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The InviGenius®

Walk-away DNA/RNA sample preparation

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CONTENT

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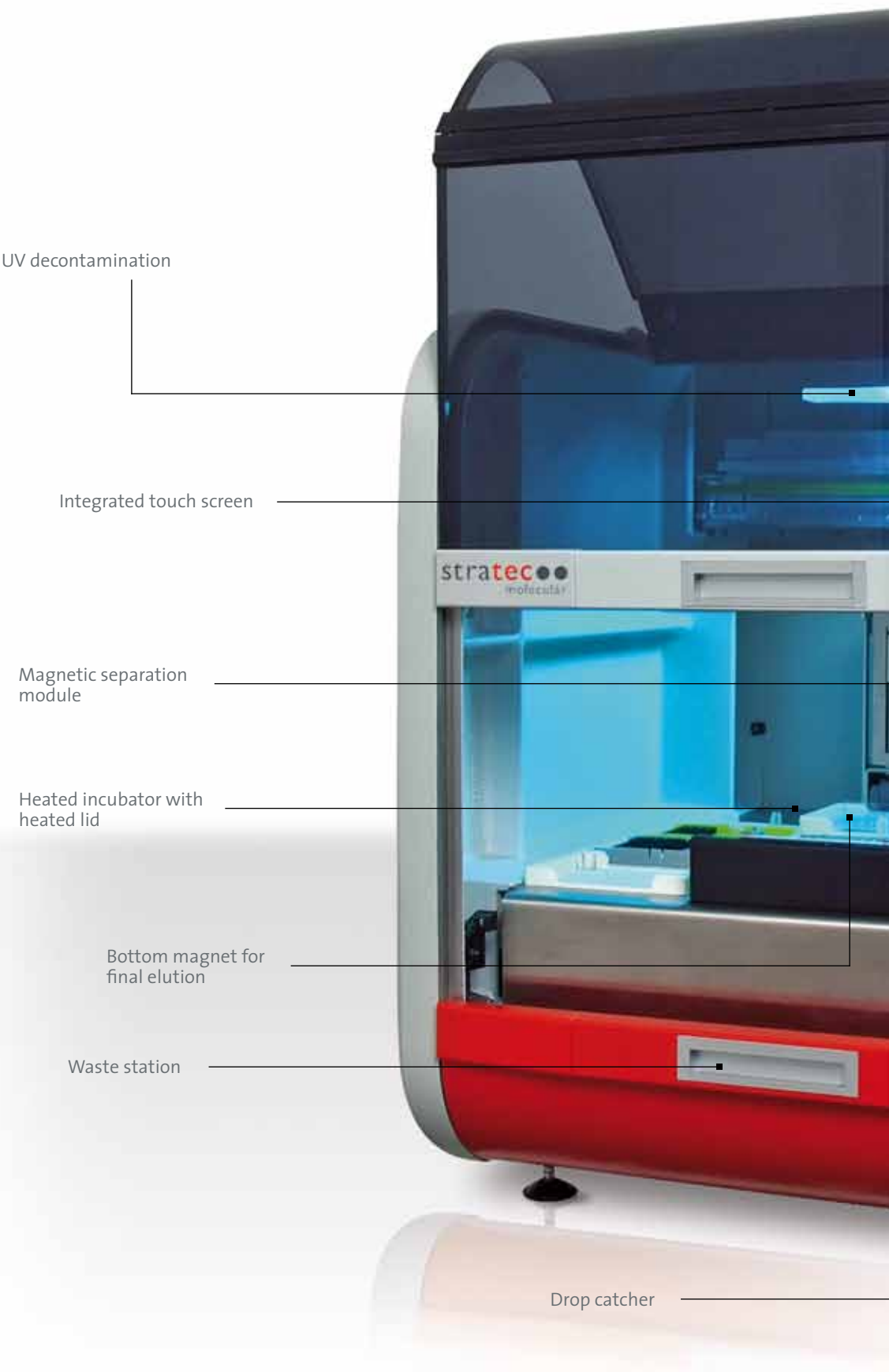

SUPERIOR AUTOMATED SAMPLE PREPARATION

The InviGenius® provides advanced and reliable performance in automated nucleic acid sample preparation. The combination of well-established magnetic bead based InviMag® technology and state-of-the-art process automation allows for standardization and streamlining of laboratory workflows. Innovative functionality and optimized protocols result in reliable performance and superior DNA and RNA quality.

