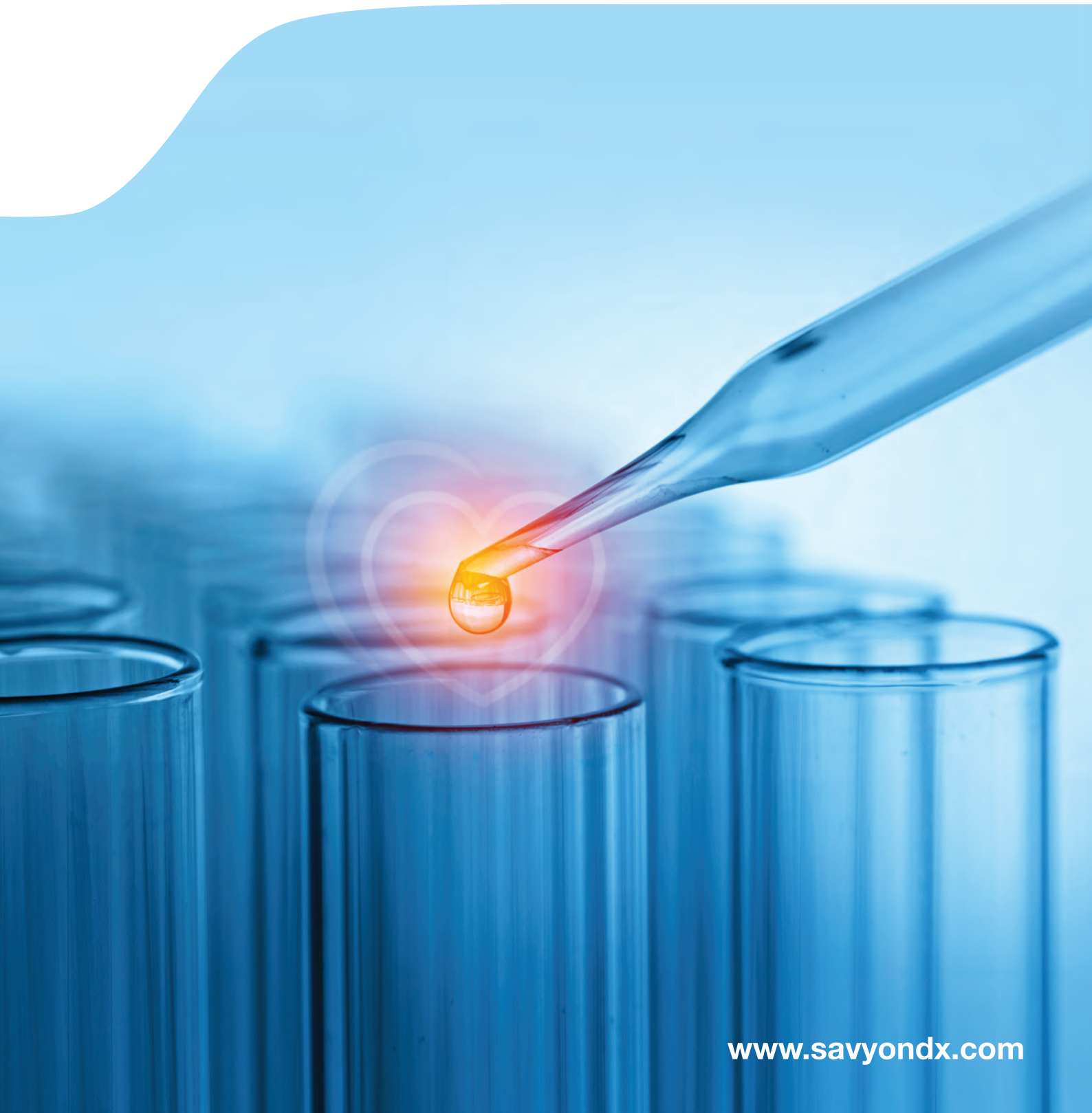


Product Catalog





Company Profile

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 over 80 distributors.

