



- Sexually Transmitted Diseases
- Respiratory Tract Infections
- Drug Resistant Hospital Acquired Infections
- Microbial and Parasitic Gastroenteritis
- Genetic Carriers Screening
- Pharmacogenetics
- Diseases Predisposition Markers
- Urinary Tract Infections
- Women's Health







Company Profile

Savyon Diagnostics, a member of the "Gamida Diagnostics Division" group of companies, develops, manufactures and markets high quality diagnostic tests and systems for the detection of Infectious Diseases and Genetic Screening for more than 25 years through a worldwide network of over 80 distributors.

Savyon Diagnostics product lines can be categorized according to areas of disease diagnosis:

- Sexually Transmitted Diseases
- Respiratory Tract Infections
- Drug Resistant Hospital Acquired Infections
- Microbial and Parasitic Gastroenteritis
- Genetic Carriers Screening
- Urinary Tract Infections
- Women's Health

Savyon Diagnostics tests are based upon various immunological and molecular biology techniques (Micro Arrays, ELISA, MIF, IPA, Lateral Flow etc.) and also maintains a myriad of patents related to these products. The company possesses the unique expertise of producing quality core biologicals including: antigens, antibodies, recombinant proteins and nucleic acid-based probes, while using cutting edge technology to manufacture the products to the high standards upon which laboratories and research institutions have come to depend.

Most of Savyon Diagnostics products are developed by our experienced and skilled R&D team who maintain close relationships with international key opinion leaders and academic institutions. Building on its innovative R&D capabilities, Savyon Diagnostics has recently introduced the novel bench-top microarray system, the NanoCHIP®XL analyzer that enables fully automated high throughput testing of DNA/RNA.

Savyon Diagnostics is accredited with the highest international quality standards of research, development and manufacture, including ISO 13485. The company's products are all CE certified and those sold in the USA are FDA approved. In Canada Savyon has CMDCAS, ISO 13485 (2003) and selected products are cleared by the SFDA for sale in China.

Building upon our excellence in manufacturing, Savyon Diagnostics also specializes in contract manufacturing services for numerous companies varying from startups to medium and large enterprises.



►► SeroCT[™] and SeroCT[™] RT

The SeroCTTM is the first ELISA based assay for the detection of *C. trachomatis* antibodies in which *C. trachomatis* species specific peptides are used as antigens. The peptides used in the kit originate from Chlamydia species specific immunodominant proteins. The peptides share common sequences with all serovars of *C. trachomatis* and present no homology to other Chlamydia species.

SeroCTTM offers high sensitivity and specificity in detecting anti-chlamydia IgG and IgA antibodies and allows complete diagnosis of acute, past and chronic infection. No cross species reactivity was observed, especially with *C. pneumoniae*.

The SeroCTTM RT kit represents a new configuration of this test enabling shorter incubations at room temperature and Ready-to-Use (RTU) conjugate solution.

Main advantages of the RT line:

- Short procedure
- Ready-To-Use reagents
- Room temperature incubations
- Compatible with automation

SeroCT™ IgG SeroCT™ IgA	96/192 tests 96/192 tests	181-01 183-01	
SeroCT™ RT IgG	96 tests	1181-01	
SeroCT™ RT IgA	96 tests	1183-01	Gene Wash buffer Verifigation consenses See Conse
		STOCT IN SECULATION OF THE SEC	REAL TOWNS AND ADDRESS AND ADD

▶▶ SeroELISA™ Chlamydia

The SeroELISA™ Chlamydia product line is intended for the determination of IgG, IgA and IgM antibodies to Chlamydia in human serum by ELISA.

The SeroELISA™ Chlamydia test employs the L2 serovar broadly reacting antigen of *C. trachomatis*. It detects antibodies to *C. trachomatis*, *C. psittaci* and *C. pneumoniae* (TWAR).

SeroELISA™ Chlamydia IgG	96 Tests	111-01
SeroELISA™ Chlamydia TRUE-IgM	96 Tests	112-01
SeroELISA™ Chlamydia IgA	96 Tests	113-01

▶▶ QuickStripe™ Chlamydia Ag

The QuickStripe Chlamydia Ag is a rapid test for qualitative detection of Chlamydia antigen within minutes. The test utilizes antibodies specific for Chlamydia to selectively detect chlamydial antigen from cervical or urethral swabs and urinary specimens.