The InviGenius® is a breakthrough platform with full in-process control specially optimized for delivering premium quality nucleic acid for a variety of diagnostic laboratory procedures*.

**) In compliance with the Directive 98/79/EC on in vitro diagnostic medical devices (IVD-Directive). Products which are CE-marked according to the IVD-Directive can be used for diagnostic applications in countries where this directive is recognized. The device is not approved by the US FDA.*

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The InviGenius® - Ultimate safety of set-up and operation

With its innovative functionality the InviGenius® delivers exceptional process safety in a completely monitored operation environment. Elaborate software control and intuitive user guidance enable full process documentation and prevent sample tracking errors.

- Loading racks for primary tubes
- Integrated barcode reader for samples identification during loading
  - Prevention of human errors
  - Tracking of samples

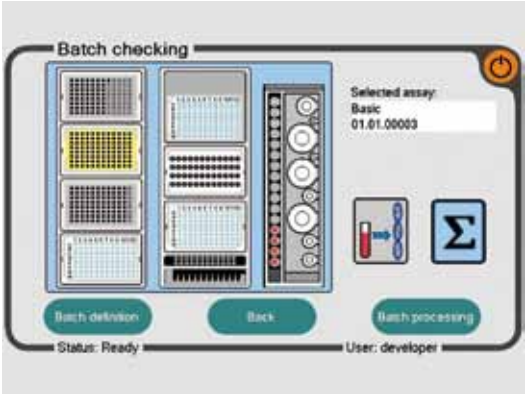
Examples of compatible primary tubes:

- Sarstedt Monovette®
- BD Vacutainer®
- TERUMO Venosafe®
- Greiner Bio-One Vacuette®

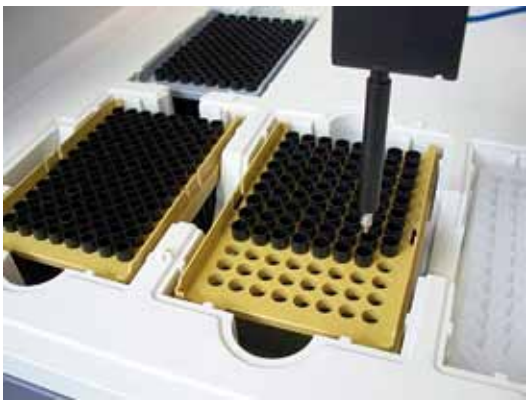
- Loading rack with flexible reagent positioning and automated reagent detection
  - Prevention of human errors
  - Verification of correct reagents
  - Verification of valid expiration dates

THE InviGenius® DELIVERS PURE PERFORMANCE:

- Extract and purify DNA and RNA from up to 12 liquid samples in parallel
- Up to 4 ml sample volume
- Total in-process control
- Advanced process safety and standardized sample preparation
- Proven performance-leading magnetic-particle chemistry
- CE-marked according to IVD-directive



- Inventory checks before and during run
- Software-supported setup of reagents, waste and disposables
- Defined and protected protocols prevent user-errors



- Air displacement pipettor with liquid level sensing capability utilizing barometric and capacitive measurement technology
- Reduced maintenance and waste - no system liquid is required
- Prevention of cross contamination through use of filter tips and intelligent routing

ADDITIONAL PIPETTING OPTIONS:

- Aliquot pipetting of eluates for generation of replicates, e.g. for PCR
- Pre-mix of samples to prevent clogging and for sample resuspension

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Fully automated walk-away purification for routine applications

The InviGenius® is a true walk-away system for DNA/RNA extraction and purification from clinical samples - providing a reliable "Sample in - Eluate out" technology!