Savyon Diagnostics offers a range of Over-The-Counter diagnostic kits allowing easy-to-use diagnostics in the comfort of one's home. An accompanying mobile application allows the patient to share his/her results with their personal physician to provide a holistic at home diagnostics solution. Savyon Diagnostics is also developing solutions for labs providing personalized medical care.

Savyon Diagnostics tests are based upon various immunological and molecular biology techniques (ELISA, Lateral Flow, RT-PCR, MIF, IPA and others). The company possesses the unique “know how” of producing quality core biologicals including: antigens, antibodies and nucleic acid-based probes, while using cutting edge technologies to manufacture the products to the high standards that laboratories and research institutions have come to depend upon.

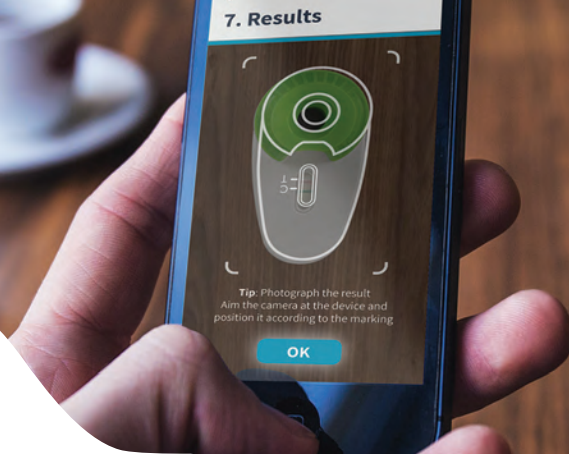
Savyon Diagnostics is accredited with the highest international quality standards of research, development and manufacture, including ISO 13485-2016. The company's products are all CE IVD certified and those products sold in the USA, China, Mexico, Brazil and Australia are FDA, CFDA, ANVISA, COFERIS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

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 upon our excellence in research, development and manufacturing, Savyon Diagnostics also offers contract development and manufacturing services. Numerous successful development and manufacturing projects have been completed or are currently ongoing with companies varying from startups to medium and large multinational enterprises.

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Home Diagnostics



INTRODUCTION

Savyon Diagnostics offers a new home test product line to allow the patient a holistic solution for the management of highly prevalent infectious diseases and medical conditions, all in the comfort and safety of his/her own home at his/her leisure.

Savyon's solution includes an easy to use self-testing device and an accompanying easy-to-use mobile application, connecting the patient's result to their healthcare provider. This option provides a reliable solution for complete care without going to the clinic.

Features:

- One step self-testing device
- Simple and Easy Operation
- Results within 10 minutes
- Reliable results
- Visual Interpretation or by mobile application for online medical assistance
- Direct communication with the doctor through the app.

Product	Description	Features Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
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
Savvycheck SARS-CoV-2 Ag Test (Self-Testing)	A rapid, easy-to-use, at-home test for the detection of SARS-CoV-2 Ag (nucleocapsid protein) from nasal samples	For self testing • Results obtained in 10 min • One step assay • >97% sensitivity vs. RT-PCR for Ct < 30 • > 98% specificity vs. RT-PCR Nasal swab	1T	42014	CE ₀₄₈₃



Under development

Savvycheck Strep A Test (Self-Testing)	A rapid, easy-to-use, at-home test for the detection of <i>Group A Streptococcus</i> antigen in Throat Swabs	For self testing • Results obtained in 10 min • one step assay Throat swab	1T		
Savvycheck H. pylori Ag Test (Self-Testing)	A rapid, easy-to-use, at-home test for the detection of <i>H. pylori</i> antigen in stool samples	For self testing • Results obtained in 10 min • one step assay Stool sample	1T		

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.

