Tiêu chuẩn Chủ sở hữu công bố áp dụng

Thành phố Hồ Chí Minh, ngày 24 tháng 02 năm 2026

Người đại diện hợp pháp của cơ sở

Giám đốc

Digitally signed by CÔNG TY TNHH TM DV VINH TÍN

Phạm Ngọc Dũng

Autobio Diagnostics Co.,Ltd

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EU Declaration of Conformity

MANUFACTURER:

Autobio Diagnostics Co., Ltd.

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National Eco & Tech Development Area

Zhengzhou

China

450016

SRN: CN-MF-000003348

EUROPEAN REPRESENTATIVE:

QbD RepS BV

Groenenborgerlaan 16

2610 Wilrijk

Belgium

SRN: BE-AR-000000040

PRODUCT:

Please refer to the Annex to this Declaration

PRODUCT CODE:

Please refer to the Annex to this Declaration

CLASSIFICATION:

Please refer to the Annex to this Declaration

STANDARD APPLIED:

1) EN ISO 13485:2016

2) ISO 14971:2019

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3) EN ISO 18113-1:2011

4) EN ISO 18113-2:2011

5) EN ISO 15223-1:2016

6) EN 13612:2002

7) EN ISO 23640:2015

8) EN 13641:2002

We, Autobio Diagnostics Co., Ltd., declare under our sole responsibility that the above IVD medical devices, covered by Annex VIII, meet the provisions of the REGULATION (EU) 2017/746 concerning *in vitro* diagnostic medical devices, based on the conformity assessment procedure in Annex IX, which apply to them.

We herewith declare that the above mentioned product meets the provisions of the REGULATION (EU) 2017/746 for medical device. All supporting documentations retained under the premises of the manufacture.

The product complies with the general safety and performance requirements in accordance with Annex I of the REGULATION (EU) 2017/746.

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Name: Guangyu Fu

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SIGNATURE:_____

DATE: March 25, 2025

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Annex to EC Declaration of Conformity

No.	Product Name	REF Number	BASIC UDI-DI	Class	Rule	Intended Purpose
1	T4 CLIA Microparticles	CME0201/ CME0202/ CME0203/ CME0204/ CME0205/ CME0206/ CME0207/ CME0208/ CME0209/ CME0210	697015090000002GL	B	6	The T4 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of thyroxine (T4) in human serum. The measurement of T4 is used as an aid in the diagnosis of thyroid disorders. Clinical determination of T4 is mainly used as an aid to diagnose hypothyroidism, hyperthyroidism, to evaluate the effectiveness of treatment of thyroid diseases, and to identify, diagnosis and exclusion of self-thyroid diseases. It cannot be used for the diagnosis of thyroid cancer.
2	AutoLumo T4 Calibrators	CA120801/ CA120802/ CA120803/ CA120804	697015090000002GL	B	6	AutoLumo T4 Calibrators are used for calibrating the quantitative T4 CLIA Microparticles assay on Autolumo immunoassay

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						analyzers.
3	TSH CLIA Microparticles	CME0301/ CME0302/ CME0303/ CME0304/ CME0305/ CME0306/ CME0307/ CME0308/ CME0309/ CME0310	697015090000003 GN	B	6	The TSH CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of human thyroid stimulating hormone (TSH) in human serum. The measurement of TSH is used as an aid in the diagnosis of thyroid disorders. When thyroid function changes, TSH is a sensitive indicator reflecting the function of hypothalamic-adenohypophysia-thyroid axis. Clinical determination of TSH is mainly used as: (1) an aid in diagnosis of clinical or sub-clinical hyperthyroidism and hypothyroidism; (2)Monitoring L-T4 replacement therapy for primary hypothyroidism; (3) an aid in diagnosis of Euthyroid Sick Syndrome (ESS); (4)an aid in diagnosis of central hypothyroidism (pituitary and hypothalamic); (5) an

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						aid in diagnosis of inappropriate TSH secretion syndrome (thyroid hormone resistance syndrome).
4	AutoLumo TSH Calibrators	CA120901/ CA120902/ CA120903/ CA120904	697015090000003 GN	B	6	AutoLumo TSH Calibrators are used for calibrating the quantitative TSH CLIA Microparticles assay on Autolumo immunoassay analyzers.
5	T3 CLIA Microparticles	CME0101/ CME0102/ CME0103/ CME0104/ CME0105/ CME0106/ CME0107/ CME0108/ CME0109/ CME0110	697015090000001 GJ	B	6	The T3 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of triiodothyronine (T3) in human serum. The measurement of T3 is used as an aid to diagnosis of thyroid disorders. Clinical

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						determination of T3 is used as an aid to diagnose hypothyroidism, hyperthyroidism, to evaluate the effectiveness of treatment of thyroid diseases.
6	AutoLumo T3 Calibrators	CA120701/ CA120702/ CA120703/ CA120704	697015090000001 GJ	B	6	AutoLumo T3 Calibrators are used for calibrating the quantitative T3 CLIA Microparticles assay on Autolumo immunoassay analyzers.
7	FT3 CLIA Microparticles	CME0401/ CME0402/ CME0403/ CME0404/ CME0405/ CME0406/ CME0407/ CME0408/ CME0409/ CME0410	697015090000004 GQ	B	6	The FT3 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of FT3 (free triiodothyronine) in human serum. The measurement of FT3 is used as an aid in the diagnosis of thyroid disorders. Clinical determination of FT3 is mainly used as: (1) an aid in diagnosis of clinical hyperthyroidis
8	AutoLumo FT3 Calibrators	CA121001/ CA121002/ CA121003/ CA121004	697015090000004 GQ	B	6	AutoLumo FT3 Calibrators are used for calibrating the quantitative FT3 CLIA Microparticles assay on Autolumo

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						immunoassay analyzers.
9	FT4 CLIA Microparticles	CME0501/ CME0502/ CME0503/ CME0504/ CME0505/ CME0506/ CME0507/ CME0508/ CME0509/ CME0510	697015090000005 GS	B	6	The FT4 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of FT4 (free thyroxine) in human serum and plasma. The measurement of FT4 is used as an aid in the diagnosis of thyroid disorders. Clinical determination of FT4 is mainly used as an aid to diagnose hypothyroidism, hyperthyroidi
10	AutoLumo FT4 Calibrators	CA121101/ CA121102/ CA121103/ CA121104	697015090000005 GS	B	6	AutoLumo FT4 Calibrators are used for calibrating the quantitative FT4 CLIA Microparticles assay on Autolumo immunoassay analyzers.
11	Positive Blood Culture Pretreatment Reagent	MSA04	697015090000061 H4	A	5	This is a pretreatment reagent which used for the identification of positive blood culture microorganisms using the AUTOF MS. It is used in conjunction with other clinical and diagnosis procedures as an aid in the early diagnosis of, for example, bloodstream infection.

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12	Filamentous Fungi Pretreatment Reagent	MSA05	697015090000062H6	A	5	This is a reagent which used for pretreatment of Filamentous Fungi in the identification of measurand for using with Autof ms.
13	CHCA Matrix for use with AUTOF MS	MSA03	697015090000060H2	A	5	CHCA Matrix for use with AUTOF MS is used in conjunction with Autof ms for pretreatment of bacteria and fungi (except for filamentous fungi) in clinical identification.
14	Sample Pretreatment Reagent	MSA01	697015090000058HF	A	5	Sample pretreatment reagent is a reagent which used for pretreatment of bacteria and fungi in the identification of measurand for using with MALDI-TOF MS.
15	System Wash	CM00401/CM00403	697015090000052H3	A	5	System Wash is a concentrate which used for cleaning sample pipettor during the reaction process in the detection of measurand for in vitro diagnostic detection assay. This assay is for professional use only.
16	Wash Buffer	CM00301/CM00302/CM00303/CM00304/CM00305/CM00306	697015090000051GZ	A	5	Wash Buffer is used for cleaning during the reaction process in the detection of measurand for in vitro diagnostic detection assay. This assay is for professional use only.

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17	Diluent Universal	CM00201/ CM00202	697015090000050 GX	A	5	Used in conjugation with immune detection kits for the dilution of clinical samples. This assay is for professional use only.
18	Chemiluminescent Substrate	CM00101/ CM00102/ CM00103	697015090000049 HE	A	5	Chemiluminescent Substrate is used in conjunction with matching reagent kits which based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) technology in the detection of measurand for in vitro diagnostic.
19	Nucleic Acid Extraction&Purification Reagent	PCRB0101/ PCRB0102/ PCRB0103/ PCRB0104	697015090000088 HQ	A	5	Nucleic Acid Extraction & Purification Reagent is a reagent used for extraction, enrichment and purification of nucleic acid.
20	Sample Preservation Solution	PCRG0101/ PCRG0102/ PCRG0103/ PCRG0104/ PCRG0105/ PCRG0106/ PCRG0107/ PCRG0108/ PCRG0109/ PCRG0110/ PCRG0111/ PCRG0112/ PCRG0113	697015090000093 HH	A	5	Sample Preservation Solution is used for preservation of tissues and cytopathological samples, and keeping the integrity of nucleic acid for the following extraction process.

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21	Aerobic culture bottle FA	MC0301	697015090000057 HD	A	5	This product is used for in vitro cultivation and detection of aerobic bacteria, facultative anaerobic bacteria, and fungi in blood, lavage fluid, ascites, pleural fluid, and cerebrospinal fluid.
22	Anaerobic culture bottle FN	MC0302	697015090000076 HH	A	5	This product is used for in vitro cultivation and detection of anaerobic and facultative anaerobic bacteria in blood, lavage fluid, ascites, pleural fluid, and cerebrospinal fluid.
23	Aerobic culture bottle PF	MC0303	697015090000077 HK	A	5	This product is used for in vitro cultivation and detection of aerobic bacteria, facultative anaerobic bacteria, and fungi in children's blood, lavage fluid, ascites, pleural fluid, and cerebrospinal fluid.
24	Bi-state Blood Culture Bottle	M0601	697015090000097 HR	A	5	Ready to use culture medium based assay for the qualitative detection of microorganisms in body fluids like blood, ascites, cerebrospinal fluid etc, offering isolated strains to carry out susceptibility tests. This assay is for professional use only.

