



Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We,

Savyon Diagnostics Ltd.

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Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of products on the attached Annex to EC Declaration of Conformity

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

The current applicable standards were used to prove the products conformity with the essential requirements of the above directive as defined in the Savyon Diagnostics Ltd., internal procedure QA-927 entitled: List of Standards.

The QA-927 List of Standards is attached.

Corporate Contact Information

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SIGNATURE:

Date : 04.04.2022

Valid to: 02.02.2024

Stamp:

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Annex to EC Declaration of Conformity

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Catalogue reference number	Commercial name	Generic Device Term	Short description and intended use	GMDN/ED MS code	Class**
1	A240-01	SeroHSV1	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for the qualitative detection of specific antibodies to Herpes Simplex Virus Type 1 in human serum	30804	NonA/NonB
2	A250-01	SeroHSV2	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for the qualitative detection of specific antibodies to Herpes Simplex Virus Type 2 in human serum	30804	NonA/NonB
3	A151-01	SeroHSV IgM	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for the semi-qualitative detection of specific IgM antibodies to Herpes Simplex Virus Type 1 & 2 in human serum	30806	NonA/NonB
4	A152-01	SeroHSV IgG	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for the semi-qualitative detection of specific IgG antibodies to Herpes Simplex Virus Type 1 & 2 in human serum	30805	NonA/NonB
5	A231-01	SeroPertussis IgG	IVD ELISA test	Enzyme Linked Immunosorbent Assay (ELISA) for the qualitative detection of specific IgG antibodies to <i>Bordetella Pertussis</i> in human serum	50517	NonA/NonB
6	A233-01	SeroPertussis IgA/IgM	IVD ELISA test	Enzyme Linked Immunosorbent Assay (ELISA) for the qualitative detection of specific IgA and/or IgM antibodies to <i>Bordetella Pertussis</i> in human serum	50517	NonA/NonB
7	A1231-01	SeroPertussis Toxin IgG	IVD ELISA test	Enzyme Linked Immunosorbent Assay (ELISA) for the quantitative determination of specific IgG antibodies to <i>Bordetella Pertussis</i> Toxin in human serum	50517	NonA/NonB
8	A1233-01	SeroPertussis Toxin IgA	IVD ELISA test	Enzyme Linked Immunosorbent Assay (ELISA) for the quantitative determination of specific IgA antibodies to <i>Bordetella Pertussis</i> Toxin in human serum	50517	NonA/NonB
9	A261-01, B261-01	SeroMP™ IgG	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for the semi-quantitative detection of specific IgG antibodies to <i>Mycoplasma pneumoniae</i> in human serum	30704	NonA/NonB
10	A262-01, B262-01	SeroMP™ IgM	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for the semi-quantitative detection of specific IgM antibodies to <i>Mycoplasma pneumoniae</i> in human serum	30704	NonA/NonB
11	A263-01, B263-01	SeroMP™ IgA	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for the semi-quantitative detection of specific IgA antibodies to <i>Mycoplasma pneumoniae</i> in human serum	30704	NonA/NonB
12	A1261-01	SeroMP™ Recombinant IgG	IVD ELISA test	Enzyme -Linked Immunosorbent Assay (ELISA) for semi-quantitative detection of specific IgG antibodies to <i>Mycoplasma pneumoniae</i> in human serum	15010803	NonA/NonB
13	A1262-01	SeroMP™ Recombinant IgM	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for semi-quantitative detection of specific IgM antibodies to <i>Mycoplasma pneumoniae</i> in human serum	15010803	NonA/NonB