Features:

- 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 & Approvals		
			Tests/ kit	Catalog Number	
SeroCT 	ELISA for qualitative detection of serum IgG and IgA antibodies to <i>Chlamydia trachomatis</i>	Peptide-based antigens • Species-specific • Highly specific and sensitive • Simple interpretation of results • 87% and 91% agreement with MIF (gold standard) for IgG and IgA respectively Serum	IgG 96T	A181-01	CE ₀₄₈₃
			IgA 96T	A183-01	
SeroCP 	ELISA for qualitative detection of serum IgG , IgM and IgA antibodies to <i>Chlamydia pneumoniae</i>	Highly purified <i>C. pneumoniae</i> (TWAR-183) elementary bodies as antigens • Species-specific • For IgG - 95%/97% sensitivity/specificity as compared with MIF (gold standard) • For IgM - 91%/95% sensitivity/specificity as compared with MIF • For IgA - 98%/97% sensitivity/specificity as compared with MIF Serum	IgG 96T	A191-01	CE ₀₄₈₃
			IgM 96T	A192-01	
			IgA 96T	A193-01	
SeroCP Quant 	ELISA for semi-quantitative determination of serum IgG and IgA antibodies to <i>Chlamydia pneumoniae</i>	All features of SeroCP plus: A set of 3 calibrators (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	IgG 96T	A291-01	CE ₀₄₈₃
			IgA 96T	A293-01	
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
			IgM 96T	A112-01	CE ₀₄₈₃
			IgA 96T	A113-01	FDA CE ₀₄₈₃



Product	Description	Features Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
SeroMP 	ELISA for semi-quantitative determination of serum IgG , IgM and IgA antibodies to <i>Mycoplasma pneumoniae</i>	Based on highly purified <i>M. pneumoniae</i> native antigen enriched with the pathogenic-state P1 adhesin • A set of 3 calibrators (P10, P50 and P75) allows for semi-quantitative determination of results (as expressed in BU/mL) • Ready to use conjugate • For IgG - 95%/100% sensitivity/specificity as compared with consensus results (2 commercial assays) • For IgM - 98%/96% sensitivity/specificity as compared with consensus • For IgA - 92%/80% sensitivity/specificity as compared with consensus Serum	IgG 96T	A261-01	FDA CE
			IgG 192T	B261-01	
			IgM 96T	A262-01	
			IgM 192T	B262-01	
			IgA 96T	A263-01	
			IgA 192T	B263-01	
SeroPertussis 	ELISA for semi-quantitative determination of serum IgG antibodies, and qualitative determination of IgA/IgM antibodies to <i>Bordetella pertussis</i>	Based on highly purified <i>B. pertussis</i> native antigen enriched with pertussis toxin and FHA • A set of 3 calibrators (P10, P50 and P75) allows for semi-quantitative determination of IgG (as expressed in BU/mL) • Can detect both <i>B. pertussis</i> and <i>B. parapertussis</i> Serum	IgG 96T	A231-01	CE
			IgA/IgM 96T	A233-01	
SeroPertussis Toxin 	ELISA for quantitative determination of serum IgG and IgA antibodies to <i>Bordetella pertussis</i> Toxin	Based on highly purified <i>B. pertussis</i> Toxin as antigen • Specific for <i>B. pertussis</i> and does not react with <i>B. parapertussis</i> • A set of 3 calibrators (C30, C60 and C120), calibrated according to the WHO International Standard (NIBSC Code 06/140) allows for quantitative determination of IgG and IgA (as expressed in IU/mL) Serum	IgG 96T	A1231-01	CE
			IgA 96T	A1233-01	
SeroELISA SARS-CoV-2 (QUANT) 	Highly sensitive and specific ELISA test for quantitative determination of IgG antibodies to SARS-CoV-2 according to First WHO International Standard for anti SARS CoV 2 immunoglobulin (human) NIBSC code 20/136	Highly Sensitive-Utilizes purified S1 RBD antigen • Specificity –Over 99% • Short Protocol–Short incubations steps • Quantitative–Results are provided in U/mL according to the WHO international standard (20/136) • Versatile–Serum, plasma samples • Automation–Automation protocol available Serum/Plasma	IgG 96T	171-01	CE
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 <i>Helicobacter pylori</i>	• 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
CoproELISA C. difficile GDH 	ELISA for detection of <i>Clostridium difficile</i> Glutamate Dehydrogenase (GDH)	• Based on monoclonal antibodies to <i>C. difficile</i> GDH • No cross-reactivity with other enteric pathogens • Manual and automated protocols • Ready to use reagents • 97%/96% sensitivity/specificity as compared with commercial FDA-approved EIA Fecal Sample	96T	784-01	CE
CoproELISA C. difficile Tox A/B 	ELISA for detection of <i>Clostridium difficile</i> Toxins A and B	• Based on polyclonal antibodies to <i>C. difficile</i> Toxins A and B • No cross-reactivity with other Clostridial toxins or monoglucosyl transferases • Manual and automated protocols • Ready to use reagents • 100%/98% sensitivity/specificity as compared with commercial FDA-approved EIA Fecal Sample	96T	794-01	CE