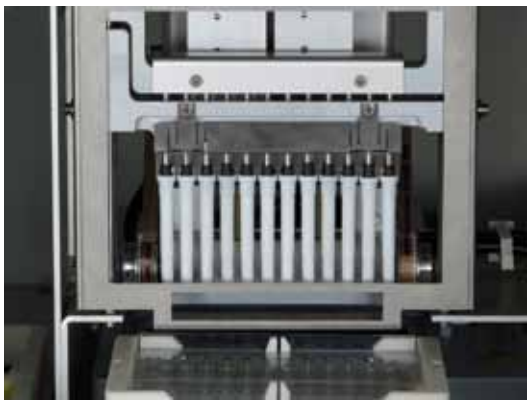
No user intervention is necessary from sample loading to extracted DNA/RNA.

- Heated incubator - automated heated lysis (up to 90 °C) on board. A heated lid prevents aerosol formation and condensation.

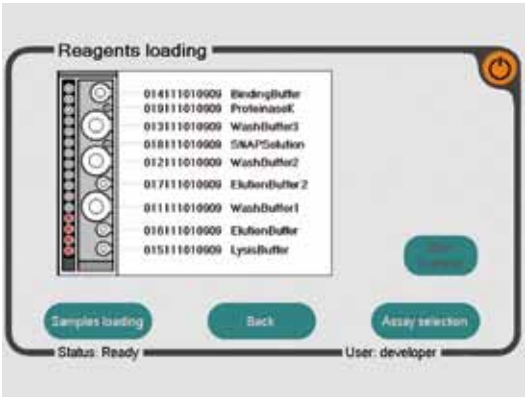
- Magnetic separation module with 12 magnetic rods - for transfer of magnetic bead bound DNA or RNA and for sample mixing.

FURTHER SAFETY FEATURES:

- Bottom magnets - prevent carry-over of beads into the eluate
- Drop catcher - minimizes the risk of cross contamination
- UV light - enables reliable decontamination of the worktable



- Automatic detection of sheath presence to ensure process safety



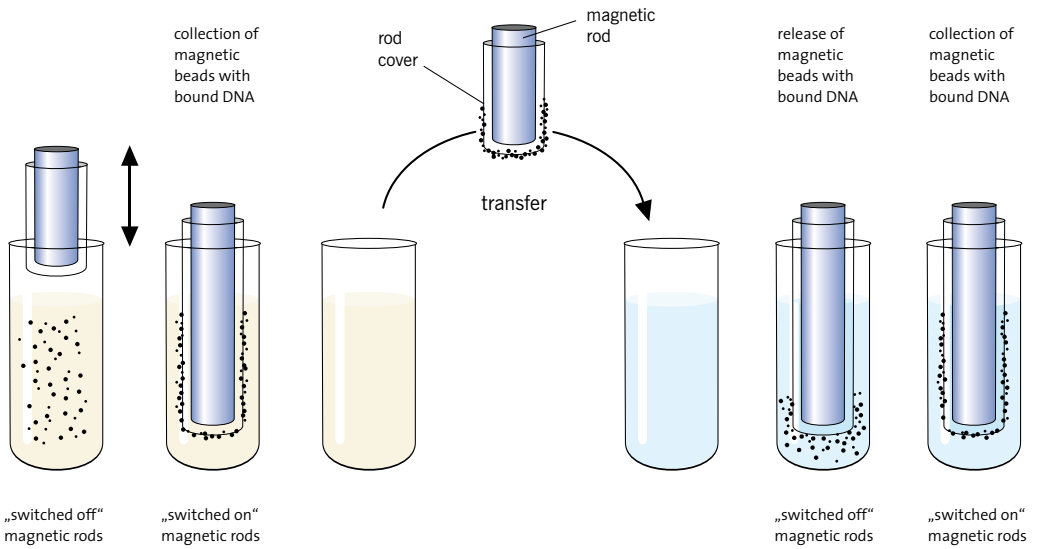
- Intuitive, easy to use software - an integrated touch screen enables easy protocol selection and system set up. Software is designed to integrate with a LIMS system as well. No external keyboard or mouse is required.

ADVANCED TROUBLESHOOTING:

- Acoustic signal, e.g. in case of closed bottles, clotted sample
- Flagging of problematic samples
- Automatic hard disk space management

The InviGenius® takes efficiency to a new level

The InviGenius® controls an array of magnetic rods that can collect or release magnetic particles. After sample lysis the nucleic acids are bound to the magnetic particles and transferred through the extraction, purification, and elution processes. This circumvents pipetting errors. The eluted pure nucleic acids are ready-to-use for subsequent downstream applications.



