



Universal Nucleic Acid Purification Product Line

Superior flexibility combined
with efficient sample and cost management

Benefits in simplicity and efficiency

The new STRATEC Molecular Universal kit series simplifies laboratory workflows by using one uniform protocol for purification of different nucleic acids from a variety of molecular diagnostic relevant samples. The InviMag® and Invisorb® Universal kits provide a robust and reliable purification system for genomic DNA, bacterial DNA, viral DNA and viral RNA. Collecting batches of similar specimens or sorting by nucleic acid type is not necessary anymore. One kit can be used for various applications of infectious and genetic diseases diagnostics either in combination with several robotic systems or for manual use.

Simplicity

- One kit for a variety of starting materials and isolation of different nucleic acids under uniform conditions
- One chemistry for use in combination with spin columns, filter plates or magnetic beads
- Efficient utilization of 96 well plates



Efficiency

- Time saving and less error prone
- Less preparation steps – no mixing up different reagents
- Higher cost efficiency and less sample processing effort during daily laboratory work
- For various applications either in combination with several robotic systems or for manual use



Sensitivity

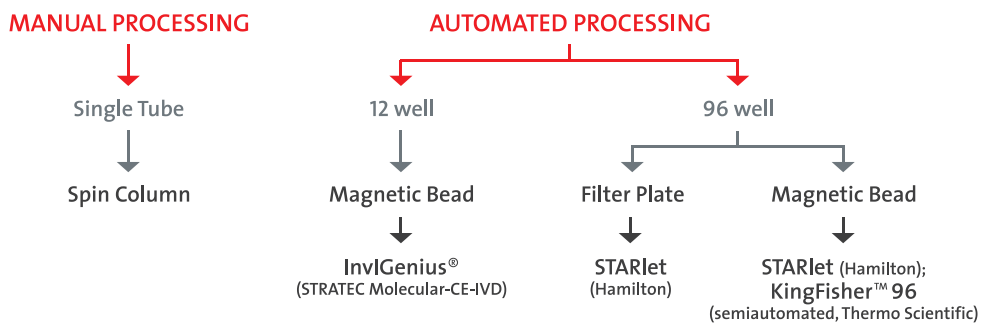
- Realized yields and sensitivities are comparable with specialized kits
- Excellent simultaneous isolation of internal extraction controls

Simplification of the daily routine via the use of one uniform protocol for all applications reduces the average cost, labor and sources of error.

Smarter nucleic acid purification

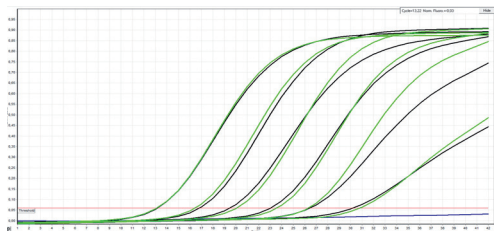
Product specification:	Kit for simultaneous isolation of genomic DNA, bacterial DNA, viral DNA & viral RNA
Amount of material:	200 µl, (100 µl for whole blood)
Starting material:	cell free body fluids, (serum, plasma, CSF, urine), whole blood (stabilized with EDTA or Citrate, no Heparin) rinse liquid from swabs or transport media, supernatant from stool suspension, sputum, bronchoalveolar lavage (BAL), sperms or semen, amniotic fluid, supernatant from organ abrasion, bacterial or viral cultures

The Invisorb® and InviMag® Universal protocols are adapted to various laboratory automation platforms including the InviGenius® (STRATEC Molecular), MICROLAB® STARlet (Hamilton) and KingFisher™ (Thermo Scientific).



Unparalleled performance

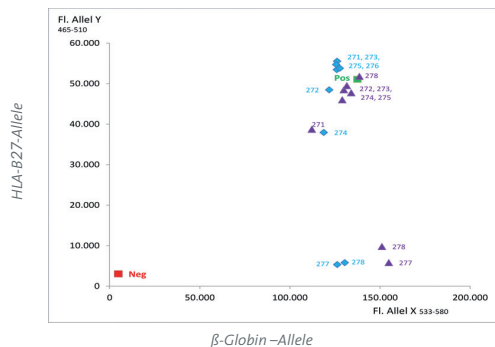
The Universal Kit series delivers excellent performance and reproducible results with sensitivity comparable to specialized extraction kits. The purified nucleic acid is ready for downstream analyses.



Influenza A detection

- 200 µl allantoic fluid (infected with Influenza A Subtype H9N2)
- Dilution series: 10 - 10⁻⁵
- Invisorb® Universal HTS 96 Kit/ STARlet (black)
- Spin Virus RNA Kit from a competitor (green).
- Detection of Influenza A with in-house PCR (FAM) and Rotor-GENE Q (Qiagen)

Result: sensitivity of isolated viral RNA using a universal kit is absolute comparable with the sensitivity of the specific kit



HLA-B27 detection

- 200 µl human blood (1:1 dilute with water)
- InviMag® Universal Kit/ STARlet (blue)
- Spin Blood Kit from competitor (violet)
- Detection of HLA-B27 with "in-house" PCR (FAM)
- Internal control: β-Globin (YAKYE)

Result: quality and yield of isolated DNA is comparable regarding genotyping of the HLA-B27 allele.