MIF/IPA



INTRODUCTION

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

Features:

- 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 Microimmunofluorescence Assay (MIF) for the differential determination of <i>C. pneumoniae</i> , <i>C. trachomatis</i> and <i>C. psittaci</i> specific IgG, IgM or IgA antibodies"	The "gold-standard" in Chlamydia serodiagnostics • Species or antibody isotype-specific assays • Results expressed in endpoint titer • Convenient slide design • Excellent correlation with semi-quantitative ELISA tests • 93%/93%/100% agreement with reference commercial MIF for <i>C. trachomatis</i> , <i>C. pneumoniae</i> and <i>C. psittaci</i> , respectively • 99%/97%/100% agreement with reference commercial MIF for IgG, IgM and IgA, respectively Serum	IgG 105T	511-01	CE ₀₄₈₃
			IgM 105T	512-01	
			IgA 105T	513-01	
			C.ps 105T	570-01	
			C.tr 105T	580-01	
			C.pn 105T	590-01	
IPAzyme 	Indirect Immunoperoxidase Assay (IPA) for the detection and titration of anti <i>Chlamydia</i> specific IgG, IgA and IgM antibodies in human serum	Does not require fluorescence microscope • Highly sensitive • Allows for examination determination and titration of Chlamydial antigen while perserving cellular morphology for examination Serum	IgG/IgA 144T	011-01	CE ₀₄₈₃
			IgM 96T	012-01	



Rapid Tests








INTRODUCTION










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.

Features:

- Rapid Lateral Flow Immunochromatographic Assay (LFIA) & Enzymatic (Uriscreeen) 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 Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
Coprostrip C. difficile GDH+ToxA+ToxB 	Rapid combo test for simultaneous detection of C. difficile GDH, Toxin A and Toxin B	LFIA • 3-in-1: Simultaneous 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 C. difficile GDH 	Rapid test for detection of C. difficile Glutamate Dehydrogenase (GDH)	LFIA • No cross reactivity with other enteric pathogens • Over 99% agreement with commercial rapid test for detection of C. difficile GDH • Over 99% agreement with CoproELISA C. difficile GDH (Catalog # 784-01) Fecal Sample	20T	41222	CE
Coprostrip C. difficile Toxins A&B 	Rapid test for detection of C. difficile Toxins A & B	LFIA • 2-in-1: Simultaneous detection of Toxin A and Toxin B allowing for determination of toxinogenic CDAD in one test • Differentiation of Toxins A and B allowing for differentiation of hypervirulent strains • No cross reactivity with other enteric pathogens or other clostridial glycosyltransferases • Over 99% agreement with commercial rapid test for detection of C. difficile toxins • Over 99% agreement with CoproELISA C. difficile Tox A/B (Catalog # 794-01) Fecal Sample	20T	41223	CE
Coprostrip H. pylori 	Rapid test for detection of H. pylori 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