14	A1263-01	SeroMP™ Recombinant IgA	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the semi-quantitative detection of specific IgA antibodies to <i>Mycoplasma pneumoniae</i> in human serum	15010803	NonA/NonB
15	734-01	CoproELISA <i>Cryptosporidium</i>	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) to detect <i>Cryptosporidium spp.</i> antigens in human feces	52162	NonA/NonB
16	714-01	CoproELISA <i>Blastocystis</i>	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Blastocystis spp.</i> antigens in human feces	15051090	NonA/NonB
17	724-01	CoproELISA <i>Giardia</i>	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Giardia lamblia</i> antigens in human feces	15051008	NonA/NonB
18	744-01	CoproELISA <i>Giardia/Cryptosporidium</i>	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Giardia lamblia</i> and <i>Cryptosporidium spp.</i> antigens in human feces	15300390	NonA/NonB
19	754-01	CoproELISA <i>Entamoeba</i>	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Entamoeba</i> antigens in human feces	15051001	NonA/NonB
20	764-01	CoproELISA <i>Dientamoeba</i>	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Dientamoeba fragilis</i> antigens in human feces	15051090	NonA/NonB
21	784-01	CoproELISA™ <i>C. difficile</i> GDH	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Clostridium difficile</i> GDH in human feces	15019002	NonA/NonB
22	794-01	CoproELISA™ <i>C. difficile</i> Tox A/B	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Clostridium difficile</i> toxin A and toxin B Antigens in human feces	15019002	NonA/NonB
23	774-01	CoproELISA™ <i>H. pylori</i>	IVD ELISA test	Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of <i>Clostridium difficile</i> toxin A and toxin B Antigens in human feces	15010401	NonA/NonB
24	41218	CoproStrip <i>Cryptosporidium</i>	IVD RAPID kit	Rapid, one step test for the qualitative detection of <i>Cryptosporidium</i> antigens in human feces	15700501	NonA/NonB
25	41217	CoproStrip <i>Giardia</i>	IVD RAPID kit	Rapid, one step test for the qualitative detection of <i>Giardia</i> antigens in human feces	15700501	NonA/NonB
26	41219	CoproStrip <i>Giardia/ Cryptosporidium</i>	IVD RAPID kit	Rapid, one step test for the qualitative detection of <i>Cryptosporidium</i> and <i>Giardia</i> antigens in human feces	15700501	NonA/NonB
27	41223	Coprostrip C. difficile Toxin A/B	IVD RAPID kit	Rapid, one step test for the qualitative detection of Toxin A and B of <i>C. difficile</i> antigens in human feces	15700106	NonA/NonB

28	41222	Coprostrip C. difficile GDH	IVD RAPID kit	Rapid, one step test to detect Clostridium difficile glutamate dehydrogenase antigen in human feces	15700106	NonA/NonB
29	41220-10	Coprostrip C. difficile Positive control set	IVD RAPID kit	External quality control set for Cat# 41220 to detect Clostridium difficile Glutamate Dehydrogenase (GDH), Toxin A and Toxin B in human faeces	15500101	NonA/NonB
30	41220	CoproStrip™ C. difficile GDH+Tox A+Tox B	IVD RAPID kit	Rapid, one step test for the simultaneous qualitative detection of <i>Clostridium difficile</i> Glutamate Dehydrogenase (GDH), Toxin A and Toxin B antigens in human feces	15700106	NonA/NonB
31	41221	CoproStrip™ H. pylori	IVD RAPID kit	Rapid, one step test for the qualitative detection of <i>Helicobacter pylori</i> (<i>H. pylori</i>) antigens in human feces	15700102	NonA/NonB
32	41103	QuickStripe™ H. pylori	IVD RAPID kit	One step rapid, visual chromatographic immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigen in fecal samples	30691	NonA/NonB
33	41202	QuickStripe™ Strep A	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of Strep A antigen in throat swab specimens	30710	NonA/NonB
34	41216	QuickStripe™ Strep B	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of Strep B antigen in throat swab specimens	15700104	NonA/NonB
35	41207	QuickStripe™ Adeno/Rota	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of Adenovirus or Rotavirus antigens in human fecal samples	38442	NonA/NonB
36	41206	QuickStripe™ Adenovirus	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of <i>Adenovirus</i> antigens in human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate) to aid in the diagnosis of <i>Adenovirus</i> respiratory infection	41274	NonA/NonB
37	41205	QuickStripe™ Rotavirus	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of Rotavirus antigen in human fecal samples	30815	NonA/NonB
38	41209	QuickStripe™ RSV	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of respiratory syncytial virus (RSV) antigens in human nasopharyngeal specimens to aid in the diagnosis of RSV infection	30814	NonA/NonB
39	41110	QuickStripe™ hCG	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy	30332	NonA/NonB
40	41213	QuickStripe™ Syphilis	IVD RAPID kit	Rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to <i>Treponema Pallidum</i> (TP) in whole blood, serum or plasma to aid in the diagnosis of Syphilis	30687	NonA/NonB
41	41203	QuickStripe™ Gonorrhea	IVD RAPID kit	Rapid chromatographic immunoassay for the visual detection of gonorrhea antigen in secretory specimens from the urogenital system and in urine, as an aid in the diagnosis of gonococcus infection	15048090	NonA/NonB
42	41108	QuickStripe™ Malaria	IVD RAPID kit	Rapid chromatographic Immunoassay for detection of antibodies of all isotypes (IgG, IgM, IgA) specific to Plasmodium falciparum and Plasmodium vivax simultaneously in human serum, plasma or whole blood	15048090	NonA/NonB

