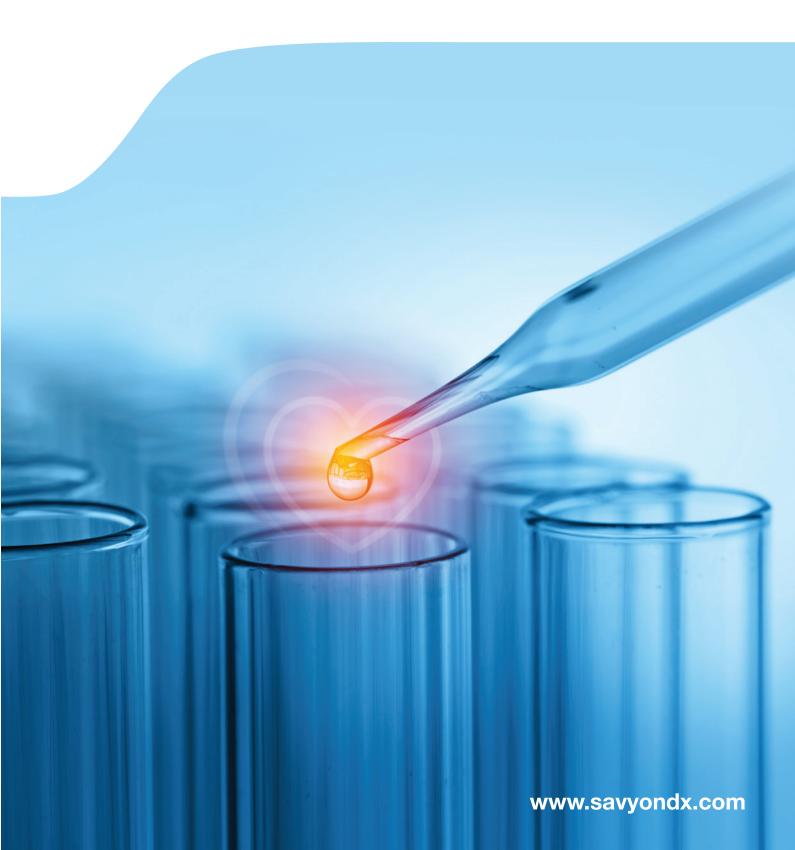
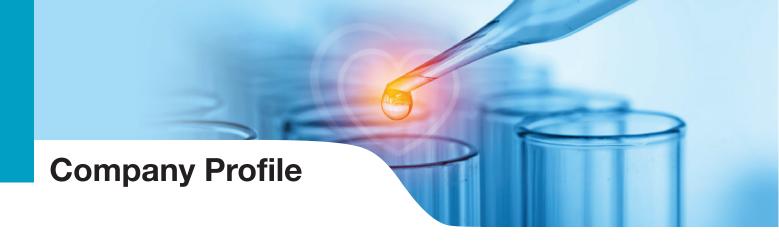


Product Catalog





Savyon Diagnostics develops, manufactures and markets high quality diagnostic kits and systems for the detection of Infectious Diseases for more than 35 years through a worldwide network of distributors.

Savyon Diagnostics offers a range of In Vitro Diagnostics kits for clinical laboratories, Point Of Care (POC) and Over-The-Counter kits allowing easy-to-use diagnostics in the comfort of one's home.

Savyon Diagnostics products are based upon various immunological and molecular biology techniques (ELISA, Lateral Flow, RT-PCR, MIF and others) and are developed by our experienced and skilled R&D team who maintain close relationships with international key opinion leaders and academic institutions. This collaboration expands Savyon's innovation in the field of in vitro diagnostics and enables the company to harness technologies and biomarkers that can be used in promoting diagnostics and in answering unmet clinical needs.

Savyon Diagnostics is accredited with the highest international quality standards of research, development and manufacture, including ISO 13485-2016. The company's products are all CE certified and those products sold in the USA, China, Mexico, Brazil and Australia are FDA, CFDA, ANVISA, COFERIS and TGA approved, respectively.

