



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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T.a.v. mevrouw O. Teirlinck
Esdoornlaan 13
3951 DB Maarn

Farmatec

Bezoekadres:
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<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:

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Datum: 4 augustus 2020
Betreft: Mutatieverzoek

Ons kenmerk:

CIBG-20203810

Bijlagen

Uw aanvraag

3 augustus 2020

*Correspondentie uitsluitend
richten aan het retouradres met
vermelding van de datum en het
kenmerk van deze brief.*

Geachte mevrouw Teirlinck,

Op 3 augustus 2020 ontving ik uw mutatieverzoek. Dit is in het systeem Notis
verwerkt.

Onderstaande producten zijn gewijzigd:

CLIA Test Kits

Diagnostic Automation / Cortez Diagnostics (NL-CA002-26776)

ELISA Test Kits

Diagnostic Automation / Cortez Diagnostics (NL-CA002-26777)

IFA Test Kits

Diagnostic Automation / Cortez Diagnostics (NL-CA002-26778)

Rapid Test

**Diagnostic Automation / Cortez Diagnostics (NL-
CA002-26779) Serology Test Kits**

Diagnostic Automation / Cortez Diagnostics (NL-CA002-26780)

Vertrouwende u hiermee voldoende te hebben geïnformeerd.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde



Appendix

List of devices.

Elisa				
ELISA Device Group	Document / page Catalogue	Risk Classification	GMDN code	First CE-marking
Allergy				
Total Human IgE	1801-18, 1801-16	Low Risk	30275	2003-11-12
Human Specific IgG	5154-8	Low Risk	44211	2018-06-11
Human Specific IgG4	5155-8	Low Risk	44211	2018-06-11
Human Specific IgE (20 Seasonal Allergens)	5150-8	Low Risk	44211	2018-06-11
Human Specific IgE (20 Atopic Allergens)	5151-8	Low Risk	44211	2018-06-11
Human Specific IgE (20 Food Allergens)	5152-8	Low Risk	44211	2018-06-11
Human Specific IgE (20 Perennial Allergens)	5153-8	Low Risk	44211	2018-06-11
Anemia				
Vitamin B12	3125-15	Low Risk	30384	2011-09-26
Folate	3127-15	Low Risk	30378	2010-06-29
sTfR-Transferrin Soluble Receptor	3126-15	Low Risk	30253	2010-06-29
Ferritin	1606-18, 1601-16	Low Risk	30377	2003-11-12
Autoimmune Disease				
Anti CCP	3175-17	Low Risk	44202	2012-05-23
Anti-Phospholipid	2560-6, 2560-17	Low Risk	30582	2018-06-11
Beta 2 Glycoprotein 1 IgA	1494-11	Low Risk	30478	2016-09-15
Beta 2 Glycoprotein 1 IgG	1495-11	Low Risk	30478	2016-09-15
Beta 2 Glycoprotein 1 IgM	1496-11	Low Risk	30478	2016-09-15



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I M M U N O D I A G N O S T I C S

Transglutaminase IgG	3174-17	Low Risk	44385	2012-05-23
Transglutaminase IgA	3173-17	Low Risk	44385	2012-05-23
ANA Screen	5102-2	Low Risk	30454	2003-11-12
ENA Profile	2506-2	Low Risk	30455	2003-11-12
ENA Combined Screen	2552-2	Low Risk	30455	2003-11-12
Sm/RNP	2558-2	Low Risk	30464	2003-11-12
Sm	2570-2	Low Risk	17276	2003-11-12
RNP	2510-1	Low Risk	40218	2018-06-11
Jo-1	2557-2	Low Risk	30461	2003-11-12
Scl-70	2559-2	Low Risk	30463	2003-11-12
SS-A (Ro)	2555-2	Low Risk	44202	2003-11-12
SS-B (La)	2556-2	Low Risk	44202	2003-11-12
dsDNA	2553-1	Low Risk	30458	2003-11-12
Cardiolipin IgG	1491-2, 1491-11	Low Risk	30475	2003-11-12
Cardiolipin IgM	1492-2, 1492-11	Low Risk	30475	2003-11-12
Cardiolipin IgA	1493-2, 1493-11	Low Risk	30475	2003-11-12
Cardiolipin IgG, A, M	1490-1	Low Risk	30475	2003-11-12
Histone	2571-1	Low Risk	44202	2003-11-12
Rheumatoid Factor (RF) IgM	2550-1	Low Risk	30500	2003-11-12
Mitochondria	1420-1	Low Risk	30476	2003-11-12
Thyroglobulin	1421-1	Low Risk	30315	2003-11-12
PR3 (c-ANCA)	1445-1, 1445-2	Low Risk	30484	2003-11-12
ANCA screen IgG	1681-2	Low Risk	30483	2003-11-12
MPO ,Myeloperoxidase (p-ANCA)	1441-2	Low Risk	30483	2003-11-12
Gliadin IgG	1021-2	Low Risk	30480	2003-11-12
Gliadin IgA	1022-2	Low Risk	30480	2003-11-12

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Email: onestep@rapidtest.com – Website: www.rapidtest.com

TPO	1446-2	Low Risk	30317	2008-06-01
Cancer (Tumor markers)				
Prostatic Acid Phosphatase (PAP)	4227-11	Low Risk	34226	2003-11-12
b2-Microglobulin	4200-18, 4200-16	Low Risk	30296	2003-11-12
AFP (Alpha Fetoprotein)	5101-16	Low Risk	43480	2003-11-12
CEA	5201-16	Low Risk	30288	2003-11-12
CA-15-3	6333-16	Low Risk	30279	2003-11-12
CA-12-5	6502-16	Low Risk	30283	2003-11-12
CA-19-9	6909-16	Low Risk	30280	2003-11-12
NSE	6334-16	Low Risk	30301	2003-11-12
Free Beta HCG	4221-16, 4221-18	Low Risk	30333	2003-11-12
Pro-GRP (Gastrin-Releasing Peptide)	7015-49	Low Risk	44438	2018-06-11
S100B	1792-17	Low Risk	44431	2018-06-11
Bone Metabolism				
Intact PTH	1735-6,1735-15	Low Risk	30353	2003-11-12
25- OH Vitamin D	2065-6,2065-15	Low Risk	30350	2003-11-12
Cardiac				
Digoxin	1669-15	Low Risk	30386	2005-11-11
CK-MB	1005-15	Low Risk	30499	2003-11-12
Troponin I	1105-18	Low Risk	30266	2003-11-12
Myoglobin	1667-18	Low Risk	30264	2003-11-12
C-Reactive Protein (CRP)	1668-18	Low Risk	30499	2003-11-12
LP (a)	1740-1	Low Risk	44441	2018-06-11
Diabetes				
Insulin	1606-15	Low Risk	30338	2003-11-12



