

ADRESÁT/TO	Místo dodání/Place of delivery
TestLine Clinical Diagnostics s.r.o.	Křižkova 188/68
Lenka Hanáková	Brno
	612 00
	Česká republika/Czech Republic

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CERTIFIKÁT VOLNÉHO PRODEJE / CERTIFICATE OF FREE SALE

Číslo certifikátu / *Certificate reference number*: 00011084
Země vývozu / *Exporting (certifying) country*: Czech Republic
Platnost do / *Valid until*: 09.03.2021

Státní ústav pro kontrolu léčiv, se sídlem v Praze 10, Šrobárova 48, Česká republika, jako orgán příslušný k vydání certifikátu volného prodeje podle § 9 písm. n) zákona č. 268/2014 Sb., o zdravotnických prostředcích a o změně zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů (dále jen „zákon o zdravotnických prostředcích“), který zapracovává příslušné předpisy Evropské unie (Směrnice Rady 93/42/EHS ze dne 14. června 1993, Směrnice Rady 90/385/EHS ze dne 20. června 1990, Směrnice Evropského parlamentu a Rady 98/79/ES ze dne 27. října 1998 a Rozhodnutí Komise 2010/227/EU ze dne 19. dubna 2010, a upravuje zacházení se zdravotnickými prostředky a jejich příslušenstvím), provedl podle § 38 odst. 1 tohoto zákona ověření v Registru zdravotnických prostředků.

V souladu s § 38 odst. 2 zákona o zdravotnických prostředcích Státní ústav pro kontrolu léčiv tímto osvědčuje, že níže uvedený zdravotnický prostředek (uvedené zdravotnické prostředky) splnil/y ke dni vydání tohoto certifikátu podmínky pro uvedení na trh. Tento Certifikát volného prodeje se vydává výrobcí notifikovaného zdravotnického prostředku (notifikovaných zdravotnických prostředků) usazenému na území České republiky na základě jeho žádosti a za účelem vývozu tohoto zdravotnického prostředku (těchto zdravotnických prostředků) mimo členské státy EU.

The State Institute for Drug Control, registered address Prague 10, Srobarova 48, Czech Republic, as the competent authority for issuance of a Certificate of Free Sale under section 9 letter n) of Act No. 268/2014 Coll., on Medical Devices and on Amendments to Act No. 634/2004 Coll., on Administrative Fees, as amended (hereinafter referred to as “the Act”), which implements the relevant EU legislation (Council Directive 93/42/EEC of 14 June 1993, Council Directive 90/385/EEC of 20 June 1990, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 and Commission Decision 2010/227/EU of 19 April 2010, and regulates the treatment of medical devices and their accessories), in accordance with section 38 paragraph 1 of the Act carried out the verification in the Registry of Medical Devices.

The State Institute for Drug Control in accordance with section 38 paragraph 2 of the Act hereby certifies that the below mentioned medical device(s) meet(s) on the date of issue of this Certificate all legal requirements in order to be placed on the market. The Certificate of Free Sale is granted to the manufacturer of a notified

medical device(s) established within the territory of the Czech Republic for the purposes of the medical device(s) export outside the EU Member States.

Žadatel (Výrobce) / Applicant (Manufacturer)

Jméno společnosti / Company name: TestLine Clinical Diagnostics s.r.o.
IČ společnosti / ID or similar number of the company: 47913240
Adresa sídla / Address of the registered office: Křižíkova 188/68
61200 Brno – Královo Pole
Česká republika/Czech Republic
Registrační číslo výrobce / Registration number of the Manufacturer: 002276

Certifikovaný zdravotnický prostředek (Certifikované zdravotnické prostředky) / Certified Medical device(s)

Notifikovaný zdravotnický prostředek (Notifikované zdravotnické prostředky) / Notified medical device(s)		
Název zdravotnického prostředku (abecedně) Medical device name (in alphabetical order)	Evidenční číslo Asset No.	Generická skupina GMDN name
Medical device version name Název varianty zdravotnického prostředku		Catalogue No. Katalogové číslo
Antibody index - software	00014429	Laboratory analyser operation system software IVD
Antibody index - software		SwAI01
Array Reader C-series	00882656	Microplate reader IVD, automated
Array Reader C-series		ARCIX096
Barbital buffer for CF – 5× conc.	00037655	Buffered sample diluent IVD, manual
Barbital buffer for CF – 5× conc.		Bp0500
BLOT Helicobacter pylori IgA	00015114	Helicobacter pylori total antibody IVD, kit, immunoblot
BLOT Helicobacter pylori IgA		HpAB16
BLOT Helicobacter pylori IgG	00015106	Helicobacter pylori total antibody IVD, kit, immunoblot
BLOT Helicobacter pylori IgG		HpGB16
BLOT Toxocara IgG	00015093	Toxocara canis immunoglobulin G (IgG) antibody IVD, reagent
BLOT Toxocara IgG		TcGB16
BLOT Toxoplasma IgA	00015085	Toxoplasma gondii immunoglobulin A (IgA)/IgG/IgM antibody IVD, reagent
BLOT Toxoplasma IgA		TgAB16

BLOT Toxoplasma IgG	00015077	Toxoplasma gondii immunoglobulin A (IgA)/IgG/IgM antibody IVD, reagent
BLOT Toxoplasma IgG		TgGB16
BLOT Toxoplasma IgM	00015069	Toxoplasma gondii immunoglobulin A (IgA)/IgG/IgM antibody IVD, reagent
BLOT Toxoplasma IgM		TgMB16
BLOT-LINE ANA	00004167	Multiple antinuclear antibody (ANA) screening IVD, kit, multiplex
BLOT-LINE ANA		ANAL20
BLOT-LINE ANCA-3	00660201	Multiple anti-neutrophil cytoplasmic antibody (ANCA) IVD, kit, multiplex
BLOT-LINE ANCA-3		ANC3L20
BLOT-LINE Bordetella IgA	00045719	Multiple Bordetella species antibody IVD, reagent
BLOT-LINE Bordetella IgA		BpAL20
BLOT-LINE Bordetella IgG	00045727	Multiple Bordetella species antibody IVD, reagent
BLOT-LINE Bordetella IgG		BpGL20
BLOT-LINE Bordetella IgM	00095644	Multiple Bordetella species antibody IVD, reagent
		BpML20
BLOT-LINE Borrelia afzelii IgG	00012538	Borrelia afzelii total antibody IVD, kit, immunoblot
BLOT-LINE Borrelia afzelii IgG		BaGL20
BLOT-LINE Borrelia afzelii IgM	00012511	Borrelia afzelii total antibody IVD, kit, immunoblot
BLOT-LINE Borrelia afzelii IgM		BaML20
BLOT-LINE Borrelia b. sensu stricto IgG	00041486	Borrelia burgdorferi total antibody IVD, kit, immunoblot
BLOT-LINE Borrelia b. sensu stricto IgG		BsGL20
BLOT-LINE Borrelia b. sensu stricto IgM	00041478	Borrelia burgdorferi total antibody IVD, kit, immunoblot
BLOT-LINE Borrelia b. sensu stricto IgM		BsML20