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25	Anaerobic Blood Culture Bottle	M0602	697015090000098 HT	A	5	Ready to use culture medium based assay for the qualitative detection of microorganisms in body fluids like blood, ascites, cerebrospinal fluid etc, offering isolated strains to carry out susceptibility tests.
26	Whole Blood Pretreatment Reagent	PCRG0201/ PCRG0202/ PCRG0203/ PCRG0204/ PCRG0205	697015090000113 GW	A	5	Whole Blood Pretreatment Reagent is a reagent used for the release of nucleic acid in whole blood, and the obtained processed samples are used for nucleic acid extraction and detection.
27	Sputum Pretreatment Reagent	PCRG0301	697015090000114 GY	A	5	Sputum Pretreatment Reagent is a reagent used for the pretreatment of sputum samples, and the obtained processed samples are used for nucleic acid extraction and detection.
28	Swab Pretreatment Reagent	PCRG0401/ PCRG0402/ PCRG0403/ PCRG0404/ PCRG0405/ PCRG0406	697015090000211 GX	A	5	Swab Pretreatment Reagent is a reagent used to rinse swab specimens for the following nucleic acid extraction and detection processes.
29	Sample Release Reagent	CMT1401/ CMT1402/ CMT1403/ CMT1404	697015090000360 HH	A	5	This assay is used for the pretreatment of clinical samples to make the immune kits test substance released from the state of binding

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						with other substances.
30	Nucleic Acid Sample Pretreatment Reagent	ACID0101/ ACID0102/ ACID0103	697015090000368 HZ	A	5	Nucleic Acid sample pretreatment reagent is a reagent used for pretreatment, enrichment and purification of nucleic acid for MALDI TOF MS.
31	AutoLumo HBsAg Calibrators	CA020101/ CA020102	697015090000117 H6	D	1	AutoLumo HBsAg Calibrators are used for calibrating the quantitative HBsAg CLIA Microparticles assay on Autolumo immunoassay analyzers.
32	HBsAg CLIA Microparticles	CMC1201/ CMC1202/ CMC1203/ CMC1204/ CMC1205/ CMC1206/ CMC1207/ CMC1208/ CMC1209/ CMC1210	697015090000117 H6	D	1	The HBsAg CLIA Microparticles assay and AutoLumo HBsAg Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of HBsAg (Hepatitis B Surface Antigen) in human serum or plasma. Clinical determination of HBsAg is used as an aid to diagnosis the presence of HBV infection; to monitor the course of the disease and the efficacy of therapy in persons with HBV infections; to as part

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						of prenatal care in order to initiate suitable measures for preventing as far as possible the transmission of an HBV infection to the newborn child.This assay is intended to be used as a screening assay of blood donations.
33	Lytic Anaerobic Culture Bottle	MC0501/ MC0502/ MC0503	697015090000364 HR	A	5	Lytic Anaerobic Culture Bottle is for the qualitative recovery and detection of anaerobic and facultative anaerobic microorganisms from blood and other normally sterile body fluids
34	TRAb CLIA Microparticles	CME1001 / CME1002 / CME1003 / CME1004/ CME1005	697015090000118 H8	B	6	TRAb CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of autoantibodies to TSH receptor in human serum using a recombinant thyroid receptor antibody. The anti- TSH receptor determination is used as an aid in the differential diagnosis of patients of Graves' disease within those of

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						thyroid disorders. This device is used for professional use only.
35	Anti-CCP IgG CLIA Microparticles	CMQ1401 / CMQ1402 / CMQ1403 / CMQ1404 / CMQ1405/ CMQ1406/ CMQ1407/ CMQ1408/ CMQ1409/ CMQ1410	697015090000116 H4	B	6	Anti-CCP IgG CLIA Microparticles is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of IgG antibodies to cyclic citrullinated peptide in human serum or plasma. The results of the assay are intended to be used as an aid in the diagnosis of rheumatoid arthritis in combination with other clinical and laboratory findings. Autoantibody levels represent one parameter in a multi-criteria diagnostic process, encompassing both clinical and laboratory-based assessments.
36	AutoLumo Anti-CCP IgG Calibrators	CA010201 / CA010202/ CA010203 / CA010204	697015090000116 H4	B	6	AutoLumo Anti-CCP IgG Calibrators are used for calibrating the quantitative Anti-CCP IgG CLIA Microparticles assay on AutoLumo immunoassay analyzers.

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37	Anti-dsDNA IgG CLIA Microparticles	CMQ2301/ CMQ2302/ CMQ2303/ CMQ2304/ CMQ2305/ CMQ2306/ CMQ2307/ CMQ2308/ CMQ2309/ CMQ2310	697015090000325 HF	B	6	This Anti-dsDNA IgG CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-dsDNA IgG in human serum and plasma. This assay is to be used as an aid in the diagnosis of systemic lupus erythematosus.
38	AutoLumo Anti-dsDNA IgG Calibrators	CA012901/ CA012902/ CA012903/ CA012904	697015090000325 HF	B	6	AutoLumo Anti-dsDNA IgG Calibrators are used for calibrating the quantitative Anti-dsDNA IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
39	ANA IgG CLIA Microparticles	CMQ3301/ CMQ3302/ CMQ3303/ CMQ3304/ CMQ3305/ CMQ3306/ CMQ3307/ CMQ3308/ CMQ3309/ CMQ3310	697015090000326 HH	B	6	This ANA IgG CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the qualitative determination of ANA IgG in human serum or plasma. This assay is to be used as an aid in the diagnosis of autoimmune diseases, such as systemic lupus erythematosus, Sjogren's syndrome, systemic sclerosis, polymyositis/ dermatomyositis, mixed connective tissue

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						disease and other diseases.
40	AutoLumo ANA IgG Calibrators	CA013001/ CA013002/ CA013003/ CA013004	697015090000326 HH	B	6	AutoLumo ANA IgG Calibrators are used for calibrating the qualitative ANA IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
41	RF CLIA Microparticles	CMQ1001 / CMQ1002 / CMQ1003 / CMQ1004 / CMQ1005/ CMQ1006 / CMQ1007 / CMQ1008 / CMQ1009 / CMQ1010	697015090000301 GZ	B	6	This RF CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of rheumatoid factor (RF) in human serum or plasma. This assay is to be used as an aid in the diagnosis of Rheumatoid Arthritis(RA).
42	AutoLumo RF Calibrators	CA010401/ CA010402/ CA010403/ CA010404	697015090000301 GZ	B	6	AutoLumo RF Calibrators are used for calibrating the quantitative RF CLIA Microparticles assay on Autolumo immunoassay analyzers.

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43	RF IgM CLIA Microparticles	CMQ1101 / CMQ1102 / CMQ1103 / CMQ1104/ CMQ1105/ CMQ1106/ CMQ1107/ CMQ1108/ CMQ1109/ CMQ1110	697015090000302 H3	B	6	This RF IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of rheumatoid factor (RF) IgM in human serum or plasma. This assay is to be used as an aid in the diagnosis of Rheumatoid Arthritis(RA). The main subtype in serum of RF is IgM, which is found in 85% to 95% of patients with rheumatoid arthritis.
44	AutoLumo RF IgM Calibrators	CA010501/ CA010502/ CA010503/ CA010504	697015090000302 H3	B	6	AutoLumo RF IgM Calibrators are used for calibrating the quantitative RF IgM CLIA Microparticles assay on Autolumo immunoassay analyzers.
45	RF IgG CLIA Microparticles	CMQ1201 / CMQ1202 / CMQ1203 / CMQ1204/ CMQ1205/ CMQ1206/ CMQ1207/ CMQ1208/ CMQ1209/ CMQ1210	697015090000303 H5	B	6	This RF IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of rheumatoid factor (RF) IgG in human serum or plasma. This assay is to be used as an aid in the

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						diagnosis of Rheumatoid Arthritis(RA). IgG RF is closely associated with synovitis, vasculitis and joint symptoms in patients.
46	AutoLumo RF IgG Calibrators	CA010601/ CA010602/ CA010603/ CA010604	697015090000303 H5	B	6	AutoLumo RF IgG Calibrators are used for calibrating the quantitative RF IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
47	RF IgA CLIA Microparticles	CMQ1301 / CMQ1302 / CMQ1303 / CMQ1304/ CMQ1305/ CMQ1306/ CMQ1307/ CMQ1308/ CMQ1309/ CMQ1310	697015090000304 H7	B	6	This RF IgA CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of rheumatoid factor (RF) IgA in human serum or plasma. This assay is to be used as an aid in the diagnosis of Rheumatoid Arthritis(RA). IgA RF was significantly associated with the severity of arthritis symptoms and bone destruction in patients.
48	AutoLumo RF IgA Calibrators	CA010701/ CA010702/ CA010703/ CA010704	697015090000304 H7	B	6	AutoLumo RF IgA Calibrators are used for calibrating the quantitative RF IgA CLIA Microparticles

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						assay on Autolumo immunoassay analyzers.
49	Preservation	CMO0901/ CMO0902/ CMO0903/ CMO0904/ CMO0905	697015090000369 J3	A	5	Preservation is a coverslip solution for laboratory use as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the assay.
50	E2 CLIA Microparticles	CMF0501/ CMF0502/ CMF0503/ CMF0504/ CMF0505/ CMF0506/ CMF0507/ CMF0508/ CMF0509/ CMF0510	697015090000030 GR	B	6	The E2 CLIA Microparticles assay and AutoLumo E2 Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of E2 (Estradiol) concentration in human serum. The determination of estradiol is utilized as an aid in the elucidation of fertility disorders in the hypothalamus pituitary gonad axis, as a indicator in irregular menstruation patients, monitor the fertility therapy and determining the time of ovulation within the framework of in vitro fertilization

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						(IVF).
51	PRG CLIA Microparticles	CMF0601/ CMF0602/ CMF0603/ CMF0604/ CMF0605/ CMF0605/ CMF0606/ CMF0607/ CMF0608/ CMF0609/ CMF0610	697015090000031 GT	B	6	The PRG CLIA Microparticles assay and AutoLumo PRG Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system of PRG (Progesterone) concentration in human serum. The determination of progesterone is utilized in fertility diagnosis for the detection of ovulation and assessment of the luteal phase.
52	Testosterone CLIA Microparticles	CMF0401/ CMF0402/ CMF0403/ CMF0404/ CMF0405/ CMF0406/ CMF0407/ CMF0408/ CMF0409/ CMF0410	697015090000029 H8	B	6	The Testosterone CLIA Microparticles assay and AutoLumo Testosterone Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative

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						determination of Testosterone concentration in human serum. Testosterone is used as an aid in the diagnosis of precocious puberty and hypogonadism in men, and hypertrichosis and menstrual abnormalities in women.
53	LH CLIA Microparticles	CMF0101/ CMF0102/ CMF0103/ CMF0104/ CMF0105/ CMF0106/ CMF0107/ CMF0108/ CMF0109/ CMF0110	697015090000026 H2	B	6	The LH CLIA Microparticles assay and AutoLumo LH Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of LH (Luteinizing Hormone) concentration in human serum. The determination of LH concentration can be used to determine the functional status of pituitary and gonad, which is of great significance for the diagnosis and differentiation of many endocrine and gynecological diseases.

