

ADDENDUM TO EU DECLARATION OF CONFORMITY

VERSION (2022-05-25)

We, IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg, Germany, declare under our sole responsibility that the products listed in the annex to this Addendum meet the essential requirements of the directive 98/79/EG of 27 October 1998 on in vitro diagnostic medical devices.

The reason for this addendum is:

- Extension of validity of the Declaration of Conformity Version (2022-05-25), as the expiration date applied is the date of the ISO 13485 certificate, which was renewed to 2026-07-01
- Reduction of products listed in the Annex of the DoC, due to switch to IVDR or product discontinuation

As per IVDR transitional provisions in article 110, the current Declaration of Conformity (DoC) may not be changed after the implementation date of 26th May 2022, therefore this addendum has been created to update information in the DoC without the need to revise the valid IVD CE declaration under IVDD.

IBL International GmbH established an assessment according to the MDCG 2022-6:


"Assessment for amendment of Tecan-IBL Declaration of Conformity (DoC) under IVDD after 2022-05-26"

This document concluded that the deletion of products from the DoC and extension of the DoC's validity are not considered significant changes in intended purpose or design and the DoC can be amended without losing its validity. Updated information in this addendum is acceptable.

With this addendum, the declaration of conformity version 2022-05-25 is valid until 2026-07-01, unless it will be replaced or annulated; and the valid list of products are in the Annex to this Addendum.

This addendum is authorized by representatives of IBL International GmbH.

Hamburg,

DocuSigned by:
Dr. Dagmar Kasper
 Signer Name: Dr. Dagmar Kasper
Signing Reason: I approve this document
Signing Time: 2024-04-15 | 1:32:25 PM CEST
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Managing Director
Dr. Dagmar Kasper

DocuSigned by:
Nicola Kaiser
 Signer Name: Nicola Kaiser
Signing Reason: I approve this document
Signing Time: 2024-04-15 | 1:28:35 PM CEST
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RA Manager
Nicola Kaiser

Annex to Addendum

Cat.- No.	Product name	Determinations	EDMA CODE
30121976	Receptor Acetylcholine Autoantibodies (RACAb) RIA	30	12.10.90.23
30143814	TriCat TM Urine ELISA	3x96	12.06.30.01
30146128	CatCombi Urine ELISA	2x96	12.06.30.01
30146129	Adrenaline Urine ELISA	96	12.06.90.13
30146130	Noradrenaline Urine ELISA	96	12.06.90.14
30146131	Dopamine Urine ELISA	96	12.06.90.15
30164033	HMGB1 express ELISA	96	13.06.01.90
30166211	sInterleukin-2-Receptor ELISA	96	13.06.01.12
30191875	Steroid Panel LC-MS	96	12.06.90.90
30112111	PR3 IgG (c-ANCA) capture ELISA	96	12.10.90.10
30121046	Estriol high sensitive Saliva ELISA	96	12.05.02.02
30121968	Receptor Acetylcholine Autoantibodies (RACAb) RIA	100	12.10.90.23
30123153	Reverse T3 (rT3) ELISA	96	12.04.01.04
30126762	Adiponectin ELISA	96	12.06.90.90
30132293	Transglutaminase IgG ELISA	12x8	12.10.90.21
30132295	Transglutaminase IgA ELISA	12x8	12.10.90.21
30150318	Anti-Müllerian Hormone (AMH) ELISA	96	12.05.01.90
AX53101	Active-B12 (Holotranscobalamin) ELISA	96	12.07.02.04
DB52011	Angiotensin I (PRA) ELISA	12x8	12.06.02.02
DB52021	5alpha-Dihydrotestosterone ELISA	12x8	12.05.01.10
DB52031	Pregnenolone ELISA	12x8	12.05.02.90
DB52051	Estrone ELISA	12x8	12.05.02.04
DB52161	Androstenedione ELISA	12x8	12.05.01.01
DB52171	Androstane-diol-Glucuronide ELISA	12x8	12.05.01.12
DB52181	Free Testosterone ELISA	12x8	12.05.01.10
DM52181	Free Testosterone II. Gen. ELISA	12x8	12.05.01.10
DM59171	IgA Saliva ELISA	12x8	12.01.01.01
DM59211	CIC-C1q ELISA	12x8	12.11.01.08
DM59221	CIC-C3d ELISA	12x8	12.11.01.08
EU59131	CRP ELISA	12x8	12.11.01.09
EU59151	CRP high sensitive ELISA	12x8	12.11.01.09
MD53001	Leptin ELISA	12x8	12.06.90.17
MD53011	Leptin sensitive ELISA	12x8	12.06.90.17
MD58011	IGF-1 ELISA	12x8	12.06.04.03
MD58031	IGFBP-3 ELISA	12x8	12.06.04.06
MG11091	Androstenedione RIA (CT)	96	12.05.01.01
MG11101	Renin (active) IRMA (CT)	96	12.06.02.05
MG11111	11-Desoxycortisol RIA (CT)	96	12.05.01.14
MG12061	Cortisol RIA (CT)	96	12.06.02.04
MG12101	17beta-Estradiol RIA (CT)	96	12.05.01.03
MG12171	Progesterone RIA (CT)	96	12.05.01.06
MG12181	17-OH-Progesterone RIA (CT)	96	12.05.01.07
MG12191	Testosterone RIA (CT)	96	12.05.01.10
MG13051	Aldosterone RIA (CT)	96	12.06.02.01
NM56011	Erythropoietin ELISA	96	12.07.01.01
NM59011	Calcitonin ELISA	96	12.06.03.02
NM59041	Parathyroid hormone intact ELISA	96	12.06.03.13
RE11021	cAMP RIA	100	12.06.03.07
RE21031	ARAb Blocking RIA	100	12.10.90.23
RE21033	ARAb Blocking RIA	30	12.10.90.23