BLOT-LINE Borrelia garinii IgG	00012503	Borrelia garinii immunoglobulin G (IgG) antibody IVD, reagent
BLOT-LINE Borrelia garinii IgG		BgGL20
BLOT-LINE Borrelia garinii IgM	00012490	Borrelia garinii immunoglobulin M (IgM) antibody IVD, reagent
BLOT-LINE Borrelia garinii IgM		BgML20
BLOT-LINE Borrelia/HGA IgG	00000115	Borrelia burgdorferi total antibody IVD, kit, immunoblot
BLOT-LINE Borrelia/HGA IgG		BGL020
BLOT-LINE Borrelia/HGA IgM	00000430	Borrelia burgdorferi total antibody IVD, kit, immunoblot
BLOT-LINE Borrelia/HGA IgM		BML020
BLOT-LINE EBV IgA	00902944	Esptein-Barr virus (EBV) antigen IVD, antibody
BLOT-LINE EBV IgA		EBAL20
BLOT-LINE EBV IgG	00781599	Epstein-Barr virus (EBV) immunoglobulin G (IgG) antibody IVD, kit, immunoblot
BLOT-LINE EBV IgG		EBGL20
BLOT-LINE EBV IgM	00781601	Epstein-Barr virus (EBV) immunoglobulin M (IgM) antibody IVD, reagent
BLOT-LINE EBV IgM		EBML20
BLOT-LINE ENA plus	00004028	Multiple extractable nuclear antigen auto-antibody (anti-ENA) screening IVD, kit, multiplex
BLOT-LINE ENA plus		ENAL20
BLOT-LINE Helicobacter IgA	00261075	Helicobacter pylori total antibody IVD, kit, immunoblot
BLOT-LINE Helicobacter IgA		HpAL20
BLOT-LINE Helicobacter IgG	00261083	Helicobacter pylori total antibody IVD, kit, immunoblot
BLOT-LINE Helicobacter IgG		HpGL20
BLOT-LINE Chlamydia IgA	00046770	Multiple Chlamydia species immunoglobulin A (IgA) antibody IVD, reagent
BLOT-LINE Chlamydia IgA		CAL020
BLOT-LINE Chlamydia IgG	00046762	Multiple Chlamydia species

		immunoglobulin G (IgG) antibody IVD, reagent
BLOT-LINE Chlamydia IgG		CGL020
BLOT-LINE Chlamydia pneumoniae IgA	00046789	Multiple Chlamydia species immunoglobulin A (IgA) antibody IVD, reagent
BLOT-LINE Chlamydia pneumoniae IgA		CpAL20
BLOT-LINE Chlamydia pneumoniae IgG	00046797	Multiple Chlamydia species immunoglobulin G (IgG) antibody IVD, reagent
BLOT-LINE Chlamydia pneumoniae IgG		CpGL20
BLOT-LINE Chlamydia pneumoniae IgM	00264655	Chlamydia pneumoniae total antibody IVD, reagent
BLOT-LINE Chlamydia pneumoniae IgM		CpML20
BLOT-LINE Chlamydia trachomatis IgA	00041005	Chlamydia trachomatis total antibody IVD, reagent
BLOT-LINE Chlamydia trachomatis IgA		CtAL20
BLOT-LINE Chlamydia trachomatis IgG	00040993	Chlamydia trachomatis total antibody IVD, reagent
BLOT-LINE Chlamydia trachomatis IgG		CtGL20
BLOT-LINE Mycoplasma IgA	00889655	Mycoplasma pneumoniae antigen IVD, reagent
BLOT-LINE Mycoplasma IgA		MyAL20
BLOT-LINE Mycoplasma IgG	00889639	Mycoplasma pneumoniae antigen IVD, reagent
BLOT-LINE Mycoplasma IgG		MyGL20
BLOT-LINE Mycoplasma IgM	00889647	Mycoplasma pneumoniae antigen IVD, reagent
BLOT-LINE Mycoplasma IgM		MyML20
BLOT-LINE Treponema IgG	00038447	Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, reagent
BLOT-LINE Treponema IgG		TpGL20
BLOT-LINE Treponema IgM	00038439	Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, reagent
BLOT-LINE Treponema IgM		TpML20

BLOT-LINE Yersinia IgA	00585491	Multiple Yersinia species total antibody IVD, reagent
BLOT-LINE Yersinia IgA		YAL020
BLOT-LINE Yersinia IgG	00585504	Multiple Yersinia species total antibody IVD, reagent
BLOT-LINE Yersinia IgG		YGL020
BLOT-LINE Yersinia IgM	00585512	Multiple Yersinia species total antibody IVD, reagent
BLOT-LINE Yersinia IgM		YML020
BlueBLOT-LINE Bordetella IgA	00724754	Multiple Bordetella species antibody IVD, reagent
BlueBLOT-LINE Bordetella IgA		BD-BpAL24
BlueBLOT-LINE Bordetella IgG	00724746	Multiple Bordetella species antibody IVD, reagent
BlueBLOT-LINE Bordetella IgG		BD-BpGL24
BlueBLOT-LINE Borrelia IgM	00076275	Borrelia burgdorferi total antibody IVD, kit, immunoblot
		BD-BML024
BlueBLOT-LINE EBV IgG	00847762	Epstein-Barr virus (EBV) immunoglobulin G (IgG) antibody IVD, kit, immunoblot
BlueBLOT-LINE EBV IgG		BD-EBGL24
BlueBLOT-LINE EBV IgM	00847770	Epstein-Barr virus (EBV) immunoglobulin M (IgM) antibody IVD, reagent
BlueBLOT-LINE EBV IgM		BD-EBML24
BlueBLOT-LINE Helicobacter IgA	00781572	Helicobacter pylori total antibody IVD, kit, immunoblot
BlueBLOT-LINE Helicobacter IgA		BD-HpAL24
BlueBLOT-LINE Helicobacter IgG	00781580	Helicobacter pylori total antibody IVD, kit, immunoblot
BlueBLOT-LINE Helicobacter IgG		BD-HpGL24
BlueBLOT-LINE Chlamydia IgA	00305349	Multiple Chlamydia species immunoglobulin A (IgA) antibody IVD, reagent
BlueBLOT-LINE Chlamydia IgA		BD-CAL024
BlueBLOT-LINE Chlamydia IgG	00305357	Multiple Chlamydia species immunoglobulin G (IgG) antibody IVD, reagent