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ELISA

INTRODUCTION

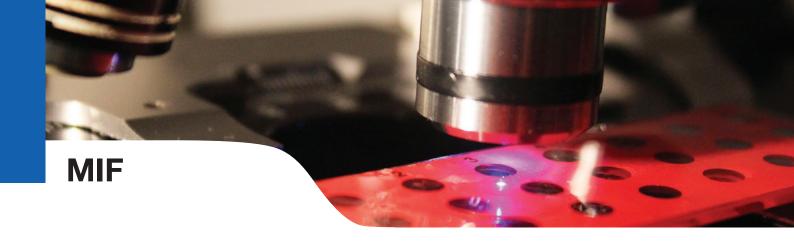
Savyon Diagnostics offers a comprehensive line of Enzyme-Linked Immunosorbent Assays (ELISA) for clinical diagnostic use. Assays include our globally recognized line of infectious serology tests (The Sero Line), a wide range of direct antigen capture ELISA tests for enteric pathogens (The Copro Line), and our unique Haptoglobin typing ELISA for assessing the risk of cardiovascular complications in diabetic patients.

- Superior clinical and analytical performance
- Proprietary state of the art core biologicals Antigens, antibodies and enzyme conjugates
- Ready-to-use color-coded unified reagents
- Automation compatibility with all common ELISA processors
- · Short and unified running protocols
- Convenience Based on break-apart 8 wells strip format, equally suited for both high or low volume use
- For quantitative or semi-quantitative assays Built-in controls for standard curve

Product	Description	Features Sample Type	Ordering Info & Approval		provals
			Tests/ kit	Catalog Number	
SeroCT	ELISA for qualitative detection of	Peptide-based antigens • Species-specific • Highly specific and sensitive • Simple interpretation of results	IgG 96T	A181-01	CE ₀₄₈₃
, ©	serum IgG and IgA antibodies to Chlamydia trachomatis	87% and 91% agreement with MIF (gold standard) for IgG and IgA respectively Serum	IgA 96T	A183-01	0.00
SeroCP	ELISA for qualitative detection of	Highly purified <i>C. pneumoniae</i> (TWAR-183)	IgG 96T	A191-01	CE ₀₄₈₃
ala	serum IgG, IgM and IgA antibodies to <i>Chlamydia pneumoniae</i>	• For igG - 95%/97% sensitivity/specificity as ig	IgM 96T	A192-01	- 0463
		IgA 96T	A193-01		
SeroCP	ELISA for semi-quantitative	All features of SeroCP plus: A set of 3 calibrators	IgG 96T	A291-01	CE ₀₄₈₃
Quant	determination of serum IgG and IgA antibodies to <i>Chlamydia</i> pneumoniae	(P10, P50 and P100) allow for semi-quantitative determination of results (as expressed in BU/mL) • Results can be correlated with endpoint titer results as expressed in SeroFIA • 97% and 94% agreement with SeroCP for IgG and IgA, respectively Serum	IgA 96T	A293-01	0.00
SeroELISA	ELISA for qualitative detection of serum IgG, IgM and IgA antibodies to <i>Chlamydia genus</i> Based on purified L2 serovar MOMP antigen • <i>Chlamydia</i> genus-specific • Highly sensitive • Simple interpretation of results • Ready to use conjugate • For all antibody classes - 95% agreement with IPAzyme Serum		IgG 96T	A111-01	FDA CE ₀₄₈₃
m M			IgM 96T	A112-01	CE ₀₄₈₃
			IgA 96T	A113-01	FDA CE ₀₄₈₃