Cat.- No.	Product name	Determinations	EDMA CODE
RE29301	Melatonin direct Serum/Plasma/Saliva RIA	100	12.06.90.06
RE51021	MuSK-Ab ELISA	96	12.10.90.90
RE52001	anti-Sperm Ab ELISA	12x8	12.10.90.13
RE52029	Spermatozoa-Ab ELISA	12x8	12.10.90.13
RE52041	17beta-Estradiol ELISA	12x8	12.05.01.03
RE52071	17-OH-Progesterone ELISA	12x8	12.05.01.07
RE52111	LH Urine ELISA	12x8	12.05.01.05
RE52121	FSH ELISA	12x8	12.05.01.04
RE52151	Testosterone ELISA	12x8	12.05.01.10
RE52181	DHEA-S ELISA	12x8	12.05.01.02
RE52211	Corticosterone ELISA	12x8	12.05.01.15
RE52221	DHEA ELISA	12x8	12.05.01.02
RE52231	Progesterone ELISA	12x8	12.05.01.06
RE52241	Cortisol Urine ELISA	12x8	12.06.02.04
RE52271	17-OH- Progesterone Saliva ELISA	12x8	12.05.01.07
RE52281	Progesterone Saliva ELISA	12x8	12.05.01.06
RE52301	Aldosterone ELISA	96	12.06.02.01
RE52361	PLGF ELISA	96	12.05.02.90
RE52611	Cortisol Saliva ELISA	12x8	12.06.02.04
RE52661	DHEA-S Saliva ELISA	12x8	12.05.01.02
RE52681	Estrone Saliva ELISA	12x8	12.05.02.04
RE53011	C-Peptide ELISA	12x8	12.06.01.01
RE53031	Proinsulin ELISA	12x8	12.06.01.08
RE53071	Chromogranin A ELISA	96	12.03.01.90
RE53081	ACTH ELISA	96	12.06.04.01
RE53141	Osteocalcin (1-43/49) specific ELISA	12x8	12.06.03.12
RE53151	Leptin ELISA	12x8	12.06.90.17
RE53171	Insulin ELISA	12x8	12.06.01.03
RE53321	Renin (active) ELISA	96	12.06.02.05
RE53971	Chromogranin A ELISA	12x8	12.03.01.90
RE54021	Melatonin ELISA	12x8	12.06.90.06
RE54031	Melatonin-Sulfate Urine ELISA	12x8	12.06.90.06
RE54041	Melatonin direct Saliva ELISA	12x8	12.06.90.06
RE54101	CYFRA 21-1 ELISA	12x8	12.03.01.20
RE54111	CA72-4 ELISA	12x8	12.03.01.05
RE55231	FT3 ELISA	12x8	12.04.01.05
RE55241	FT4 ELISA	12x8	12.04.01.07
RE56351	Haemophilus influenzae B IgG ELISA	12x8	15.01.90.90
RE56371	Helicobacter pylori IgA ELISA	12x8	15.01.04.03
RE56381	Helicobacter pylori IgG ELISA	12x8	15.01.04.03
RE56391	Helicobacter pylori IgM ELISA	12x8	15.01.04.03
RE57201	Borrelia + VlsE IgG ELISA	12x8	15.01.06.05
RE57211	Borrelia 14kDa + OspC IgM ELISA	12x8	15.01.06.06
RE57401	TBE virus (FSME) IgG ELISA	12x8	15.04.80.12
RE57451	Hantavirus Hantaan IgG/IgM ELISA	12x8	15.04.80.90
RE57461	Hantavirus Puumala IgG/IgM ELISA	12x8	15.04.80.90
RE58691	Chagas (Trypanosoma cruzi) IgG ELISA	12x8	15.05.10.02
RE58891	Fecal Helicobacter pylori-Antigen ELISA	96	15.01.04.01
RE59121	Serotonin ELISA	12x8	12.03.90.17
RE59131	5-HIAA ELISA	12x8	12.03.90.05
RE59161	Dopamine ELISA	12x8	12.06.90.15
RE59171	Normetanephrine ELISA	12x8	12.03.90.90