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54	FSH CLIA Microparticles	CMF0201/ CMF0202/ CMF0203/ CMF0204/ CMF0205/ CMF0206/ CMF0207/ CMF0208/ CMF0209/ CMF0210	697015090000027 H4	B	6	The FSH CLIA Microparticles assay and AutoLumo FSH Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of FSH (Follicle-Stimulating Hormone) concentration in human serum. FSH is used as an aid in the diagnosis of endocrine disease.
55	PRL CLIA Microparticles	CMF0301/ CMF0302/ CMF0303/ CMF0304/ CMF0305/ CMF0306/ CMF0307/ CMF0308/ CMF0309/ CMF0310	697015090000028 H6	B	6	The PRL CLIA Microparticles assay and AutoLumo PRL Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of PRL (Prolactin) concentration in human serum. The determination of prolactin is utilized in the diagnosis of hyperprolactinemia and other endocrine diseases.

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56	Insulin CLIA Microparticles	CMG0101/ CMG0102/ CMG0103/ CMG0104/ CMG0105/ CMG0106/ CMG0107/ CMG0108/ CMG0109/ CMG0110	697015090000072 H9	C	3 | g	The Insulin CLIA Microparticles assay and AutoLumo Insulin Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative detection of Insulin in human serum. Serum insulin determinations are performed on patients withsymptoms of hypoglycemia and may be useful in classifying the differenttypes of diabetes.
57	C-Peptide CLIA Microparticles	CMG0201/ CMG0202/ CMG0203/ CMG0204/ CMG0205/ CMG0206/ CMG0207/ CMG0208/ CMG0209/ CMG0210	697015090000073 HB	C	3 | g	The C-Peptide CLIA Microparticles assay and AutoLumo C-Peptide Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative detection of C-Peptide in human serum. The assay is intended for use as an aid in the diagnosis and management of patients with abnormal insulin secretion.

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58	cTnI CLIA Microparticles	CMH0201/ CMH0202/ CMH0203/ CMH0204/ CMH0205/ CMH0206/ CM0207/ CMH0208/ CMH0209/ CMH0210	697015090000036 H5	C	3 | j	The cTnI CLIA Microparticles assay and AutoLumo cTnI Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative de-termination of cardiac troponin I (cTnI) concentration in human serum and plasma (heparin or sodium citrate). CTnI is an important marker for the diagnosis of myocardial injury, especially acute myocardial infarction.
59	MYO CLIA Microparticles	CMH0101/ CMH0102/ CMH0103/ CMH0104/ CMH0105/ CMH0106/ CMH0107/ CMH0108/ CMH0109/ CMH0110	697015090000035 H3	C	3 | j	The MYO CLIA Microparticles assay and AutoLumo MYO Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Myoglobin (MYO) concentration in human serum and plasma (EDTA, heparin or sodium citrate). MYO is an important marker for the diagnosis of myocardial injury, especially acute myocardial infarction.

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60	AMH CLIA Microparticles	CMS0501/ CMS0502/ CMS0503/ CMS0504/ CMS0505/ CMS0506/ CMS0507/ CMS0508/ CMS0509/ CMS0510	697015090000047 HA	B	6	The AMH CLIA Microparticles assay and AutoLumo AMH Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative detection of AMH (Anti-Müllerian Hormone) in human serum. AMH is primarily used to assess ovarian reserve capacity.
61	hs-CRP CLIA Microparticles	CMR0101/ CMR0102/ CMR0103/ CMR0104/ CMR0105/ CMR0106/ CMR0107/ CMR0108/ CMR0109/ CMR0110	697015090000042 GY	C	3 | j	The hs-CRP CLIA Microparticles assay and AutoLumo hs-CRP Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of hs-CRP (high-sensitivity C-Reactive Protein) in human serum and plasma (EDTA, heparin or sodium citrate). CRP levels is correlated with the occurrence and severity of inflammation. CRP measurements can also be useful as an aid in the identification of inflammation caused cardiovascular disease.

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62	PCT CLIA Microparticles	CMR0201/ CMR0202/ CMR0203/ CMR0204/ CMR0205/ CMR0206/ CMR0207/ CMR0208/ CMR0209/ CMR0210	697015090000043 H2	C	3 | j	The PCT CLIA Microparticles assay and AutoLumo PCT Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of PCT (Procalcitonin) in human serum and plasma (heparin, EDTA). PCT is used as an aid in 1) the early detection and dynamic monitoring of clinically relevant bacterial infections; 2) prognosis of sepsis.
63	tPSA CLIA Microparticles	CMB0301/ CMB0302/ CMB0303/ CMB0304/ CMB0305/ CMB0306/ CMB0307/ CMB0308/ CMB0309/ CMB0310	697015090000111 GS	C	3 | h	The tPSA CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of tPSA (total prostatic specific antigen) in human serum. tPSA is a aid for diagnostic of patients with prostatitis or trauma, prostate cancer, or prostate treatment.

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64	fPSA CLIA Microparticles	CMB0501/ CMB0502/ CMB0503/ CMB0504/ CMB0505/ CMB0506/ CMB0507/ CMB0508/ CMB0509/ CMB0510	697015090000112 GU	C	3 | h	The fPSA CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of fPSA (free prostatic specific antigen) in human serum. fPSA is a aid for diagnostic of patients with prostatitis or trauma, prostate cancer, or prostate treatment.
65	IL-6 CLIA Microparticle	CMH0501/ CMH0502/ CMH0503/ CMH0504/ CMH0505/ CMH0506/ CMH0507/ CMH0508/ CMH0509/ CMH0510	697015090000044 H4	C	3 | j	The IL-6 CLIA Microparticles assay and AutoLumo IL-6 Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Interleukin-6 (IL-6) in human serum and plasma (EDTA). Clinical determination of Interleukin-6 is useful in monitoring the response of systemic inflammatory response syndrome (SIRS) and sepsis. The device is an automated device used for patients suspected

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						with inflammatory response syndrome, and it is for professional laboratory use.
66	BNP CLIA Microparticles	CMH0801/ CMH0802/ CMH0803/ CMH0804/ CMH0805/ CMH0806/ CMH0807/ CMH0808/ CMH0809/ CMH0810	697015090000082 HC	C	3 | g	The BNP CLIA Microparticles assay and AutoLumo BNP Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative de-termination of B-type natriureticpeptide (BNP) concentration in human plasma. BNP is used in the diagnosis, differentiation, risk stratification and prognosis evaluation of heart failure.
67	AutoLumo Insulin Calibrators	CA090101/ CA090102/ CA090103/ CA090104	697015090000072 H9	C	3 | g	AutoLumo Insulin Calibrators are used for calibrating the quantitative Insulin CLIA Microparticles assay on Autolumo immunoassay analyzers
68	AutoLumo C-Peptide Calibrators	CA090201/ CA090202/ CA090203/ CA090204	697015090000073 HB	C	3 | g	AutoLumo C-Peptide Calibrators are used for calibrating the quantitative C-Peptide

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						CLIA Microparticles assay on Autolumo immunoassay analyzers
69	AutoLumo BNP Calibrators	CA100101/ CA100102/ CA100103/ CA100104	697015090000082 HC	C	3 | g	AutoLumo BNP Calibrators are used for calibrating the quantitative BNP CLIA Microparticles assay on Autolumo immunoassay analyzers
70	AutoLumo cTnI Calibrators	CA100201/ CA100202/ CA100203/ CA100204	697015090000036 H5	C	3 | j	AutoLumo cTnI Calibrators are used for calibrating the quantitative cTnI CLIA Microparticles assay on Autolumo immunoassay analyzers
71	AutoLumo MYO Calibrators	CA100501/ CA100502/ CA100503/ CA100504	697015090000035 H3	C	3 | j	AutoLumo MYO Calibrators are used for calibrating the quantitative MYO CLIA Microparticles assay on Autolumo immunoassay analyzers
72	AutoLumo hs-CRP Calibrators	CA100301/ CA100302/ CA100303/ CA100304	697015090000042 GY	C	3 | j	AutoLumo hs-CRP Calibrators are used for calibrating the quantitative hs-CRP CLIA Microparticles assay on Autolumo immunoassay analyzers
73	AutoLumo PCT Calibrators	CA100601/ CA100602/ CA100603/ CA100604	697015090000043 H2	C	3 | j	AutoLumo PCT Calibrators are used for calibrating the quantitative PCT CLIA Microparticles assay on Autolumo immunoassay analyzers
74	AutoLumo IL-6 Calibrators	CA100401/ CA100402/ CA100403/ CA100404	697015090000044 H4	C	3 | j	AutoLumo IL-6 Calibrators are used for calibrating the quantitative IL-6 CLIA Microparticles assay on Autolumo immunoassay

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						analyzers
75	AutoLumo AMH Calibrators	CA050301/ CA050302/ CA050303/ CA050304	697015090000047 HA	B	6	AutoLumo AMH Calibrators are used for calibrating the quantitative AMH CLIA Microparticles assay on Autolumo immunoassay analyzers
76	AutoLumo E2 Calibrators	CA080101/ CA080102/ CA080103/ CA080104	697015090000030 GR	B	6	AutoLumo E2 Calibrators are used for calibrating the quantitative E2 CLIA Microparticles assay on Autolumo immunoassay analyzers
77	AutoLumo PRG Calibrators	CA080201/ CA080202/ CA080203/ CA080204	697015090000031 GT	B	6	AutoLumo PRG Calibrators are used for calibrating the quantitative PRG CLIA Microparticles assay on Autolumo immunoassay analyzers
78	AutoLumo Testosterone Calibrators	CA080301/ CA080302/ CA080303/ CA080304	697015090000029 H8	B	6	AutoLumo Testosterone Calibrators are used for calibrating the quantitative Testosterone CLIA Microparticles assay on Autolumo immunoassay analyzers
79	AutoLumo LH Calibrators	CA080401/ CA080402/ CA080403/ CA080404	697015090000026 H2	B	6	AutoLumo LH Calibrators are used for calibrating the quantitative LH CLIA Microparticles assay on Autolumo immunoassay analyzers
80	AutoLumo FSH Calibrators	CA080501/ CA080502/ CA080503/ CA080504	697015090000027 H4	B	6	AutoLumo FSH Calibrators are used for calibrating the quantitative FSH CLIA Microparticles assay on Autolumo immunoassay analyzers