The InviMag® technology for the InviGenius® system increases laboratory efficiency by allowing for fewer kits, in combination with optimized protocols, to cover a broad range of starting materials and applications. Sample volumes up to 4 ml can be processed, providing increased nucleic acid yields for genomic applications and higher sensitivity in viruses and bacteria detections.

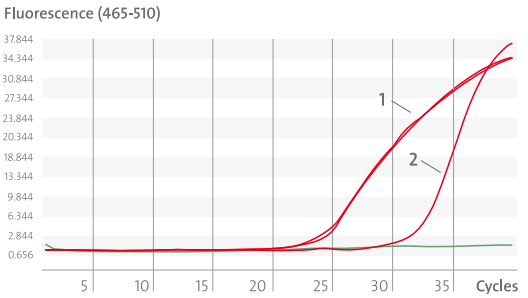
The InviGenius® - Kits and applications

NUCLEIC ACID	STARTING MATERIAL	PRODUCT NAME
Genomic, bacterial, viral DNA & viral RNA	200 µl whole human blood (EDTA, citrate), plasma, serum, cell-free body fluids, rinse liquid from swabs, supernatant from stool suspensions, sputum, BAL, urine	InviMag® Universal Kit/ IG
Viral and bacterial DNA & viral RNA	500 µl plasma, serum, cell-free body fluids, rinse liquid from swabs, supernatant from stool suspensions, sputum, BAL, urine	InviMag® Pathogen Midi Kit/ IG
Genomic DNA	200 µl whole human blood (EDTA, citrate) 2 ml whole human blood (EDTA, citrate) 4 ml whole human blood (EDTA, citrate)	InviMag® Blood DNA Mini Kit/ IG InviMag® Blood DNA Maxi Kit/ IG InviMag® Blood DNA Giga Kit/ IG
	1.6 ml SalivaGene® stabilized saliva samples	InviMag® SalivaGene DNA Kit/ IG
	4ml plasma, serum, amniotic fluid	InviMag® Free Circulating DNA Kit/ IG
Viral DNA	200 µl whole human blood (EDTA, citrate), plasma, serum, cell-free body fluids, rinse liquid from swabs, transport media	InviMag® Virus DNA Mini Kit/ IG
Viral RNA	200 µl plasma, serum, cell-free body fluids, rinse liquid from swabs, cell culture supernatants 50 mg stool sample (supernatant from stool suspension)	InviMag® Virus RNA Mini Kit/ IG

The InviMag® technology incorporates many years of experience in developing magnetic bead based kits for automated systems. The InviMag® kits rely upon STRATEC Molecular proprietary formulations and ensure superior results for the extraction and purification of DNA and RNA. We are constantly developing new and additional applications to run on the InviGenius®.

1. One isolation kit for various starting materials and nucleic acid types - InviMag® Universal Kit/ IG

Fig. 1: VIRAL RNA FROM SPUTUM

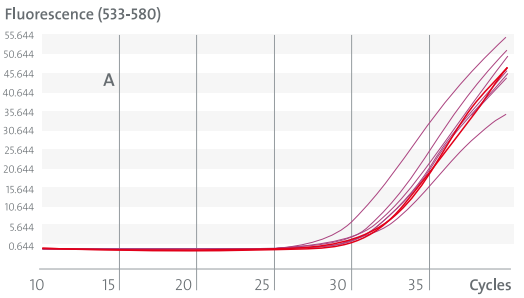


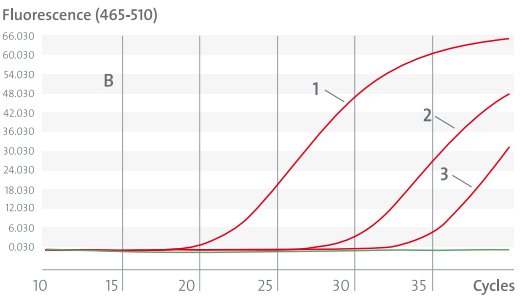
RNA from human metapneumovirus was isolated from sputum samples using the InviMag® Universal Kit/ IG and the spin column based Invisorb® Spin Virus RNA Mini Kit from STRATEC Molecular. 10 µl of the eluted RNA were amplified using the "dia Human metapneumovirus" assay from Mikrogen Diagnostik (Neuried, Germany). Both extraction methods showed comparable CT values.