Cat.- No.	Product name	Determinations	EDMA CODE
RE59181	Metanephrine ELISA	12x8	12.03.90.90
RE59202	MetCombi Plasma ELISA	2x96	12.06.30.90
RE59221	Histamine ELISA	12x8	12.02.01.90
RE59242	CatCombi ELISA	2x96	12.06.30.01
RE59251	Adrenalin ELISA	12x8	12.06.90.13
RE59261	Noradrenalin ELISA	12x8	12.06.90.14
RE59321	Neopterin ELISA	12x8	12.06.90.07
RE59355D	Neopterin ELISA	480	12.06.90.07
RE59395	TriCat TM ELISA	3x96	12.06.30.01
RE59651	Amyloid-beta (1-40) CSF ELISA	96	12.12.90.90
RE59661	Amyloid-beta (1-42) CSF ELISA	96	12.12.90.90
RE62021	Progesterone Luminescence Immunoassay	12x8	12.05.01.06
RE62029	Progesterone Luminescence Immunoassay	960	12.05.01.06
RE62031	Testosterone Luminescence Immunoassay	12x8	12.05.01.10
RE62039.	Testosterone Luminescence Immunoassay	960	12.05.01.10
RE62051	DHEA Luminescence Immunoassay	12x8	12.05.01.02
RE62059	DHEA Luminescence Immunoassay	960	12.05.01.02
RE62111	Cortisol Saliva Luminescence Immunoassay	96	12.06.02.04
RE62119	Cortisol Saliva Luminescence Immunoassay	960	12.06.02.04
RE62141	17beta-Estradiol Saliva Luminescence Immunoassay	12x8	12.05.01.03
RE62149	17beta-Estradiol Saliva Luminescence Immunoassay	960	12.05.01.03
RE68015	IRT Neonatal Luminescence Immunoassay	480	12.01.90.08
RE68019	IRT Neonatal Luminescence Immunoassay	2400	12.01.90.08
RE70151	ANA Hep-2 Screen ELISA	96	12.10.01.90
RE70341	Rheumatoid Factor IgA/IgG/IgM ELISA	96	12.11.01.10
RE70411	Phospholipid IgG/IgM Screen ELISA	96	12.10.90.03
RE70461	Cholin IgG/IgM ELISA	96	13.02.06.01
RE70521	Cardiolipin-Ab IgG/IgM ELISA	96	12.10.90.01
RE70791	SLA-Ab ELISA	96	12.10.90.17
RE70821	Transglutaminase IgA ELISA	96	12.10.90.21
RE70831	Transglutaminase IgG ELISA	96	12.10.90.21
RE70881	Intrinsic Factor-Ab ELISA	96	12.07.02.10
RE70891	Parietalcell-Ab ELISA	96	12.10.90.11
RE70911	LKM-1-Ab ELISA	96	12.10.90.08
RE70931	Mitochondrial (AMA)-M2-Ab ELISA	96	12.10.90.02
RE75011	Cardiolipin IgG ELISA	96	12.10.90.01
RE75021	Cardiolipin IgM ELISA	96	12.10.90.01
RE75041	beta 2-Glycoprotein 1 IgA ELISA	96	12.10.90.04
RE75051	beta 2-Glycoprotein 1 IgG ELISA	96	12.10.90.04
RE75061	beta 2-Glycoprotein 1 IgM ELISA	96	12.10.90.04
RE75201	dsDNA-Ab ELISA	96	12.10.01.05
RE75211	U1-RNP-Ab ELISA	96	12.10.01.14
RE75221	Sm-Ab ELISA	96	12.10.01.11
RE75231	SS-A/Ro-Ab ELISA	96	12.10.01.12
RE75241	SS-B/La-Ab ELISA	96	12.10.01.12
RE75251	Scl-70-Ab ELISA	96	12.10.01.10
RE75271	Jo-1-Ab ELISA	96	12.10.01.08
RE75401	ANA Profile 8 ELISA	96	12.10.01.90
RE75411	ENA Screen 6 ELISA	96	12.10.01.02
RE75421	ANA Screen 8 ELISA	96	12.10.01.01
RE75501	Thyroglobulin -Ab ELISA	96	12.10.03.04
RE75511	Thyroid Peroxidase-Ab ELISA	96	12.10.03.01
RE75601	Myeloperoxidase-Ab ELISA	96	12.10.90.09