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C-peptide	1293-15	Low Risk	30336	2003-11-12
Leptin	1742-38	Low Risk	43010	2016-09-15
IAA	1790-17	Low Risk	30339	2018-06-11
Anti-GAD	1791-17	Low Risk	30340	2018-06-11

Drug Tests

Amphetamine	7010-47	Low Risk	30422	2018-06-11
Barbiturate	7011-47	Low Risk	30424	2018-06-11
Benzodiazepines	7012-47	Low Risk	30425	2018-06-11
Cannabinoids (THCA/CTHC)	7013-47	Low Risk	30426	2018-06-11
Cocaine / Benzoyllecgonine	7014-47	Low Risk	30428	2018-06-11
Cotinine	7015-47	Low Risk	30429	2018-06-11
Fentanyl	7016-47	Low Risk	31582	2018-06-11
Methamphetamine	7017-47	Low Risk	30423	2018-06-11
Morphine	7018-47	Low Risk	30433	2018-06-11
Opiates	7019-47	Low Risk	30434	2018-06-11
PCP (Phencyclidine)	7020-47	Low Risk	30435	2018-06-11

Fertility (Reproduction Function)

Human Growth Hormone (HGH)	1901-16, 1901-18	Low Risk	30333	2003-11-12
HCG Visual	4102-16	Low Risk	30513	2003-11-12
Beta hCG (Total)	4201-16,4201-18	Low Risk	30332	2003-11-12
FSH	4224-16, 4224-18	Low Risk	31533	2003-11-12
LH	4225-16, 4225-18	Low Risk	38246	2003-11-12
Prolactin	4226-16, 4226-18	Low Risk	30325	2005-06-21
PAPP-A	4229-6, 4229-15	Low Risk	31533	2008-06-01
SHBG	2043-6, 2043-17	Low Risk	30326	2016-09-15

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Infectious Diseases

Adenovirus IgG	6101-8	Low Risk	39468	2003-11-12
Adenovirus IgA	6103-8	Low Risk	39468	2003-11-12
Adenovirus IgM	6102-8	Low Risk	39468	2003-11-12
Influenza A IgA	5104-8	Low Risk	39463	2003-11-12
Influenza A IgG	5105-8	Low Risk	39463	2003-11-12
Influenza A IgM	5106-8	Low Risk	39463	2003-11-12
Influenza B IgA	5107-8	Low Risk	39463	2003-11-12
Influenza B IgG	5108-8	Low Risk	39463	2003-11-12
Influenza B IgM	5109-8	Low Risk	39463	2003-11-12
Chikungunya IgG	8112-25	Low Risk	32481	2016-09-15
Chikungunya IgM	8112-25	Low Risk	32481	2016-09-15
Mycobacterium Tuberculosis (TB) IgA	5110-8	Low Risk	30635	2003-11-12
Mycobacterium Tuberculosis (TB) IgG	5111-8	Low Risk	30635	2003-11-12
Mycobacterium Tuberculosis (TB) IgM	5112-8	Low Risk	30635	2003-11-12
Herpes Simplex 1 IgG (HSV1 IgA)	1400-11	Low Risk	38870	2018-06-11
Herpes Simplex 1 IgG (HSV1 IgG)	1401-11	Low Risk	38870	2003-11-12
Herpes Simplex 1 IgM (HSV1 IgM)	1402-11	Low Risk	38870	2003-11-12
Herpes Simplex 2 IgG (HSV1 IgA)	1399-11	Low Risk	38875	2018-06-11
Herpes Simplex 2 IgG (HSV2 IgG)	1403-11	Low Risk	38875	2003-11-12
Herpes Simplex 2 IgM (HSV2 IgM)	1404-11	Low Risk	38875	2003-11-12
Herpes Simplex 1,2 IgG (HSV1,2 IgG)	1443-11	Low Risk	40176	2003-11-12
Herpes Simplex 1,2 IgM (HSV1,2 IgM)	1444-11	Low Risk	40176	2003-11-12
Epstein Barr Virus VCA IgA (EBV, VCA IgA)	1414-11	Low Risk	30809	2018-06-11
Epstein Barr Virus VCA IgG (EBV, VCA IgG)	1405-2	Low Risk	30809	2003-11-12

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Epstein Barr Virus VCA IgM (EBV, VCA IgM)	1406-2	Low Risk	30809	2003-11-12
Epstein-Barr Viral Capsid Antigen (P-18) IgG	1405-1	Low Risk	30809	2003-11-12
Epstein Barr Virus Early Antigen (EA) IgM	1418-16	Low Risk	30809	2016-09-15
Epstein Barr Virus Early Antigen (EA) IgG	1415-11, 1415-2	Low Risk	30809	2003-11-12
Epstein Barr Virus Nuclear Antigen (EBNA) IgG	1425-1	Low Risk	30808	2003-11-12
Epstein Barr Virus Nuclear Antigen (EBNA) IgM	1426-1	Low Risk	30808	2003-11-12
Measles IgG	1408-1, 1408-11	Low Risk	44019	2003-11-12
Measles IgM	1409-1, 1409-11	Low Risk	44019	2003-11-12
Mumps IgG	1410-1, 1410-11	Low Risk	33908	2003-11-12
Mumps IgM	1411-11, 1411-1	Low Risk	33908	2003-11-12
Mycoplasma pneumonia IgG	8042-2	Low Risk	30657	2003-11-12
Mycoplasma pneumonia IgM	8043-2	Low Risk	30657	2003-11-12
Syphilis (TPA) IgG	1463-1	Low Risk	30685	2003-11-12
Syphilis (TPA) IgM	1464-6	Low Risk	30685	2003-11-12
Syphilis (TPA) IgG/IgM	1465-12	Low Risk	30685	2018-06-11
Legionella Total G/M/A	1651-2	Low Risk	30692	2003-11-12
Legionella IgG/IgM	1652-1	Low Risk	30692	2018-06-11
H. pylori IgG	1503-2, 1503-11	Low Risk	30691	2003-11-12
H. pylori IgA	1505-11	Low Risk	30691	2003-11-12
H-Pylori IgM	1504-11	Low Risk	30691	2003-11-12
H. pylori Antigen	1506-11	Low Risk	30691	2016-09-15
Varicella-Zoster IgG	1412-1, 1412-2, 1412-11	Low Risk	44027	2003-11-12
Varicella-Zoster IgM	1413-1, 1413-2, 1413-11	Low Risk	44027	2003-11-12
Brucella IgG	1501-8	Low Risk	30713	2003-11-12

