness, fever and swollen glands. Diphtheria is transmitted from human contact through respiratory droplets, such as coughing or sneezing. If untreated, the diphtheria toxin can get into the bloodstream causing damage to the kidneys, nerves and heart. Extremely rare but serious complications include suffocation and partial paralysis.




Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® <i>Corynebacterium diphtheriae</i> / <i>tox-genes-FRT</i>	H-2842-1-CE	  	1000 GE/ml nasopharyngeal swabs, oropharyngeal swabs, swabs from disease sites RIBO-prep	<i>C. diphtheriae</i> DNA and genes encoding toxins of <i>C. diphtheriae</i> and <i>C.</i> <i>ulcerans</i>	QL	CE	110

Norovirus

Norovirus is one of the most common cause of gastroenteritis. Infection is characterized by diarrhea, vomiting and stomach pain. Fever or headaches may also occur. *Norovirus* causes about 18% of all cases of acute gastroenteritis worldwide (Ahmed et al., 2014).

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® <i>Norovirus GI</i> / <i>GII-FRT</i>	H-2751-1-3-CE	  	1 x 10 ³ GE/ml biopsy material of gastric mucosa DNA-sorb-B RIBO-prep	<i>Noroviruses</i> genogroups 1 and 2 (<i>Norovirus GI</i> and <i>GII</i>) RNA	QL	CE	55




Human herpes virus 7

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® <i>HHV7-screen/</i> <i>monitor-FRT</i>	H-2431-1-1-CE	  	5 x 10 ² GE/ml blood plasma, whole blood, saliva RIBO-prep	<i>human herpes virus</i> <i>type 7 (HHV7)</i> DNA	QN	CE	110




JC virus and BK virus

The JC virus or John Cunningham virus is a type of human polyomavirus. The virus causes progressive multifocal leukoencephalopathy (PML) and other diseases only in cases of immunodeficiency or immunosuppression.

The BK virus is similar to the JC virus, since their genomes share 75% sequence similarity. The BK virus rarely causes disease but is typically associated with patients who have had a kidney transplant.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® JCV-BKV screen/monitor-FRT	H-2441-1-1-CE	  	5x10 ² GE/ml whole blood, cerebrospinal fluid, urine RIBO-prep	JC virus (JCV) DNA and BK virus (BKV) DNA	QN	CE	110

Hepatitis C virus




Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® HCV-genotype-FRT	R-V1-G(1-4)-2x(RG, iQ, Mx, Dt, SC)-CE	  	Analytical sensitivity***** (page 65) RIBO-sorb RIBO-prep	hepatitis C virus (HCV) genotypes 1a, 1b, 2, 3a, and 4	QL Diff	CE	55

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Corynebacterium diphtheriae




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
Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® Corynebacterium diphtheriae / tox-genes-FRT	H-2842-1-CE	  	1000 GE/ml nasopharyngeal swabs, oropharyngeal swabs, swabs from disease sites RIBO-prep	<i>C. diphtheriae</i> DNA and genes encoding toxins of <i>C. diphtheriae</i> and <i>C. ulcerans</i>	QL	CE	110

Norovirus

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Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® Norovirus GI / GII-FRT	H-2751-1-3-CE	  	1 x 10 ³ GE/ml biopsy material of gastric mucosa DNA-sorb-B RIBO-prep	<i>Noroviruses</i> genogroups 1 and 2 (<i>Norovirus GI</i> and <i>GII</i>) RNA	QL	CE	55

Human herpes virus 7

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® HHV7-screen/monitor-FRT	H-2431-1-1-CE	  	5 x 10 ² GE/ml blood plasma, whole blood, saliva RIBO-prep	human herpes virus type 7 (HHV7) DNA	QN	CE	110

High-risk human papillomavirus

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® HPV HCR-screen-titre-FRT	R-V31-F-CE		1 x 10 ³ GE/ml vaginal swabs, scrapes of membrane mucosa of cervix uteri and urethra, endocervical scrapes DNA-sorb-AM	HCR HPV DNA 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 types	QL QN No Diff (only 16, 18, 45 genotypes)	CE	110

DNA extraction kit MAGNO-sorb-URO

Kit type	Catalog number	Description	CE/RUO	Number of tested samples
MAGNO-sorb-URO	K4-2181-100-CE	intended for extraction of DNA from the biological material (vaginal, cervical, urethral discharge; urine) for subsequent qualitative or quantitative detection of DNA of pathogens which causes sexually transmitted infections, other infections of reproductive organs and urinary tract by the polymerase chain reaction (PCR)	CE	100

Borrelia miyamotoi

B. miyamotoi can be transferred to humans through the ticks. The infection can cause fever, headache, fatigue and muscle aches.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® <i>Borrelia miyamotoi</i> -FRT	H-2791-1-CE		1 x 10 ³ copies/ml blood, tissue (autopsy, biopsy) material, cerebrospinal fluid, ticks MAGNO-sorb RIBO-prep	<i>Borrelia miyamotoi</i> DNA	QL	CE	55

Rickettsia conorii

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® <i>Rickettsia conorii</i> -FRT	H-2741-1-CE		1 x 10 ³ copies/ml blood, tissue (autopsy, biopsy) material, cerebrospinal fluid, ticks MAGNO-sorb RIBO-prep	<i>Rickettsia conorii</i> DNA	QL	CE	55

Yellow fever virus

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® Yellow fever virus-FRT	H-2461-1-CE		1000 copies/ml blood plasma, mosquitoes (homogenate), urine, saliva 5000 copies/ml tissue (autopsy, biopsy) material RIBO-prep	Yellow fever virus (YFV) RNA	QL	CE	55

Ebola multiprime kit

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/RUO	Number of tested samples
AmpliSens® <i>FiloA</i> -screen-FRT	H-2781-1-4-CE		1,000 copies/ml whole blood or its components RIBO-zol-B RIBO-prep	RNA of EBOV Zaire, SUDV, MARV of Filoviridae family	QL	CE	96