Cat.- No.	Product name	Determinations	EDMA CODE
RE75741	Modified Gliadin Peptide IgA ELISA	96	12.10.90.06
RE75751	Modified Gliadin Peptide IgG ELISA	96	12.10.90.06
RE80015	Phenylalanine (PKU) neonatal Screening Assay	480	11.02.01.36
RE80019	Phenylalanine (PKU) neonatal Screening Assay	2400	11.02.01.36
RE80111	alpha-Amylase Saliva Assay	12x8	11.01.01.90

EU Declaration of Conformity

EU Konformitätserklärung

UE Déclaration de conformité

Dichiarazione di conformità UE

This declaration of conformity is issued under the sole responsibility of the manufacturer:
Diese Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt:
Cette déclaration de conformité est établie sous la seule responsabilité du fabricant:
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante :

IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

The products listed in the annex to this document meet the essential requirements of the directive 98/79/EG of 27. October 1998 on in vitro diagnostic medical devices.

Die Produkte, die im Anhang zu diesem Dokument aufgelistet sind, entsprechen den grundlegenden Anforderungen der Richtlinie 98/79/EG vom 27. Oktober 1998 über In-vitro-Diagnostika.

Les produits listés dans l'annexe de ce document sont conformes aux exigences fondamentales de la Directive 98/79/CE des réactifs de Diagnostic In Vitro.

I prodotti elencati negli allegati di questo documento, rispettano I requisiti essenziali della direttiva 98/79/EG del 27 Ottobre 1998 dei reagenti per Diagnostica in Vitro.

Tecan IBL International GmbH maintains a quality system certified to the following standards:

Tecan IBL International GmbH unterhält ein nach folgenden Standards zertifiziertes Qualitätssystem:

Tecan IBL International GmbH maintient un système de qualité certifié selon les normes suivantes:

Tecan IBL International GmbH mantiene un sistema di qualità certificato secondo i seguenti standard:

EN ISO 9001: 2015

Quality management systems – Requirements

EN ISO 13485: 2016

Medical devices – quality Management Systems – Requirements for regulatory purposes

This declaration is valid until 2023-07-01, unless it will be replaced or annulated.

Diese Erklärung ist gültig bis zum 2023-07-01, wenn nicht widerrufen oder ersetzt.

Cette déclaration est valide jusqu'au 2023-07-01, sauf remplacement ou révocation.

Questa dichiarazione è valida sino al 2023-07-01, se non modificata o annullata.

Hamburg, 2022-05-25

DocuSigned by:
Dr. Dagmar Kasper
Signer Name: Dr. Dagmar Kasper
Signing Reason: I approve this document
Signing Time: 2022-05-25 | 3:29:57 PM CEST
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Managing Director
Dr. Dagmar Kasper

DocuSigned by:
Nicola Kaiser
Signer Name: Nicola Kaiser
Signing Reason: I approve this document
Signing Time: 2022-05-25 | 2:55:51 PM CEST
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RA Manager
Nicola Kaiser