QuickStripe™ Chlamydia Ag41101QuickStripe™ Chlamydia Ag with Positive Control41115

Main advantages of the SeroELISA Chlamydia:

- Genus Specific
- TRUE-IgM procedure eliminates RF and IgG interference
- Ideal for both high and low volume laboratories
- Compatible with automation

▶▶ SeroFIA™ Chlamydia

The SeroFIA™ Chlamydia product line consists of specific Microimmunofluorescence assays (MIF) for the determination of IgG, IgM and IgA antibodies to *Chlamydia pneumoniae*, *Chlamydia trachomatis* and *Chlamydia psittaci* in human serum.

The user-friendly SeroFIA™ Chlamydia slides contain (one row of seven antigen-coated wells) for each of the three chlamydial species, or alternatively a whole slide contains antigens for only one chlamydial species.

Simultaneous differentiation of the three chlamydial species

The performance of the SeroFIATM Chlamydia was found to be in excellent agreement with both commercial and in-house conventional MIF test results.

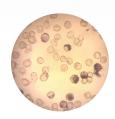
SeroFIA TM	IgG Chlamydia	105 tests	511-01
SeroFIA™	IgM Chlamydia	105 tests	512-01
SeroFIA™	IgA Chlamydia	105 tests	513-01
SeroFIA™	C. psittaci	105 tests	570-01
SeroFIA™	C. trachomatis	105 tests	580-01
SeroFIA™	C. pneumoniae	105 tests	590-01



▶▶ IPAzyme™ Chlamydia

IPAzyme™ Chlamydia product line is an indirect ImmunoPeroxidase Assay (IPA) intended for the detection and titration of anti-Chlamydia specific IgG, IgA and IgM antibodies in human serum.

IPAzyme[™] Chlamydia IgG/IgA 144 tests 011-01 IPAzyme[™] Chlamydia TRUE-IgM 96 tests 012-01



Results are easily read using a regular light microscope

▶▶ SeroHSV[™]

Savyon Diagnostics offers a complete panel for the detection of Herpes Simplex antibodies in human sera.

SeroHSV1[™] is a highly specific and sensitive competitive ELISA test for the screening of HSV1 antibodies – no cross-reaction with HSV2.

SeroHSV2™ is a qualitative Competitive Binding ELISA Assay for the detection of specific antibodies to HSV2. This test is of value for the detection of those patients who were previously exposed to HSV2 virus. No cross-reaction with HSV1 and Varicella zoster virus (VZV).

SeroHSVTM IgG and IgM are semi-quantitative ELISA tests for the detection of specific IgG and IgM antibodies, respectively to HSV types 1 & 2 in human serum.

SeroHSV1™	96 tests	240-01
SeroHSV2™	96 tests	250-01
SeroHSV™ IgG	96 tests	152-01
SeroHSV™ IgM	96 tests	151-01

►► SeroCP™ and SeroCP™ RT

SeroCPTM is an ELISA based test for qualitative detection of *Chlamydia pneumoniae*. This test is the perfect screening tool for the detection of *C. pneumoniae* antibodies in human serum. The assay utilizes purified elementary bodies of *C. pneumoniae* (TWAR-183) as antigens to detect the antibody response.

The SeroCPTM RT kit represents a new configuration of this test enabling shorter incubations at room temperature and Ready-to-Use (RTU) conjugate solution.

The SeroCPTM and SeroCPTM RT tests offers complete antibody profiling of IgM, IgG and IgA to *C. pneumoniae* and presents high accordance with MIF assays.

SeroCP™ IgG	96 tests	191-01	SeroCP™ RT IgG	96 tests	1191-01
SeroCP™ IgM	96 tests	192-01	SeroCP™ RT IgM	96 tests	1192-01
SeroCP™ IgA	96 tests	193-01	SeroCP™ RT IgA	96 tests	1193-01

▶▶ SeroCP[™] Quant

SeroCPTM Quant is a 2nd generation assay for the semi-quantitative determination of IgG and IgA antibodies to C. pneumoniae. The assay utilizes 3 calibrators – P10, P50 and P75 – that are included in the kit and are used to create a standard curve. Thus, sample absorbance is interpreted to antibody titer in BU/ml units. The interpolated BU/ml units can be converted into SeroFIATM - MIF end-point titer, by using the conversion table as detailed in the Instructions for Use. The assay can be used for defining the kinetics of IgG and IgA antibodies in paired sera thus offering an improved diagnostic value.