43	41210	PregnanStick™ IVD RAPID kit		Rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy	30332	NonA/NonB
44	41013	Savycheck Vaginal Yeast Test (POC)	IVD RAPID kit	Rapid lateral flow based assay for the qualitative detection of <i>Candida</i> antigens in cervical secretion sampled by a swab	15060102	NonA/NonB
45	41013-01	KANDIDA TEST- Kvasinkovy Test (POC)	IVD RAPID kit	Rapid lateral flow based assay for the qualitative detection of <i>Candida</i> antigens in cervical secretion sampled by a swab	15060102	NonA/NonB
46	41013-02	GENITEST VAGINÄLAS KANDIDOZES Tests (POC)	IVD RAPID kit	Rapid lateral flow based assay for the qualitative detection of <i>Candida</i> antigens in cervical secretion sampled by a swab	15060102	NonA/NonB
47	41013-03	Vaginalinès kandidozés testas (POC)	IVD RAPID kit	Rapid lateral flow based assay for the qualitative detection of <i>Candida</i> antigens in cervical secretion sampled by a swab	15060102	NonA/NonB
48	41013-04	Vaginaalse kandidoosi	IVD RAPID kit	Rapid lateral flow based assay for the qualitative detection of <i>Candida</i> antigens in cervical secretion sampled by a swab	15060102	NonA/NonB
49	101-01	Uriscreen™ (POC)	IVD RAPID kit	Rapid UTI Screening test for bacteriuria and presence of somatic cells in urine	33380	NonA/NonB
50	101-01S	URINFEKT TEST (POC)	IVD RAPID kit	Rapid UTI Screening test for bacteriuria and presence of somatic cells in urine	33380	NonA/NonB
51	800171, 800172, 800174, 800175	NaOH (1N), HCL (6N) Buffers	IVD REAGENTS	HCl, 6N and NaOH, 1N Buffers are chemical solutions for urine collection		NonA/NonB
52	800272	NanoChip ® CF14	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 14 mutations in the human cystic fibrosis transmembrane conductance regulator gene (CFTR) common to the Sephardic, Ashkenazi, Yemeni, and Iraqi Jewish populations	16010101	NonA/NonB
53	800672	NanoChip® CF14/ TAYSACHS	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 14 mutations in the human cystic fibrosis transmembrane conductance regulator gene (CFTR) and 8 mutations in the TAY SACHS HEXA gene	16010290	NonA/NonB
54	800572	NanoChip ® TAY SACHS	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of six genetic mutations in the human HEXA gene. The amplified DNA is tested for the following mutations: 1278 InsTATC, IVS12 +1G>C, G269S, R170Q, DF304/305 and IVS5-2 A>G	16010110	NonA/NonB
55	800001	NanoChip ® CF19	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 19 mutations in the human cystic fibrosis transmembrane conductance regulator gene (CFTR)	16010101	NonA/NonB
56	A800019, B800019	NanoChip ® AJP 14	IVD NanoChip Genetic Kit	To detect and identify in amplified human DNA a panel of 14 genetic diseases common to the Ashkenazi Jewish populations	16020190	NonA/NonB
57	803001	NanoChip ® CF70	IVD NanoChip Genetic kit	To detect 70 mutations of the human cystic fibrosis transmembrane conductance regulator gene (CFTR) in Italian population in amplified human DNA	16010101	NonA/NonB