Product	Description	Features Sample Type	Ordering	Ordering Info & Approv	
			Tests/ kit	Catalog Number	
SeroMP	ELISA for semi-quantitative	Based on highly purified <i>M. pneumoniae</i> native antigen enriched with the pathogenic-state P1 adhesin •	IgG 96T	A261-01	FDA
ala	determination of serum IgG, IgM and IgA antibodies to	A set of 3 calibrators (P10, P50 and P75) allows	IgG 192T	B261-01	CE
	Mycoplasma pneumoniae	for semi-quantitative determination of results (as expressed in BU/mL) • Ready to use conjugate • For	IgM 96T	A262-01	
		IgG - 95%/100% sensitivity/specificity as compared with consensus results (2 commercial assays) • For	IgM 192T	B262-01	
		IgM - 98%/96% sensitivity/specificity as compared with concensus • For IgA - 92%/80% sensitivity/specificity	IgA 96T	A263-01	
	as compared with concensus Serum	IgA 192T	B263-01		
SeroPertussis	ELISA for semi-quantitative	Based on highly purified <i>B. pertussis</i> native antigen	IgG 96T	A231-01	CE
613	determination of serum IgG antibodies, and qualitative determination of IgA/IgM antibodies to Bordetella pertussis	es, and qualitative ation of IgA/IgM and P/5) allows for semi-quantitative determination of IgG (as expressed in BU/mL) • Can detect both B. pertussis and B. parapertussis Serum		A233-01	
Haptoglobin Typing ELISA	ELISA for qualitative detection of Haptoglobin phenotypes (Hp 1-1, Hp 2-1, or Hp 2-2) in human serum/ plasma of diabetic patients as an aid in predicting risk of coronary arterial and cardiovascular disease	The only available EIA for high-throughput Haptoglobin phenotyping • Based on patented monoclonal antibodies which differentially bind to the different Hp isomers • A highly valuable tool for prognosis of CVD risk in diabetic patients and as a pharmacogenetic tool to assess the benefit of high dose vitamin E in such patients • Manual and automated protocols • Ready to use reagents • 98%/99% sensitivity/specificity for Hp 1-1, and Hp 2-1, 100%/99.5% sensitivity/specificity for Hp 2-2 as compared with standard electrophoretic techniques Serum/Plasma	96T	710-01	CE
CoproELISA H. pylori	ELISA for detection of Helicobacter pylori	Based on monoclonal antibodies to <i>H. pylori</i> Compatible with a variety of common preservatives (including formalin and SAF • No cross-reactivity with other enteric pathogens • Manual and automated protocols • Ready to use reagents • 96% agreement as compared with commercial FDA-approved EIA Fecal Sample	96T	774-01	CE





Savyon Diagnostics SeroFIA™ Microimmuoassays offers a gold standard detection method for determination of IgG, IgM and IgA antibodies to Chlamydia species.

- Superior clinical and analytical performance
- Proprietary state of the art biological antigens, antibodies and enzyme or fluorophore conjugates
- Convenient slide design

Product	Description	Features Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
SeroFIA	"Semi-quantitative	The "gold-standard" in Chlamydia serodiagnostics •	IgG 105T	511-01	CE ₀₄₈₃
- 7	Microimmunofluorescence	Species or antibody isotype-specific assays • Results expressed in endpoint titer • Convenient slide design •	IgM 105T	512-01	0483
xOT	Assay (MIF) for the differential determination	Excellent correlation with semi-quantitative ELISA tests	IgA 105T	513-01]
64	of <i>C. pneumoniae</i> , <i>C. trachomatis</i> and <i>C. psittaci</i> specific IgG, IgM or IgA antibodies"	• 93%/93%/100% agreement with reference commercial MIF for <i>C. trachomatis, C. pneumoniae</i> and <i>C. psittaci,</i> respectively • 99%/97%/100% agreement with reference commercial MIF for IgG, IgM and IgA, respectively Serum			







Savyon Diagnostics offers a wide portfolio of rapid tests for professional and self-use. We offer a wide range of tests for upper and lower respiratory tract infections, gastrointestinal pathogens, sexually-transmitted infections, urinary tract infections as well as tests for self- or professional assessment indications associated with women's health.

- Rapid Lateral Flow Immunochromatographic Assay (LFIA) & Enzymatic (Uriscreen) test
- · Reliable results
- Literature-supported superior performance
- · Simple and rapid operation
- Minimal (1-2 min) hands-on time
- Sample collection disposables included (e.g., swabs, vials, pipettes)
- Integrated and/or external controls
- · Long shelf life
- Clear cut visual interpretation
- No need for instrumentation
- Selected combo tests for multiple targets
- CE-IVD
- Affordable
- Results obtained in 10 min