1 - positive patient samples
2 - positive control

Data kindly provided by M. Haesner, Medizinisches Labor Prof. Schenk/ Dr. Ansorge, Magdeburg, Germany.

Fig. 2: BACTERIAL DNA ISOLATION (GRAM-POSITIVE BACTERIA)



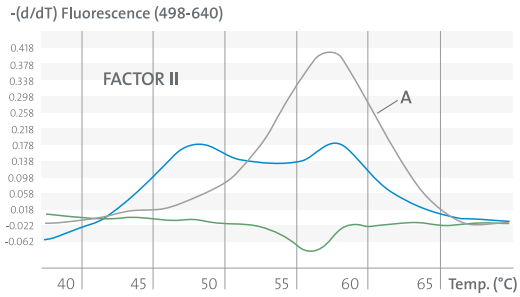


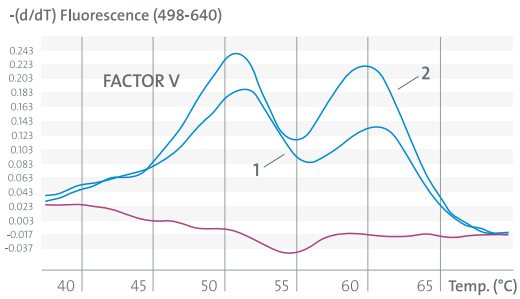
Bacterial DNA was isolated from twelve potentially infectious patient samples (sputum samples, bacteria culture from swab) using the InviMag® Universal Kit/ IG. 10 µl of the eluted DNA were amplified using the „MutaPLATE M. tuberculosis„ real-time PCR assay from Immundiagnostik AG (Bensheim, Germany).

A: internal controls of all 12 samples – were amplified, without any inhibition
B: red - TBC positive patient samples [swab (1); sputum (2) internal control (3)]
green - TBC negative patient samples (valid negative results)

Data kindly provided by M. Haesner, Medizinisches Labor Prof. Schenk/ Dr. Ansorge, Magdeburg, Germany.

Fig. 3: GENOMIC DNA ISOLATION FROM BLOOD SAMPLES





Genomic DNA was isolated from 200 µl of human blood using the InviMag® Universal Kit/ IG. 10 µl of isolated DNA were amplified using the „RealStar Faktor II PCR Kit 3.0„ und „RealStar Faktor V PCR Kit 3.0„ from Altona Diagnostics (Hamburg, Germany).

Factor II: Patient sample - wild-type
Factor V: Patient sample - heterozygous for factor V

Factor II:
green - negative control
blue - positive control
grey - patient sample, wild-type (A)

Factor V:
purple - negative control
blue - positive control (1)
blue - patient sample, heterozygous (2)

Data kindly provided by M. Haesner, Medizinisches Labor Prof. Schenk/ Dr. Ansorge, Magdeburg, Germany.

Tab. 1: ISOLATION OF NUCLEIC ACIDS FROM TWELVE DIFFERENT PATHOGEN CONTAINING SAMPLES IN THE SAME RUN

DNA/RNA from different viruses and bacteria species were isolated using the InviMag® Universal Kit/ IG in the same run in parallel. For comparison an equivalent STRATEC Molecular spin kit was used with aliquots of the same sample. DNA/RNA eluates were analyzed via real-time PCR using the assays listed below. The results show comparable CT values.