SeroCP™	Quant	IgG	96 tests	291-01
SeroCPTM	Quant	IαA	96 tests	293-01

Main advantages of the QUANT line:

- Quantitative results provide valuable diagnostic information on the state of the infection
- High correlation with MIF results (end-point titer)
- Compatible with automation

Performance

SeroCPTM Quant IgG sensitivity/specificity

MIF SeroCP Quant	Positive	Negative
Positive	209	3
Negative	15	100
Total	224	103

Sensitivity = 93% Specificity = 98%

SeroCPTM Quant IqA sensitivity/specificity

MIF	Positive	Negative
SeroCP Quant		
Positive	211	1
Negative	12	93
Total	223	94

Sensitivity = 93% Specificity = 99%

►► SeroFIATM Chlamydia and SeroELISATM (for additional information see pages 3-4)

SeroFIA™ IgG Chlamydia	105 tests	511-01
SeroFIA™ IgM Chlamydia	105 tests	512-01
SeroFIA™ IgA Chlamydia	105 tests	513-01
SeroFIA™ C. psittaci	105 tests	570-01
SeroFIA™ C. pneumoniae	105 tests	590-01
SeroELISA™ Chlamydia IgG	96 tests	111-01
SeroELISA™ Chlamydia TRUE-IgM	96 tests	112-01
SeroELISA™ Chlamydia IgA	96 tests	113-01

▶▶ SeroMP™

The SeroMP[™] test line is intended for semi-quantitative determination of IgG, IgM and IgA antibodies to *Mycoplasma pneumoniae* in human serum. This assay utilizes a unique enriched P1 membrane protein preparation of *M. pneumoniae* antigen. Semi-quantitation of the results is obtained by utilizing ready to use calibrators - P10, P50 and P75. A complete antibody profile allows for better diagnosis and treatment.

$\textbf{SeroMP}^{\text{\tiny TM}}$	IgG	96/192	tests	261-01
SeroMPTM	IgM	96/192	tests	262-01
SeroMPTM	IgA	96/192	tests	263-01

▶▶ SeroMP[™] Recombinant

SeroMPTM Recombinant is a semi-quantitative ELISA test for the determination of IgG, IgM and IgA antibodies to *M. pneumoniae* recombinant antigens. The kit is semi-quantitative, utilizing three ready to use (RTU) calibrators.

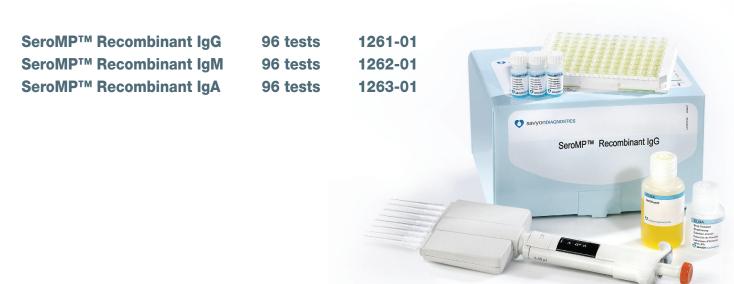
The SeroMPTM Recombinant represents improved performance parameters in different aspects:

- 1. The SeroMP Recombinant IgG uses pure P1 antigen on the plate and IgM uses a mixture of native Ag and pure P1 antigen that enables a clear differentiation between sick and healthy populations EVEN WHEN USING SINGLE (UN-PAIRED) SAMPLING.
- 2. Elimination of the IgG and the IgM borderline allows better differentiation between sick and healthy populations.
- 3. The kit enables a differential determination of specific IgG, IgA and IgM antibodies, as well as the possibility to adapt the assay for automation.

Study at University of Alabama (Prof. K. Waites): Comparing Savyon's SeroMP™ Recombinant with two commercial kits and an in-house University of Alabama (UAB) test.