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81	AutoLumo PRL Calibrators	CA080601/ CA080602/ CA080603/ CA080604	697015090000028 H6	B	6	AutoLumo PRL Calibrators are used for calibrating the quantitative PRL CLIA Microparticles assay on Autolumo immunoassay analyzers
82	AutoLumo tPSA Calibrators	CA061301/ CA061302/ CA061303/ CA061304	697015090000111 GS	C	3 | h	AutoLumo tPSA Calibrators are used for calibrating the quantitative tPSA CLIA Microparticles assay on Autolumo immunoassay analyzers.
83	AutoLumo fPSA Calibrators	CA061401/ CA061402/ CA061403/ CA061404	697015090000112 GU	C	3 | h	AutoLumo fPSA Calibrators are used for calibrating the quantitative fPSA CLIA Microparticles assay on Autolumo immunoassay analyzers.
84	CEA CLIA Microparticles	CMB0201 / CMB0202 / CMB0203 / CMB0204/ CMB0205/ CMB0206/ CMB0207/ CMB0208/ CMB0209/ CMB0210	697015090000007 GW	C	3 | h	The CEA CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CEA (carcinoembryonic antigen) in human serum. Clinical determination of CEA is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of tumors in digestive system, respiratory system, reproductive system and

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						urinary system.
85	AutoLumo CEA Calibrators	CA060601/ CA060602/ CA060603/ CA060604	697015090000007 GW	C	3 | h	AutoLumo CEA Calibrators are used for calibrating the quantitative CEA CLIA Microparticles assay on Autolumo immunoassay analyzers.
86	CA125 CLIA Microparticles	CMB0601 / CMB0602 / CMB0603 / CMB0604/ CMB0605/ CMB0606/ CMB0607/ CMB0608/ CMB0609/ CMB0610	697015090000008 GY	C	3 | h	The CA125 CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CA125 (Carbohydrate Antigen 125) in human serum. Clinical determination of CA125 is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of ovarian cancer.
87	AutoLumo CA125 Calibrators	CA060501/ CA060502/ CA060503/ CA060504	697015090000008 GY	C	3 | h	AutoLumo CA125 Calibrators are used for calibrating the quantitative CA125 CLIA Microparticles assay on Autolumo immunoassay analyzers.

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88	NSE CLIA Microparticles	CMB1101 / CMB1102 / CMB1103 / CMB1104/ CMB1105/ CMB1106/ CMB1107/ CMB1108/ CMB1109/ CMB1110	697015090000013 GR	C	3 | h	The NSE CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of NSE (Neuron Specific Enolase) in human serum. Clinical determination of NSE is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of diseases including neuroblastoma and small cell lung cancers.
89	AutoLumo NSE Calibrators	CA061201/ CA061202/ CA061203/ CA061204	697015090000013 GR	C	3 | h	AutoLumo NSE Calibrators are used for calibrating the quantitative NSE CLIA Microparticles assay on Autolumo immunoassay analyzers.
90	AFP CLIA Microparticles	CMB0101 / CMB0102 / CMB0103 / CMB0104/ CMB0105/ CMB0106/ CMB0107/ CMB0108/ CMB0109/ CMB0110	697015090000006 GU	C	3 | h	The AFP CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of AFP (alpha-fetoprotein) in human serum. Clinical determination of AFP is used as an aid to

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						diagnose hepatocellular carcinoma. It is not intended for prenatal screening use.
91	AutoLumo AFP Calibrators	CA060701/ CA060702/ CA060703/ CA060704	697015090000006 GU	C	3 | h	AutoLumo AFP Calibrators are used for calibrating the quantitative AFP CLIA Microparticles assay on Autolumo immunoassay analyzers.
92	Ferritin CLIA Microparticles	CMB0901 / CMB0902 / CMB0903 / CMB0904/ CMB0905/ CMB0906/ CMB0907/ CMB0908/ CMB0909/ CMB0910	697015090000011 GM	C	3 | h	The Ferritin CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Ferritin in human serum. Clinical determination of Ferritin is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of diseases including hepatoma and iron-deficiency anemia.
93	AutoLumo Ferritin Calibrators	CA060901/ CA060902/ CA060903/ CA060904	697015090000011 GM	C	3 | h	AutoLumo Ferritin Calibrators are used for calibrating the quantitative Ferritin CLIA Microparticles assay on Autolumo immunoassay analyzers.

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94	β2-Microglobulin CLIA Microparticles	CMB1001 / CMB1002 / CMB1003 / CMB1004/ CMB1005/ CMB1006/ CMB1007/ CMB1008/ CMB1009/ CMB1010	697015090000012 GP	B	6	The β2-Microglobulin CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of β2-Microglobulin in human serum. Clinical determination of β2-Microglobulin is used as an aid of kidney diseases diagnose, which relates to glomerular filtration and renal tubular reabsorption. It cannot be used for the diagnosis of tumor diseases.
95	AutoLumo β2-Microglobulin Calibrators	CA061101/ CA061102/ CA061103/ CA061104	697015090000012 GP	B	6	AutoLumo β2-Microglobulin Calibrators are used for calibrating the quantitative β2-Microglobulin CLIA Microparticles assay on Autolumo immunoassay analyzers.
96	SCCA CLIA Microparticles	CMB1301 / CMB1302 / CMB1303 / CMB1304/ CMB1305/ CMB1306/ CMB1307/ CMB1308/ CMB1309/ CMB1310	697015090000014 GT	C	3 | h	The SCCA CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of SCCA (squamous cell carcinoma

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						antigen) in human serum. Clinical determination of SCCA is used as for dynamic monitoring of patients, which acts as an aid of disease progression
97	AutoLumo SCCA Calibrators	CA060801/ CA060802/ CA060803/ CA060804	697015090000014 GT	C	3 | h	AutoLumo SCCA Calibrators are used for calibrating the quantitative SCCA CLIA Microparticles assay on Autolumo immunoassay analyzers.
98	CA15-3 CLIA Microparticles	CMB0701 / CMB0702 / CMB0703 / CMB0704/ CMB0705/ CMB0706/ CMB0707/ CMB0708/ CMB0709/ CMB0710	697015090000009 H2	C	3 | h	The CA15-3 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CA15-3 (Carbohydrate Antigen 15-3) in human serum. Clinical determination of CA15-3 is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of breast cancer.
99	AutoLumo CA15-3 Calibrators	CA060101/ CA060102/ CA060103/ CA060104	697015090000009 H2	C	3 | h	AutoLumo CA15-3 Calibrators are used for calibrating the quantitative CA15-3 CLIA Microparticles assay on Autolumo immunoassay analyzers.

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100	CA72-4 CLIA Microparticles	CMB1401 / CMB1402 / CMB1403 / CMB1404/ CMB1405/ CMB1406/ CMB1407/ CMB1408/ CMB1409/ CMB1410	697015090000015 GV	C	3 | h	The CA72-4 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CA72-4 (Carbohydrate Antigen 72-4) in human serum. Clinical determination of CA72-4 is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of diseases including gastric cancer and ovary cancer.
101	AutoLumo CA72-4 Calibrators	CA060201/ CA060202/ CA060203/ CA060204	697015090000015 GV	C	3 | h	AutoLumo CA72-4 Calibrators are used for calibrating the quantitative CA72-4 CLIA Microparticles assay on Autolumo immunoassay analyzers.
102	CA242 CLIA Microparticles	CMB1701 / CMB1702 / CMB1703 / CMB1704/ CMB1705/ CMB1706/ CMB1707/ CMB1708/ CMB1709/ CMB1710	697015090000016 GX	C	3 | h	The CA242 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CA242 (Carbohydrate Antigen 242) in human serum. Clinical determination

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						of CA242 is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of diseases including digestive tract malignant tumors.
103	AutoLumo CA242 Calibrators	CA060301/ CA060302/ CA060303/ CA060304	697015090000016 GX	C	3 | h	AutoLumo CA242 Calibrators are used for calibrating the quantitative CA242 CLIA Microparticles assay on Autolumo immunoassay analyzers.
104	CA19-9 CLIA Microparticles	CMB0801 / CMB0802 / CMB0803 / CMB0804/ CMB0805/ CMB0806/ CMB0807/ CMB0808/ CMB0809/ CMB0810	697015090000010 GK	C	3 | h	The CA19-9 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CA19-9 (Carbohydrate Antigen 19-9) in human serum. Clinical determination of CA19-9 is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of digestive tract malignant tumors such as pancreas.
105	AutoLumo CA19-9 Calibrators	CA060401/ CA060402/ CA060403/ CA060404	697015090000010 GK	C	3 | h	AutoLumo CA19-9 Calibrators are used for calibrating the quantitative CA19-9 CLIA

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						Microparticles assay on Autolumo immunoassay analyzers.
106	PIVKA-II CLIA Microparticles	CMB2001 / CMB2002 / CMB2003 / CMB2004/ CMB2005/ CMB2006/ CMB2007/ CMB2008/ CMB2009/ CMB2010	697015090000083HE	C	3 | h	The PIVKA-II CLIA Microparticles assay is together are based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of PIVKA-II (Protein Induced by Vitamin K Absence or Antagonist-II) in human serum. Clinical determination of PIVKA-II is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of liver cancer.
107	AutoLumo PIVKA-II Calibrators	CA061001/ CA061002/ CA061003/ CA061004	697015090000083HE	C	3 | h	AutoLumo PIVKA-Ⅱ Calibrators are used for calibrating the quantitative PIVKA-Ⅱ CLIA Microparticles assay on Autolumo immunoassay analyzers.
108	Rubella IgG CLIA Microparticles	CMK0801/ CMK0802/ CMK0803/ CMK0804/ CMK0805	697015090000106GZ	C	3 | e	This Rubella IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Rubella

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						IgG (IgG antibodies to rubella virus) in human serum or plasma. Rubella IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. The device is an automated device and it is for professional laboratory use.
109	Rubella IgM CLIA Microparticles	CMK0301/ CMK0302/ CMK0303/ CMK0304/ CMK0305	697015090000101 GP	C	3 | e	The Rubella IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Rubella IgM (IgM antibodies to Rubella) in human serum or plasma. Rubella IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women.
110	Toxo IgG CLIA Microparticles	CMK0601/ CMK0602/ CMK0603/ CMK0604/ CMK0605	697015090000104 GV	C	3 | e	The Toxo IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Toxo IgG (specific IgG