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Brucella IgA	1507-8	Low Risk	30713	2003-09-08
Brucella IgM	1502-8	Low Risk	30713	2003-11-12
HEV IgG	1888-12	Low Risk	30757	2018-06-11
HEV IgM	1876-12	Low Risk	30758	2003-11-12
HEV Ab	1877-12	Low Risk	30756	2003-11-12
Lyme Disease IgG	1428-2	Low Risk	30697	2008-06-01
Lyme Disease IgM	1424-2	Low Risk	30697	2008-06-01
Lyme Disease IgG, M	1423-2	Low Risk	30697	2008-06-01
Bordetella Pertussis IgA	5117-8	Low Risk	37723	2008-06-01
Bordetella Pertussis IgG	5118-8	Low Risk	37723	2008-06-01
Bordetella Pertussis IgM	5119-8	Low Risk	37723	2008-06-01
RSV IgA	5113-8	Low Risk	30814	2008-06-01
RSV IgG	5114-8	Low Risk	30814	2008-06-01
RSV IgM	5115-8	Low Risk	30814	2008-06-01
Anti-Tetanus Toxoid	8900-28	Low Risk	38876	2018-06-11
Diphtheria Toxoid IgG	1760-28	Low Risk	33499	2018-06-11
Salmonella typhi IgG	6150-47	Low Risk	30709	2018-06-11
Salmonella typhi IgM	6151-47	Low Risk	30709	2018-06-11
HPV IgG	1889-6 1889-6	Low Risk	30812	2018-06-11
Borrelia VlsE1/pepC10 IgG/IgM	1427-2	Low Risk	50568	
Aspergillus Galactomannan Antigen	1509-8	Low Risk	51988	
Parasitology Antibody Detection				
Schistosoma IgG	8209-35	Low Risk	30824	2003-11-12
Chagas	8100-35, 8100-33	Low Risk	30820	2003-11-12
Cysticercosis IgG (T.Solium)	8105-35	Low Risk	39979	2003-11-12

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Dengue IgG/IgM	8115-35	Low Risk	32481	2003-11-12
Dengue IgG/infectious	8116-35	Low Risk	32481	2003-11-12
Dengue IgM	8117-35	Low Risk	32481	2003-11-12
Dengue NS1 Antigen	8404-25	Low Risk	32481	2012-06-26
E. histolytica IgG (Amebiasis)	8201-35	Low Risk	39979	2003-11-12
Echinococcus IgG	8202-35	Low Risk	30822	2003-11-12
Fasciola IgG	8119-35	Low Risk	34068	2018-06-11
Fasciola gigantica	8120-35	Low Risk	34068	2018-06-11
Filaria IgG4	8211-25	Low Risk	34068	2018-06-11
Leishmania	8203-35, 8203-25	Low Risk	30823	2003-11-12
Leptospira IgG	8204-35	Low Risk	30716	2003-11-12
Leptospira IgM	8208-35	Low Risk	30716	2003-11-12
Leptospira IgG/IgM	8210-35	Low Risk	30716	2018-06-11
Toxocara IgG	8206-35	Low Risk	34068	2003-11-12
Trichinella IgG	8207-35	Low Risk	33379	2003-11-12
Japanese Encephalitis IgG	8402-25	Low Risk	44321	2005-11-09
Japanese Encephalitis IgM	8403-25	Low Risk	44321	2005-11-09
West Nile IgG	8400-25	Low Risk	42926	2005-11-09
West Nile IgM	8401-25	Low Risk	42926	2005-11-09
Scrub typhus IgG	8406-25	Low Risk	44028	2007-01-05
Scrub typhus IgM	8405-25	Low Risk	44028	2007-01-05
Ascaris IgG	8212-35	Low Risk	39979	2011-25-07
Strongyloides IgG	8319-35	Low Risk	34068	2008-06-01
Parasitology Antigen detection				
Adenovirus (Fecal)	8300-3	Low Risk	41274	2003-11-12

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Camplobacter (Fecal)	8320-3	Low Risk	34016	2018-06-11
Cryptosporidium (Fecal)	8301-3	Low Risk	30675	2003-11-12
Crypto/Giardia (Fecal)	8310-3	Low Risk	36173	2018-06-11
E. Coli 0157 (Fecal)	8302-3	Low Risk	37727	2003-11-12
E. histolytica/dispar	8307-3	Low Risk	39979	2003-11-12
E. Coli Verotoxin (Fecal)	8303-3	Low Risk	37727	2003-11-12
Giardia	8304-3	Low Risk	36173	2003-11-12
Legionella Urinary Antigen (Urine)	8305-3	Low Risk	30692	2003-11-12
Rotavirus (Fecal)	8306-3	Low Risk	30815	2003-11-12

Steroid

Aldosterone	4230-6	Low Risk	31428	2018-06-11
Cortisol	6101-15	Low Risk	31394	2003-11-12
Cortisol Saliva	7101-38	Low Risk	31394	2016-09-15
Estradiol	2046-18	Low Risk	30321	2003-11-12
DHEA-S	2055-15,2055-17	Low Risk	30320	2003-11-12
DHEA	2056-6, 2056-15	Low Risk	39894	2003-11-12
Progesterone	2077-18	Low Risk	30323	2003-11-12
Testosterone	2095-18	Low Risk	30327	2003-11-12
Testosterone Saliva	7095-38	Low Risk	30327	2018-06-11
Free Testosterone	2925-15, 2925-17	Low Risk	30327	2003-11-12
Androstenedione	1038-17	Low Risk	30321	2003-11-12
Free Estriol	3171-15, 3171-17	Low Risk	30330	2012-05-23
Dihydrotestosterones (DHT)	2042-38	Low Risk	30327	2018-06-11
17-alpha hydroxy Progesterone	1292-15	Low Risk	30324	2005-06-21