Product	Description	Features	Orderin	ng Info & Ap	provals
		Sample Type		Catalog Number	
Coprostrip C. difficile GDH+ToxA+ToxB	Rapid combo test for simultaneous detection of <i>C. difficile</i> GDH, Toxin A and Toxin B	LFIA • 3-in-1: Simultanous detection of GDH, Toxin A and Toxin B allowing for screening in confirmation of CDAD in one test • Differentiation of Toxin A and Toxin B - allowing for differentiation of hypervirulent strains • Compatible to the guidelines recommendation of GDH screening in combination with toxin testing to improve sensitivity • No cross reactivity with other enteric pathogens or other clostridial glycosyltransferases • Over 99% agreement with commercial rapid test for detection of C. difficile GDH and toxins Fecal Sample	20T	41220	CE
Coprostrip C. difficile Positive Control Set	External Quality Control Set for Coprostrip C. difficile GDH+ToxA+ToxB (Catalog # 41220)	Ready to Use Positive control set for GDH, Toxin A and Toxin B • Easy to use - supplied in dropper bottles • Sufficient for 20 individual tests for each parameter • Compatible with EU guidelines for laboratory external quality control Ready to Use Control Set	20T	41220-10	CE
Coprostrip H. pylori	Rapid test for detection of <i>H. pylori</i> antigen in stool samples	LFIA • No cross reactivity with other enteric pathogens • 94% sensitivity and 99% specificity as compared with commercial ELISA test for detection of H. pylori stool antigen (HpSA) Fecal Sample	20T	41221	CE
Coprostrip H. pylori Positive control	External Quality Control for Coprostrip <i>H. pylori</i> (Catalog # 41221)	Ready to Use Positive control set for Coprostrip H. pylori Easy to use - supplied in a dropper bottle • Sufficient for 20 individual tests • Compatible with EU guidelines for laboratory external quality control Ready to Use Control Set	20T	41221-10	CE
Coprostrip Giardia	Rapid test for detection of Giardia lamblia	LFIA • No cross reactivity with other enteric pathogens • >99% agreement with microscopic examination of wet mounts Fecal Sample	20T	41217	CE



Product	Description	Features	Ordering Info & Approvals		
		Sample Type	Tests/ kit	Catalog Number	
Quickstripe Chlamydia Ag	Rapid test for detection of Chlamydia trachomatis specific antigen	LFIA • No cross reactivity with other STIs or with other chlamydial species • LoD = 1x10E5 Chlamydia EB/test • As compared vs. a commercial rapid immunoassay (INSTALERT) the test exhibits 97%/98% sensitivity/specificity for female cervical swabs, 98%/97% sensitivity/specificity for male urethral swabs, and 99%/94% sensitivity/specificity for urine samples Urine, Cervical or Urethral Swab	20T	41101	CE ₀₄₈₃
Quickstripe Chlamydia Ag with Positive Control	Rapid test for detection of Chlamydia trachomatis specific antigen (External Positive Control Incl.)	All features as in 41101 • External Positive control Reagent for Laboratory quality control Included in the kit Urine, Cervical or Urethral Swab	20T	41115	CE ₀₄₈₃
Quickstripe Strep A	Rapid test for detection of Group A Streptococcus pyogenes antigen	LFIA • No cross reactivity with a broad list of other respiratory pathogens • Includes external positive and negative controls • LoD = 1X10E4 CFU • As compared with culture, the test exhibits >98% sensitivity and specificity Pharyngeal Swab	20T	41202	CE
Quickstripe Strep B	Rapid test for detection of Group B Streptococcus (GBS) antigens	LFIA • As compared with culture, the test exhibits 91% sensitivity and 98% specificity Vaginal / Rectal / General Swabs	25T	41216	CE
Quickstripe hCG	Rapid test for detection of human chorionic gonadotropin (hCG) at the sensitivity of 25 mIU/mL	LFIA • LoD = 25 mIU/mL • As compared with a reference commercial rapid EIA, the test exhibits 100% sensitivity and 100% specificity on both urine and serum (N=72) samples • Cassette format • No cross reactivity or interference by LH (300 mIU/mL), FSH (1,000 mIU/mL), or TSH (1,000 mIU/mL)	25T	41110	CE
Savvycheck Vaginal Yeast Infection Test (POC)	Rapid test for the detection of vaginal yeast infection (candida species) for professional use	LFIA • All features and characeristics as the OTC version (42013) • A box containing 20 tests for professional (OB/GYN) use Vaginal Swab	20T	41013	CE ₀₄₈₃
Savvycheck Vaginal Yeast Infection Test (Self-Testing)	A rapid, easy-to-use, at-home test for the detection of vaginal yeast (<i>Candida spp.</i>) in vaginal discharge	OTC - for self testing of Vaginal Candidiasis: Positive result - self antimycotic treatment (OTC), Negative result - medical consultation • One-step assay • Results obtained in 10 min • Vaginal swab included • >94% sensitivity vs. culture • >98% specificity Vaginal swab	1T	42013	CE ₀₄₈₃
Uriscreen™	Rapid Urinary Tract Infection (UTI) Screen test for the detection of bacteriuria and presence of somatic cells	Easy to Use • Results in 10 sec • CE and FDA (OTC/POC) cleared • CLIA-weaved • LoD = 5X10E4 CFU/mL • Fits POC, OTC, clinical laboratory and veterinary use (large and small animals) • Negative Predictive Value (NPV) >95% Urine	20T	101-01	FDA/CE