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						antibodies to Toxoplasma gondii) in human serum or plasma. Toxo IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. It cannot be used for the blood screening.
111	Toxo IgM CLIA Microparticles	CMK0101/ CMK0102/ CMK0103/ CMK0104/ CMK0105	697015090000099 HV	C	3 | e	The Toxo IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Toxo IgM (IgM antibodies to Toxoplasma gondii) in human serum or plasma. Toxo IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. It cannot be used for the blood screening.
112	CMV IgG CLIA Microparticles	CMK0701/ CMK0702/ CMK0703/ CMK0704/ CMK0705	697015090000105 GX	C	3 | e	The CMV IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CMV IgG (specific IgG antibodies to

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						Cytomegalovirus) in human serum or plasma. CMV IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. It cannot be used for the blood screening.
113	CMV IgM CLIA Microparticles	CMK0201/ CMK0202/ CMK0203/ CMK0204/ CMK0205	697015090000100GM	C	3 | e	The CMV IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CMV IgM (specific IgM antibodies to Cytomegalovirus) in human serum or plasma. CMV IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. It cannot be used for the blood screening.
114	HSV-1 IgG CLIA Microparticles	CMK0901/ CMK0902/ CMK0903/ CMK0904/ CMK0905	697015090000107H3	C	3 | e	The HSV-1 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of HSV-1 IgG (IgG antibodies to herpes simplex virus type 1) in human serum

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						or plasma. HSV-1 IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women.
115	HSV-1 IgM CLIA Microparticles	CMK0401/ CMK0402/ CMK0403/ CMK0404/ CMK0405	697015090000102 GR	C	3 | e	The HSV-1 IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of HSV-1 IgM (IgM antibodies to herpes simplex virus type 1) in human serum or plasma. HSV-1 IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women.
116	HSV-2 IgG CLIA Microparticles	CMK1001/ CMK1002/ CMK1003/ CMK1004/ CMK1005	697015090000108 H5	C	3 | e	The HSV-2 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of HSV-2 IgG (IgG antibodies to herpes simplex virus type 2) in human serum or plasma. HSV-2 IgG is used as an aid in the

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						diagnosis of the immune status of an individual, including pre-natal screening of women.
117	HSV-2 IgM CLIA Microparticles	CMK0501/ CMK0502/ CMK0503/ CMK0504/ CMK0505	697015090000103 GT	C	3 | e	The HSV-2 IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of HSV-2 IgM (IgM antibodies to herpes simplex virus type 2) in human serum or plasma. HSV-2 IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women.
118	Mycobacterial Culture Bottle	MC0401/ MC0402/ MC0403	697015090000063 H8	C	3 | c	Mycobacterial Culture Bottle is for the qualitative detection of mycobacteria from sputum specimens on automated analyzers. Clinical determination of Mycobacterial Culture Bottle is used as an aid to diagnosis diseases caused by mycobacteria, such as tuberculosis.

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119	Mycoplasma TIES	M0206	697015090000056HB	C	3 | a	Dehydrated culture medium based assay for the screening, indicative enumeration, identification, typing and antimicrobial susceptibility testing of UP (Ureaplasma parvum), UU (Ureaplasma urealyticum) and MH (Mycoplasma hominis) in human genitourinary tract. This device is intended using on manual.
120	Mycoplasma IES	M0205	697015090000055H9	C	3 | a	Dehydrated culture medium based assay for the screening, indicative enumeration, identification and antimicrobial susceptibility testing of UU (Ureaplasma urealyticum and Ureaplasma parvum) and MH (Mycoplasma hominis) in human genitourinary tract.This device is intended using on manual.
121	Mycoplasma IES Plus	MA06	697015090000081HA	C	3 | a	Dehydrated culture medium based assay for the screening, indicative enumeration, identification and antimicrobial susceptibility testing of UU (Ureaplasma urealyticum and Ureaplasma parvum) and MH (Mycoplasma hominis) in human genitourinary

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						tract.This device is intended using on manual.
122	Anti-TPO CLIA Microparticles	CME0701/ CME0702/ CME0703/ CME0704/ CME0705/ CME0706/ CME0707/ CME0708/ CME0709/ CME0710	697015090000023 GU	B	6	This assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of anti-TPO (antibody to thyroid peroxidase) in human serum. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases.
123	AutoLumo Anti-TPO Calibrators	CA120101/ CA120102/ CA120103/ CA120104	697015090000023 GU	B	6	AutoLumo Anti-TPO Calibrators are used for calibrating the quantitative Anti-TPO CLIA Microparticles assay on Autolumo immunoassay analyzers.
124	TG CLIA Microparticles	CME0801/ CME0802/ CME0803/ CME0804/ CME0805/ CME0806/ CME0807/ CME0808/ CME0809/ CME0810	697015090000024 GW	C	3 | h	The TG CLIA Microparticles assay is used based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative de-termination of TG (Thyroglobulin) in human serum. Elevated TG concentrations have been reported in different

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						thyroid conditions such as Graves' disease, Hashimoto's disease, thyroid adenoma and thyroid carcinoma. It can be used as an aid for the post operative follow up of patients with differentiated thyroid carcinoma (DTC). It can also be helpful to distinguish between sub-acute thyroiditis and factitious thyrotoxicosis.
125	AutoLumo TG Calibrators	CA120301/ CA120302/ CA120303/ CA120304	697015090000024 GW	C	3 | h	AutoLumo TG Calibrators are used for calibrating the quantitative TG CLIA Microparticles assay on Autolumo immunoassay analyzers.
126	PTH CLIA Microparticles	CME0901/ CME0902/ CME0903/ CME0904/ CME0905/ CME0906/ CME0907/ CME0908/ CME0909/ CME0910	697015090000025 GY	B	6	The PTH CLIA Microparticles assay is used based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of PTH in human serum or plasma (EDTA). The determination of PTH is used as an aid in the differential diagnosis of hypercalcemia and hypocalcemia.
127	AutoLumo PTH Calibrators	CA120201/ CA120202/ CA120203/ CA120204	697015090000025 GY	B	6	AutoLumo PTH Calibrators are used for calibrating the quantitative PTH CLIA Microparticles

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						assay on Autolumo immunoassay analyzers.
128	Osteocalcin CLIA Microparticles	CMS0101/ CMS0102/ CMS0103/ CMS0104/ CMS0105/ CMS0106/ CMS0107/ CMS0108/ CMS0109/ CMS0110	697015090000045H6	B	6	The Osteocalcin CLIA Microparticles assay is used based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of osteocalcin in human serum or plasma (EDTA or heparin). The determination of osteocalcin is used for the control of antiresorptives therapeutic efficiency, e.g. for patients with osteoporosis.
129	AutoLumo Osteocalcin Calibrators	CA110101/ CA110102/ CA110103/ CA110104	697015090000045H6	B	6	AutoLumo Osteocalcin Calibrators are used for calibrating the quantitative Osteocalcin CLIA Microparticles assay on Autolumo immunoassay analyzers.
130	25-OH Vitamin D CLIA Microparticles	CMS0401/ CMS0402/ CMS0403/ CMS0404/ CMS0405/ CMS0406/ CMS0407/ CMS0408/ CMS0409/ CMS0410	697015090000075HF	B	6	The 25-OH Vitamin D CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of 25-OH Vitamin D in human serum or plasma (EDTA, heparin

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						and sodium citrate). This assay is to be used as an aid in the assessment of vitamin D sufficiency.
131	AutoLumo 25-OH Vitamin D Calibrators	CA110301/ CA110302/ CA110303/ CA110304	697015090000075 HF	B	6	AutoLumo 25-OH Vitamin D Calibrators are used for calibrating the quantitative 25-OH Vitamin D CLIA Microparticles assay on AutoLumo immunoassay analyzers.
132	Calcitonin CLIA Microparticles	CMS0601/ CMS0602/ CMS0603/ CMS0604/ CMS0605/ CMS0606/ CMS0607/ CMS0608/ CMS0609/ CMS0610	697015090000048 HC	C	3 | h	The Calcitonin CLIA Microparticles assay is used based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of calcitonin in human serum. The calcitonin determination intended to be used as an aid in the diagnosis and management of diseases involving the thyroid gland, including carcinoma in conjunction with other clinical and laboratory findings.
133	AutoLumo Calcitonin Calibrators	CA110201/ CA110202/ CA110203/ CA110204	697015090000048 HC	C	3 | h	AutoLumo Calcitonin Calibrators are used for calibrating the quantitative Calcitonin CLIA Microparticles assay on Autolumo

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						immunoassay analyzers.
134	Cortisol CLIA Microparticles	CMD0301/ CMD0302/ CMD0303/ CMD0304/ CMD0305/ CMD0306/ CMD0307/ CMD0308/ CMD0309/ CMD0310	697015090000020GN	C	3 | j	The Cortisol CLIA Microparticles assay and AutoLumo Cortisol Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Cortisol in human serum, plasma (EDTA) or urine. Clinical determination of Cortisol is used as an aid for the recognition and management of functional disorders of the adrenal gland.
135	AutoLumo Cortisol Calibrators	CA030101/ CA030102/ CA030103/ CA030104	697015090000020GN	C	3 | j	The Cortisol CLIA Microparticles assay and AutoLumo Cortisol Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Cortisol in human serum, plasma (EDTA) or urine. Clinical determination of Cortisol is used as an aid for the

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						recognition and management of functional disorders of the adrenal gland.
136	ACTH CLIA Microparticles	CMD0201/ CMD0202/ CMD0203/ CMD0204/ CMD0205/ CMD0206/ CMD0207/ CMD0208/ CMD0209/ CMD0210	697015090000019H5	B	6	The ACTH CLIA Microparticles assay and AutoLumo ACTH Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for thequantitative determination of ACTH (Adrenocorticotropic Hormone) in human plasma (EDTA). Clinical determination of ACTH is used as an aid 1) to diagnosis and treat of abnormal ACTH secretion of the pituitary; 2) to identify ectopic ACTH which is not secreted by the pituitary; 3)to identify adrenal dysfunction.