Thyroid

T3	3144-16, 3144-18	Low Risk	30314	2003-11-12
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T4	3149-16, 3149-18	Low Risk	30312	2003-11-12
TSH	3122-16, 3122-18	Low Risk	30489	2003-11-12
U-TSH	3123-16, 3123-18	Low Risk	30489	2003-11-12
Free T4	3146-15	Low Risk	30308	2003-11-12
Free T3	3148-15	Low Risk	30309	2003-11-12
Reverse T3	3145-38	Low Risk	30311	2018-06-11
T Uptake	3176-15	Low Risk	30313	2003-11-12

NeoNatal Panel

NNT4 (NeoNatal T4)	3150-15	Low Risk	30273	2003-11-12
NTSH (NeoNatal TSH)	3124-15	Low Risk	30310	2005-11-11
N-TBG (NeoNatal TBG)	4115-15	Low Risk	30316	2018-06-11
N-17OHPG (Neo Natal 17-OH progesterone)	4116-15	Low Risk	30324	2018-06-11

IFA

IFA Device Group	Document / page Catalogue	Risk Classification	GMDN code	First CE-marking
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Autoimmune Diseases and others:

ANA Rat Liver IFA Kit	210708D	Low Risk	41420	2003-11-12
ANA Mouse Kidney IFA Kit	22078D	Low Risk	41420	2003-11-12
ANA HEP-2 IFA Kit	231005D, 231005DE, 230512D, 230512DE	Low Risk	17269	2003-11-12
AMA IFA Kit	240806D	Low Risk	17267	2003-11-12
AAS IFA Kit	250608D	Low Risk	30274	2003-11-12
AAS Rat Kidney Stomach Liver Tissue	250609D	Low Risk	30274	2013-12-19
AAS Mouse Kidney Stomach Liver Tissue	250610D	Low Risk	30274	2013-12-19
ASMA IFA Kit	260806D	Low Risk	30274	2003-11-12



ATA IFA Kit	270806D	Low Risk	30274	2003-11-12
ASA IFA Kit	280806D	Low Risk	30274	2003-11-12
nDNA IFA Kit	320608D	Low Risk	30274	2003-11-12

Bacterial Diseases:

Legionella Antibody IFA Kit (group 1-6)	331008-6D	Low Risk	30694	2003-11-12
FTA-ABS Double Stain (Syphilis) IFA Kit	351010-DS	Low Risk	32455	2003-11-12
FTA-ABS(Syphilis) IFA Kit	351010	Low Risk	32455	2013-12-19
FTA-ABS (Syphilis) Titrable IFA Kit	351010-T	Low Risk	32455	2003-11-12
B.Burdoferi (Lyme) IgG/IgM IFA Kit	361010-G/MD	Low Risk	30697	2003-11-12

Viral diseases:

HSV-1 IgG IFA Kit	381010-G	Low Risk	39502	2008-06-01
HSV-2 IgG IFA Kit	391010-G	Low Risk	39502	2008-06-01
EBV-VCA IgG IFA Kit	401010-G	Low Risk	33971	2008-06-01
EBV-VCA IgM IFA Kit	401005-MD	Low Risk	33971	2008-06-01
EBV-EA IFA Kit	401010-EA	Low Risk	33971	2018-06-11
EBV-NA IgG IFA Kit	401010-NA	Low Risk	33971	2018-06-11
Measles IgG IFA Kit	250611D	Low Risk	44019	2008-06-01
Varicella-Zoster Virus IgG IFA Kit	421010-G	Low Risk	44027	2008-06-01

Rapidtest

Rapidtest Device Group	Document / page Catalogue	Risk Classificati on	GMDN code	First CE- marking
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Allergy

IgE Serum RapiCard™ InstaTest	15150-1-22	Low Risk	30275	2003-11-12
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Bone Metabolism

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Vitamin D RapiCard™ InstaTest (Whole Blood)	117791-1-44	Low Risk	30349	2018-06-11
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Cancer

Hemo Fecal Occult Blood RapiCard™ InstaTest	13010-1-23,13010-1-19	Low Risk	38217	2003-11-12
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Hemo Fecal Occult Blood RapiDip™ InstaTest	13091-1-23,13091-1-44	Low Risk	38217	2003-11-12
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CEA

CEA RapiCard™ InstaTest (Serum/Plasma)	13062-1-22	Low Risk	30288	2003-11-12
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CEA RapiCard™ InstaTest (Serum/WB/Plasma)	13060-1-44	Low Risk	30288	2003-11-12
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AFP

AFP RapiDip™ InstaTest (Serum/Plasma)	13042-1-22	Low Risk	30295	2003-11-12
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AFP RapiCard™ InstaTest (Serum/plasma/WB)	13043-40-44	Low Risk	30295	2003-11-12
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Cardiac markers

CK-MB RapiCard InstaTest(Serum)	166776-1-21	Low Risk	30499	2003-11-12
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CK-MB RapiCard InstaTest(Serum/Plasma/Whole Blood)	166776-1-44,166777-1- 21	Low Risk	30499	2003-11-12
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C-Reactive Protein (CRP) RapiCard™ InstaTest (Serum)	166770-1-21	Low Risk	30507	2003-11-12
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C-Reactive Protein (CRP) RapiCard™ InstaTest (Serum/Plasma/Whole Blood)	166800-1-44, 166800-1- 21	Low Risk	30507	2003-11-12
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D-Dimer RapiCard™ InstaTest (Plasma/Whole Blood)	175770-1-44	Low Risk	30576	2016-09-15
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D-Dimer RapiCard™ InstaTest (Serum/Plasma/Whole Blood)	175770-1-44	Low Risk	30576	2016-09-15
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Myoglobin RapiCard™ InstaTest (Serum/Plasma/Whole Blood)	166774-1-44, 166774-1- 21	Low Risk	30264	2003-11-12
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Troponin I RapiCard™ InstaTest (Serum)	166771-1-19,166771-1- 23	Low Risk	30266	2003-11-12
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Troponin I RapiCard™ InstaTest (Serum/Plasma)	166773-1-37	Low Risk	30266	2003-11-12
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Troponin I Serum/Whole Blood RapiCard™ InstaTest	166772-1-19,166772-1- 23,166772-1-44	Low Risk	30266	2003-11-12
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3 in 1 Troponin I/Myoglobin/CKMB RapiCard InstaTest (Serum/Plasma)	166779-1-37	Low Risk	42649	2003-11-12
3 in 1 Troponin I/Myoglobin/CKMB RapiCard InstaTest (Serum/Plasma/Whole Blood)	166780-1-23	Low Risk	42649	2003-11-12