Reference: PCR + Culture + UAB (paired sera)

	PCR+Culture	UAB	SAVYON	Competitor 1	Competitor 2
True POS	21	18	19	20	20
False POS			6	15	19
True NEG	30	30	24	15	11
False NEG		3	2	1	1



▶▶ SeroPertussis[™]

The SeroPertussis[™] line utilizes purified *Bordetella pertussis extract*, enriched with Pertussis Toxin (PT) and Filamentous Hemagglutinin (FHA) as antigens for detecting specific antibodies for *B. pertussis* in human serum.

The SeroPertussis[™] IgG is a semi-quantitative assay using 3 ready to use calibrators; P10, P50 and P75 – used for generating a standard curve correlating absorbance values with arbitrary antibody titer as expressed in BU/ml units.

The SeroPertussis IgA/IgM is a qualitative assay designed to provide flexibility in detecting IgA and/or IgM antibodies.

These tests are the perfect screening tool for the detection of *B. pertussis* and offer complete profiling of IgM, IgG and IgA antibodies to this pathogen.

SeroPertussis™ IgG 96 tests 231-01 SeroPertussis™ IgA/IgM 96 tests 233-01

▶▶ SeroPertussis Toxin[™]

The SeroPertussis Toxin line utilizes highly purified pertussis toxin (PT) as the immobilized antigen, thus eliminating cross reaction with *B. parapertussis*. Use of International-WHO standard based calibrators allows for quantitative determination of IgG and IgA antibody titers to PT as expressed in IU/ml.

These kits were designed and developed according to the recent EU recommendations for serodiagnosis of *B. pertussis*, which were established upon meta-analysis of generated data from a sero-epidemiological survey performed in different countries across Europe, USA and Australia (Gusio et al. 2011).

SeroPertussisTM Toxin offers the customers a simple, rapid and convenient solution for calculation and interpretation of the results which is fully compatible with automatic processing.



▶▶ QuickStripe[™] Strep A

The QuickStripe™ Strep A is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

This test is for professional use.

QuickStripe™ Strep A 20 tests 41202

▶▶ QuickStripe™ RSV

The QuickStripe™ RSV is a rapid qualitative immunochromatographic assay for the detection of Respiratory Syncytial Virus (RSV) antigens in human nasopharyngeal specimens to aid in the diagnosis of RSV infection.

This test is for professional use.

QuickStripe™ RSV 25 tests 41209

▶▶ QuickStripe[™] Adenovirus

The QuickStripe™ Adenovirus is a rapid immunochromatographic assay for the qualitative detection of Adenovirus antigens in human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate) to aid in the diagnosis of Adenovirus respiratory infection.

This test is for professional use.

QuickStripe™ Adenovirus 25 tests 41206

Savyon Diagnostics is offering a complete panel of ELISA-based tests for detection of common gastrointestinal protozoan parasites and bacteria. The **CoproELISA**TM line of products enables distinctive detection of the five most common parasites (*Giardia lamblia, Cryptosporidium spp. Blastocystis hominis, Entamoeba histolytica/dispar and Dientamoeba fragilis*), along with the bacteria *Clostridium difficile* and *Helicobacter pylori*.

CoproELISATM provides the bacteriology/parasitology laboratory with the means for manual and automated testing protocols, enabling rapid and economical solution for fecal workup, thus saving lab space and a laborious sample processing of unpleasant samples, as well as not requiring extensively trained personnel.

The CoproStrip™ line of immunochromatographic tests for detection of Giardia and/ or Cryptosporidial infections represents an ideal solution for rapid testing in low-medium throughput laboratories, at the physician's office and for confirmatory differentiation between Giardia and Cryptosporidium associated infections.

FAST AND EASY SOLUTIONS FOR DETECTION OF ENTERIC PARASITES

▶▶ Giardia & Cryptosporidium

CoproELISATM Giardia, CoproELISATM Cryptosporidium and CoproELISATM Giardia/ Cryptosporidium are ELISA-based tests for screening and differentiation of these two common GI parasites. The tests exhibit high levels of sensitivity and specificity and are compatible with both fresh and formalin/SAF preserved samples. For low-medium throughput laboratories, point of care setups and for confirmatory differentiation, the CoproStripTM line of products represents the ideal solution.