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137	AutoLumo ACTH Calibrators	CA030201/ CA030202/ CA030203/ CA030204	697015090000019H5	B	6	The ACTH CLIA Microparticles assay and AutoLumo ACTH Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for thequantitative determination of ACTH (Adrenocorticotropic Hormone) in human plasma (EDTA). Clinical determination of ACTH is used as an aid 1) to diagnosis and treat of abnormal ACTH secretion of the pituitary; 2) to identify ectopic ACTH which is not secreted by the pituitary; 3)to identify adrenal dysfunction.
138	Renin CLIA Microparticles	CMD0401/ CMD0402/ CMD0403/ CMD0404/ CMD0405/ CMD0406/ CMD0407/ CMD0408/ CMD0409/ CMD0410	697015090000021GQ	B	6	The Renin CLIA Microparticles assay and AutoLumo Renin Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Renin in human plasma (EDTA). Clinical determination of Renin is used as an aid 1) to diagnosis of hypertension or

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						renovascular hypertension due to renal artery stenosis; 2) to assist the clinician in deciding whether to conduct renal vascular imaging studies; 3) to diagnosis of primary aldosteronism; 4) to provide effective information for the occurrence of complications of cardiovascular system in patients with essential hypertension.
139	AutoLumo Renin Calibrators	CA030301/ CA030302/ CA030303/ CA030304	697015090000021GQ	B	6	The Renin CLIA Microparticles assay and AutoLumo Renin Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Renin in human plasma (EDTA). Clinical determination of Renin is used as an aid 1) to diagnosis of hypertension or renovascular hypertension due to renal artery stenosis; 2) to assist the clinician in deciding whether to conduct renal vascular imaging studies; 3) to diagnosis

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						of primary aldosteronism; 4) to provide effective information for the occurrence of complications of cardiovascular system in patients with essential hypertension.
140	HGH CLIA Microparticles	CML0201/ CML0202/ CML0203/ CML0204/ CML0205/ CML0206/ CML0207/ CML0208/ CML0209/ CML0210	697015090000040 GU	B	6	The HGH CLIA Microparticles assay and AutoLumo HGH Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of HGH (Human Growth Hormone) concentration in human serum and plasma (Heparin). Clinical determination of HGH is used as an aid to diagnosis of growth-related diseases.
141	AutoLumo HGH Calibrators	CA040101/ CA040102/ CA040103/ CA040104	697015090000040 GU	B	6	The HGH CLIA Microparticles assay and AutoLumo HGH Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system

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						for the quantitative determination of HGH (Human Growth Hormone) concentration in human serum and plasma (Heparin). Clinical determination of HGH is used as an aid to diagnosis of growth-related diseases.
142	IGF-1 CLIA Microparticles	CML0101/ CML0102/ CML0103/ CML0104/ CML0105/ CML0106/ CML0107/ CML0108/ CML0109/ CML0110	697015090000039 HB	B	6	The IGF-1 CLIA Microparticles assay and AutoLumo IGF-1 Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Insulin-like Growth Factor I (IGF-I) concentration in human serum and plasma (Heparin). Clinical determination of IGF-1 is used as an aid 1) as an auxiliary evaluation index for growth disorder; 2) to diagnosis of GH deficiency and overdose; 3) as an indicator of whether the treatment of gigantism and acromegaly is effective.

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143	AutoLumo IGF-1 Calibrators	CA040201/ CA040202/ CA040203/ CA040204	697015090000039 HB	B	6	The IGF-1 CLIA Microparticles assay and AutoLumo IGF-1 Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Insulin-like Growth Factor I (IGF-I) concentration in human serum and plasma (Heparin). Clinical determination of IGF-1 is used as an aid 1) as an auxiliary evaluation index for growth disorder; 2) to diagnosis of GH deficiency and overdose; 3) as an indicator of whether the treatment of gigantism and acromegaly is effective.

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144	17α-OHP CLIA Microparticles	CMF0901/ CMF0902/ CMF0903/ CMF0904/ CMF0905/ CMF0906/ CMF0907/ CMF0908/ CMF0909/ CMF0910	697015090000034 GZ	B	6	The 17α-OHP CLIA Microparticles assay and AutoLumo 17α-OHP Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of 17α-OHP (17α-Hydroxyprogesterone) in human serum.Elevated 17α-OHP level is a specific marker for screening congenital adrenal hyperplasia (CAH) caused by 21-hydroxylase deficiency, and can also be used to monitor drug dose and efficacy.Elevated levels of 17α-OHP were associated with masculinity in infant girls.Rapid physical growth during childhood and adolescence;Delayed menarche, primary amenorrhea and hirsutism in girls;An important indicator of clinical manifestations such as acne, baldness or unexplained infertility in adult men or women.
145	AutoLumo 17α-OHP Calibrators	CA080701/ CA080702/ CA080703/ CA080704	697015090000034 GZ	B	6	AutoLumo 17α-OHP Calibrators are used for calibrating the quantitative 17α-OHP

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						CLIA Microparticles assay on Autolumo immunoassay analyzers
146	DHEA-S CLIA Microparticles	CMF0701/ CMF0702/ CMF0703/ CMF0704/ CMF0705/ CMF0706/ CMF0707/ CMF0708/ CMF0709/ CMF0710	697015090000032 GV	B	6	The DHEA-S CLIA Microparticles assay and AutoLumo DHEA-S Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of DHEA-S (Dehydroepiandrosterone sulfate) in human serum. Measurement of DHEA- S can be useful in the diagnostic work- up of female patients presenting with clinical symptoms of hyperandrogenism.
147	AutoLumo DHEA-S Calibrators	CA080801/ CA080802/ CA080803/ CA080804	697015090000032 GV	B	6	AutoLumo DHEA-S Calibrators are used for calibrating the quantitative DHEA-S CLIA Microparticles assay on Autolumo immunoassay analyzers
148	SHBG CLIA Microparticles	CMF0801/ CMF0802/ CMF0803/ CMF0804/ CMF0805/ CMF0806/ CMF0807/ CMF0808/ CMF0809/ CMF0810	697015090000033 GX	B	6	The SHBG CLIA Microparticles assay and AutoLumo SHBG Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system

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						for the quantitative determination of SHBG (Sex hormone-binding globulin) in human serum. Low SHBG titer can be an important indicator of an excessive/ chronic androgenic action where androgen levels are normal, but where clinical symptoms would seem to indicate androgen in excess.
149	AutoLumo SHBG Calibrators	CA080901/ CA080902/ CA080903/ CA080904	697015090000033GX	B	6	AutoLumo SHBG Calibrators are used for calibrating the quantitative SHBG CLIA Microparticles assay on Autolumo immunoassay analyzers
150	Folate CLIA Microparticles	CMS0201 / CMS0202 / CMS0203 / CMS0204/ CMS0205	697015090000046H8	B	6	The Folate CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of folate concentration in human serum. Clinical determination of Folate is used as an aid 1) to diagnosis of megaloblastic anemia; 2) to diagnosis of hyperhomocysteinemia; 3) to provide advice on nutrition during pregnancy to prevent

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						neonatal nerve duct defects; 4) monitor the adolescent gorwth and development.
151	Vitamin B12 CLIA Microparticles	CMS0301 / CMS0302 / CMS0303 / CMS0304/ CMS0305	697015090000074 HD	B	6	The Vitamin B12 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of Vitamin B12 concentration in human serum. Clinical determination of Vitamin B12 is used as an aid 1) to diagnosis of megaloblastic anemia; 2) to diagnosis of hyperhomocysteinemia; 3) to monitor the development and prognosis of diseases of Alzheimer's disease, depression, and Parkinson's disease, vascular dementia and cognitive impairment; 4) to provide advice on nutrition during pregnancy to prevent neonatal nerve duct defects; 5) monitor the adolescent gorwth and

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						development.
152	tIgE CLIA Microparticles	CMQ0601/ CMQ0602/ CMQ0603/ CMQ0604/ CMQ0605/ CMQ0606/ CMQ0607/ CMQ0608/ CMQ0609/ CMQ0610	697015090000053 H5	B	6	The tIgE CLIA Microparticles assay and AutoLumo tIgE Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of quantitative determination of total IgE in human serum and plasma (EDTA, heparin). Clinical determination of total IgE in serum and plasma is used as an aid to diagnosis of allergic diseases.
153	AutoLumo tIgE Calibrators	CA010101/ CA010102 CA010103/ CA010104	697015090000053 H5	B	6	AutoLumo tIgE Calibrators are used for calibrating the quantitative tIgE CLIA Microparticles assay on Autolumo immunoassay

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						analyzers.
154	β-hCG CLIA Microparticles	CMN0301 / CMN0302 / CMN0303 / CMN0304/ CMN0305/ CMN0306/ CMN0307/ CMN0308/ CMN0309/ CMN0310	697015090000041 GW	C	3 | h	The β-hCG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of β-hCG (β-Human Chorionic Gonadotropin) in human serum. Clinical determination of β-hCG is used for dynamic monitoring of patients, which acts as an aid in early detection and monitoring of pregnancy and aid of disease progression or treatment determination of diseases including ectopic pregnancy and choriocarcinoma. It cannot be used for the diagnosis of Down's syndrome.
155	AutoLumo β-hCG Calibrators	CA070101/ CA070102/ CA070103/ CA070104	697015090000041 GW	C	3 | h	AutoLumo β-hCG Calibrators are used for calibrating the quantitative β-hCG CLIA Microparticles assay on Autolumo immunoassay analyzers.