BlueBLOT-LINE Chlamydia IgG		BD-CGL024
BlueBLOT-LINE Treponema IgG	00732789	Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, reagent
BlueBLOT-LINE Treponema IgG		BD-TpGL24
BlueBLOT-LINE Treponema IgM	00732797	Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, reagent
BlueBLOT-LINE Treponema IgM		BD-TpML24
BlueBLOT-LINE Yersinia IgA	00882218	Multiple Yersinia species total antibody IVD, reagent
BlueBLOT-LINE Yersinia IgA		BD-YAL024
BlueBLOT-LINE Yersinia IgG	00882226	Multiple Yersinia species total antibody IVD, reagent
BlueBLOT-LINE Yersinia IgG		BD-YGL024
Bordetella parapertussis-AR-Aglutinin	00015173	Multiple Bordetella species antibody IVD, reagent
Bordetella parapertussis-AR-Aglutinin		BppAg5
Bordetella parapertussis-AR-Positive Control lyophil.	00015157	Multiple Bordetella species antibody IVD, control
Bordetella parapertussis-AR-Positive Control lyophil.		BppP01
Bordetella pertussis-AR-Aglutinin	00015181	Multiple Bordetella species antibody IVD, reagent
Bordetella pertussis-AR-Aglutinin		BpeAg5
Bordetella pertussis-AR-Positive control lyophil.	00015165	Multiple Bordetella species antibody IVD, control
Bordetella pertussis-AR-Positive control lyophil.		BpeP01
Borrelia garinii AI - Standard IgG	00027238	Borrelia garinii immunoglobulin G (IgG) antibody IVD, calibrator
Borrelia garinii AI - Standard IgG		BgGAI2
Borrelia garinii AI - Standard IgM	00027211	Borrelia garinii immunoglobulin M (IgM) antibody IVD, calibrator
Borrelia garinii AI - Standard IgM		BgMAI2
Borrelia recombinant AI - Standard IgG	00027246	Borrelia burgdorferi immunoglobulin G (IgG) antibody IVD, calibrator
Borrelia recombinant AI - Standard IgG		BrGAI2
Borrelia recombinant AI - Standard IgM	00027254	Borrelia burgdorferi immunoglobulin M (IgM)

		antibody IVD, calibrator
Borrelia recombinant AI - Standard IgM		BrMAI2
Certifikované kontrolní sérum TLX (skupina B dle přílohy č.2 NV č.56/2015 Sb.)	00009881	Total immunoglobulin/gamma globulin IVD, calibrator
Negativní certifikované kontrolní sérum Pozitivní certifikované kontrolní sérum		XXXTLN XXXTLP
Certifikované kontrolní sérum TLX (skupina jiné dle přílohy č.2 NV č.56/2015 Sb.)	00009902	Total immunoglobulin/gamma globulin IVD, calibrator
Negativní certifikované kontrolní sérum Pozitivní certifikované kontrolní sérum		XXXTLN XXXTLP
CF - AMBOCEPTORset	00037663	Complement reagent IVD
CF - AMBOCEPTORset (0,5 ml) CF - AMBOCEPTORset (1 ml)		KFAs00 KFAs01
CMV - CF - Ag lyophil.	00022234	Cytomegalovirus (CMV) antigen IVD, reagent
CMV - CF - Ag lyophil.		CMvKF1
EIA Adenovirus IgA	00888767	Adenovirus immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Adenovirus IgA SmartEIA Adenovirus IgA		AdA096 SK-AdA096
EIA Adenovirus IgG	00888775	Adenovirus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Adenovirus IgG SmartEIA Adenovirus IgG		AdG096 SK-AdG096
EIA Adenovirus IgM	00888783	Adenovirus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Adenovirus IgM SmartEIA Adenovirus IgM		AdM096 SK-AdM096
EIA ASCA IgA	00017953	Saccharomyces cerevisiae immunoglobulin A (IgA) antibody IVD, kit enzyme immunoassay (EIA)
EIA ASCA IgA SmartEIA ASCA IgA		ScA096 SK-ScA096

EIA ASCA IgG	00017961	Saccharomyces cerevisiae immunoglobulin G (IgG) antibody IVD, kit enzyme immunoassay (EIA)
EIA ASCA IgG SmartEIA ASCA IgG		ScG096 SK-ScG096
EIA Bordetella parapertussis IgA	00155686	Multiple Bordetella species antibody IVD, reagent
EIA Bordetella parapertussis IgA SmartEIA Bordetella parapertussis IgA		BppA96 SK-BppA96
EIA Bordetella parapertussis IgG	00155643	Multiple Bordetella species antibody IVD, reagent
EIA Bordetella parapertussis IgG SmartEIA Bordetella parapertussis IgG		BppG96 SK-BppG96
EIA Bordetella parapertussis IgM	00155627	Multiple Bordetella species antibody IVD, reagent
EIA Bordetella parapertussis IgM SmartEIA Bordetella parapertussis IgM		BppM96 SK-BppM96
EIA Bordetella pertussis Toxin IgA	00040731	Bordetella pertussis immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Bordetella pertussis Toxin IgA SmartEIA Bordetella pertussis Toxin IgA		BpAT96 SK-BpAT96
EIA Bordetella pertussis Toxin IgG	00040758	Bordetella pertussis immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Bordetella pertussis Toxin IgG SmartEIA Bordetella pertussis Toxin IgG		BpGT96 SK-BpGT96
EIA Bordetella pertussis Toxin IgM	00044855	Bordetella pertussis immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Bordetella pertussis Toxin IgM SmartEIA Bordetella pertussis Toxin IgM		BpMT96 SK-BpMT96
EIA Borrelia afzelii IgM (192)	00002129	Borrelia afzelii immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia afzelii IgM (192) SmartEIA Borrelia afzelii IgM (192)		BaM192 SK-BaM192