Ensured sensitivity

The data presented in the table below demonstrate the equivalence of the universal protocol in terms of sensitivity of extracted nucleic acids from clinical samples compared to specific manual or automated methods for the extraction of genomic DNA, bacterial DNA, viral RNA and DNA.

Starting Material	Pathogen - using STARlet	Nucleic acid specific Kits from competitors	InviMag® Universal Kit/ STARlet	Invisorb® Universal Kit/ STARlet
supernatant from stool susp.	Adenovirus	14.92	14.49	15.41
swabs from cloaca	Avian coronavirus	16.98	17.08	16.15
bronchial secrete	<i>Bordetella pertussis</i>	24.77	24.98	24.51
supernatant from stool susp.	<i>Campylobacter spp.</i>	23.27	23.27	22.70
tracheal secrete / BAL	<i>Mycoplasma pneumonia</i>	27.61	27.07	26.98
	Pathogen - using InviGenius®		InviMag® Universal Kit/IG	
swab	MRSA	23.56	22.88	
sputum	<i>Mycobacterium tuberculosis</i>	30.46	27.17	
swab	<i>Neisseria gonorrhoeae</i>	23.12	21.55	
	Pathogen - using KingFisher™ Flex 96		InviMag® Universal Kit/ KF Flex 96	
rinsed liquid from swab	Influenza A	26.68	24.91	
supernatant from stool susp.	Norovirus	26.46	26.52	
supernatant from stool susp.	<i>Chlostridium difficile</i>	29.54	29.18	
	Pathogen - using Spin columns		Invisorb® Spin Universal Kit	
amniotic fluid	Avian Influenza A	32.96	24.51	
bacterial culture	<i>Riemerella anatipestifer</i>	24.03	23.98	

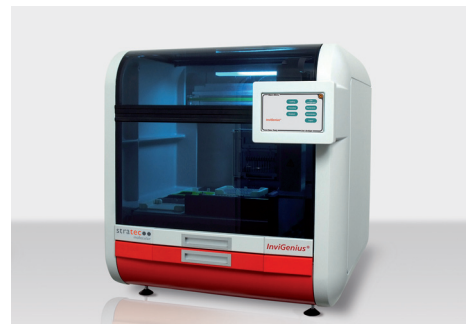
Product	Package Size	Catalogue Number
Invisorb® Spin Universal Kit	10 purifications	1050100900
	50 purifications	1050100200
	250 purifications	1050100300
InviMag® Universal Kit/ IG (for use on the InviGenius®, STRATEC Molecular GmbH)	8 x 12 purifications	2450120100
InviMag® Universal Kit/ KFDuo (for use on KingFisher™ DUO, Thermo Fisher Scientific)	8 x 12 purifications	2450130100
	40 x 12 purifications	2450130200
InviMag® Universal Kit/ KF96 (for use on KingFisher™ Flex, Thermo Fisher Scientific)	1 x 96 purifications	7450300100
	5 x 96 purifications	7450300200
Invisorb® Universal HTS 96 Kit/ STARlet (for use on MICROLAB® STARlet, Hamilton)	4 x 96 purifications	7150330300
	24 x 96 purifications	7150330400
InviMag® Universal Kit/ STARlet (for use on MICROLAB® STARlet, Hamilton)	4 x 96 purifications	7450330300
	24 x 96 purifications	7450330400

Automation of the InviMag® and Invisorb® Universal Kits

The flexible and efficient Universal Kit product line includes several kits for use on laboratory automation platforms using filter plates or magnetic beads for high- or low-throughput. The ability to combine the three different robotic systems below with the Universal Kits allows selecting a solution that fits to any budget, throughput and application requirements.

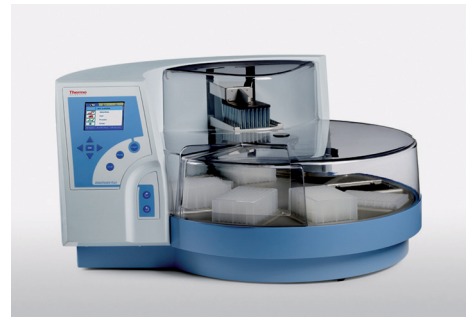
InviGenius® (STRATEC Molecular)

- Magnetic bead based
- Walk-away processing
- Air-displacement pipettor
- Up to 80 samples in 8h (12 samples per run)
- “Sample in – Eluate out” technology
- Total in-process control
- Advanced process safety and standardized sample preparation
- CE-marked according to IVD-directive*



KingFisher™ Flex 96 (Thermo Scientific)

- Magnetic bead based
- Semi-automated processing
- 96 samples per run / up to 5 runs in 8h
- Processing of incomplete lysed materials possible



Microlab® STARlet Workstation (Hamilton)

- Magnetic beads or filter plates
- Walk-away processing
- Air-displacement pipettor
- 96 samples per run / up to 3 runs in 8h
- Total in-process control



*) Products which are CE-marked according to the IVD-Directive can be used for diagnostic applications in countries where this directive is recognized.