Drug Test

Alcohol Urine RapiDip InstaTest	121012-1-23,121012-1-44	Low Risk	30443	2013-12-19
Alcohol Saliva RapiDip InstaTest	121000-1-23,121000-1-44	Low Risk	30443	2003-11-12
Amphetamine Urine RapiCard™ InstaTest	121020-1-21	Low Risk	30516	2003-11-12
Amphetamine Urine RapiDip™ InstaTest	121021-1-21,121021-1-44	Low Risk	30516	2003-11-12
Barbiturates Urine RapiCard InstaTest	121060-1-21	Low Risk	30517	2003-11-12
Barbiturates Urine RapiDip™ InstaTest	121062-1-19,121062-1-21,121062-1-44	Low Risk	30517	2003-11-12
Buprenorphine Urine RapiCard™ InstaTest	121003-1-21	Low Risk	31584	2003-11-12
Buprenorphine Urine RapiDip™ InstaTest	121004-1-21	Low Risk	31584	2003-11-12
Benzodiazepine Urine RapiCard™ InstaTest	121061-1-21	Low Risk	30518	2003-11-12
Benzodiazepine Urine RapiDip™ InstaTest	121063-1-19,121063-21,121063-1-44	Low Risk	30518	2003-11-12
Cocaine Urine RapiCard™ InstaTest	121040-1-19,121040-1-21,121040-1-44	Low Risk	30520	2003-11-12
Cocaine Urine RapiDip™ InstaTest	121041-1-19,121041-1-21,121041-1-44	Low Risk	30520	2003-11-12
Cotinine RapiCard™ InstaTest	100801-1-19	Low Risk	30429	2018-06-11
Cotinine RapiCard™ InstaTest	121140-1-44	Low Risk	30429	2018-06-11
Cotinine RapiDip™ InstaTest	121141-1-44	Low Risk	30429	2018-06-11
EDDP Urine RapiCard™ InstaTest	121005-1-21,121005-1-44	Low Risk	30521	2003-11-12
EDDP Urine RapiDip™ InstaTest	121091-1-21	Low Risk	30521	2003-11-12
Fentanyl Urine RapiCard™ InstaTest	121151-1-23	Low Risk	31582	2016-09-15
Fentanyl Urine RapiDip™ InstaTest	121152-1-23	Low Risk	31582	2016-09-15
K2 (Synthetic Marijuana) Urine RapiCard™ InstaTest	121153-1-23	Low Risk	31582	2016-09-15

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K2 (Synthetic Marijuana) Urine RapiDip™ InstaTest	121154-1-23, 121154-1-44	Low Risk	31582	2016-09-15
Ketamine Urine RapiDip™ InstaTest	120302-1-23	Low Risk	31582	2016-09-15
Ketamine Urine RapiDip™ InstaTest	120301-1-23	Low Risk	31582	2016-09-15
MDMA(Ecstasy) RapiCard InstaTest	121030-1-23	Low Risk	30423	2003-11-12
MDMA(Ecstasy) RapiDip InstaTest	121033-1-44	Low Risk	30423	2003-11-12
Methadone (MTD) Urine Urine RapiCard™ InstaTest	122109-1-21,122109-1-44	Low Risk	31596	2003-11-12
Methadone (MTD) Urine Urine RapiDip™ InstaTest	122113-1-21,122113-1-44	Low Risk	31596	2003-11-12
Methamphetamine Urine RapiCard™ InstaTest	121035-1-21	Low Risk	30423	2003-11-12
Methamphetamine Urine RapiDip™ InstaTest	121036-1-21	Low Risk	30423	2003-11-12
MPD (Methylphenidate) Urine RapiCard™ InstaTest	121149-1-23,121149-1-44	Low Risk	31582	2016-09-15
MPD (Methylphenidate) Urine RapiDip™ InstaTest	121150-1-23,121150-1-44	Low Risk	31582	2016-15
Marijuana (THC)Urine RapiCard™ InstaTest	121027-1-19,121027-1-21,121027-1-44	Low Risk	30519	2003-11-12
Marijuana (THC) Urine RapiDip™ InstaTest	121028-1-21,121028-1-44	Low Risk	30519	2003-11-12
Opiates Urine RapiCard™ InstaTest	120304-1,120304-1-44	Low Risk	30522	2003-11-12
Opiates Urine RapiDip™ InstaTest	1203031-1,1203031-1-44	Low Risk	30522	2003-11-12
Oxycodone Urine RapiCard™ InstaTest	121002-1-21	Low Risk	31584	2008-06-01
Oxycodone Urine RapiDip™ InstaTest	121001-1-21	Low Risk	31584	2008-06-01
Phencyclidine (PCP) Urine RapiCard™ InstaTest	121065-1-21	Low Risk	30523	2003-11-12
Phencyclidine (PCP) Urine RapiDip™ InstaTest	121080-1-21	Low Risk	30435	2003-11-12
Propoxyphene RapiDip™ InstaTest	120311-50-44	Low Risk	30436	2018-06-11
Tricyclic Antidepressants(TCA) RapiCard™ InstaTest	121025-1-21,121025-1-44	Low Risk	30524	2003-11-12
Tricyclic Antidepressants(TCA) RapiDip™ InstaTest	121031-1-21,121031-1-44	Low Risk	30523	2003-11-12
Tramadol Urine RapiCard™ InstaTest	121007-1-23	Low Risk	31582	2016-09-15