Product	Description	Features Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
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
H. pylori Saliva Test 	Rapid test for detection of <i>H. pylori</i> antigen in salivary fluid	LFIA • Can be used in a POC setup • No need to send out samples and wait for results; inform the patient immediately • No cross reactivity with other oral or enteric pathogens • >99% sensitivity and 96% specificity as compared with Urea Breath Test (UBT) Saliva	10T	41121	CE
Coprostrip Giardia 	Rapid test for detection of <i>Giardia lamblia</i>	LFIA • No cross reactivity with other enteric pathogens • >99% agreement with microscopic examination of wet mounts Fecal Sample	20T	41217	CE
Coprostrip Cryptosporidium 	Rapid test for detection of <i>Cryptosporidium spp.</i>	LFIA • No cross reactivity with other enteric pathogens • >99% agreement with microscopy Fecal Sample	20T	41218	CE
Coprostrip Giardia / Cryptosporidium 	Rapid test for differential detection of <i>Giardia lamblia</i> and <i>Cryptosporidium spp.</i>	LFIA • Simultaneous differential detection of giardia and Cryptosporidium • Test line and control line in different color • No cross reactivity with other enteric pathogens • >97%/99% sensitivity/specificity for Giardia and 99%/99% sensitivity/specificity for Cryptosporidium as compared with microscopy Fecal Sample	20T	41219	CE
Quickstripe Rotavirus 	Rapid test for detection of <i>Rotavirus</i>	LFIA • Test line and Internal control line in different colors • No cross reactivity with other enteric pathogens • 99%/98% sensitivity/specificity as compared to a commercial ELISA test Fecal Sample	25T	41205	CE
Quickstripe Adeno/Rota 	Rapid test for differential detection of enteric <i>Adenovirus</i> and <i>Rotavirus</i>	LFIA • Simultaneous differential detection of both enteric Adenovirus and Rotavirus • Each test line and Internal control line in different colors • No cross reactivity with other enteric pathogens (incl pther enteric viruses e.g., Norovirus GI/II and Astrovirus) or other non-enteric Adenoviruses • 95%/100% agreement for Adenovirus/Rotavirus as compared with a commercial rapid immunoassay Fecal Sample	25T	41207	CE
Quickstripe Chlamydia Ag 	Rapid test for detection of <i>Chlamydia trachomatis</i> 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 <i>Chlamydia trachomatis</i> 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



Product	Description	Features Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
Savvycheck SARS-CoV-2 Ag. (POC) 	A unique platform device for rapid detection of SARS-CoV-2 Ag test is an easy-to-use rapid test that gives you results in just 10 minutes. The test detects SARS-CoV-2 antigens in human nasal secretion samples collected with a sterile nasal swab.	Results obtained in 10 min • Short & easy procedure • Visual reading of the test result • No instrument or additional equipment necessary • High accordance with RT PCR Nasal Swab	20T	41014	CE
Quickstripe SARS-CoV-2 Antigen Test 	Rapid immunochromatographic test for detection of SARS-CoV-2 antigens present in human nasopharynx.	Results obtained in 15 min • No cross reactivity with a broad list of other respiratory pathogens • User-Friendly - setup time <1 min • Visual reading of the test result • No instrument or additional equipment necessary • High accordance with RT PCR Nasal Swab	20T	41102	CE
Quickstripe SARS-CoV-2 IgG/IgM 	Rapid immunochromatographic test for detection of antibody content against SARS-CoV-2 in clinical samples (serum/plasma/whole blood).	Results obtained in 15 min • High sensitivity and early stage detection of IgM antibodies when compared with PCR detection of viral RNA, allowing for a convenient and rapid diagnostic tool for COVID-19 • User-Friendly - setup time <1 min • Visual reading of the test result • No instrument or additional equipment necessary serum/plasma/whole blood	20T	41226	CE
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 Legionella pneumophila 	Rapid test for detection of Legionella pneumophila antigen	LFIA • No cross reactivity with a broad list of other pathogens • As compared with a commercial FDA-approved EIA for Legionella urinary antigen the test exhibits >98% sensitivity and >99.9% specificity Urine	20T	41225	CE
Quickstripe Streptococcus pneumoniae 	Rapid test for detection of Streptococcus pneumoniae antigen	LFIA • No cross reactivity with Influenza A/B virus or Adenovirus as compared with a commercial rapid EIA for detection of S. pneumoniae, the test exhibits >95% sensitivity and 99% specificity Urine	20T	41224	CE
Quickstripe Mycoplasma pneumoniae IgM 	Rapid test for detection of IgM antibodies to Mycoplasma pneumoniae	LFIA • No cross reactivity with antibodies to HIV, Hepatitis A, B, C, E or syphilis • As compared with a commercial EIA for M. pneumoniae IgM, the test exhibits >98% sensitivity and >99% specificity Whole Blood / Serum / Plasma	20T	41208	CE
Quickstripe Adenovirus 	Rapid test for detection of Adenovirus antigen	LFIA • No cross reactivity with influenza A/B or RSV • As compared with two commercial rapid EIAs for respiratory Adenovirus , the test exhibits 100% sensitivity and specificity Nasopharyngeal swab / Wash / Aspirate	25T	41206	CE
Quickstripe RSV 	Rapid test for detection of Respiratory Syncytial Virus (RSV) antigens	LFIA • No cross reactivity with influenza A/B or RSV • As compared with two commercial rapid EIAs for respiratory Adenovirus , the test exhibits 100% sensitivity and specificity Nasopharyngeal swab / Wash / Aspirate	25T	41209	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