Annex / Anhang / Annexe / Annex

Cat.- No.	Product name	Determinations	EDMA CODE
30121976	Receptor Acetylcholine Autoantibodies (RACAb) RIA	30	12.10.90.23
30143814	TriCat TM Urine ELISA	3x96	12.06.30.01
30146128	CatCombi Urine ELISA	2x96	12.06.30.01
30146129	Adrenaline Urine ELISA	96	12.06.90.13
30146130	Noradrenaline Urine ELISA	96	12.06.90.14
30146131	Dopamine Urine ELISA	96	12.06.90.15
30164033	HMGB1 express ELISA	96	13.06.01.90
30166211	sInterleukin-2-Receptor ELISA	96	13.06.01.12
30181829	SARS-CoV-2 S1/RBD IgG Ab ELISA	96	15.04.80.90
30191875	Steroid Panel LC-MS	96	12.06.90.90
30112111	PR3 IgG (c-ANCA) capture ELISA	96	12.10.90.10
30113465	Adenovirus IgA ELISA	12x8	15.04.80.01
30113466	Adenovirus IgG ELISA	12x8	15.04.80.01
30113467	Adenovirus IgM ELISA	12x8	15.04.80.01
30113468	Aspergillus fumigatus IgG ELISA	12x8	15.06.01.01
30113471	Aspergillus fumigatus IgM ELISA	12x8	15.06.01.01
30113477	Borrelia burgdorferi IgG ELISA	12x8	15.01.06.05
30113479	Brucella IgG ELISA	12x8	15.01.90.01
30113480	Brucella IgM ELISA	12x8	15.01.90.01
30113617	Candida albicans IgA ELISA	12x8	15.06.01.02
30113618	Candida albicans IgG ELISA	12x8	15.06.01.02
30113619	Candida albicans IgM ELISA	12x8	15.06.01.02
30113623	Echinococcus IgG ELISA	12x8	15.05.10.04
30114049	Influenza A IgA ELISA	12x8	15.04.80.04
30114050	Influenza A IgG ELISA	12x8	15.04.80.04
30114051	Influenza A IgM ELISA	12x8	15.04.80.04
30114052	Influenza B IgA ELISA	12x8	15.04.80.04
30114053	Influenza B IgG ELISA	12x8	15.04.80.04
30114054	Influenza B IgM ELISA	12x8	15.04.80.04
30114056	Measles virus IgG ELISA	12x8	15.04.80.07
30114067	Parainfluenza 1/2/3 IgA ELISA	12x8	15.04.80.04
30114068	Parainfluenza 1/2/3 IgG ELISA	12x8	15.04.80.04
30114070	Respiratory syncytial virus IgG ELISA	12x8	15.04.80.05
30114071	Respiratory syncytial virus IgM ELISA	12x8	15.04.80.05
30121045	17beta-Estradiol Saliva ELISA	96	12.05.01.03
30121046	Estriol high sensitive Saliva ELISA	96	12.05.02.02
30121968	Receptor Acetylcholine Autoantibodies (RACAb) RIA	100	12.10.90.23
30123153	Reverse T3 (rT3) ELISA	96	12.04.01.04
30126469	Chromogranin A ELISA	96	12.03.01.90
30126762	Adiponectin ELISA	96	12.06.90.90
30132293	Transglutaminase IgG ELISA	12x8	12.10.90.21
30132295	Transglutaminase IgA ELISA	12x8	12.10.90.21
30150318	Anti-Müllerian Hormone (AMH) ELISA	96	12.05.01.90
AX53101	Active-B12 (Holotranscobalamin) ELISA	96	12.07.02.04
BE59311	PMN-Elastase ELISA	96	13.06.01.90
DB52011	Angiotensin I (PRA) ELISA	12x8	12.06.02.02
DB52021	5alpha- Dihydrotestosterone (DHT) ELISA	12x8	12.05.01.10
DB52031	Pregnenolone ELISA	12x8	12.05.02.90