Overview

The following table presents all validated starting materials for use with the Universal Kit panel in combination with the different robotic platforms IG (InviGenius®), SB (STARlet with magnetic beads) SP (STARlet with Filter plate), KF (KingFisher™). It summarizes further the compatibility of the eluted nucleic acid with a wide variety of commercial detection assays.

IG	SB	SP	KF	Pathogen	Starting Material	Detection System ^{Producer}
x	x	x	x	<i>Bordetella pertussis</i> / <i>parapertussis</i>	bronchial and tracheal secrete / sputum	RIDA®GENE Bordetella ¹
x	x	x	x	<i>Campylobacter ssp.</i>	supernatant from stool suspension	RIDA®GENE Bacterial Stool Panel ¹
x	x	x	x	<i>Chlamydia trachomatis</i>	urine	Cobas Taqman CT V2.0 ²
x				<i>Chlamydia vaginalis</i>	rinsed liquid from swab, urine	Light Mix® Kit ⁸
x				<i>Chlamydomydia pneumoniae</i>	sputum	Diagenode Mycoplasma pneumoniae & Chlamydomydia pneumoniae Real Time PCR Kit ⁵
x	x	x	x	<i>Clostridium difficile</i>	supernatant from stool suspension	RIDA®GENE CD Toxin A/B ¹
x				EPEC/EHEC	supernatant from stool suspension	RIDA®GENE EHEC/EPEC ¹
x				<i>Legionella pneumophila</i>	sputum	in-house PCR
x	x	x	x	MRSA	colony, skin swab	GeneOhm MRSA Kit ⁴ , RIDA®GENE MRSA ¹
x				<i>Mycobacteria tuberculosis compl.</i>	sputum, rinsed liquid from swab, saliva	MTB ELITE MGB Kit ³ , MTB compl. ⁵ ; MutaPLATE M. tuberculosis ⁷
x			x	<i>Mycoplasma pneumophila</i>	sputum	Diagenode Mycoplasma & Pneumophila Real Time PCR Kit ⁵
x				<i>Neisseria gonorrhoeae</i>	rinsed liquid from swab, urine	Diagenode Neisseria gonorrhoeae Real Time PCR Kit ⁵
x	x	x		Adeno - Virus	rinsed liquid from swab, supernatant from stool suspension	Adeno-Virus ⁵ , RIDA®GENE Rotavirus/Adenovirus Duplex ¹
x	x	x	x	Human Cytomegalovirus (CMV)	breast milk, serum, plasma, blood from stool suspension	CMV ELITE MGB Kit ³ , RealStar® CMV PCR Kit ⁶
x			x	Ebstein Barr Virus (EBV)	blood, plasma	EBV ELITE MGB Kit ³ , RealStar® EBV PCR Kit ⁶
	x	x		Human Papilloma Virus (HPV)	cell homogenate, transport media, rinsed liquid from swab	HPV16 High Risk real time PCR Kit ³ , HPV18 High Risk real time PCR Kit ³ , RealStar® alpha Herpesvirus PCR Kit ⁶
	x	x		Herpes Simplex Virus	lyophilized cell-lysate / liquor	RealStar® HSV PCR Kit ⁶
x				JCV-Enterovirus	plasma, urine	JCV ELITE MGB Kit ³
x				Metapneumo Virus	sputum	Diagenode Human Metapneumovirus (R-DiaMPV) ⁵
			x	Parvo B19 Virus	serum	in-house PCR
	x	x		Varicella Zoster Virus	rinsed liquid from swab	RealStar® VZV PCR Kit ⁶
x				Enterovirus	plasma	Enterovirus Q-PCR Alert Kit ³
x	x	x	x	Influenza A / B & H1/N1	rinsed liquid from swab	Influenza S&T RT PCR Kit 2.0 ⁶
x	x	x	x	Norovirus	supernatant from stool suspension	RIDA®GENE Norovirus ¹
	x	x		Rotavirus	supernatant from stool suspension	RIDA®GENE Rotavirus / Adenovirus Duplex ¹
x			x	Respiratorical Syntecial Virus (RSV)	tracheal secrete	RealStar® RSV RT-PCR Kit ⁶
	x	x		HLA-B27	blood (EDTA, Citrate)	in-house PCR
			x	Beta Globin from Digene	cyto material	in-house PCR
x			x	Factor II and V	blood (EDTA, Citrate)	RealStar® Faktor II PCR Kit 3.0 ⁶ ; RealStar® Faktor V PCR Kit 3.0 ⁶
x				Haemochromatosis	blood (EDTA, Citrate)	HFE Duplex ⁸

1) R-Biopharm AG 2) Roche Diagnostics International AG 3) Nanogen Advanced Diagnostic S.p.A. 4) Becton Dickinson GmbH
5) Mikrogen GmbH 6) Altona Diagnostics GmbH 7) Immundiagnostik AG 8) Tib Molbiol GmbH