EIA Borrelia afzelii VlsE IgG (192)	00002137	Borrelia afzelii immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia afzelii VlsE IgG SmartEIA Borrelia afzelii VlsE IgG		BaGVD2 SK-BaGVD2
EIA Borrelia b. sensu stricto IgM	00002700	Borrelia burgdorferi immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia b. sensu stricto IgM SmartEIA Borrelia b. sensu stricto IgM		BsM096 SK-BsM096
EIA Borrelia b. sensu stricto VlsE IgG	00002719	Borrelia burgdorferi immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia b. sensu stricto VlsE IgG SmartEIA Borrelia b. sensu stricto VlsE IgG		BsGV96 SK-BsGV96
EIA Borrelia garinii IgM (192)	00001919	Borrelia garinii immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia garinii IgM (192) SmartEIA Borrelia garinii IgM		BgM192 SK-BgM192
EIA Borrelia garinii VlsE IgG (192)	00001898	Borrelia garinii immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia garinii VlsE IgG (192) SmartEIA Borrelia garinii VlsE IgG		BgGVD2 SK-BgGVD2
EIA Borrelia IgM	00004685	Borrelia burgdorferi immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia IgM SmartEIA Borrelia IgM		BM0096 SK-BM0096
EIA Borrelia recombinant IgG (192)	00004693	Borrelia burgdorferi immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia recombinant IgG (192) SmartEIA Borrelia recombinant IgG		BrG192 SK-BrG096

EIA Borrelia recombinant IgM (192)	00004706	Borrelia burgdorferi immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia recombinant IgM (192) SmartEIA Borrelia recombinant IgM		BrM192 SK-BrM096
EIA Borrelia VlsE IgG	00004677	Borrelia burgdorferi immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Borrelia VlsE IgG SmartEIA Borrelia VlsE IgG		BGV096 SK-BGV096
EIA CCP IgA	00014453	Cyclic citrullinated peptide antibody (anti-CCP) IVD, kit, enzyme immunoassay (EIA)
EIA CCP IgA SmartEIA CCP IgA		CCPA96 SK-CCPA96
EIA CCP IgG	00014445	Cyclic citrullinated peptide antibody (anti-CCP) IVD, kit, enzyme immunoassay (EIA)
EIA CCP IgG SmartEIA CCP IgG		CCPG96 SK-CCPG96
EIA Centromere	00040141	Centromere antibody IVD, kit, enzyme immunoassay (EIA)
EIA Centromere SmartEIA Centromere		CEN096 SK-CEN096
EIA CMV IgA	00007819	Cytomegalovirus (CMV) total antibody IVD, kit, enzyme immunoassay (EIA)
EIA CMV IgA SmartEIA CMV IgA		CMA096 SK-CMA096
EIA CMV IgG	00007827	Cytomegalovirus (CMV) total antibody IVD, kit, enzyme immunoassay (EIA)
EIA CMV IgG SmartEIA CMV IgG		CMG096 SK-CMG096
EIA CMV IgM	00007835	Cytomegalovirus (CMV) total antibody IVD, kit, enzyme immunoassay (EIA)
EIA CMV IgM SmartEIA CMV IgM		CMM096 SK-CMM096

EIA COVID-19 NP IgA	00894278	SARS-CoV-2 immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA COVID-19 NP IgA SmartEIA COVID-19 NP IgA		CoNA96 SK-CoNA96
EIA COVID-19 NP IgG	00894286	SARS-CoV-2 immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA COVID-19 NP IgG SmartEIA COVID-19 NP IgG		CoNG96 SK-CoNG96
EIA COVID-19 NP IgM	00894294	SARS-CoV-2 immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA COVID-19 NP IgM SmartEIA COVID-19 NP IgM		CoNM96 SK-CoNM96
EIA COVID-19 RBD IgA	00897129	SARS-CoV-2 immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA COVID-19 RBD IgA SmartEIA COVID-19 RBD IgA		CoRA96 SK-CoRA96
EIA COVID-19 RBD IgG	00897137	SARS-CoV-2 immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA COVID-19 RBD IgG SmartEIA COVID-19 RBD IgG		CoRG96 SK-CoRG96
EIA COVID-19 RBD IgM	00897145	SARS-CoV-2 immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA COVID-19 RBD IgM SmartEIA COVID-19 RBD IgM		CoRM96 SK-CoRM96
EIA dsDNA	00760472	Double stranded DNA antibody (anti-dsDNA) IVD, kit, enzyme immunoassay (EIA)
EIA dsDNA SmartEIA dsDNA		DNA096 SK-DNA096
EIA EBV EA-D IgG	00013274	Epstein-Barr virus (EBV) early antigen (EA) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA EBV EA-D IgG SmartEIA EBV EA-D IgG		EAG096 SK-EAG096

EIA EBV EA-D IgM	00013266	Epstein-Barr virus (EBV) early antigen (EA) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA EBV EA-D IgM SmartEIA EBV EA-D IgM		EAM096 SK-EAM096
EIA EBV EBNA-1 IgG	00013258	Epstein-Barr virus nuclear antigen (EBNA) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA EBV EBNA-1 IgG EIA EBV EBNA-1 IgG (192) SmartEIA EBV EBNA-1 IgG		EBG096 EBG192 SK-EBG096
EIA EBV EBNA-1 IgM	00013231	Epstein-Barr virus nuclear antigen (EBNA) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA EBV EBNA-1 IgM SmartEIA EBV EBNA-1 IgM		EBM096 SK-EBM096
EIA EBV VCA IgA	00013223	Epstein-Barr virus (EBV) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA EBV VCA IgA SmartEIA EBV VCA IgA		VCA096 SK-VCA096
EIA EBV VCA IgG	00013215	Epstein-Barr virus (EBV) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA EBV VCA IgG EIA EBV VCA IgG (192) SmartEIA EBV VCA IgG		VCG096 VCG192 SK-VCG096
EIA EBV VCA IgM	00013207	Epstein-Barr virus (EBV) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA EBV VCA IgM EIA EBV VCA IgM (192) SmartEIA EBV VCA IgM		VCM096 VCM192 SK-VCM096
EIA ENA profile	00813351	Multiple extractable nuclear antigen auto-antibody (anti-ENA) screening IVD, kit, enzyme immunoassay (EIA)