Cat.- No.	Product name	Determinations	EDMA CODE
DB52051	Estrone ELISA	12x8	12.05.02.04
DB52161	Androstenedione ELISA	12x8	12.05.01.01
DB52171	Androstane-diol-Glucuronide ELISA	12x8	12.05.01.12
DB52181	Free Testosterone ELISA	12x8	12.05.01.10
DB62021	Estrone Saliva Luminescence Immunoassay	96	12.05.02.04
DM52181	Free Testosterone II. Gen. ELISA	12x8	12.05.01.10
DM59171	IgA Saliva ELISA	96	12.01.01.01
DM59211	CIC-C1q ELISA	96	12.11.01.08
DM59221	CIC-C3d ELISA	96	12.11.01.08
EU59131	CRP ELISA	12x8	12.11.01.09
EU59151	CRP high sensitive ELISA	12x8	12.11.01.09
MD53001	Leptin ELISA	12x8	12.06.90.17
MD53011	Leptin sensitive ELISA	12x8	12.06.90.17
MD58011	IGF-1 ELISA	12x8	12.06.04.03
MD58031	IGFBP-3 ELISA	12x8	12.06.04.06
MG11091	Androstenedione RIA (CT)	96	12.05.01.01
MG11101	Renin (active) IRMA (CT)	96	12.06.02.05
MG11111	11-Desoxycortisol RIA (CT)	96	12.05.01.14
MG12061	Cortisol RIA (CT)	96	12.06.02.04
MG12101	17beta-Estradiol RIA (CT)	96	12.05.01.03
MG12171	Progesterone RIA (CT)	96	12.05.01.06
MG12181	17-OH-Progesterone RIA (CT)	96	12.05.01.07
MG12191	Testosterone RIA (CT)	96	12.05.01.10
MG13051	Aldosterone RIA (CT)	96	12.06.02.01
NM56011	Erythropoietin ELISA	96	12.07.01.01
NM59011	Calcitonin ELISA	96	12.06.03.02
NM59041	Parathyroid hormone intact ELISA	96	12.06.03.13
RE11021	cAMP RIA	100	12.06.03.07
RE19011	dsDNA-Ab RIA	100	12.10.01.05
RE21021	Acetylcholine Receptor Autoantibodies (ARAb) RRA	100	12.10.90.23
RE21023	Acetylcholine Receptor Autoantibodies (ARAb) RRA	30	12.10.90.23
RE21031	ARAb Blocking RIA	100	12.10.90.23
RE21033	ARAb Blocking RIA	30	12.10.90.23
RE29071	cGMP RIA	100	12.06.90.19
RE29075	cGMP RIA	500	12.06.90.19
RE29111	MetCombi Plasma RIA	100	12.06.30.90
RE29191	MetCombi Urine RIA	2x50	12.06.30.90
RE29291	KatCombi RIA	2x50	12.06.30.01
RE29301	Melatonin direct Serum/Plasma/Saliva RIA	100	12.06.90.06
RE29315	Adrenalin RIA	50	12.06.90.13
RE29325	Noradrenalin RIA	50	12.06.90.14
RE29395	TriCat TM RIA	3x50	12.06.30.01
RE51021	MuSK-Ab ELISA	96	12.10.90.90
RE52001	anti-Sperm Ab ELISA	12x8	12.10.90.13
RE52029	Spermatozoa-Ab ELISA	12x8	12.10.90.13
RE52041	17beta-Estradiol ELISA	12x8	12.05.01.03
RE52061	Cortisol ELISA	12x8	12.06.02.04
RE52071	17-OH-Progesterone ELISA	12x8	12.05.01.07
RE52111	LH Urine ELISA	12x8	12.05.01.05
RE52121	FSH ELISA	12x8	12.05.01.04
RE52151	Testosterone ELISA	12x8	12.05.01.10
RE52181	DHEA-S ELISA	12x8	12.05.01.02

Cat.- No.	Product name	Determinations	EDMA CODE
RE52211	Corticosterone ELISA	12x8	12.05.01.15
RE52221	DHEA ELISA	12x8	12.05.01.02
RE52231	Progesterone ELISA	12x8	12.05.01.06
RE52241	Cortisol Urine ELISA	12x8	12.06.02.04
RE52271	17-OH- Progesterone Saliva ELISA	12x8	12.05.01.07
RE52281	Progesterone Saliva ELISA	12x8	12.05.01.06
RE52301	Aldosterone ELISA	96	12.06.02.01
RE52361	PLGF ELISA	96	12.05.02.90
RE52611	Cortisol Saliva ELISA	12x8	12.06.02.04
RE52631	Testosterone Saliva ELISA	12x8	12.05.01.10
RE52651	DHEA Saliva ELISA	12x8	12.05.01.02
RE52661	DHEA-S Saliva ELISA	96	12.05.01.02
RE52681	Estrone Saliva ELISA	12x8	12.05.02.04
RE53011	C-Peptide ELISA	12x8	12.06.01.01
RE53031	Proinsulin ELISA	12x8	12.06.01.08
RE53041	25-OH-Vitamin D ELISA	96	12.06.03.10
RE53071	Chromogranin A ELISA	96	12.03.01.90
RE53081	ACTH ELISA	96	12.06.04.01
RE53141	Osteocalcin (1-43/49) specific ELISA	12x8	12.06.03.12
RE53151	Leptin ELISA	12x8	12.06.90.17
RE53171	Insulin ELISA	12x8	12.06.01.03
RE53321	Renin (active) ELISA	96	12.06.02.05
RE53971	Chromogranin A ELISA	12x8	12.03.01.90
RE54021	Melatonin ELISA	12x8	12.06.90.06
RE54031	Melatonin-Sulfate Urine ELISA	12x8	12.06.90.06
RE54041	Melatonin direct Saliva ELISA	12x8	12.06.90.06
RE54101	CYFRA 21-1 ELISA	12x8	12.03.01.20
RE54111	CA72-4 ELISA	12x8	12.03.01.05
RE55231	FT3 ELISA	12x8	12.04.01.05
RE55241	FT4 ELISA	12x8	12.04.01.07
RE56221	Epstein-Barr virus EA IgG ELISA	12x8	15.04.04.04
RE56251	Epstein-Barr virus EBNA-1 IgG ELISA	12x8	15.04.04.04
RE56351	Haemophilus influenzae B IgG ELISA	12x8	15.01.90.90
RE56371	Helicobacter pylori IgA ELISA	12x8	15.01.04.03
RE56381	Helicobacter pylori IgG ELISA	12x8	15.01.04.03
RE56391	Helicobacter pylori IgM ELISA	12x8	15.01.04.03
RE56921	Poliovirus IgG ELISA	12x8	15.04.90.90
RE57141	Measles virus IgG ELISA	12x8	15.04.80.07
RE57151	Measles virus IgM micro- capture ELISA	12x8	15.04.80.07
RE57201	Borrelia + VlsE IgG ELISA	12x8	15.01.06.05
RE57211	Borrelia 14kDa + OspC IgM ELISA	12x8	15.01.06.06
RE57281	Parvovirus B19 IgG ELISA	12x8	15.04.80.09
RE57311	Epstein-Barr virus EA IgG ELISA	12x8	15.04.04.04
RE57351	Epstein-Barr virus VCA IgG ELISA	12x8	15.04.04.04
RE57361	Epstein-Barr virus IgM micro- capture ELISA	12x8	15.04.04.04
RE57401	TBE virus (FSME) IgG ELISA	12x8	15.04.80.12
RE57451	Hantavirus Hantaan IgG/IgM ELISA	12x8	15.04.80.90
RE57461	Hantavirus Puumala IgG/IgM ELISA	12x8	15.04.80.90
RE57901	Herpes simplex virus 1 IgG ELISA	12x8	15.04.03.08
RE57911	Herpes simplex virus 1 IgM ELISA	12x8	15.04.03.09
RE57921	Herpes simplex virus 2 IgG ELISA	12x8	15.04.03.11
RE57931	Herpes simplex virus 2 IgM ELISA	12x8	15.04.03.12