Savyon Diagnostics offers a wide portfolio of Real Time PCR tests. Savyon's RT-PCR SAVVYGEN product line includes a wide range of tests for the detection of Gastrointestinal Pathogens, Sexually Transmitted Infections, Respiratory Tract Infections and Tropical Diseases

- User friendly Setup time < 5min
- Results obtained in 60min
- Full compatibility with most common RT-Thermocyclers
- Compatibility with most manual and automated DNA extraction techniques
- Integrated internal control guarantees appropriate validated results

Product	Description	Features	Orderin	g Info & Ap	provals
		Sample Type	Tests/ kit	Catalog Number	
Savvygen STI CT/NG/TV	Multiplexed RT-PCR for simultanious detection and differentiation of <i>Chlamydia trachomatis (CT)</i> , <i>Neisseria gonorrhoeae (NG)</i> and/or <i>Trichomonas vaginalis (TV)</i> infections	Ready to use master mixes • Common thermocycling profile -can be tested together with other STI panels (615-01, 616-01, 617-01) • As compared with two commercial molecular techniques (RT-PCR and microarray), the tests exhibits sensitivity/specificity levels of 99%/100%, 100%/100% and 100%/100% for CT, NG and TV, respectively (N = 376) Urine / Urogenital Swab	48T	618-01	CE ₀₄₈₃
Savvygen STI MG/MH	Multiplexed RT-PCR for simultanious detection and differentiation of <i>Mycoplasma genitalium (MG)</i> and/or <i>Mycoplasma hominis (MH)</i> infections	Ready to use master mixes • Common thermocycling profile -can be tested together with other STI panels (616-01, 617-01, 618-01) • As compared with two commercial molecular techniques (RT-PCR and microarray), the test exhibits sensitivity/specificity levels of 100%/100% for both MG and MH (N = 241) Urine / Urogenital Swab	48T	615-01	CE
Savvygen STI UU/UP	Multiplexed RT-PCR for simultanious detection and differentiation of <i>Ureaplasma urealyticum (UU)</i> and/or <i>Ureaplasma parvum (UP)</i> infections	Ready to use master mixes • Common thermocycling profile -can be tested together with other STI panels (615-01, 616-01, 618-01) • As compared with two commercial molecular techniques (RT-PCR and microarray), the tests exhibits sensitivity/specificity levels of 100%/100% for both UU and UP (N = 230) Urine / Urogenital Swab	48T	617-01	CE
Savvygen Flu A / Flu B / RSV	Multiplexed RT-PCR for simultanious detection and differentiation of <i>Influenza A virus</i> , <i>Influenza B virus</i> and <i>Respiratory Syncytial Virus</i> (RSV)	Ready to use liophyllized in-well master mixes • Transport and storage at ambient temperature • Common thermocycling profile -can be tested together with other respiratory panels (613-01, 623-01) • As compared with Simplexa Flu A/B & RSV (Diasorin), the test exhibits sensitivity/specificity levels of 96.4%/100%, 100%/100% and 97.6%/100% for Flu A, Flu B and RSV, respectively (N = 259) • As compared with Clart PneumoVir (Genomica), the test exhibits sensitivity/specificity levels of 96.2%/100%, 97.7%/100% and 100%/100% for Flu A, Flu B and RSV, respectively (N = 305) Nasopharyngeal Swab / Wash / Aspirate	48T	612-01	CE
Savvygen HSV 1+2/VZV	Multiplexed RT-PCR for simultanious detection and differentiation of <i>Herpes Simplex Virus (Types 1 and 2)</i> and <i>Varicella Zoster virus (VZV)</i>	Ready to use liophyllized in-well master mixes • Transport and storage at ambient temperature • LoD = 10 copies • As tested on 5 QCMD panels and 2 INSTAND panels (HSV-1 N=13, HSV-2 N=12, VZV N=14), 100% accordance was found as compared with the validated EQA reports UTM / Genital Swabs / Urine / Plasma	48T	622-01	CE