EIA ENA profile SmartEIA ENA profile		ENA012 SK-ENA012
EIA ENA profile plus	00813378	Multiple extractable nuclear antigen auto-antibody (anti-ENA) screening IVD, kit, enzyme immunoassay (EIA)
EIA ENA profile plus SmartEIA ENA profile plus		ENAp12 SK-ENAp12
EIA ENA screen plus	00001847	Multiple extractable nuclear antigen auto-antibody (anti-ENA) screening IVD, kit, enzyme immunoassay (EIA)
EIA ENA screen plus SmartEIA ENA screen plus		ENA096 SK-ENA096
EIA Gliadin DA IgA	00000457	Gliadin antibody IVD, kit, enzyme immunoassay (EIA)
EIA Gliadin DA IgA SmartEIA Gliadin DA IgA		GDA096 SK-GDA096
EIA Gliadin DA IgG	00000465	Gliadin antibody IVD, kit, enzyme immunoassay (EIA)
EIA Gliadin DA IgG SmartEIA Gliadin DA IgG		GDG096 SK-GDG096
EIA Gliadin IgA	00000019	Gliadin antibody IVD, kit, enzyme immunoassay (EIA)
EIA Gliadin IgA SmartEIA Gliadin IgA		GIA096 SK-GIA096
EIA Gliadin IgG	00000449	Gliadin antibody IVD, kit, enzyme immunoassay (EIA)
EIA Gliadin IgG SmartEIA Gliadin IgG		GIG096 SK-GIG096
EIA Helibacter MONO IgA	00013362	Helicobacter pylori immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Helibacter MONO IgA SmartEIA Helibacter MONO IgA		HMA096 SK-HMA096
EIA Helibacter MONO IgG	00013370	Helicobacter pylori immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Helibacter MONO IgG		HMG096

SmartEIA Helibacter MONO IgG		SK-HMG096
EIA Helibacter MONO IgM	00013389	Helicobacter pylori immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Helibacter MONO IgM SmartEIA Helibacter MONO IgM		HMM096 SK-HMM096
EIA HSV 1+2 IgA	00001281	Herpes simplex virus 1 & 2 (HSV1 & 2) antigen IVD, kit, enzyme immunoassay (EIA)
EIA HSV 1+2 IgA SmartEIA HSV 1+2 IgA		HSVA96 SK-HSVG96
EIA HSV 1+2 IgG	00013346	Herpes simplex virus 1 & 2 (HSV1 & 2) antigen IVD, kit, enzyme immunoassay (EIA)
EIA HSV 1+2 IgG SmartEIA HSV 1+2 IgG		HSVG96 SK-HSVG096
EIA HSV 1+2 IgM	00013354	Herpes simplex virus 1 & 2 (HSV1 & 2) antigen IVD, kit, enzyme immunoassay (EIA)
EIA HSV 1+2 IgM SmartEIA HSV 1+2 IgM		HSVM96 SK-HSVM96
EIA Chlamydia IgA	00019334	Multiple Chlamydia species immunoglobulin A (IgA) antibody IVD, reagent
EIA Chlamydia IgA SmartEIA Chlamydia IgA		ChA096 SK-ChA096
EIA Chlamydia IgG	00019342	Multiple Chlamydia species immunoglobulin G (IgG) antibody IVD, reagent
EIA Chlamydia IgG SmartEIA Chlamydia IgG		ChG096 SK-ChG096
EIA Chlamydia IgM	00019422	Multiple Chlamydia species immunoglobulin M (IgM) antibody IVD, reagent
EIA Chlamydia IgM SmartEIA Chlamydia IgM		ChM096 SK-ChM096
EIA Chlamydia pneumoniae IgA	00019414	Chlamydia pneumoniae immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)

EIA Chlamydia pneumoniae IgA SmartEIA Chlamydia pneumoniae IgA		ChpA96 SK-ChpA96
EIA Chlamydia pneumoniae IgG	00019406	Chlamydia pneumoniae immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Chlamydia pneumoniae IgG SmartEIA Chlamydia pneumoniae IgG		ChpG96 SK-ChpG96
EIA Chlamydia pneumoniae IgM	00019393	Chlamydia pneumoniae immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Chlamydia pneumoniae IgM SmartEIA Chlamydia pneumoniae IgM		ChpM96 SK-ChpM96
EIA Chlamydia pneumoniae REC IgA	00262991	Chlamydia pneumoniae immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Chlamydia pneumoniae REC IgA SmartEIA Chlamydia pneumoniae REC IgA		CpAR96 SK-CpAR96
EIA Chlamydia pneumoniae REC IgG	00264671	Chlamydia pneumoniae immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Chlamydia pneumoniae REC IgG SmartEIA Chlamydia pneumoniae REC IgG		CpGR96 SK-CpGR96
EIA Chlamydia trachomatis IgA	00019377	Chlamydia trachomatis immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Chlamydia trachomatis IgA SmartEIA Chlamydia trachomatis IgA		ChtA96 SK-ChtA96
EIA Chlamydia trachomatis IgG	00019369	Chlamydia trachomatis immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Chlamydia trachomatis IgG SmartEIA Chlamydia trachomatis IgG		ChtG96 SK-ChtG96
EIA Chlamydia trachomatis IgM	00019350	Chlamydia trachomatis immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)

EIA Chlamydia trachomatis IgM SmartEIA Chlamydia trachomatis IgM		ChtM96 SK-ChtM96
EIA Influenza A IgA	00890808	Influenza A virus immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Influenza A IgA SmartEIA Influenza A IgA		InAA96 SK-InAA96
EIA Influenza A IgG	00890816	Influenza A virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Influenza A IgG SmartEIA Influenza A IgG		InAG96 SK-InAG96
EIA Influenza A IgM	00890824	Influenza A virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Influenza A IgM SmartEIA Influenza A IgM		InAM96 SK-InAM96
EIA Influenza B IgA	00890832	Influenza B virus immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Influenza B IgA SmartEIA Influenza B IgA		InBA96 SK-InBA96
EIA Influenza B IgA	00890832	Influenza B virus immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Influenza B IgA SmartEIA Influenza B IgA		InBA96 SK-InBA96
EIA Influenza B IgA	00890832	Influenza B virus immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Influenza B IgA SmartEIA Influenza B IgA		InBA96 SK-InBA96
EIA Influenza B IgG	00890840	Influenza B virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)