STARTING MATERIAL	PATHOGEN	SPIN KIT	CT: UNIVERSAL	CT:SPIN	ASSAY
stool*	*Norovirus*	Invisorb® Virus RNA Mini Kit	27.06	27.06	RIDA GENE Norovirus [1]
swab from urethra**	*Neisseria gonorrhoeae*	RTP® Bacteria DNA Mini Kit	21.55	23.12	Neisseria gonorrheae [2]
swab**	*MRSA*	RTP® Bacteria DNA Mini Kit	22.88	23.56	GeneOhm MRSA Kits [3]
stool*	*EHEC*	PSP® Spin Stool DNA Kit	26.12	27.00	RIDA GENE EHEC/EPEC rt PCR [1]
urine	*Chlamydia trachomatis*	RTP® Bacteria DNA Mini Kit	32.71	32.37	Cobas Taqman CT V2.0 [4]
stool*	*Clostridium difficile*	RTP® Bacteria DNA Mini Kit	32.76	30.34	RIDA GENE CD TOX A/B V [1]
sputum****	*Mycobacterium tuberculosis*	RTP® Mycobacteria Kit	27.17	30.46	MTB compl [2]
sputum	*Metapneumo Virus*	Invisorb® Virus RNA Mini Kit	23.79	24.00	Metapneumo Virus [2]
lyophilized cell lysate***	*Influenza A/B (inkl. H1N1 & H5N1)*	Invisorb® Virus RNA Mini Kit	24.73	24.03	Influenza S&T RT PCR Kit2.0 [5]
sputum	*Mycoplasma pneumophila*	RTP® Bacteria DNA Mini Kit	34.32	29.58	Mycoplasma & Pneumophila [2]
swab**	*Adeno-Virus*	Invisorb® Virus DNA Mini Kit	32.00	32.00	Adeno-Virus [2]

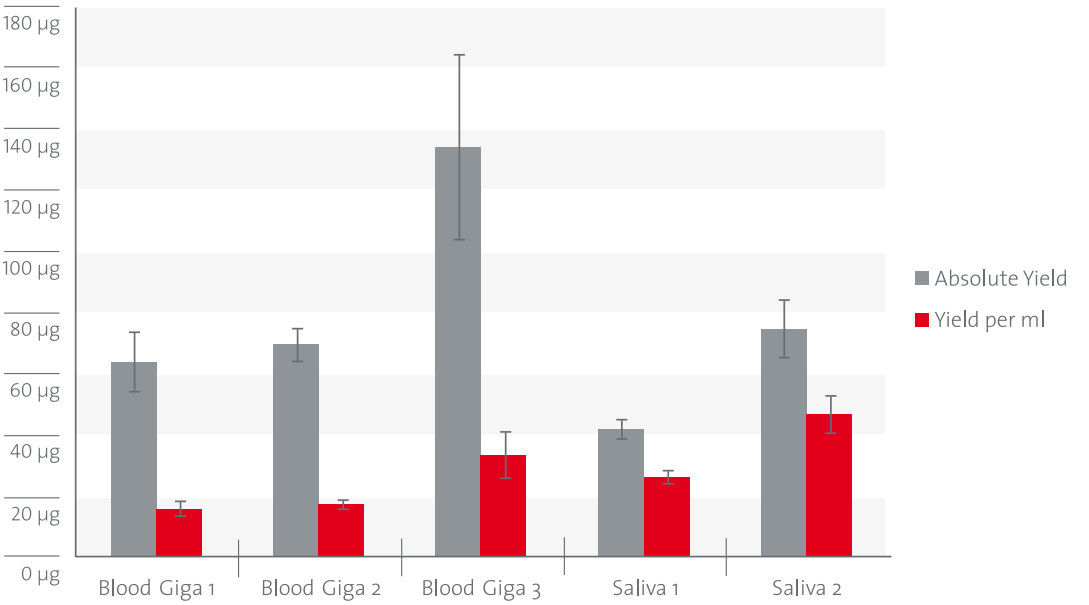
**) supernatant from 50 mg stool, resuspended in 600 µl RNAse-free water, centrifuged at 2000 rpm for 2 min*
***) rinsed in 600 µl RNAse-free water*
****) resuspended in 1 ml bidest. water*
*****) sample is mixed with 20 vol % NAC Buffer and incubated for 10 min at 95 °C*

1: R-Biopharm
2: Mikrogen
3: BD
4: Roche Diagnostics
5: Altona Diagnostics

Data kindly provided by M. Haesner, Medizinisches Labor Prof. Schenk/ Dr. Ansorge, Magdeburg, Germany.