Product	Description	Features Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
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) Urine / Serum	25T	41110	CE
PregnanStick 	Rapid test strips for detection of human chorionic gonadotropin (hCG) at the sensitivity of 25 mIU/mL	LFIA • As compared with a reference commercial rapid EIA, the test exhibits 100% sensitivity and 100% specificity on both urine and serum samples • Strip format • No cross reactivity or interference by LH (300 mIU/mL), FSH (1,000 mIU/mL), or TSH (1,000 mIU/mL) Urine / Serum	50T/100T	41210	CE
Savvycheck Early Pregnancy Test 	Rapid self test for the detection of human chorionic gonadotropin (hCG) at the sensitivity of 10 mIU/mL	LFIA • For OTC use • Results obtained in 1-3 min • LoD = 10 mIU/mL • Easy to Use midstream test • >99% accuracy Urine	1/2T	42015	CE ₀₄₈₃
Savvycheck Ovulation Predictor 	Rapid self testing for the detection of Luteinizing Hormone (LH) as an aid to identify days of probable ovulation	LFIA • For OTC use • Results obtained in 1-3 min • Easy to Use midstream test • >99% accuracy Urine	7T	42011	CE ₀₄₈₃
Savvycheck Vaginal Yeast Infection Test (POC) 	Rapid test for the detection of vaginal yeast infection (candida species) for professional use	LFIA • All features and characteristics as the OTC version (42013) • A box containing 20 tests for professional (OB/GYN) use Vaginal Swab	20T	41013	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



Real-Time PCR











INTRODUCTION

Savvygen Diagnostics offers a wide portfolio of Real Time PCR tests. Savvygen'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

Features:

- 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 Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
Savvygen STI CT/NG/TV 	Multiplexed RT-PCR for simultaneous detection and differentiation of <i>Chlamydia trachomatis</i> (CT) , <i>Neisseria gonorrhoeae</i> (NG) and/or <i>Trichomonas vaginalis</i> (TV) 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 simultaneous detection and differentiation of <i>Mycoplasma genitalium</i> (MG) and/or <i>Mycoplasma hominis</i> (MH) 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 simultaneous detection and differentiation of <i>Ureaplasma urealyticum</i> (UU) and/or <i>Ureaplasma parvum</i> (UP) 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 SARS-CoV-2 	Multiplexed RT-PCR for qualitative detection and differentiation of SARS-CoV-2 (2019 Novel Coronavirus) in clinical respiratory samples from patients with signs and respiratory symptoms. additional patient's outcomes.	Detection of 2 genes (ORF1ab + N gene) • Ready to use liophilized in-well master mixes • Results obtained in 1:15h • Transport and storage at ambient Temp • User-Friendly - setup and hands-on time <5 min • Common thermocycling profile - can be tested together with other respiratory panels (613-01, 623-01) • Full compatibility with most common RT-thermocyclers • Compatible with most manual and automated DNA extraction techniques • Integrated internal controls guarantee appropriate validated results Nasal or Nasopharyngeal Swab / Oropharyngeal Swab	48T	625-01	CE
			96T	626-01	
Savvygen SARS-CoV-2 Plus 	Multiplexed RT-PCR for qualitative detection and differentiation of SARS-CoV-2 (2019 Novel Coronavirus) in clinical respiratory samples from patients with signs and respiratory symptoms. additional patient's outcomes.	Detection of 3 genes (RdRp + N gene + E gene) • Ready to use master mixes • Results obtained in 1:15h • User-Friendly - setup time <5 min • Full compatibility with most common RT-thermocyclers • Compatible with most manual and automated DNA extraction techniques • Integrated internal controls guarantee appropriate validated results Nasal or Nasopharyngeal Swab / Oropharyngeal Swab	96T	627-10	CE

Product	Description	Features Sample Type	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
Savvygen Flu A / Flu B / RSV 	Multiplexed RT-PCR for simultaneous detection and differentiation of Influenza A virus, Influenza B virus and Respiratory Syncytial Virus (RSV)	Ready to use liophilized 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 Bordetella pertussis 	Multiplexed RT-PCR for simultaneous detection and differentiation of B. pertussis, B. paraptussis and B. holmesii	Ready to use liophilized in-well master mixes • Transport and storage at ambient temperature • Common thermocycling profile -can be tested together with other respiratory panels (612-01, 623-01) Nasopharyngeal Swab / Wash / Aspirate	48T	613-01	CE
Savvygen Pneumocystis jirovecii 	RT-PCR for detection of Pneumocystis jirovecii	Ready to use liophilized in-well master mixes • Transport and storage at ambient temperature • Common thermocycling profile -can be tested together with other respiratory panels (612-01, 613-01) • Integrated Quantitative Standard (QS) allowing for quantitative results (Copy Number) • LoD = 10 copies • As compared with a commercial RT-PCR for PCP, the test exhibit sensitivity/specificity levels of 100%/100% Bronchoalveolar Lavage (BAL) / Respiratory Wash / Aspirate	48T	623-01	CE
Savvygen Tick-Borne 	Multiplexed RT-PCR for simultaneous detection and differentiation of <i>viral RNA or genomic DNA of TBEV, Rickettsia spp., Babesia spp., Ehrlichia spp., Borrelia spp., Anaplasma phagocitophylum and Coxiella burnetii</i>	Ready to use lyophilized in-well master mixes • Results obtained in 75 min • Transport and storage at ambient Temp • User-Friendly - setup and hands-on time <5 min • Full compatibility with most common RT-thermocyclers • Compatible with most manual and automated DNA extraction techniques Blood, serum, tissue samples and microbiological culture from ticks, biopsy skin, cerebrospinal fluid (CSF) and synovial fluid	48T	624-01	CE
Savvygen HSV 1+2/VZV 	Multiplexed RT-PCR for simultaneous detection and differentiation of Herpes Simplex Virus (Types 1 and 2) and Varicella Zoster virus (VZV)	Ready to use liophilized 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
Savvygen GI Bacterial Panel 	Multiplexed RT-PCR for simultaneous detection and differentiation of Salmonella enterocolitica, Campylobacter and Shigella/enteroinvasive Escherichia coli (EIEC)	Ready to use liophilized 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 <i>Salmonella</i> , <i>Campylobacter</i> and <i>Shigella/EIEC</i> , respectively (N = 400) Fecal Sample	48T	620-01	CE
Savvygen GI Parasite Panel 	Multiplexed RT-PCR for simultaneous detection and differentiation of Giardia lamblia, Cryptosporidium spp. and Entamoeba histolytica	Ready to use liophilized 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 <i>Cryptosporidium/Giardia/E. histolytica</i> , respectively (N = 172) Fecal Sample	48T	619-01	CE
Savvygen H. pylori & Antibiotic Resistance 	Multiplexed RT-PCR for the identification and differentiation of H. pylori bacteria and a panel of 11 mutations related to its antibiotic resistance to Clarithromycin and Levofloxacin 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 Biopsy specimens	96T	621-01	CE