EIA Influenza B IgG SmartEIA Influenza B IgG		InBG96 SK-InBG96
EIA Influenza B IgM	00890859	Influenza B virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Influenza B IgM SmartEIA Influenza B IgM		InBM96 SK-InBM96
EIA Jo-1	00040125	Jo-1 antibody IVD, kit, enzyme immunoassay (EIA)
EIA Jo-1 SmartEIA Jo-1		Jo1096 SK-Jo1096
EIA Measles IgG	00798825	Measles virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Measles IgG SmartEIA Measles IgG		MeG096 SK-MeG096
EIA Measles IgM	00798833	Measles virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Measles IgM SmartEIA Measles IgM		MeM096 SK-MeM096
EIA MILK IgA	00000123	Lactoferrin IVD, control
EIA Milk IgA SmartEIA MILK IgA		MiA096 SK-MiA096
EIA MILK IgG	00000422	Lactoferrin IVD, control
EIA Milk IgG SmartEIA Milk IgG		MiG096 SK-MiG096
EIA MILK IgM	00000414	Lactoferrin IVD, control
EIA MILK IgM SmartEIA MILK IgM		MiM096 SK-MiM096
EIA Mumps IgA	00813386	Mumps virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mumps IgA SmartEIA Mumps IgA		MuA096 SK-MuA096
EIA Mumps IgG	00813394	Mumps virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mumps IgG SmartEIA Mumps IgG		MuG096 SK-MuG096

EIA Mumps IgM	00813407	Mumps virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mumps IgM SmartEIA Mumps IgM		MuM096 SK-MuM096
EIA Mycoplasma IgA	00013987	Mycoplasma pneumoniae immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mycoplasma IgA SmartEIA Mycoplasma IgA		MyA096 SK-MyA096
EIA Mycoplasma IgG	00013979	Mycoplasma pneumoniae immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mycoplasma IgG SmartEIA Mycoplasma IgG		MyG096 SK-MyG096
EIA Mycoplasma IgM	00013960	Mycoplasma pneumoniae immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mycoplasma IgM SmartEIA Mycoplasma IgM		MyM096 SK-MyM096
EIA Mycoplasma REC IgA	00747649	Mycoplasma pneumoniae immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mycoplasma REC IgA SmartEIA Mycoplasma REC IgA		MyAR96 SK-MyAR96
EIA Mycoplasma REC IgG	00747657	Mycoplasma pneumoniae immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mycoplasma REC IgG SmartEIA Mycoplasma REC IgG		MyGR96 SK-MyGR96
EIA Mycoplasma REC IgM	00766516	Mycoplasma pneumoniae immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Mycoplasma REC IgM SmartEIA Mycoplasma REC IgM		MyMR096 SK-MyMR96
EIA Parainfluenza mix IgA	00893988	Multiple human parainfluenza

		virus immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Parainfluenza mix IgA SmartEIA Parainfluenza mix IgA		PaiA96 SK-PaiA96
EIA Parainfluenza mix IgG	00893996	Multiple human parainfluenza virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Parainfluenza mix IgG SmartEIA Parainfluenza mix IgG		PaiG96 SK-PaiG96
EIA Parainfluenza mix IgM	00894008	Multiple human parainfluenza virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Parainfluenza mix IgM SmartEIA Parainfluenza mix IgM		PaiM96 SK-PaiM96
EIA PCP IgG	00038471	Streptococcus pneumoniae immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA PCP IgG SmartEIA PCP IgG		PCG096 SK-PCG096
EIA RF IgA	00014496	Rheumatoid factor IVD, kit, enzyme immunoassay (EIA)
EIA RF IgA SmartEIA RF IgA		RFA096 SK-RFA096
EIA RF IgG	00014488	Rheumatoid factor IVD, kit, enzyme immunoassay (EIA)
EIA RF IgG SmartEIA RF IgG		RFG096 SK-RFG096
EIA RF IgM	00014461	Rheumatoid factor IVD, kit, enzyme immunoassay (EIA)
EIA RF IgM SmartEIA RF IgM		RFM096 SK-RFM096
EIA RF screen	00263003	Multiple rheumatoid arthritis- associated antibody IVD, kit, enzyme immunoassay (EIA)
EIA RF screen SmartEIA RF screen		RF0096 SK-RF0096
EIA RSV IgA	00893945	Respiratory syncytial virus (RSV)

		immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
EIA RSV IgA SmartEIA RSV IgA		RSA096 SK-RSA096
EIA RSV IgG	00893953	Respiratory syncytial virus (RSV) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA RSV IgG SmartEIA RSV IgG		RSG096 SK-RSG096
EIA RSV IgM	00893961	Respiratory syncytial virus (RSV) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA RSV IgM SmartEIA RSV IgM		RSM096 SK-RSM096
EIA Rubella IgG	00321517	Rubella virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Rubella IgG SmartEIA Rubella IgG		RubG96 SK-RubG96
EIA Rubella IgM	00321525	Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Rubella IgM SmartEIA Rubella IgM		RubM96 SK-RubM96
EIA Scl-70	00040109	Scleroderma-70 antibody (anti- Scl-70) IVD, kit, enzyme immunoassay (EIA)
EIA Scl-70 SmartEIA Scl-70		Scl096 SK-Scl096
EIA Sm	00041996	Sm/RNP antibody IVD, kit, enzyme immunoassay (EIA)
EIA Sm SmartEIA Sm		Sm0096 SK-Sm0096
EIA SS-A	00040117	SSA/Ro antibody (Sjogren's antibody) IVD, kit, enzyme immunoassay (EIA)
EIA SS-A SmartEIA SS-A		SSA096 SK-SSA096