Product	Description	Features	Ordering	Info & Ap	provals
		Sample Type	Tests/ kit	Catalog Number	
Savvygen GI Bacterial Panel	Multiplexed RT-PCR for simultanious detection and differentiation of Salmonella enterocolitica, Campylobacter and Shigella/enteroinvasive Escherichia coli (EIEC)	Ready to use liophyllized in-well master mixes Transport and storage at ambient temperature Common thermocycling profile -can be tested together with other GI panels (619-01, 601-01 to 611-01) As compared with a commercial RT-PCR test for detection of enteric pathogens, the test exhibited sensitivity levels of 100% for all pathogens and specificity levels of 99.7%, 96.2% and 100% for Salmonella, Campylobacter and Shigella/EIEC, respectively (N = 400)	48T	620-01	CE
Savvygen GI Parasite Panel	Multiplexed RT-PCR for simultanious detection and differentiation of <i>Giardia lamblia</i> , <i>Cryptosporidium spp.</i> and <i>Entamoeba histolytica</i>	Ready to use liophyllized in-well master mixes Transport and storage at ambient temperature Common thermocycling profile -can be tested together with other GI panels (620-01, 601-01 to 611-01) As compared with two commercial RT-PCR tests for detection of enteric parasites, the test exhibited sensitivity levels of 97.4%/100%/100% and specificity levels of 97.7%/98.2%/99.3% for Cryptosporidium/Giardia/E. histolytica, respectively (N = 172)	48T	619-01	CE
Savvygen H. pylori & Antibiotic Resistance	Multiplexed RT-PCR for the identification and differentiation of <i>H. pylori</i> bacteria and a panel of 11 mutations related to its antibiotic resistance to Clarithromycin from stool or biopsy (colony) samples of symptomatic patients.	Ready to use master mixes • Results obtained in 60 min • A first line screening assay for H. pylori & Two antibiotic resistances • Allows personalized antibiotic treatment by the GP • Reduce healthcare expenses due to accurate antibiotic treatment • Reduce doctor appointments and prevention of unnecessary endoscopy procedure • Integrated internal controls guarantee appropriate validated results • Compatible with CFX-96 (Bio-Rad), LC96 (Roche) Stool or Biopcy specimens	96T	621-01	CE



The Savvygen extraction kits are to be used with the Savvygen Extractor instrument to provide high yield and quality nucleic acid.

Features:

- Validated with Savvygen RT-PCR kits
- 22 min fully automated protocol
- Simultaneous extraction of 1-48 samples