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Tramadol Urine RapiDip™ InstaTest	121118-1-23	Low Risk	31582	2016-09-15
Opiates/Heroin/Morphine Urine RapiCard™ InstaTest	121058-1-21	Low Risk	30522	2003-11-12
Opiates/Heroin/Morphine Urine RapiDip™ InstaTest	121059-1-1-,121059-1-21	Low Risk	30522	2003-11-12
2-Drug RapiCard™ InstaTest (Any Combination)	121117-1-21, 121117-1-44	Low Risk	30261	2003-11-12
3-Drug RapiCard™ InstaTest (Any Combination)	121100-1-21, 121100-1-44	Low Risk	30261	2003-11-12
4-Drug RapiCard InstaTest (Any Combination)	121078-1-21,121078-1-44	Low Risk	30261	2003-11-12
5-Drug RapiCard™ InstaTest (Any Combination)	121074-1-21,121074-1-44	Low Risk	30261	2003-11-12
6-Drug RapiCard™ InstaTest (Any Combination)	121116-1-19, 121116-21121116-1-44	Low Risk	30261	2003-11-12
2-Drug RapiDip™ InstaTest (Any Combination)	121043-1-1-,121133-1-21,121133-1-44	Low Risk	30261	2003-11-12
3-Drug RapiDip™ InstaTest, (Any Combination)	121119-1-21,121119-1-44	Low Risk	30261	2003-11-12
4-Drug RapiDip™ InstaTest, (Any Combination)	121134-1-21,121134-1-44	Low Risk	30261	2003-11-12
5-Drug RapiDip™ InstaTest, (Any Combination)	121089-1-21,121089-144	Low Risk	30261	2003-11-12
6-Drug RapiDip™ InstaTest, (Any Combination)	122021-1-19,122021-1-21,122021-1-44	Low Risk	30261	2003-11-12
7-Drug RapiDip™ InstaTest, (Any Combination)	121103-1-21,121103-1-44	Low Risk	30261	2003-11-12
8-Drug RapiDip™ InstaTest, (Any Combination)	121069-1-21,121069-1-44	Low Risk	30261	2003-11-12
9-Drug RapiDip™ InstaTest, (Any Combination)	121068-1-21,121068-1-44	Low Risk	30261	2003-11-12
10-Drug RapiDip™ InstaTest, (Any Combination)	121097-1-21,121097-1-44	Low Risk	30261	2003-11-12
11-Drug RapiDip™ InstaTest, (Any Combination)	150202-1-44	Low Risk	30261	2003-11-12
12-Drug RapiDip™ InstaTest, (Any Combination)	150203-1-19	Low Risk	30261	2003-11-12
DOA Saliva plus Alcohol RapiDip™ InstaTest	121069-1AL-44	Low Risk	30261	2016-09-15
Drug Test Plus Alcohol				
2-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121133-1AL-23	Low Risk	30261	2003-11-12

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3-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121119-1AL-23	Low Risk	30261	2003-11-12
4-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121134-1AL-23	Low Risk	30261	2003-11-12
5-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121089-1AL-23	Low Risk	30261	2003-11-12
6-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121116-1AL-23	Low Risk	30261	2003-11-12
7-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121103-1AL-23	Low Risk	30261	2003-11-12
8-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121069-1AL-23	Low Risk	30261	2003-11-12
9-Drug (Any Combination) + Alcohol RapiDip™ InstaTest	121068-1AL-23	Low Risk	30261	2003-11-12

Drug Test RapiCup

2-Drug RapiCup InstaTest (Any Combination)	121083-1-21	Low Risk	30261	2003-11-12
3-Drug RapiCup InstaTest (Any Combination)	121086-1-21	Low Risk	30261	2003-11-12
4-Drug RapiCup InstaTest (Any Combination)	121087-1-21	Low Risk	30261	2003-11-12
5-Drug RapiCup InstaTest (Any Combination)	121107-1-19, 121107-1- 21	Low Risk	30261	2003-11-12
6-Drug RapiCup InstaTest (Any Combination)	121108-1-21	Low Risk	30261	2003-11-12
7-Drug RapiCup InstaTest (Any Combination)	121121-1-21	Low Risk	30261	2003-11-12
8-Drug RapiCup InstaTest (Any Combination)	121122-1-21	Low Risk	30261	2003-11-12
9-Drug RapiCup InstaTest (Any Combination)	121109-1-21	Low Risk	30261	2003-11-12
10-Drug RapiCup InstaTest (Any Combination)	121112-1-21	Low Risk	30261	2003-11-12
10-Drug RapiCup InstaTest (Any Combination)+ Alcohol	121113-1-44	Low Risk	30261	2003-11-12

Infectious Diseases and others

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Legionella Urinary Antigen Test)	176075-1-23	Low Risk	30692	2008-06-01
Adeno/Rotavirus Antigen RapiCard™ InstaTest	176067-1-23	Low Risk	42994	2009-02-21
Adeno Antigen RapiCard™ InstaTest	176068-1-23	Low Risk	42994	2009-02-21
Rotavirus Antigen RapiCard™ InstaTest	176066-1-23	Low Risk	30815	2009-02-21
Chagas RapiDip™ InstaTest	146119-25-25	Low Risk	30820	2005-11-09
Chikungunya IgG/IgM RapiCard™ InstaTest	174110-25-23, 174110-1-44	Low Risk	42994	2016-09-15
Gonorrhea RapiCard™ InstaTest	176510-1-44	Low Risk	38851	2003-11-12
Gonorrhea RapiDip™ InstaTest	176512-1-20	Low Risk	38851	2003-11-12
Influenza A&B RapiCard™ InstaTest	178901-1-44	Low Risk	30813	2018-06-11
Leishmania Visceral RapiDip™ InstaTest	176070-25-25	Low Risk	30823	2003-11-12
Leishmania Cutaneous RapiDip™ InstaTest	176071-25-25	Low Risk	30823	2003-11-12
Leptospira IgG/IgM	156110-1-44	Low Risk	30716	2018-06-11
Syphilis RapiCard™ InstaTest	176501-1-44	Low Risk	30687	2003-11-12
Syphilis RapiDip™ InstaTest	12,176502-1-44	Low Risk	30687	2003-11-12
Mononucleosis RapiCard™ InstaTest (S/P)	176522-25-22	Low Risk	30826	2003-11-12
Mononucleosis RapiCard™ InstaTest (S/P/WB)	176521-1-44	Low Risk	30810	2016-09-15
Strep A RapiCard™ InstaTest	176550-1-44,176550-25-23	Low Risk	30826	2003-11-12
Strep B RapiCard™ InstaTest	176551-1-44	Low Risk	30827	2018-06-11
H1N1 RapiDip™ InstaTest	191000-1-50	Low Risk	43228	2018-06-11
H. Pylori RapiCard™ InstaTest(serum)	118562-1-19	Low Risk	30825	2003-11-12
H. Pylori RapiCard™ InstaTest (Serum/Plasma)	118561-1-23	Low Risk	30825	2003-11-12
H. Pylori RapiCard™ InstaTest (Serum/Whole Blood)	118562-25-19	Low Risk	30825	2018-06-11
H. Pylori Antigen RapiCard™ InstaTest	118564-1-23,118564-1-44	Low Risk	30689	2007-09-21
HAV IgM RapiCard™ InstaTest	118779-1-44	Low Risk	40228	2018-06-11