CoproELISA™ Giardia	96 tests	724-01
CoproELISA™ Cryptosporidium	96 tests	734-01
CoproELISA™ Giardia / Cryptosporidium	96 tests	744-01
CoproStrip™ Giardia	20 tests	41217
CoproStrip™ Cryptosporidium	20 tests	41218
CoproStrip™ Giardia / Cryptosporidium	20 tests	41219



▶▶ Blastocystis hominis

CoproELISA™ Blastocystis is the first commercially available test for the detection of Blastocystis antigens in fecal specimens. The test is based on an ELISA platform providing qualitative results within a short time and requiring only minimal exposure to the specimen. The test offers unprecedented sensitivity and specificity levels with both fresh and formalin/SAF preserved samples.

►► Entamoeba histolytica/dispar

CoproELISA™ Entamoeba is an ELISA-based test for detection of *Entamoeba histolytica* and Entamoeba dispar antigens in fecal specimens. A combination of both polyclonal and monoclonal antibodies directed against Entamoeba cells provides high levels of sensitivity as compared to other commercially available tests, without compromising on specificity. The test is compatible with fresh and frozen samples.

In Development

Dientamoeba fragilis

CoproELISA TM Dientamoeba is the first commercial immunoassay for detection of D. fragilis. The test is compatible with both fresh and formalin/SAF preserved samples.

CoproELISA™ Blastocystis96 tests714-01CoproELISA™ Entamoeba96 tests754-01CoproELISA™ Dientamoeba96 tests764-01

CoproELISA™ line advantages:

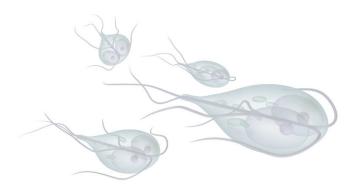
- Accurate high sensitivity & specificity
- Modular break apart plates allowing low, med & high throughput
- Minimal exposure to the specimen
- User-Friendly
- Simple interpretation of result
- Compatible with automation

►► Rotavirus and Adenovirus

QuickStripeTM Rotavirus and QuickStripeTM Adeno/Rota are rapid immunochromatographic tests intended for screening of Rotavirus and Adenovirus in human fecal samples. Diagnosis of these viruses is based on detection of viral particles in the feces. These particles, shed in large numbers during infection, are detected by immuno-diagnostic methods, allowing for accurate diagnosis of these viral infections.

This test is for professional use.

QuickStripe Rotavirus 25 tests 41205 QuickStripe Adeno/Rota 25 tests 41207



▶▶ Clostridium difficile

The CoproELISATM *C. difficile* GDH is an ELISA-based test for detection of Clostridium difficile-specific glutamate dehydrogenase (GDH) in human fecal specimens and is used as a first line screening test for *C. difficile* Associated Diarrhea (CDAD). The test offers early and accurate elimination of negative results with results within one hour.

The CoproELISATM *C. difficile* Toxin A/B is an ELISA-based test provides rapid and accurate detection of *C. difficile* toxins A&B in stool specimens from persons suspected of having *C. difficile* infection.

A suggested testing algorithm for screening and confirmation of CDAD employs GDH ELISA for determining the presence of *C. difficile*, followed by Toxin A/B ELISA for confirmation and determination of toxinogenic potential.

CoproELISA™ C. difficile GDH96 tests784-01CoproELISA™ C. difficile Toxin A/B96 tests794-01

▶▶ Helicobacter pylori

CoproELISATM *H. pylori* test is a qualitative ELISA test for the detection of *H. pylori* antigens in human stool samples. Test results are obtained within an hour and are intended to aid the clinician in the diagnosis of *H. pylori* gastric infection.

CoproELISA™ H. Pylori 96 tests 774-01

CoproELISA™ C. difficile Common Protocol:

Add 50 µl of HRP-Conjugate and 100 µl of diluted specimens

Incubate 50 min at 37°C

Wash

Add TMB-Substrate Incubate 15 min at room temperature

Add Stop Solution

Read absorbance at OD 450/620 nm





▶▶ SavvyCheck™

SavvyCheck™ Vaginal Yeast Test is a rapid test intended for detection of vulvovaginal candidiasis in women complaining of symptoms of vaginal infection. The test is intended to be used by both healthcare professionals, as well as by patients.

The test offers high sensitivity and specificity and allows for management of antifungal therapy within minutes, saving the need for microscopy and/ or culture for confirmation.