2. Automated DNA extraction from large volume blood samples - InviMag® Blood DNA Giga Kit/ IG

Fig. 4: HIGHEST DNA YIELDS



Genomic DNA was isolated from 4 ml of twelve samples from six different bloods using the InviMag® Blood DNA Giga Kit/ IG and 24 stabilized saliva samples from 2 saliva pools were extracted using the InviMag® SalivaGene DNA Kit/ IG. All samples were measured by a NanoDrop photometer for absorptions at 230, 260, 280 and 320 nm. Each data point represents the average of four independent extractions. A total yield of 50 µg - 140 µg DNA was obtained using the InviMag® Blood DNA Giga Kit/ IG. The saliva protocol from 1.6 ml of starting material resulted in approx. 40 µg - 100 µg DNA.

All protocols provided high DNA yields in high quality. Therefore the DNA amount is suitable for a variety of downstream applications which need large amounts of template DNA, e.g. next generation sequencing.

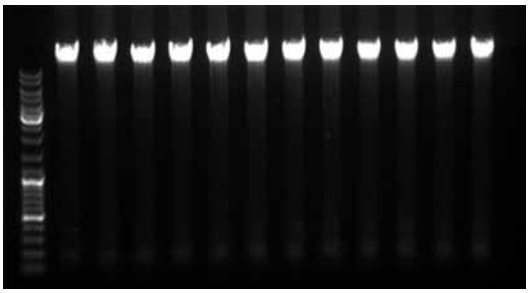
3. Genomic DNA from saliva using the SalivaGene Collector

SalivaGene Collector tubes (barcode labeled) can directly be placed into the sample loading racks of the InviGenius®.

Fig. 5: SalivaGene COLLECTOR

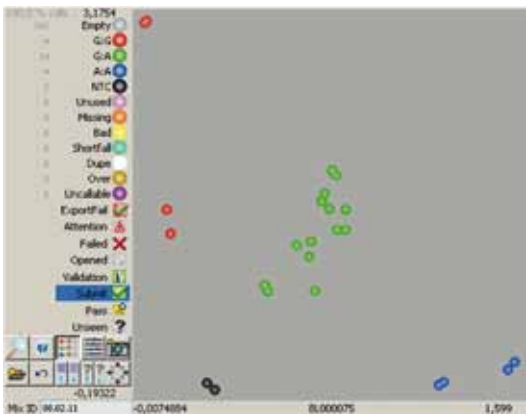
The SalivaGene Collector introduces a breakthrough simplification of saliva collection designed to provide highest DNA yields in high quality. The patented lyophilized stabilization buffer supersedes cooling of samples and stabilizes genomic DNA for 12 months at room temperature.

Fig. 6: SEAMLESS INTEGRATION INTO AUTOMATIC WORKFLOWS



Genomic DNA was automatically purified from 1.6 ml of stabilized saliva samples (pooled samples of ten different donors) using the InviMag® SalivaGene DNA Kit/ IG. 10 µl were analyzed on a 0.8 % agarose gel stained with ethidium bromide. (Marker - GeneRuler™ DNA Ladder, Fermentas)

Fig. 7: GENOTYPING RESULTS FOR SNP RS9934438 IN *VKORC1* GEN



Genotyping of selected SNPs (Single Nucleotide Polymorphisms) for 11 randomly selected individuals was performed using a KASP assay system (KBioscience, Herts, UK). Genomic DNA of each subject was tested in duplicates. A genotyping accuracy rate of 100% was obtained. The genotyping success rate was between 91 and 100%.
Genotyped samples marked in red are homozygous for the G-, those marked in blue are homozygous for the A-allele. Heterozygous samples are marked green. Two negative controls (marked in black) were included on each genotyping plate.

The gene product of VCORC1 is involved in metabolism of coumarin derivative drugs (Warfarin®, Marcumar®).

Data kindly provided by Prof. D. Steinberger, bio.logis - Center for Human Genetics, Frankfurt am Main, Germany.