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156	Anti-SS-A/ Ro IgG CLIA Microparticles	CMQ0701 / CMQ0702 / CMQ0703 / CMQ0704 / CMQ0705/ CMQ0706/ CMQ0707/ CMQ0708/ CMQ0709/ CMQ0710	697015090000305H9	B	6	The Anti-SS-A/ Ro IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-SS-A/ Ro IgG in human serum or plasma. This assay is to be used as an aid in the diagnosis of Sjogren's Syndrome(SS).
157	Anti-Ro-52 IgG CLIA Microparticles	CMQ0801 / CMQ0802 / CMQ0803 / CMQ0804 / CMQ0805/ CMQ0806/ CMQ0807/ CMQ0808/ CMQ0809/ CMQ0810	697015090000306HB	B	6	The Anti-Ro-52 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-Ro-52 IgG in human serum or plasma.This assay is to be used as an aid in the diagnosis of Sjogren's Syndrome(SS).
158	Anti-SS-B IgG CLIA Microparticles	CMQ0901 / CMQ0902 / CMQ0903 / CMQ0904 / CMQ0905/ CMQ0906/ CMQ0907/ CMQ0908/ CMQ0909/ CMQ0910	697015090000307HD	B	6	The Anti-SS-B IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-SS-B IgG in human serum

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						or plasma. This assay is to be used as an aid in the diagnosis of Sjogren's Syndrome(SS) and Systemic Lupus Erythematosus(SLE).
159	Anti-Scl-70 IgG CLIA Microparticles	CMQ1801 / CMQ1802 / CMQ1803 / CMQ1804/ CMQ1805/ CMQ1806/ CMQ1807/ CMQ1808/ CMQ1809/ CMQ1810	697015090000308HF	B	6	The Anti-Scl-70 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-topoisomerase I IgG antibody (anti-Scl-70 IgG) in human serum or plasma. This assay is to be used as an aid in the diagnosis of systemic scleroderma.
160	Anti-Jo-1 IgG CLIA Microparticles	CMQ1901 / CMQ1902 / CMQ1903 / CMQ1904/ CMQ1905/ CMQ1906/ CMQ1907/ CMQ1908/ CMQ1909/ CMQ1910	697015090000309HH	B	6	The Anti-Jo-1 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-histidyl-tRNA synthetase IgG antibody (anti-Jo-1 IgG) in human serum or plasma. This assay is to be used as an aid in the diagnosis of polymyositis/ dermatomyositis (PM/

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						DM).
161	Anti-Sm IgG CLIA Microparticles	CMQ2001 / CMQ2002 / CMQ2003 / CMQ2004/ CMQ2005/ CMQ2006/ CMQ2007/ CMQ2008/ CMQ2009/ CMQ2010	697015090000310H2	B	6	The Anti-Sm IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-Sm IgG in human serum or plasma.This assay is to be used as an aid in the diagnosis of Systemic Lupus Erythematosus(SLE).
162	Anti-nRNP/ Sm IgG CLIA Microparticles	CMQ2101 / CMQ2102 / CMQ2103 / CMQ2104/ CMQ2105/ CMQ2106/ CMQ2107/ CMQ2108/ CMQ2109/ CMQ2110	697015090000311H4	B	6	The Anti-nRNP/ Sm IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-nRNP/ Sm IgG in human serum or plasma.This assay is to be used as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Mixed connective tissue disease (MCTD).

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163	Anti-Ribosomal P IgG CLIA Microparticles	CMQ2201 / CMQ2202 / CMQ2203 / CMQ2204/ CMQ2205/ CMQ2206/ CMQ2207/ CMQ2208/ CMQ2209/ CMQ2210	697015090000312H6	B	6	The Anti-Ribosomal P IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-Ribosomal P IgG in human serum or plasma.This assay is to be used as an aid in the diagnosis of the mental symptoms and disease activity of neuropsychiatric lupus.
164	Anti-PR3 IgG CLIA Microparticles	CMQ1501 / CMQ1502 / CMQ1503 / CMQ1504/ CMQ1505/ CMQ1506/ CMQ1507/ CMQ1508/ CMQ1509/ CMQ1510	697015090000313H8	B	6	The Anti-PR3 IgG CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-neutrophil cytoplasmic proteinase 3 (Anti-PR3) IgG in human serum or plasma. This assay is to be used as an aid in the diagnosis of Granulomatous polyvasculitis (GPA).
165	Anti-MPO IgG CLIA Microparticles	CMQ1601 / CMQ1602 / CMQ1603 / CMQ1604/ CMQ1605/ CMQ1606/ CMQ1607/ CMQ1608/	697015090000314HA	B	6	The Anti-MPO IgG CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative

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		CMQ1609/ CMQ1610				determination of anti-neutrophil cytoplasmic myeloperoxidase (Anti-MPO) IgG in human serum. This assay is to be used as an aid in the diagnosis of Systemic small vasculitis (SSV).
166	Anti-GBM IgG CLIA Microparticles	CMQ1701 / CMQ1702 / CMQ1703 / CMQ1704/ CMQ1705/ CMQ1706/ CMQ1707/ CMQ1708/ CMQ1709/ CMQ1710	697015090000315 HC	B	6	This Anti-GBM IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-glomerular basement membrane (Anti-GBM) IgG in human serum or plasma. This assay is to be used as an aid in the diagnosis of pulmonary hemorrhage nephritis syndrome (Goodpasture's syndrome), acute glomerulonep
167	AMA-M2 IgG CLIA Microparticles	CMQ2401/ CMQ2402/ CMQ2403/ CMQ2404/ CMQ2405/ CMQ2406/ CMQ2407/ CMQ2408/ CMQ2409/ CMQ2410	697015090000316 HE	B	6	The AMA-M2 IgG CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of AMA-M2 IgG in human serum and plasma. This assay is to be used as an aid in the diagnosis of primary biliary

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						cholangitis(PBC).
168	Anti-gp210 IgG CLIA Microparticles	CMQ2501/ CMQ2502/ CMQ2503/ CMQ2504/ CMQ2505/ CMQ2506/ CMQ2507/ CMQ2508/ CMQ2509/ CMQ2510	697015090000317 HG	B	6	The Anti-gp210 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-gp210 IgG in human serum and plasma. This assay is to be used as an aid in the diagnosis of primary biliary cholangitis(PBC).
169	Anti-sp100 IgG CLIA Microparticles	CMQ2601/ CMQ2602/ CMQ2603/ CMQ2604/ CMQ2605/ CMQ2606/ CMQ2607/ CMQ2608/ CMQ2609/ CMQ2610	697015090000318 HJ	B	6	This Anti-sp100 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of anti-sp100 IgG in human serum and plasma. This assay is to be used as an aid in the diagnosis of primary biliary cholangitis (PBC).

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170	GADA CLIA Microparticles	CMQ2701/ CMQ2702/ CMQ2703/ CMQ2704/ CMQ2705/ CMQ2706/ CMQ2707/ CMQ2708/ CMQ2709/ CMQ2710	697015090000319 HL	C	Rule 3 | g	The GADA CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Glutamic acid decarboxylase antibody(GADA) in human serum and plasma. This assay is to be used as an aid in the diagnosis of type 1 diabetes.
171	IAA CLIA Microparticles	CMQ2801/ CMQ2802/ CMQ2803/ CMQ2804/ CMQ2805/ CMQ2806/ CMQ2807/ CMQ2808/ CMQ2809/ CMQ2810	697015090000320 H5	C	Rule 3 | g	The IAA CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-insulin antibody (IAA) in human serum. This assay is to be used as an aid in the diagnosis of autoimmune diabetes mellitus, especially type 1 diabetes mellitus (T1DM) in children.
172	ICA CLIA Microparticles	CMQ3901/ CMQ3902/ CMQ3903/ CMQ3904/ CMQ3905/ CMQ3906/ CMQ3907/ CMQ3908/	697015090000374 HU	C	Rule 3 | g	The ICA CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system

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		CMQ3909/ CMQ3910				for the qualitative determination of ICA in human serum and plasma. This assay is to be used as an aid in the diagnosis of type I diabetes.
173	IA-2A CLIA Microparticles	CMQ3801/ CMQ3802/ CMQ3803/ CMQ3804/ CMQ3805/ CMQ3806/ CMQ3807/ CMQ3808/ CMQ3809/ CMQ3810	697015090000373 HS	C	Rule 3 | g	The IA-2A CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of IA-2A in human serum and plasma. This assay is to be used as an aid in the diagnosis of type I diabetes.
174	AutoLumo Anti-SS-A/ Ro IgG Calibrators	CA010801/ CA010802/ CA010803/ CA010804	697015090000305 H9	B	6	AutoLumo Anti-SS-A/ Ro IgG Calibrators are used for calibrating the quantitative Anti-SS-A/ Ro IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
175	AutoLumo Anti-Ro-52 IgG Calibrators	CA010901/ CA010902/ CA010903/ CA010904	697015090000306 HB	B	6	AutoLumo Anti-Ro-52 IgG Calibrators are used for calibrating the quantitative Anti-Ro-52 IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
176	AutoLumo Anti-SS-B IgG Calibrators	CA011001/ CA011002/ CA011003/ CA011004	697015090000307 HD	B	6	AutoLumo Anti-SS-B IgG Calibrators are used for calibrating the quantitative Anti-SS-B IgG CLIA Microparticles

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						assay on Autolumo immunoassay analyzers.
177	AutoLumo Anti-Scl-70 IgG Calibrators	CA011201/ CA011202/ CA011203/ CA011204	697015090000308 HF	B	6	AutoLumo Anti-Scl-70 IgG Calibrators are used for calibrating the quantitative Anti-Scl-70 IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
178	AutoLumo Anti-Jo-1 IgG Calibrators	CA011301/ CA011302/ CA011303/ CA011304	697015090000309 HH	B	6	AutoLumo Anti-Jo-1 IgG Calibrators are used for calibrating the quantitative Anti-Jo-1 IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
179	AutoLumo Anti-Sm IgG Calibrators	CA011401/ CA011402/ CA011403/ CA011404	697015090000310 H2	B	6	AutoLumo Anti-Sm IgG Calibrators are used for calibrating the quantitative Anti-Sm IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
180	AutoLumo Anti-nRNP/ Sm IgG Calibrators	CA011501/ CA011502/ CA011503/ CA011504	697015090000311 H4	B	6	AutoLumo Anti-nRNP/ Sm IgG Calibrators are used for calibrating the quantitative Anti-nRNP/ Sm IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
181	AutoLumo Anti-Ribosomal P IgG Calibrators	CA011601/ CA011602/ CA011603/ CA011604	697015090000312 H6	B	6	AutoLumo Anti-Ribosomal P IgG Calibrators are used for calibrating the quantitative Anti-Ribosomal P IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.

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182	AutoLumo Anti-PR3 IgG Calibrators	CA011701/ CA011702/ CA011703/ CA011704	697015090000313 H8	B	6	AutoLumo Anti-PR3 IgG Calibrators are used for calibrating the quantitative Anti-PR3 IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
183	AutoLumo Anti-MPO IgG Calibrators	CA011801/ CA011802/ CA011803/ CA011804	697015090000314 HA	B	6	AutoLumo Anti-MPO IgG Calibrators are used for calibrating the quantitative Anti-MPO IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
184	AutoLumo Anti-GBM IgG Calibrators	CA011901/ CA011902/ CA011903/ CA011904	697015090000315 HC	B	6	AutoLumo Anti-GBM IgG Calibrators are used for calibrating the quantitative Anti-GBM IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
185	AutoLumo AMA-M2 IgG Calibrators	CA012001/ CA012002/ CA012003/ CA012004	697015090000316 HE	B	6	AutoLumo AMA-M2 IgG Calibrators are used for calibrating the quantitative AMA-M2 IgG CLIA Microparticles assay on AutoLumo immunoassay analyzers.
186	AutoLumo Anti-gp210 IgG Calibrators	CA012101/ CA012102/ CA012103/ CA012104	697015090000317 HG	B	6	AutoLumo Anti-gp210 IgG Calibrators are used for calibrating the quantitative Anti-gp210 IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
187	AutoLumo Anti-sp100 IgG Calibrators	CA012201/ CA012202/ CA012203/ CA012204	697015090000318 HJ	B	6	AutoLumo Anti-sp100 IgG Calibrators are used for calibrating the quantitative Anti-sp100 IgG CLIA Microparticles assay on AutoLumo immunoassay analyzers.