58	800472	NanoChip® CONNEXIN	IVD NanoChip Genetic kit	To detect and identify 3 genetic mutations in amplified human DNA. The amplified mutations are located on two Connexin genes: 35delG and 167delT on the GJB2 gene (Connexin 26) and Cx30 deletion on the GJB6 gene (Connexin 30)	16020190	NonA/NonB
59	800672	NanoChip® GAUCHER	IVD NanoChip Genetic kit	To detect and identify a panel of seven genetic mutations in the human glucocerebrosidase gene (GBA). The amplified DNA is tested for the following mutations: 84 Ins G, V394L, IVS2+1G>A, N370S, L444P and R496H this kit also allows the identification of the RecTL allele	16020190	NonA/NonB
60	800772	NanoChip ® SMA	IVD NanoChip Genetic kit	To detect in amplified human DNA deletions of exon 7 and/or exon 8 of the SMN1 gene	16020190	NonA/NonB
61	700103	NanoChip ® FMF 12	IVD NanoChip Genetic kit	To detect and identify a panel of twelve genetic mutations in the human MEFV gene. The amplified DNA is tested for the following mutations: M694V, V726A, E148Q, M680IG>A, M680IG>C, M694I, R761H, F479L, I692del, K695R, A744S and P369S	16020190	NonA/NonB
62	899009	NanoChip ® CVP8 (Cardiovascular Panel)	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 8 genetic variants that are associated with Cardiovascular Diseases	16010190	NonA/NonB
63	899015	NanoChip ® CVP5	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 5 genetic variants that are associated with Cardiovascular Diseases	16010190	NonA/NonB
64	800016	NanoChip ® BRCA14	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 14 most common mutations in the human BRCA1 and BRCA2 genes in the Israeli population	16010190	NonA/NonB
65	800014	NanoChip ® All in one (carrier screening panel)	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 35 different genetic diseases (91 mutations) that are associated with various genetic disorders of the Israeli population, based on the specific individual ethnic origin	16010190	NonA/NonB
66	800018	NanoChip ® Beduins Panel	IVD NanoChip Genetic kit	To detect and identify in amplified human DNA a panel of 9 autosomal recessive genetic variants related to the genetic diseases common to the Israeli-Bedouin population	16010190	NonA/NonB
67	899050	NanoChip ® ICP (Infection Control Panel)	IVD NanoChip Infectious Disease kit	To detect Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant Enterococci (VRE) and Carbapenemase-producing Klebsiella pneumonia (KPC) DNA from nasal swabs in patients at risk for nasal colonization	15300100	NonA/NonB
68	899054	NanoChip ® MRSA Panel	IVD NanoChip Infectious Disease kit	To detect Methicillin-resistant Staphylococcus aureus (MRSA) DNA from nasal, groin, axilla and surgical site swabs in patients at risk for MRSA colonization	15300490	NonA/NonB
69	899058	NanoChip ® Gastrointestinal Panel (GIP)	IVD NanoChip Infectious Disease kit	From DNA of stool specimens to detect human diarrheal bacteria and parasites. The bacteria are: Salmonella spp., Shigella Campylobacter spp, and C. difficile. The parasites include Giardia lamblia, Cryptosporidium spp. and Entamoeba histolytica	15300400	NonA/NonB
70	899051	NanoChip ® GIP-Gastrointestinal Panel Combi I	IVD NanoChip Infectious Disease kit	From DNA of stool specimens to detect human diarrheal bacteria and parasites. The bacteria are: Salmonella spp., Shigella Campylobacter spp, C. difficile and STEC. The parasites include Giardia lamblia, Cryptosporidium spp. and Entamoeba histolytica	15300400	NonA/NonB
71	899057	NanoChip ® GIP-Gastrointestinal Panel Combi II	IVD NanoChip Infectious Disease kit	From DNA of stool specimens to detect human diarrheal bacteria and parasites: bacteria-Salmonella spp., Shigella spp and Campylobacter spp; parasites-Entamoeba histolytica, Entamoeba dispar, Giardia lamblia, Cryptosporidium spp., Dientamoeba fragilis and Blastocystis hominis	15300400	NonA/NonB