SPECIFICATIONS

TECHNICAL SPECIFICATIONS	
Sample volume	200 to 4000 µl (protocol-specific)
Capacity	Up to 12 samples per run
Processing Time	60 - 180 min (protocol-specific)
Magnetic rods	12 (plus bottom magnets)
Heating temperature	Heat incubator, up to 90 °C
Computer	Integrated PC
Internal software	MS Windows
User interface	Touch screen
Ports / drivers	USB, Ethernet, RS232 / 80 GB hard disc
Decontamination	UV irradiance
Dimensions	75.6 x 80 x 76.5 cm, approx 76 kg
Type	Stand-alone tabletop instrument
Pipette tips	1100 µl conductive disposable filter tips
Integrated barcode reader	2/5 Interleaved, Code 39, Code 93, Code 128, Codabar max. length of barcode: 20 digits
Air displacement pipettor	Up to 1000 µl volume range barometric and capacitive liquid level detection
Pipetting precision	Less than 2 % CV at 20 µl, less than 1 % CV at 100 µl

COMPREHENSIVE SERVICE AND SUPPORT BY A TRAINED TEAM

The InviGenius® evolved from the desire to offer a high quality and easy to use walk-away DNA/RNA extraction system. This results in minimal hands-on time, significant reduction of human error, standardization of important processes, and integration of data storage for backup and archiving.

STRATEC Molecular's dedicated team of application and technical specialists will work with you to optimize the operation of the InviGenius® in your laboratory. We offer customized on- and off site training and flexible support agreements tailored to the needs of your laboratory.

ORDERING INFORMATION

PRODUCT NAME	CATALOG NUMBER	PACKAGE SIZE
InviGenius®	5011100000	1 unit
Waste Tray/ IG (disposable)	5011100100	25 pieces
Sheaths	5011100200	100 pieces
Sheaths Bundle	5011100300	10 x 48 pieces / rack
Conductive filter tips, 1100 µl	5011100400	10 x 96 pieces / rack

KITS FOR USE ON THE InviGenius®

PRODUCT NAME	CATALOG NUMBER	PACKAGE SIZE
InviMag® Universal Kit/ IG CE	2450120100	8 x 12 preps
InviMag® Pathogen Midi Kit/ IG	2445220100	8 x 12 preps
InviMag® Blood DNA Mini Kit/ IG CE	2431120100	8 x 12 preps
InviMag® Blood DNA Maxi Kit/ IG	2431320100	8 x 12 preps
InviMag® Blood DNA Giga Kit/ IG	2431320400	8 x 12 preps
InviMag® SalivaGene DNA Kit/ IG	2435260100	8 x 12 preps
InviMag® Free Circulating DNA Kit/ IG	2439320400	8 x 12 preps
InviMag® Virus DNA Mini Kit/ IG CE	2442120100	8 x 12 preps
InviMag® Virus RNA Mini Kit/ IG CE	2443120100	8 x 12 preps

STRATEC Molecular develops and manufactures reagents and kits for DNA/RNA stabilization, extraction and purification using manual and automated systems. Established under the name Invitek in 1992, STRATEC Molecular provides innovative system solutions for nucleic acid sample preparation from any sample type. The company is internationally respected for its outstanding and high performance technology platforms and offers a broad spectrum of DNA/RNA sample preparation kits and reagents for molecular diagnostics and life science research.
Together with STRATEC Biomedical's proven and reliable instrumentation experience STRATEC Molecular will develop automated system solutions for tomorrow´s challenges in molecular diagnostic sample preparation.

STRATEC Molecular has implemented a quality system certified according to EN ISO 13485:2003 + AC:2009 and ISO 9001:2008. In addition, STRATEC Molecular products are subject to extensive quality controls. A large number of STRATEC Molecular products are CE-marked*) in compliance with the Directive 98/79/EC on in vitro diagnostic medical devices (IVD-Directive). STRATEC Molecular guarantees that all products will perform as indicated and will provide the highest quality of support.

About the STRATEC Group

The STRATEC group consists of the publicly listed parent company STRATEC Biomedical AG and of subsidiaries and second-tier subsidiaries in Germany, the USA, the UK, Switzerland and Romania. The STRATEC Biomedical AG (http://www.stratec.com) designs and manufactures fully automated systems for its partners in the fields of clinical diagnostics and biotechnology.

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

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