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Dengue Fever IgG&IgM RapiCard InstaTest	173106L-25-23	Low Risk	42994	2003-11-12
Dengue NS1 RapiDip InstaTest	173110-25-25	Low Risk	42994	2012-06-26
Dengue NS1 RapiCard InstaTest	173111-25-23	Low Risk	42994	2016-09-15
Dengue NS1Antigen& IgG/IgM antibody Duo Panel RapiCard™ InstaTest	173112-25-23	Low Risk	42994	2016-09-15
Malaria (P.f./vivax) RapiCard InstaTest (WB)	172110-25-23, 172110-1-44	Low Risk	30674	2003-11-12
Malaria (Pan-LDH) RapiCard InstaTest (WB)	172120-25-23	Low Risk	30674	2003-11-12
Malaria (P.f./Pan) RapiCard InstaTest (WB)	172120-1-44, 172130-25-23	Low Risk	30674	2018-06-11
Active Melioidosis RapiDip™ InstaTest	156119-25-25	Low Risk	42994	2016-09-15
Norovirus RapiCard InstaTest	118567-1-44	Low Risk	42718	2018-06-11
Salmonella typhi Antigen RapiCard™ InstaTest	118565-25-23	Low Risk	30709	2016-09-15
Salmonella typhi IgG/IgM RapiCard™ InstaTest	118566-1-44	Low Risk	30709	2018-06-11
Scrub typhus IgG RapiDip™ InstaTest	146117-25-25	Low Risk	30717	2011-12-20
Scrub typhus IgM RapiDip™ InstaTest	146118-25-25	Low Risk	30717	2011-12-20
Zika Virus IgG/IgM RapiCard™ InstaTest	174111-25-23	Low Risk	42994	2016-09-15
nCOV (Novel Coronavirus) IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	176552-1-20 176552-1-44L	Low Risk	64756	2020-02-16
nCOV IgG/IgM Rapid Test Cassette Single use kit (Fingerstick Whole Blood)	176553-1-20 176553-1-44L	Low Risk	64756	2020-02-16
Tuberculosis (TB) RapiCard™ InstaTest	118779-1-44	Low Risk	30658	2018-06-11
Filariasis IgG/IgM RapiCard™ InstaTest	177582-1-44	Low Risk	34068	2018-06-11
COVID-19 Antigen Instatest	176653-1	Low Risk	64787	2020-10-01

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Fertility

FSH Urine RapiCard InstaTest	198220-1-20	Low Risk	30512	2003-11-12
FSH Urine RapiDip InstaTest	198219-1-20	Low Risk	30512	2018-06-11

Ovulation

LH Ovulation Urine RapiCard InstaTest	104110-1-20	Low Risk	30515	2003-11-12
LH Midstream RapiCard InstaTest	104117-1-20	Low Risk	30515	2003-11-12
LH Urine RapiDip InstaTest (3.5mm Strip)	104113-1-20	Low Risk	30515	2003-11-12
LH Urine RapiDip™ InstaTest (5mm Strip)	104115-1-20	Low Risk	30515	2003-11-12

Pregnancy

HCG Midstream Urine RapiCard InstaTest	114360ST-1	Low Risk	30513	2003-11-12
HCG Urine RapiCard InstaTest	113028ST-1	Low Risk	30513	2003-11-12
HCG Urine RapiDip™ InstaTest (2.5mm Strip)	113042-1-20	Low Risk	30513	2003-11-12
HCG Urine RapiDip™ InstaTest (3.5mm Strip)	113043-1-20	Low Risk	30513	2003-11-12
HCG Urine RapiDip™ InstaTest (5mm Strip)	113045-1-20	Low Risk	30513	2003-11-12
HCG Combo (Urine/Serum) RapiCard™ InstaTest	113029-1-20,113029-1-19	Low Risk	30513	2003-11-12
HCG Combo (Urine/Serum) RapiDip™ InstaTest (3.5mm Strip)	113032-1-20,113032-1-44	Low Risk	30513	2003-11-12
HCG Combo (Urine/Serum/Plasma) RapiDip™ InstaTest (5mm Strip)	113030-1-20,113030-1-44	Low Risk	30513	2003-11-12
HCG Combo (Urine/Serum/Plasma) RapiDiCard™ InstaTest	113029-1-44	Low Risk	30513	2003-11-12

Others

Microalbumin RapiDip™ InstaTest	110511-1-44	Low Risk	30246	2016-09-15
Procalcitonin RapiCard™ InstaTest	110512-1-44	Low Risk	30342	2018-06-11

Veterinary

Leishmania Canine RapiDip™ InstaTest	176072-25-25	Low Risk	30823	2018-06-11
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Urine Reagent Strips

URS-1B (Blood)	URS-1B	Low Risk	33257	2003-11-12
URS-1G (Glucose)	URS-1G	Low Risk	17419	2003-11-12
URS-1P (Protein)	URS-1P	Low Risk	30225	2003-11-12
URS-1K (Ketone)	URS-1K	Low Risk	33256	2003-11-12
URS-2K (Glucose/Ketone)	URS-2K	Low Risk	30226	2003-11-12
URS-2P (Glucose/Protein)	URS-2P	Low Risk	30226	2003-11-12
URS-2P (Glucose/Protein)	URS-2P-CD	Low Risk	30226	2016-09-15
URS-3 (Glucose/Protein/pH)	URS-3	Low Risk	30226	2003-11-12
URS-4B (Glucose/Protein/pH/Blood)	URS-4B	Low Risk	30226	2003-11-12
URS-4S (Glucose/Protein/pH/SG)	URS-4S	Low Risk	30226	2003-11-12
URS-5K (Blood/Ketone/Glucose/Protein/pH)	URS-5K	Low Risk	30226	2003-11-12
URS-5U (Blood/Urobilinogen/Glucose/Protein /pH)	URS-5U	Low Risk	30226	2003-11-12
URS-6 (Blood/Ketone/Glucose/Protein/pH/Bi lirubin)	URS-6	Low Risk	30226	2003-11-12
URS-6L (Blood/Ketone/Glucose/Protein/Leuk ocyte/Bilirubin)	URS-6L	Low Risk	30226	2003-11-12
URS-7 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin)	URS-7	Low Risk	30226	2003-11-12
URS-8 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin /Nitrite)	URS-8	Low Risk	30226	2003-11-12
URS-9 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin /Nitrite /SG)	URS-9	Low Risk	30226	2003-11-12
URS-10 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG /Leukocytes)	URS-10	Low Risk	30226	2003-11-12
URS-11 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG /Leukocytes /Ascorbic Acid)	URS-11	Low Risk	30226	2003-11-12