72	899052	NanoChip ® Gastrointestinal Parasites Panel (GIP Para)	IVD NanoChip Infectious Disease kit	From DNA of stool specimens to detect human diarrheal parasites. The parasites include Entamoeba histolytica, Entamoeba dispar, Giardia lamblia, Cryptosporidium spp., Dientamoeba fragilis and Blastocystis hominis.	15300300	NonA/NonB
73	899053	NanoChip ® Gastrointestinal Bacteria Panel (GIP Bac)	IVD NanoChip Infectious Disease kit	From DNA of stool specimens to detect human diarrheal bacteria. The bacteria are: Salmonella spp., Shigella Campylobacter spp, C. difficile and STEC	15300100	NonA/NonB
74	899061	NanoChip ® Clostridium difficile Panel	IVD NanoChip Infectious Disease kit	From DNA of stool specimens to detect the Clostridium difficile antigen and its toxins from patients suspected of having C. difficile infection (CDI)	15019002	NonA/NonB
75	899017	NanoChip ® HPV Screening Panel	IVD NanoChip Infectious Disease kit	From DNA of clinical specimens to detect 18 High-Risk and 2 Low-Risk HPV subtypes. Genotyping of high-risk HPV subtypes 16 and 18, simultaneous detection of High-Risk HPV types 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82 and detection of Low-Risk HPV subtypes 6 + 11	16010190	NonA/NonB
76	800160	NanoChip ® 400 Cartridge	IVD NanoChip Cartridge	Used in conjunction with the NanoChip® 400 System, for the in vitro examination of patient samples to provide diagnostic results on the genomic variation or presence of specific nucleic acid sequences	27011001	NonA/NonB
77	800161	NanoChip ® 400 Fluidics Cartridge	IVD NanoChip Cartridge	An accessory cartridge used for routine maintenance of the NanoChip® 400 System. Buffers or other solutions are run through the cartridge to prime and rinse fluidic channels	27011001	NonA/NonB
78	800159	NanoChip ® 400	IVD NanoChip Instrument	For examination of patient samples to provide diagnostic results on the genomic variation or presence of specific nucleic acid sequences	57851	NonA/NonB
79	800165	NanoChip ® XL	IVD NanoChip Instrument	To analyze DNA or RNA in molecular biology samples for detection of variation, repeats, polymorphisms, insertions, deletion and other genetic characteristics	26021001	NonA/NonB
80	800154	NC400 Low Salt Buffer	IVD NanoCHIP General Purpose Reagent	The NC400 High Salt Buffer, Low Salt Buffer and Target Prep Buffer are general all purpose reagent buffers used for various cartridge fill/wash stages and during denaturing of double stranded DNA	11900101	NonA/NonB
81	800155	NC400 High Salt Buffer	IVD NanoCHIP General Purpose Reagent	The NC400 High Salt Buffer, Low Salt Buffer and Target Prep Buffer are general all purpose reagent buffers used for various cartridge fill/wash stages and during denaturing of double stranded DNA	11900101	NonA/NonB
82	800156	NC400 Target Prep Buffer	IVD NanoCHIP General Purpose Reagent	The NC400 High Salt Buffer, Low Salt Buffer and Target Prep Buffer are general all purpose reagent buffers used for various cartridge fill/wash stages and during denaturing of double stranded DNA	11900101	NonA/NonB
83	A710-01M	Haptoglobin (Hp) Typing ELISA	IVD ELISA test	Enzyme-linked immunoassay for the determination of Haptoglobin Phenotypes in Diabetic Serum	11020113	NonA/NonB
84	601-01	Savvygen GI-Cryptosporidium	IVD Real-time PCR test	Detection of Cryptosporidium by real time PCR in human feces	14050203	NonA/NonB