EIA SS-A/Ro52	00040096	SSA/Ro antibody (Sjogren's antibody) IVD, kit, enzyme immunoassay (EIA)
EIA SS-A/Ro52		Ro5296
EIA SS-A/Ro60	00040088	SSA/Ro antibody (Sjogren's antibody) IVD, kit, enzyme immunoassay (EIA)
EIA SS-A/Ro60		Ro6096
EIA SS-B	00040133	SSB/La antibody (Sjogren's antibody) IVD, kit, enzyme immunoassay (EIA)
EIA SS-B SmartEIA SS-B		SSB096 SK-SSB096
EIA TBE Virus IgG	00013928	Tick-borne encephalitis (TBE) virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA TBE Virus IgG SmartEIA TBE Virus IgG		TBG096 SK-TBG096
EIA TBE Virus IgM	00013901	Tick-borne encephalitis (TBE) virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA TBE Virus IgM SmartEIA TBE Virus IgM		TBM096 SK-TBM096
EIA TBEV Ig	00013944	Tick-borne encephalitis (TBE) virus total antibody IVD, kit, enzyme immunoassay (EIA)
EIA TBEV Ig		TBE096
EIA Thyroglobulin IgG	00041574	Thyroglobulin IVD, kit, enzyme immunoassay (EIA)
EIA Thyroglobulin IgG SmartEIA Thyroglobulin IgG		Tg0096 SK-Tg0096
EIA Thyroid Peroxidase IgG	00041566	Thyroid peroxidase antibody (anti-TPO/microsomal antibody) IVD, kit, enzyme immunoassay (EIA)
EIA Thyroid Peroxidase IgG SmartEIA Thyroid Peroxidase IgG		TPOx96 SK-TPOx96
EIA Toxocara IgA	00038420	Toxocara canis immunoglobulin G (IgG) antibody IVD, kit,

		enzyme immunoassay (EIA)
EIA Toxocara IgA SmartEIA Toxocara IgA		TcA096 SK-TcA096
EIA Toxocara IgG	00014293	Toxocara canis immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Toxocara IgG SmartEIA Toxocara IgG		TcG096 SK-TcG096
EIA Toxoplasma IgA	00005485	Toxoplasma gondii total antibody IVD, kit, enzyme immunoassay (EIA)
EIA Toxoplasma IgA SmartEIA Toxoplasma IgA		TgA096 SK-TgA096
EIA Toxoplasma IgE	00005477	Toxoplasma gondii total antibody IVD, kit, enzyme immunoassay (EIA)
EIA Toxoplasma IgE SmartEIA Toxoplasma IgE		TgE096 SK-TgE096
EIA Toxoplasma IgG	00005469	Toxoplasma gondii total antibody IVD, kit, enzyme immunoassay (EIA)
EIA Toxoplasma IgG SmartEIA Toxoplasma IgG		TgG096 SK-TgG096
EIA Toxoplasma IgM	00005450	Toxoplasma gondii total antibody IVD, kit, enzyme immunoassay (EIA)
EIA Toxoplasma IgM SmartEIA Toxoplasma IgM		TgM096 SK-TgM096
EIA Transglutaminase IgA	00006066	Tissue transglutaminase antibody IVD, kit, enzyme immunoassay (EIA)
EIA Transglutaminase IgA SmartEIA Transglutaminase IgA		tTA096 SK-tTA096
EIA Transglutaminase IgG	00006074	Tissue transglutaminase antibody IVD, kit, enzyme immunoassay (EIA)
EIA Transglutaminase IgG SmartEIA Transglutaminase IgG		tTG096 SK-tTG096
EIA Treponema pallidum IgG	00014314	Treponema pallidum immunoglobulin G (IgG) antibody IVD, kit, enzyme

		immunoassay (EIA)
EIA Treponema pallidum IgG SmartEIA Treponema pallidum IgG		TpG096 SK-TpG096
EIA Treponema pallidum IgM	00014322	Treponema pallidum immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Treponema pallidum IgM SmartEIA Treponema pallidum IgM		TpM096 SK-TpM096
EIA Treponema pallidum TOTAL	00014306	Treponema pallidum total antibody IVD, kit, enzyme immunoassay (EIA)
EIA Treponema pallidum TOTAL		Tp0096
EIA U1RNP	00040416	U1-RNP antibody IVD, kit, enzyme immunoassay (EIA)
EIA U1RNP SmartEIA U1RNP		RNP096 SK-RNP096
EIA VZV IgA	00044548	Varicella-zoster virus (VZV) immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
EIA VZV IgA SmartEIA VZV IgA		VZVA96 SK-VZVA96
EIA VZV IgG	00044521	Varicella-zoster virus (VZV) immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
EIA VZV IgG SmartEIA VZV IgG		VZVG96 SK-VZVG96
EIA VZV IgM	00044513	Varicella-zoster virus (VZV) immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
EIA VZV IgM SmartEIA VZV IgM		VZVM96 SK-VZVM96
EIA Yersinia enterocolitica IgA	00837265	Yersinia enterocolitica immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
SmartEIA Yersinia enterocolitica IgA EIA Yersinia enterocolitica IgA		SK-YA0096 YA0096

EIA Yersinia enterocolitica IgG	00837273	Yersinia enterocolitica immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Yersinia enterocolitica IgG SmartEIA Yersinia enterocolitica IgG		YG0096 SK-YG0096
EIA Yersinia enterocolitica IgM	00837281	Yersinia enterocolitica immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
EIA Yersinia enterocolitica IgM SmartEIA Yersinia enterocolitica IgM		YM0096 SK-YM0096
GIEMSA - ready	00016926	Stain, light microscopy, microbiology
GIEMSA - ready		Gir0L1
GIEMSA - sada roztoků	00016918	Stain, light microscopy, microbiology
GIEMSA - 10x. conc. solution Dilution buffer for GIEMSA		Gi00L1 rp0090
Gram - complete set of solutions	00016934	Stain, light microscopy, microbiology
Gram - complete set of solutions		Gs0000
HIPPUstrip	00015413	Beta-haemolytic Group B Streptococcus antigen IVD, kit, immunochromatographic test (ICT), rapid
HIPPUstrip		Hs0050
IIF AMA, ASMA IgG (Rat L/K/S)	00288155	Liver-kidney microsome 1 antibody (anti-LKM1) IVD, kit, fluorescent immunoassay
IIF AMA, ASMA IgG (Rat L/K/S)		AMAF100
IIF ANA IgG (HEp-2)	00445923	Multiple antinuclear antibody (ANA) screening IVD, kit, fluorescent immunoassay
IIF ANA IgG (HEp-2)		ANAF120
IIF dsDNA IgG (Crithidia luciliae)	00263118	Double stranded DNA antibody (anti-dsDNA) IVD, kit, fluorescent immunoassay
IIF dsDNA IgG (Crithidia luciliae)		DNAF100