DNA/RNA Extraction

INTRODUCTION

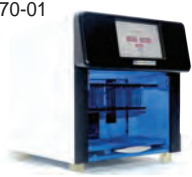
The Savvygen extraction kits are to be used with the Savvygen Extractor instrument to provide high yield and quality nucleic acid.

Features:

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

Product	Description	Features Sample Type/ Dimensions & Weight	Ordering Info & Approvals		
			Tests/ kit	Catalog Number	
Savvygen S Urogenital Extraction Kit	DNA Extraction kit for Urine / Urogenital samples	To be used on the Savvygen Extractor instrument (670-01) • Compatible for extraction of nucleic acids for Savvygen STI 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-based applications SAMPLE: Urine / Genital, Vaginal or Cervical Swab / Semen / LBC	96T (4X24)	671-01	CE
			48T (6X8)	672-01	
Savvygen S Respiratory Extraction Kit	DNA/RNA Extraction kit for Respiratory samples	To be used on the Savvygen Extractor instrument (670-01) • 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-based applications SAMPLE: Plasma, Serum, Nasal swab, Throat swab, Nasal swab, CSF and UTM. For COVID-19 samples	96T (4X24)	677-01	CE
			48T (6X8)	678-01	
Savvygen S GI Extraction Kit	DNA Extraction kit for Fecal samples samples	To be used on the Savvygen Extractor instrument (670-01) • 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-based applications SAMPLE: Stool / Rectal Swab / Perianal Swab	48T (2X24)	680-01	CE
			48T (6X8)	681-01	
Savvygen S Genomic DNA	DNA Extraction kit for Genomic DNA samples	To be used on the Savvygen Extractor instrument (670-01) • 22 min fully automated protocol for 1 to 48 samples • High DNA/RNA yield for downstream PCR-based applications SAMPLE: Whole Blood, Buffy coat swab, Buccal swab and Saliva	96T (4X24)	683-01	CE
			48T (6X8)	684-01	
Savvygen™ NA Extraction kit	DNA/RNA Extraction kit for isolation of high-quality SARS-CoV-2 RNA from human samples.	The kit is compatible with manual workflow or with Hamilton / Tecan automated extraction systems • High RNA yield & purity • Load & Run • 4 Ready to Use Reagents (Binding, Wash-1, Wash-2, Elution) • Fast Extraction- 90 min (incl. PCR setup) for 96 preps • Compatible with HAMILTON STARlet / Star robots SAMPLE: Nasal swabs, oropharyngeal swabs	96T	A689-01	CE
			192T	B689-01	
Savvygen 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 & Lysis Buffer	A Lysis buffer based on Gu-HCl for use in SARS-CoV-2 PCR sampling	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 SAMPLE: Nasal swabs, oropharyngeal swabs	1 tube- 3mL buffer	A800177	CE
			1 tube 10mL buffer	B800177	

Instruments

Product	Description	Features Sample Type	Dimensions & Weight	Ordering Info & Approvals	
				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 chemistry ensure high yield 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



Contract Manufacturing & Development Services

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	<ul style="list-style-type: none">• Environment controlled spaces (Class 10,000 and 1,000), Dry (<20% humidity) and wet (~50% humidity) rooms• 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• Modern training center and demo lab
Procedures	<ul style="list-style-type: none">• Sterile filtration (uL to Liters)• Bacterial, viral and protozoan 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	<ul style="list-style-type: none">• Procurement• Supplies• Temperature and humidity-controlled Storage• ERP-controlled inventory• Worldwide transportation and shipping



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