85	602-01	Savvygen GI-Giardia	IVD Real-time PCR test	Detection of Giardia by real time PCR in human feces	14050290	NonA/NonB
86	603-01	Savvygen GI-Entamoeba	IVD Real-time PCR test	Detection of Entamoeba histolytica by real time PCR in human feces	14050290	NonA/NonB
87	604-01	Savvygen™ GI-Salmonella	IVD Real-time PCR test	Detection of Salmonella by real time PCR in human feces	15011001	NonA/NonB
88	605-01	Savvygen™ GI-Shigella/EIEC	IVD Real-time PCR test	Detection of Shigella/EIEC by real time PCR in human feces	15014090	NonA/NonB
89	606-01	Savvygen™ GI-Campylobacter	IVD Real-time PCR test	Detection of Campylobacter by real time PCR in human feces	15011401	NonA/NonB
90	614-01L/614H	Savvygen Zika virus	IVD Real-time PCR test	Detection of the Zika virus by real time PCR in clinical samples	15048090	NonA/NonB
91	619-01L/619H	Savvygen GI Parasite Panel	IVD Real-time PCR test	Detection of Cryptosporidium, Giardia lamblia and/or Entamoeba histolytica parasites by real time PCR in human feces.	15048090	NonA/NonB
92	620-01L/620/01H	Savvygen GI Bacteria Panel	IVD Real-time PCR test	Detection of Salmonella, Campylobacter and/or Shigella/EIEC bacteria by real time PCR in human feces.	15048090	NonA/NonB
93	41121	H. pylori Saliva Test	IVD Rapid Test Bacteria Antigen	One-step test for determination of H.pylori bacteria in Human Saliva	15010401	NonA/NonB
94	899063	NanoCHIP® ZIKV/DENV/CHIKV	IVD Microarray	In vitro test for detection of Zika, dengue (I-IV), and chikungunya viruses in plasma or serum	15048090	NonA/NonB
95	800173	Formalin Filled Container	IVD	Formalin filled container for preservation of sample for a pathology test	11900190	NonA/NonB
96	607-01	Savvygen GI Adenovirus	IVD Real-time PCR test	Detection of Adenovirus by real time PCR in human feces.	15048001	NonA/NonB
97	608-01	Savvygen GI Rotavirus	IVD Real-time PCR test	Detection of Rotavirus by real time PCR in human feces.	15048006	NonA/NonB
98	609-01	Savvygen GI Astrovirus	IVD Real-time PCR test	Detection of Astrovirus by real time PCR in human feces.	15048029	NonA/NonB

99	610-01	Savvygen GI Norovirus GI	IVD Real-time PCR test	Detection of Norovirus GI by real time PCR in human feces.	15048016	NonA/NonB
100	611-01	Savvygen GI Norovirus GII	IVD Real-time PCR test	Detection of Norovirus GII by real time PCR in human feces.	15048016	NonA/NonB
101	612-01	Savvygen Flu A, Flu B, RSV	IVD Real-time PCR test	Detection of Influenza A (Flu A), Influenza B (Flu B) and/or Human Respiratory Syncytial Virus (RSV) by real time PCR from Nasal swab, UTM.	15300242	NonA/NonB
102	613-01L/613-01H	Savvygen B. pertussis	IVD Real-time PCR test	Detection of Bordetella parapertussis and/or Bordetella holmesii by real time PCR from human nasopharyngeal swabs and washes.	15014007	NonA/NonB
103	651-01/652-01	Savvygen STI Extraction Kit	IVD Real-time PCR test	A DNA extraction kit from urine, Genital/vaginal swab, EPS, Semen, cervical swab and LBC.	15904001	NonA/NonB
104	653-01/654-01	Savvygen Respiratory Extraction Kit	IVD Real-time PCR test	A DNA / RNA extraction kit from Nasal swab, UTM.	15904001	NonA/NonB
105	655-01/656-01	Savvygen GI DNA extraction kit	IVD Real-time PCR test	A DNA extraction kit from Stool, Fecal swab and Rectal swab.	15904001	NonA/NonB
106	615-01	Savygen STI MG/MH	IVD Real-time PCR test	Detection of Mycoplasma genitalium (MG) and Mycoplasma hominis (MH) by real time PCR in urine or vaginal swab	15010801	NonA/NonB
107	616-01	Savygen STI TV	IVD Real-time PCR test	Detection of Trichomonas vaginalis (TV) by real time PCR in urine or vaginal swab	15051010	NonA/NonB
108	617-01	Savygen STI UU/UP	IVD Real-time PCR test	Detection of Ureaplasma urealyticum (UU) and Ureaplasma parvum (UP) by real time PCR in urine or vaginal swab	15014090	NonA/NonB
109	41208	QuickStripe M. pneumoniae IgM	IVD RAPID kit	A rapid test for the detection of IgM antibody to Mycoplasma pneumoniae (<i>M. pneumoniae</i>) in whole blood, serum or plasma	15010803	NonA/NonB
110	41224	QuickStripe Streptococcus pneumoniae	IVD RAPID kit	A rapid test for the detection of <i>Streptococcus pneumoniae</i> Antigens in human urine	15011101	NonA/NonB
111	41225	QuickStripe Legionella pneumophila	IVD RAPID kit	A rapid test for the detection of <i>Legionella pneumophila</i> antigen in urine specimens	15010501	NonA/NonB
112	41221-10	CoproStrip H. pylori Positive Control	Control Set	External quality control for the CoproStrip H. pylori kit	11500103	NonA/NonB
113	41207-10	QuickStripe Adeno/Rota Positive Control	Control Set	External quality control of Adenovirus & Rotavirus for QuickStripe Adeno/Rota kit	11500103	NonA/NonB
114	622-01L/622-01H	Savvygen HSV1+2/VZV	IVD Real-time PCR test	Detection of herpes simplex virus types 1&2 and varicella zoster virus by real time PCR in clinical samples	15048090	NonA/NonB
115	623-01L/623-01H	Savvygen Pneumocystis jirovecii	IVD Real-time PCR test	Detection of Pneumocystis jirovecii by real time PCR in respiratory samples	15060190	NonA/NonB