Cat.- No.	Product name	Determinations	EDMA CODE
RE57941	Herpes simplex virus 1/2 IgG ELISA	12x8	15.04.03.05
RE57951	Herpes simplex virus 1/2 IgM ELISA	12x8	15.04.03.06
RE58511	Legionella pneumophila IgM ELISA	12x8	15.01.05.03
RE58571	Dengue virus NS1 ELISA	12x8	15.04.80.11
RE58671	Dengue virus IgG ELISA	12x8	15.04.80.11
RE58681	Dengue virus IgM ELISA	12x8	15.04.80.11
RE58691	Chagas (Trypanosoma cruzi) IgG ELISA	12x8	15.05.10.02
RE58721	Toxocara canis IgG ELISA	12x8	15.05.10.90
RE58731	Taenia solium IgG ELISA	12x8	15.01.90.90
RE58741	Epstein-Barr virus (EBNA) IgG ELISA	12x8	15.04.04.04
RE58751	Epstein-Barr virus (VCA) IgG ELISA	12x8	15.04.04.04
RE58761	Epstein-Barr virus (VCA) IgM ELISA	12x8	15.04.04.04
RE58891	Fecal Helicobacter pylori-Antigen ELISA	96	15.01.04.01
RE58901	Malaria-Ab ELISA	8x12	14.05.02.02
RE59061	Total-IgE ELISA	12x8	12.02.01.02
RE59121	Serotonin ELISA	12x8	12.03.90.17
RE59131	5-HIAA ELISA	12x8	12.03.90.05
RE59161	Dopamine ELISA	12x8	12.06.90.15
RE59171	Normetanephrine ELISA	12x8	12.03.90.90
RE59181	Metanephrine ELISA	12x8	12.03.90.90
RE59202	MetCombi Plasma ELISA	2x96	12.06.30.90
RE59221	Histamine ELISA	12x8	12.02.01.90
RE59242	CatCombi ELISA	2x96	12.06.30.01
RE59251	Adrenalin ELISA	12x8	12.06.90.13
RE59261	Noradrenalin ELISA	12x8	12.06.90.14
RE59321	Neopterin ELISA	12x8	12.06.90.07
RE59355	Neopterin ELISA	480	12.06.90.07
RE59355D	Neopterin ELISA	480	12.06.90.07
RE59395	TriCat TM ELISA	3x96	12.06.30.01
RE59499-292220	FinTest TM IgG4 Screen 90 ELISA	1920	12.02.01.90
RE59651	Amyloid-beta (1-40) CSF ELISA	96	12.12.90.90
RE59661	Amyloid-beta (1-42) CSF ELISA	96	12.12.90.90
RE62011	Cortisol Luminescence Immunoassay	12x8	12.06.02.04
RE62019	Cortisol Luminescence Immunoassay	960	12.06.02.04
RE62021	Progesterone Luminescence Immunoassay	12x8	12.05.01.06
RE62029	Progesterone Luminescence Immunoassay	960	12.05.01.06
RE62031	Testosterone Luminescence Immunoassay	12x8	12.05.01.10
RE62039.	Testosterone Luminescence Immunoassay	960	12.05.01.10
RE62051	DHEA Luminescence Immunoassay	12x8	12.05.01.02
RE62059	DHEA Luminescence Immunoassay	960	12.05.01.02
RE62111	Cortisol Saliva Luminescence Immunoassay	96	12.06.02.04
RE62119	Cortisol Saliva Luminescence Immunoassay	960	12.06.02.04
RE62141	17beta-Estradiol Saliva Luminescence Immunoassay	12x8	12.05.01.03
RE62149	17beta-Estradiol Saliva Luminescence Immunoassay	960	12.05.01.03
RE68015	IRT Neonatal Luminescence Immunoassay	480	12.01.90.08
RE68019	IRT Neonatal Luminescence Immunoassay	2400	12.01.90.08
RE70151	ANA Hep-2 Screen ELISA	96	12.10.01.90
RE70341	Rheumatoid Factor IgA/IgG/IgM ELISA	96	12.11.01.10
RE70411	Phospholipid IgG/IgM Screen ELISA	96	12.10.90.03
RE70461	Cholin IgG/IgM ELISA	96	13.02.06.01