The test employs a unique, patented device, enabling swab processing and sample testing in one step, thus enabling a simple and convenient testing procedure that can be performed by patients in the privacy of their own homes.

SavyCheck[™] Vaginal yeast test (OTC) 1 test 42013 SavyCheck[™] Vaginal yeast test (POC) 20 tests 41013



Main advantages of the SavvyCheck™:

- Simple: One step, ~100% operator agreement between patient to physician
- Rapid: Results within 10 minutes
- Accurate: Excellent sensitivity and specificity

▶▶ Uriscreen[™]

Uriscreen™ is a rapid, FDA/CE cleared, CLIA weaved Catalase based screening test for the detection of bacteriuria and somatic cells in urine. The test can be used by both healthcare professionals and patients. The test can also be used for screening of bacteriuria and bacteremia for veterinary use. Uriscreen™ was found to detect as low as 104 CFU with NPV>95%. The Uriscreen™ is a single test which is simple to perform, requires no equipment, inexpensive and can be completed and evaluated in about 2 minutes.



Uriscreen™ 20 tests 101-01

▶▶ QuickStripe[™] hCG

QuickStripeTM hCG is a rapid immunoassay for qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy.

QuickStripe™ hCG shows no cross-reactivity or interference with hFSH, hLH and hTSH at high physiological levels.

QuickStripe™ hCG 25 tests 41110

▶▶ QuickStripe[™] Strep B

QuickStripe™ Strep B is a rapid immunoassay for qualitative detection of Group B Streptococcus (GBS) antigen from vaginal, cervical and rectal swab specimens. It may also be performed on hemolytic colonies of streptococci grown on agar plates as a confirmatory test.

QuickStripe™ Strep B 25 tests 41216

Introducing our new fully automated NanoCHIP®XL analyzer:

FASTER. SIMPLER. SMARTER

The NanoChip®XL analyzer is a novel bench-top molecular microarray system enabling fully automated high throughput testing of DNA/RNA yielding results in the same working day and at minimal hands-on time.

Applications include Genetic Screening, Infectious Diseases, Pharmacogenetics, Cancer Genetics and Carrier Predisposition to Diseases, thus enabling medium-high throughput labs to combine all their molecular testing on one simple screening platform.

The NanoCHIP®XL System is an automated platform capable of detecting multiple targets for individual samples, and of analyzing multiple samples on the same electronic microarray with walk-away automation.

When using the NanoCHIP®XL System, molecular diagnostics labs are offered flexibility, cost savings and ease of use in a wide range of applications such as pathogen sequence detection, SNP genotyping and pharmacogenetics testing. CE-IVD approved kits are available for various applications.

Among the main benefits of the NanoCHIP®XL analyzer:

Load & Go

PCR On board allows for loading the PCR plate, reagents and cartridge, Pressing START and that's it...you are all set

Friendly & Flexible

Very simple operation, including Touch screen option. Up to 4 different assays in the same run and on the same cartridge

Fast

Improved robotics and optical mechanism- faster cartridge initialization allowing for shorter run time

Robust

Automated maintenance procedure and optical normalization



Sample-to-Answer Made Simple



Applications

Infectious Diseases

- ICP (Infection Control Panel)
- GIP (Gastrointestinal Panel)
- STD (Sexually Transmitted Diseases)
- HPV (Human Papilloma Virus)
- RTI (Respiratory Tract Infections)

Genetic Carrier Screening

- CF (Cystic Fibrosis) 14/19/51/70 mutation panels
- AJP (Ashkenazi Jewish Panel): 12 mutations
- Connexin
- Tay Sachs
- Gaucher
- Beta Thalasemia (Panel for Beta Thalasemia including 22 mutations)
- "All in One" (27 diseases)

Carriers Predisposition to Diseases

- FMF12 (Familial Mediterranean Fever including 12 mutations)
- CVP (Cardiovascular Panel)

Pharmacogenetics / Cancer Genetics

- CYP2C9/VCORC1
- CYP2D6
- CYP2C19
- KRAS/BRAF, EGFR
- BRCA

official distributor

SZABO-SCANDIC HandelsgmbH Quellenstraße 110, A-1100 Wien T. +43(0)1 489 3961-0 F. +43(0)1 489 3961-7 mail@szabo-scandic.com www.szabo-scandic.com