116	660-01	Color Compensation Set for Savvygen assay	IVD Real-time PCR test	To generate Color-compensation file by real time PCR for interpretation of multiplex assays	13070190 16020190	NonA/NonB
117	800021	NanoChip Onco Panel	IVD NanoChip Genetic kit	For the <i>in vitro</i> semi-quantitative detection of all forms of labile and chelatable iron which may be redox active	16020190	NonA/NonB
118	105.01	FeROS™ LPI kit	IVD fluorescence test	For the <i>in vitro</i> semi-quantitative detection of the redox active LPI (Labile Plasma Iron) fraction of NTBI (Non-Transferrin Bound Iron)	12070105 16020190	NonA/NonB
119	106-01	FeROS™ eLPI kit	IVD fluorescence test	For the <i>in vitro</i> semi-quantitative detection of all forms of labile and chelatable iron which may be redox active	12070105	NonA/NonB
120	624-01L/624-01H	Savvygen Tick Borne	IVD Real-time PCR test	Detection of Tick Borne diseases in clinical samples	15300490	NonA/NonB
121	671-01/672-01	Savvygen S Urogenital Extraction kit	IVD Real-time PCR test	A DNA extraction kit from urine, Genital/vaginal swab, EPS, Semen, cervical swab and LBC.	15904001	NonA/NonB
122	674-01/675-01;677-01/678-01	Savvygen S Respiratory Extraction kit	IVD Real-time PCR test	A DNA / RNA extraction kit from Nasal swab, UTM.	15904001	NonA/NonB
123	680-01/681-01	Savvygen S GI DNA extraction kit	IVD Real-time PCR test	A DNA extraction kit from Stool, Fecal swab and Rectal swab.	15904001	NonA/NonB
124	683-01/684-01	Savvygen S Genomic DNA Extraction kit	IVD Real-time PCR test	A DNA extraction kit from Whole Blood, Buffy coat, buccal swab, and saliva.	15904001	NonA/NonB
125	800176	Savyon NA Lysis Buffer	Lysis buffer	For cell lysis, binding of total nucleic acids and inactivation of nucleases	11900101	NonA/NonB
126	41226	QuickStripe SARS-CoV-2 IgG/IgM	IVD RAPID kit	To detect antibody content against SARS-CoV-2 in clinical samples (serum/plasma/whole blood)	15709008	NonA/NonB
127	625-01L/625-01H	Savvygen SARS-CoV-2	IVD Real-time PCR test	Detection of SARS-CoV-2 by real time PCR in clinical respiratory samples (48 tests)	15040901	NonA/NonB
128	626-01L/626-01H	Savvygen SARS-CoV-2	IVD Real-time PCR test	Detection of SARS-CoV-2 by real time PCR in clinical respiratory samples (96 tests)	15040901	NonA/NonB
129	689-01	Savvygen NA Extraction kit	IVD Real-time PCR test	RNA extraction from nasopharyngeal, oropharyngeal, anterior nasal, or mid-turbinate nasal swab	15904001	NonA/NonB
130	800197	Savyon Viral Transport Medium	Buffer	Collection and transport of clinical viral specimens from the sampling site to the processing laboratory	11900101	NonA/NonB
131	A800177/B800177/C800177/D800177	Savvygen Transport & Lysis Buffer	Buffer	Collection and transport of suspected clinical samples, Inactivation and lysis of SARS- CoV-2	11900101	NonA/NonB
132	612-01LE/612-01HE	Savvygen Flu A, Flu B & RSV	IVD DNA extraction reagents for automatic system	Detection of Flu A, Flu B and/or Human Respiratory Syncytial Virus (RSV) by real time PCR by nasal swab	15300242	NonA/NonB
133	622-01LE/622-01HE	Savvygen HSV1+2/VZV	IVD Real-time PCR test	Detection of herpes simplex virus types 1&2 and varicella zoster virus by real time PCR in clinical samples	15048090	NonA/NonB
134	625-01LE/625-01HE	Savvygen SARS-CoV-2	IVD Real-time PCR test	Detection of SARS-CoV-2 by real time PCR in clinical respiratory samples (48 tests)	15040901	NonA/NonB
135	626-01LE/626-01HE	Savvygen SARS-CoV-2	IVD Real-time PCR test	Detection of SARS-CoV-2 by real time PCR in clinical respiratory samples (96 tests)	15040901	NonA/NonB