Immunoblot Software	00001345	Laboratory analyser operation system software IVD
		SwIm03
INDOXYLstrip	00015405	Alpha-naphthyl acetate esterase (ANAE) IVD, reagent
INDOXYLstrip		Is0100
LEPTOSPIRA - MEDIUM	00015376	Multiple Leptospira species total antibody IVD, reagent
LEPTOSPIRA - MEDIUM LEPTOSPIRA - MEDIUM BULK		LM0020 LMb100
LEPTOSPIRA - MEDIUM MEDIKOVANÉ	00015368	Multiple Leptospira species total antibody IVD, reagent
LEPTOSPIRA - MEDIUM MEDIKOVANÉ		LMm020
Microblot-Array ANA	00844545	Multiple antinuclear antibody (ANA) screening IVD, kit, multiplex
ANAMA96		ANAMA96
Microblot-Array ANA 44	00769645	Multiple antinuclear antibody (ANA) screening IVD, kit, multiplex
Microblot-Array ANA 44		ANA44MA96
Microblot-Array ANA 45	00769637	Multiple antinuclear antibody (ANA) screening IVD, kit, multiplex
Microblot-Array ANA 45		ANA45MA96
Microblot-Array ANA plus	00869291	Multiple antinuclear antibody (ANA) screening IVD, kit, multiplex
Microblot-Array ANA plus		ANApMA96
Microblot-Array Borrelia afzelii IgG	00502596	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia afzelii IgG		BaGMA96
Microblot-Array Borrelia afzelii IgM	00502609	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia afzelii IgM		BaMMA96
Microblot-Array Borrelia b. sensu stricto IgG	00502633	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia b. sensu stricto IgG		BsGMA96

Microblot-Array Borrelia b. sensu stricto IgM	00502641	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia b. sensu stricto IgM		BsMMA96
Microblot-Array Borrelia garinii IgG	00502617	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia garinii IgG		BgGMA96
Microblot-Array Borrelia garinii IgM	00502625	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia garinii IgM		BgMMA96
Microblot-Array Borrelia IgG	00249930	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia IgG		BGMA096
Microblot-Array Borrelia IgM	00249949	Borrelia burgdorferi total antibody IVD, kit, immunoblot
Microblot-Array Borrelia IgM		BMMA096
Microblot-Array COVID-19 IgA	00905934	SARS-CoV-2 total antibody IVD, reagent
Microblot-Array COVID-19 IgA		CoVAMA96
Microblot-Array COVID-19 IgG	00905942	SARS-CoV-2 total antibody IVD, reagent
Microblot-Array COVID-19 IgG		CoVGMA96
Microblot-Array COVID-19 IgM	00905950	SARS-CoV-2 total antibody IVD, reagent
Microblot-Array COVID-19 IgM		CoVMA96
Microblot-Array EBV IgA	00900850	Epstein-Barr virus (EBV) antigen IVD, antibody
Microblot-Array EBV IgA		EBAMA96
Microblot-Array EBV IgG	00900869	Epstein-Barr virus (EBV) antigen IVD, antibody
Microblot-Array EBV IgG		EBGMA96
Microblot-Array EBV IgM	00900877	Epstein-Barr virus (EBV) antigen IVD, antibody
Microblot-Array EBV IgM		EBMA96
Microblot-Array Chlamydia IgA	00533368	Multiple Chlamydia species immunoglobulin A (IgA) antibody IVD, reagent
Microblot-Array Chlamydia IgA		CAMA096

Microblot-Array Chlamydia IgG	00533376	Multiple Chlamydia species immunoglobulin G (IgG) antibody IVD, reagent
Microblot-Array Chlamydia IgG		CGMA096
OXIstrip	00015341	Multiple Haemophilus/Neisseria bacteria species culture isolate identification IVD, kit
OXIstrip		Os0100
PYRstrip	00015333	Enterococcus species salt-tolerance broth differential medium IVD
PYRstrip		Ps0050
RF - sorb	00017005	Multiple rheumatoid arthritis-associated antibody IVD, control
RF -sorb 2 ml RF -sorb 10 ml		RFs002 RFs010
RID CIC Profiling kit (5x32)	00041072	Circulating immune complex (CIC) IVD, reagent
RID CIC Profiling kit (5x32)		RIDCIP
RID CIC Screening kit (2x80)	00041080	Circulating immune complex (CIC) IVD, reagent
RID CIC Screening kit (2x80)		RIDCIS
β - LACTAset	00015392	Beta-lactamase production microbial reagent IVD
β - LACTAset		BL0192
β - LACTAstrip	00015384	Beta-lactamase production microbial reagent IVD
β - LACTAstrip		BLs100
TA Immunocomplex	00016897	Circulating immune complex (CIC) IVD, reagent
TA Immunocomplex TA bulk Immunocomplex		CIK240 CIKb00
TBEV – CF – Ag lyophil.	00022242	Tick-borne encephalitis (TBE) virus total antibody IVD, kit, complement fixation test (CFT)
TBEV – CF – Ag lyophil.		TBEKF1

TOXO – CF – Ag lyophil.	00022226	Toxoplasma gondii total antibody IVD, kit, complement fixation test (CFT)
TOXO – CF – Ag lyophil. (0,2 ml) TOXO – CF – Ag lyophil. (0,5 ml) TOXO – CF – Ag lyophil. (1 ml)		TgKF02 TgKF05 Tg-KF1
Toxo – CF – Negative Control lyophil.	00022218	Toxoplasma gondii total antibody IVD, kit, complement fixation test (CFT)
Toxo – CF – Negative Control lyophil.		TgKFN2
Toxo – CF – Positive Control lyophil.	00022197	Toxoplasma gondii total antibody IVD, kit, complement fixation test (CFT)
Toxo – CF – Positive Control lyophil.		TgKFP2
TRIBUstrip	00015325	Multiple Haemophilus/Neisseria bacteria species culture isolate identification IVD, kit
TRIBUstrip		Ts0300
UREASAtest	00015317	Helicobacter pylori urease IVD, kit, chromogenic
UREASAtest 50 UREASAtest bulk		Ut0050 Utb100

Tento certifikát se vydává v elektronické podobě / *This Certificate is issued in electronic form.*

Ing. Petr Vykypěl
vedoucí Oddělení registrací a notifikací
Odbor zdravotnických prostředků
Státního ústavu pro kontrolu léčiv
Head of Registration and Notification Department
Medical Device Section
of State Institute for Drug Control