Cat.- No.	Product name	Determinations	EDMA CODE
RE70521	Cardiolipin-Ab IgG/IgM ELISA	96	12.10.90.01
RE70791	SLA-Ab ELISA	96	12.10.90.17
RE70821	Transglutaminase IgA ELISA	96	12.10.90.21
RE70831	Transglutaminase IgG ELISA	96	12.10.90.21
RE70881	Intrinsic Factor-Ab ELISA	96	12.07.02.10
RE70891	Parietalcell-Ab ELISA	96	12.10.90.11
RE70911	LKM-1-Ab ELISA	96	12.10.90.08
RE70931	Mitochondrial (AMA)-M2-Ab ELISA	96	12.10.90.02
RE75011	Cardiolipin IgG ELISA	96	12.10.90.01
RE75021	Cardiolipin IgM ELISA	96	12.10.90.01
RE75041	beta 2-Glycoprotein 1 IgA ELISA	96	12.10.90.04
RE75051	beta 2-Glycoprotein 1 IgG ELISA	96	12.10.90.04
RE75061	beta 2-Glycoprotein 1 IgM ELISA	96	12.10.90.04
RE75201	dsDNA-Ab ELISA	96	12.10.01.05
RE75211	U1-RNP-Ab ELISA	96	12.10.01.14
RE75221	Sm-Ab ELISA	96	12.10.01.11
RE75231	SS-A/Ro-Ab ELISA	96	12.10.01.12
RE75241	SS-B/La-Ab ELISA	96	12.10.01.12
RE75251	Scl-70-Ab ELISA	96	12.10.01.10
RE75271	Jo-1-Ab ELISA	96	12.10.01.08
RE75401	ANA Profile 8 ELISA	96	12.10.01.90
RE75411	ENA Screen 6 ELISA	96	12.10.01.02
RE75421	ANA Screen 8 ELISA	96	12.10.01.01
RE75501	Thyroglobulin -Ab ELISA	96	12.10.03.04
RE75511	Thyroid Peroxidase-Ab ELISA	96	12.10.03.01
RE75601	Myeloperoxidase-Ab ELISA	96	12.10.90.09
RE75611	Proteinase3-Ab ELISA	96	12.10.90.10
RE75621	GBM-Ab ELISA	96	12.10.90.15
RE75741	Modified Gliadin Peptide IgA ELISA	96	12.10.90.06
RE75751	Modified Gliadin Peptide IgG ELISA	96	12.10.90.06
RE75791	CCP-Ab ELISA	96	12.11.01.10
RE80015	Phenylalanine (PKU) neonatal Screening Assay	480	11.02.01.36
RE80019	Phenylalanine (PKU) neonatal Screening Assay	2400	11.02.01.36
RE80111	alpha-Amylase Saliva Assay	12x8	11.01.01.90


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Payment Events	Status	Timestamps
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