136	A800177/ B800177/ C800177/ D800177/E 800177	Savvygen Transport & Lysis Buffer	Buffer	Collection and transport of suspected clinical samples, Inactivation and lysis of SARS- CoV-2	11900101	NonA/NonB
137	171-01	SeroELISA SARS-CoV-2 IgG	IVD ELISA test	Enzyme -Linked Immunosorbent Assay to detect IgG antibodies of SARS-CoV-2 in human serum	15040905	NonA/NonB
138	172-01	SeroELISA SARS-CoV-2 IgM	IVD ELISA test	Enzyme -Linked Immunosorbent Assay to detect IgM antibodies of SARS-CoV-2 in human serum	15040906	NonA/NonB
139	173-01	SeroELISA SARS-CoV-2 IgA	IVD ELISA test	Enzyme -Linked Immunosorbent Assay to detect IgA antibodies of SARS-CoV-2 in human serum	15040907	NonA/NonB
140	627-01	Savvygen SARS-CoV-2 plus	IVD Real-time PCR test	Detection of SARS-CoV-2 in clinical respiratory samples from patients with signs and respiratory symptom	15040901	NonA/NonB
141	800022	NanoChip Onco Panel 51	IVD NanoChip Genetic kit	To detect 51 related germline genetic variants implicated in increase of breast, ovarian & colon cancer in Israeli population	16020190	NonA/NonB
142	41102	QuickStrip™ SARS-CoV-2 Antigen Test	IVD Rapid test	Rapid chromatographic immunoassay to detect SARS-CoV-2 antigens in human nasopharynx	15040901	NonA/NonB
143	41014	Savvyclick™ SARS-CoV-2 Ag	IVD Rapid test	Rapid lateral flow-based assay for qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in human nasal swab samples of individuals suspected of COVID-19	15709008	NonA/NonB
144	621-01	Savvygen™ H. pylori & Antibiotic Resistance	IVD Real-time PCR test	A test for identifying and differentiating H. pylori bacteria and 11 mutations to antibiotic resistance to Clarithromycin and	15010401	NonA/NonB
145	690-01	Savvygen™ Stool NA Extraction kit	IVD Extraction kit	A system to enable isolation of H. pylori bacteria DNA from human stool specimens, either by manual or automatic extraction of the viral RNA.	15904001	NonA/NonB
146	A41016/ B41016	Savvyclick™ H.pylori	IVD RAPID kit	A one step rapid chromatographic immunoassay to detect H. pylori antigens in human feces specimens	30691/ 15700102	NonA/NonB
147	A41017/ B41017	Savvyclick™ Strep A	IVD RAPID kit	A rapid chromatographic immunoassay to detect Strep A antigens from throat swab specimens	30710/ 15700103	NonA/NonB
148	A41018/ B41018	Savvyclick™ Fecal Occult Blood (FOB)	IVD RAPID kit	A one step chromatographic immunoassay to determine human hemoglobin (hHb) in stool samples	38217/ 11700301	NonA/NonB

Date: 04.04.2022**Stamp:**

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