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URS-11 (Urobilinogen /Blood /Ketone
/Glucose /Protein /pH/Bilirubin
/Nitrite /SG /Leukocytes /Ascorbic
Acid) /microalbumin

URS-12

Low Risk

30226

2003-11-12

CLIA

CLIA Device Group	Document / page Catalogue	Risk Classification	GMDN code	First CE-marking
Thyroid Assays				
T3	9001-16	low risk	30312	2003-11-12
T4	9003-16	low risk	30314	2003-11-12
TSH	9005-16	low risk	30318	2003-11-12
Autoimmune Thyroid Assays				
Anti-Tg	9010-11	low risk	30490	2003-11-12
Allergy Assays				
IgE	9050-16	low risk	17254	2003-11-12
Fertility Assays				
LH	9012-16	low risk	38965	2003-11-12
FSH	9013-16	low risk	30322	2003-11-12
Prolactin (PRL)	9014-16	low risk	30325	2003-11-12
hCG	9015-16	Low Risk	30513	2003-11-12
Diabetes Assay				
Insulin	9021-16	Low Risk	30338	2003-11-12
C-peptide	9022-16	Low Risk	30336	2003-11-12
Cardio-Vascular Monitoring Assay				
CRP	9053-16	Low Risk	30499	2018-06-11
Cancer Marker Assay				
AFP	9040-16	Low Risk	30295	2003-11-12

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CEA	9041-16	Low Risk	30288	2003-11-12
Free Beta hCG	9043-16	Low Risk	30333	2003-11-12
Beta 2- Microglobulin	9076-16	Low Risk	33418	2018-06-11
NSE	9056-16	Low Risk	30301	2018-06-11
CA-12-5	9057-16	Low Risk	30283	2018-06-11
CA-19-9	9059-16	Low Risk	30280	2018-06-11
CA-15-3	9075-16	Low Risk	30279	2018-06-11
Ferritin	9019-16	Low Risk	30377	2013-12-19
Allergy Assays				
IgE	9050-16	Low Risk	30275	2003-11-12
Steroid Assays				
Progesterone	9025-16	Low Risk	30294	2003-11-12
Estradiol	9028-16	Low Risk	30321	2018-06-11
Testosterone	9052-16	Low Risk	30327	2018-06-11
Infectious Disease Assays				
H. pylori IgA	9060-11	Low Risk	30691	2018-06-11
H. pylori IgG	9061-11	Low Risk	30691	2018-06-11
H. pylori IgM	9062-11	Low Risk	30691	2018-06-11
HSV 1 IgG	9065-11	Low Risk	38870	2018-06-11
HSV 1 IgM	9066-11	Low Risk	38870	2018-06-11
HSV 2 IgG	9067-11	Low Risk	38875	2018-06-11
HSV 2 IgM	9068-11	Low Risk	38875	2018-06-11
SARS-CoV-2 IgM ELISA	1500-25	Low Risk	64800	2020-02-16
SARS-CoV-2 IgG ELISA	1501-25	Low Risk	64824	2020-02-16
SARS-CoV-2 IgM ELISA	1500-15	Low Risk	64800	2020-02-16
SARS-CoV-2 IgG ELISA	1501-15	Low Risk	64824	2020-02-16

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Serology

Serology Device Group	Document / page Catalogue	Risk Classification	GMDN code	First CE-marking
CRP Latex Test Kit	310-100, 310-100-31	Low Risk	30499	2008-06-01
RF Latex Test Kit	320-100	Low Risk	30500	2008-06-01
ASO Latex Test Kit	330-50, 330-50-31	Low Risk	30495	2008-06-01
Mono Latex Test Kit	340-50, 340-50-31	Low Risk	30810	2008-06-01
RPR Latex Test Kit	500100-100, 500100-100-31	Low Risk	17393	2008-06-01
RPR Latex Test Kit	500100-500, 500100-500-31	Low Risk	17393	2008-06-01
SLE Latex Test Kit	351-50	Low Risk	30487	2008-06-01
SLE Latex Test Kit	351-50-31	Low Risk	30487	2008-06-01
TPHA (Syphilis)	350-100-31	Low Risk	32453	2018-06-11
Salmonella H Ha (Paratyphoid A)	410-5B-31	Low Risk	39453	2016-09-15
Salmonella H Hb (Paratyphoid B)	411-5B-31	Low Risk	37766	2018-06-11
Salmonella H Hc (Paratyphoid C)	412-5B-31	Low Risk	37766	2018-06-11
Salmonella H Hd (Typhoid H)	413-5B-31	Low Risk	37766	2018-06-11
Salmonella O Group A	414-5B-31	Low Risk	37766	2018-06-11
Salmonella O Group B	415-5B-31	Low Risk	37766	2018-06-11
Salmonella O Group C	416-5B-31	Low Risk	37766	2018-06-11
Salmonella O Group D	417-5B-31	Low Risk	37766	2018-06-11
Brucella Melitensis	420-5B-31	Low Risk	39536	2016-09-15
Brucella Abortus	421-5B-31	Low Risk	39536	2016-09-15
Proteus OX2	431-OX2-31	Low Risk	39543	2016-09-15

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I M M U N O D I A G N O S T I C S

Serology

Serology Device Group	Document / page Catalogue	Risk Classification	GMDN code	First CE-marking
Proteus OX19	431-OX19-31	Low Risk	39543	2016-09-15



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