Product	Description	Features	Ordering I	nfo & App	rovals
		Sample Type/ Dimensions & Weight	Tests/ kit	Catalog Number	
Savvygen S	DNA Extraction kit for	To be used on the Savvygen Extractor instrument (670-01) • Compatible for extraction of nucleic acids for Savvygen STI	96T (4X24)	671-01	CE
Urogenital Extraction Kit	Urine / Urogenital samples	RT-PCR kits (615-01, 617-01, 618-01) • 22 min fully automated protocol for 1 to 48 samples • High DNA yield for downstream PCR-basd applications SAMPLE: Urine / Genital, Vaginal or Cervical Swab / Semen / LBC	48T (6X8)	672-01	
Savvygen S	DNA/RNA Extraction kit for	To be used on the Savvygen Extractor instrument (670-01)	96T (4X24)	677-01	CE
Respiratory Extraction Kit	Respiratory samples	Compatible for extraction of nucleic acids for Savvygen RT-PCR kits (612-01, 613-01, 623-01) • 22 min fully automated protocol for 1 to 48 samples • High DNA/RNA yield for downstream PCR-basd applications SAMPLE: Plasma, Serum, Nasal swab, Throat swab, Nasal swab, CSF and UTM. For COVID-19 samples	48T (6X8)	678-01	
Savvygen S	DNA Extraction kit for	To be used on the Savvygen Extractor instrument (670-01)	48T (2X24)	680-01	CE
GI Extraction Kit	Fecal samples samples	Compatible for extraction of nucleic acids for Savvygen GI-PCR kits (619-01, 620-01) • 22 min fully automated protocol for 1 to 48 samples • High DNA yield for downstream PCR-basd applications SAMPLE: Stool / Rectal Swab / Perianal Swab	48T (6X8)	681-01	
Savvygen	DNA Extraction kit for	To be used on the Savvygen Extractor instrument (670-01) • 22	96T (4X24)	683-01	CE
S Genomic DNA	Genomic DNA samples	min fully automated protocol for 1 to 48 samples • High DNA/RNA yield for downstream PCR-basd applications SAMPLE: Whole Blood, Buffy coat swab, Buccal swab and Saliva	48T (6X8)	684-01	
Savvygen™ Stool NA Extraction kit	DNA/RNA extraction kit for isolation of bacteria from stool samples	The kit is compatible with manual workflow or with Hamilton / Tecan automated extraction systems) • High nucleic acid yield & purity) • Load & Run) • Ready to Use) • Fast Extraction-90 min (incl. PCR setup) for 96 preps Compatible with HAMILTON STARIet / Star robots SAMPLE: Stool	96 T	690-01	CE
Savyon NA Lysis Buffer	A Lysis buffer based on Gu-Thiocyanate and Triton X-100 For cell lysis and inactivation of viruses (e.g., SARS-CoV-2) and bacteria	For cell lysis, binding of total nucleic acids and inactivation of nucleases SAMPLE: Nasal swabs, oropharyngeal swabs	100mL	FC800176	CE
Savvygen Transport &	A Lysis buffer based on Gu-Hcl for use in SARS-	The Transport & Lysis Buffer is intended to be used for inactivation of SARS CoV-2, as well as other respiratory viruses and the release of viral nucleic acids. Can be used for direct sampling	1 tube- 3mL buffer	A800177	CE
Lysis Buffer	CoV-2 PCR sampling	SAMPLE: Nasal swabs, oropharyngeal swabs	1 tube 10mL buffer	B800177	

Instruments

Product	Description	Features	Dimensions Ordering Info & A		oprovals
		Sample Type	& Weight	Catalog Number	
Savvygen Extractor (NX-48S)	Automated Ultra-fast (22 min for 1 - 48 samples) DNA/RNA Extractor	Ultra-fast - Up to 48 samples in 22 min • Extremely simple to operate • Very small footprint • Setup and hands-on time <5 min for 48 samples • Magnetic silica microparticles chmistry ensure high yeald and high quality of PCR-ready DNA/RNA • Pre-filled Cartridge type of Reagent—8 or 24 Extraction Cartridge • UV Lamp/Auto door Lock • 7' Touch Screen based User interface - Easy to operate without training • Pre-programmed and User define protocols	Height: 0.39 m Depth: 0.42 m Width: 0.36 m Weight: 25 kg	670-01	CE



Savyon Diagnostics has been offering contract manufacturing and development services to biotech companies, varying from startup companies to medium and large enterprises worldwide for the last three decades. Savyon Diagnostics provides high quality products, efficient manufacturing facilities, proficient regulatory affairs services and specialized personnel at all levels. Thus providing the highest level of competence in a cost effective manner.

Savyon Diagnostics offers professional expertise in a variety of fields:

Microbiology • Immunology • Molecular biology • Protein and nucleic acid chemistry • Biochemistry • Glyco-biology

Our assay development services, include, but are not limited to assay development, prototype design, scale-up to production, compilation of SOPs and preparation of technical files for regulatory purposes.

Parameter	Features
Facilities & Instruments	 Environment controlled spaces (Class 10,000 (ISO07)), Dry Room (<20% humidity) Fully automated ELISA microplate coating, blocking, drying and labeling line Fully automated production line for lateral flow tests Automated microplate processor Biosafety level 3 laboratory Automatic dispensing and labeling Validated sterilization process
Procedures	Sterile filtration (uL to Liters) Bacterial, viral and animal cell culture culture Native and recombinant antigen production Coating of different surfaces Biochemistry and protein purification Downstream molecular biology compartmentalization Top-notch QA & RA services
Product Design	Packaging • Labeling • Manuals (print & digital)
Logistics	 Procurement Supplies Temperature and humidity-controlled Storage ERP-controlled inventory Worldwide transportation and shipping



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The Haptoglobin Typing ELISA (Cat# 710-01) is manufactured under a license from Bio-Rap Technologies Ltd.