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188	AutoLumo GADA Calibrators	CA012301/ CA012302/ CA012303/ CA012304	697015090000319 HL	C	Rule 3 | g	AutoLumo GADA Calibrators are used for calibrating the quantitative GADA CLIA Microparticles assay on Autolumo immunoassay analyzers.
189	AutoLumo IAA Calibrators	CA012401/ CA012402/ CA012403/ CA012404	697015090000320 H5	C	Rule 3 | g	AutoLumo IAA Calibrators are used for calibrating the quantitative IAA CLIA Microparticles assay on Autolumo immunoassay analyzers.
190	AutoLumo ICA Calibrators	CA013601/ CA013602/ CA013603/ CA013604	697015090000374 HU	C	Rule 3 | g	AutoLumo ICA Calibrators are used for calibrating the qualitative ICA CLIA Microparticles assay on AutoLumo immunoassay analyzers.
191	AutoLumo IA-2A Calibrators	CA013501/ CA013502/ CA013503/ CA013504	697015090000373 HS	C	Rule 3 | g	AutoLumo IA-2A Calibrators are used for calibrating the quantitative IA-2A CLIA Microparticles assay on AutoLumo immunoassay analyzers.
192	Tumor Marker Control II	ZKM0101/ ZKM0102/ ZKM0201/ ZKM0202/ ZKM0301/ ZKM0302/ ZKM0501	697015090000079 HP	C	3h	This product is intended for use as an assayed quality control to monitor the precision of tumor markers, the specified analytes are: AFP, CEA, CA125, CA19-9, CA15-3, CA50, tPSA, fPSA, Ferritin, CA72-4, NSE, SCCA, Cyfra 21-1, CA242, HE4, PGI, PGII, β 2-Microglobulin, β-HCG and TG.

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193	ToRCH IgG Control	ZKA0101/ ZKA0201/ ZKA0301/ ZKA0401/ ZKA0102/ ZKA0202/ ZKA0302/ ZKA0402	697015090000358 HW	C	3e	This product is intended for use as an assayed quality control to monitor the precision of ToRCH IgG, the specified analytes are: Toxoplasma gondii IgG, Cytomegalovirus (CMV) IgG, Rubella IgG, Herpes Simples Virus Type 1 (HSV-1) IgG, Herpes Simples Virus Type 2 (HSV-2) IgG.
194	ToRCH IgM Control	ZKB0101/ ZKB0201/ ZKB0301/ ZKB0401/ ZKB0102/ ZKB0202/ ZKB0302/ ZKB0402	697015090000359 HY	C	3e	This product is intended for use as an assayed quality control to monitor the precision of ToRCH IgM, the specified analytes are: Toxoplasma gondii IgM, Cytomegalovirus (CMV) IgM, Rubella IgM, Herpes Simples Virus Type 1 (HSV-1) IgM, Herpes Simples Virus Type 2 (HSV-2) IgM.
195	AMH Control	ZK0101L104/ ZK0101L101/ ZK0101L102/ ZK0101L103/ ZK0101L201/ ZK0101L202/ ZK0101L203/	697015090000353 HL	B	6	This product is intended for use as an assayed quality control to monitor the precision of AMH (anti-mullerian hormone).

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		ZK0101L204/ ZK0101L301/ ZK0101L302/ ZK0101L303/ ZK0101L304/ ZK0101L401				
196	Thyroid Speciality Control	ZK0501L101/ ZK0501L102/ ZK0501L103/ ZK0501L104/ ZK0501L105/ ZK0501L106/ ZK0501L107/ ZK0501L201/ ZK0501L202/ ZK0501L203/ ZK0501L204/ ZK0501L205/ ZK0501L206/ ZK0501L207/ ZK0501L30	697015090000130GW	B	6	This product is intended for use as an assayed quality control to monitor the precision of thyroid, the specified analytes are: thyroglobulin antibodies(TgAb), thyroid peroxidase antibody (TPOAb), rT3 and thyrotropin receptor antibody (TRAb).

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		1/ ZK0501L30 2/ ZK0501L30 3/ ZK0501L30 4/ ZK0501L30 5/ ZK0501L30 6/ ZK0501L30 7/ ZK0501L40 1/ ZK0501L40 2/ ZK0501L40 3/ ZK0501L40 4/ ZK0501L40 5/ ZK0501L40 6				
197	Autoimmune Marker Control I	ZKE010101 / ZKE010102 / ZKE010103 / ZKE010104 / ZKE010105 / ZKE010201 / ZKE010202 / ZKE010203	697015090000127 H9	B	6	This product is intended for use as an assayed quality control to monitor the precision of autoimmune maker, the specified analytes are: ANA IgG, Anti-dsDNA IgG, and Anti-CCP IgG.

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		/ ZKE010204 / ZKE010205 / ZKE010301 / ZKE010302 / ZKE010303 / ZKE010304 / ZKE010305				
198	Cardiac Markers Control	ZKD0107/ ZKD0207/ ZKD0307/ ZKD0108/ ZKD0208/ ZKD0308/ ZKD0109/ ZKD0209/ ZKD0309/ ZKD0105/ ZKD0205/ ZKD0305/ ZKD0405/ ZKD0406	697015090000354 HN	C	3j	This product is intended for use as an assayed quality control to monitor the precision of cardiac markers, the specified analytes are CK-MB, cTnI, cTnT, hs-CRP, BNP, NT-proBNP, H-FABP and MYO.
199	Endocrine Control II	ZKE0101/ ZKE0201/ ZKE0301/ ZKE0102/ ZKE0202/ ZKE0302/ ZKE0403	697015090000078 HM	C	3j	This product is intended for use as an assayed quality control to monitor the precision of endocrine substances, the specified analytes are: PRL, LH, FSH, Progesterone, Testosterone, E2, TSH, T3, T4, TG, FT3, FT4, C-Peptide, Insulin, IGF-1, HGH, β-HCG, ACTH, Cortisol, 17α-OHP,

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						DHEA-S, Vitamin B12, Folate, 25-OH Vitamin D and ALD.
200	Inflammation Markers Control	ZK0401L101/ ZK0401L201/ ZK0401L301/ ZK0401L102/ ZK0401L202/ ZK0401L302/ ZK0401L103/ ZK0401L203/ ZK0401L303/ ZK0401L104/ ZK0401L204/ ZK0401L304/ ZK0401L401/ ZK0401L402	697015090000355HQ	C	3e	This product is intended for use as an assayed quality control to monitor the precision of inflammation markers, the specified analytes are: Procalcitonin(PCT), C-reaction protein(CRP) and Interleukin-6(IL-6).
201	AutoLumo sIgE Calibrators	CA010301/ CA010302/ CA010303	697015090000255HK	B	6	The AutoLumo sIgE Calibrators is used for calibrating the quantitative albumen-specific IgE assay on Autolumo immunoassay analyzers.

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202	d1 CLIA Microparticles	CMQA0101/ CMQA0102/ CMQA0103/ CMQA0104/ CMQA0105/ CMQA0106/ CMQA0107	697015090000232H7	B	6	The d1 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum d1 IgE is used as an aid to diagnosis of dermatophagoides pteronyssinus allergy.
203	d2 CLIA Microparticles	CMQA0201/ CMQA0202/ CMQA0203/ CMQA0204/ CMQA0205/ CMQA0206/ CMQA0207	697015090000233H9	B	6	The d2 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum d2 IgE is used as an aid to diagnosis of dermatophagoides farinae allergy.
204	e1 CLIA Microparticles	CMQA0301/ CMQA0302/ CMQA0303/ CMQA0304/ CMQA0305/ CMQA0306/ CMQA0307	697015090000234HB	B	6	The e1 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system

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						for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum e1 IgE is used as an aid to diagnosis of cat dander allergy.
205	e5 CLIA Microparticles	CMQA0401/ CMQA0402/ CMQA0403/ CMQA0404/ CMQA0405/ CMQA0406/ CMQA0407	697015090000235 HD	B	6	The e5 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum e5 IgE is used as an aid to diagnosis of dog dander allergy.
206	h1 CLIA Microparticles	CMQA1601/ CMQA1602/ CMQA1603/ CMQA1604/ CMQA1605/ CMQA1606/ CMQA1607	697015090000247 HL	B	6	The h1 CLIA Microparticles assay is based on fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum h1 IgE is used as an aid to diagnosis of house dust allergy.

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207	m6 CLIA Microparticles	CMQA1901/ CMQA1902/ CMQA1903/ CMQA1904/ CMQA1905/ CMQA1906/ CMQA1907	697015090000250H9	B	6	The m6 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum m6 IgE is used as an aid to diagnosis of alternaria alternata allergy.
208	w6 CLIA Microparticles	CMQA2301/ CMQA2302/ CMQA2303/ CMQA2304/ CMQA2305/ CMQA2306/ CMQA2307	697015090000254HH	B	6	The w6 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum w6 IgE is used as an aid to diagnosis of mugwort allergy.
209	w1 CLIA Microparticles	CMQA2201/ CMQA2202/ CMQA2203/ CMQA2204/ CMQA2205/ CMQA2206/ CMQA2207	697015090000253HF	B	6	The w1 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical

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						determination of serum w1 IgE is used as an aid to diagnosis of common ragweed allergy.
210	i6 CLIA Microparticles	CMQA1701/ CMQA1702/ CMQA1703/ CMQA1704/ CMQA1705/ CMQA1706/ CMQA1707	697015090000248 HN	B	6	The i6 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum i6 IgE is used as an aid to diagnosis of cockroach allergy.
211	t12 CLIA Microparticles	CMQA2101/ CMQA2102/ CMQA2103/ CMQA2104/ CMQA2105/ CMQA2106/ CMQA2107	697015090000252 HD	B	6	The t12 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum t12 IgE is used as an aid to diagnosis of willow allergy.
212	m3 CLIA Microparticles	CMQA1801/ CMQA1802/ CMQA1803/ CMQA1804/ CMQA1805/ CMQA1806/	697015090000249 HQ	B	6	The m3 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA

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		CMQA1807				Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum m3 IgE is used as an aid to diagnosis of aspergillus fumigatus allergy.
213	t3 CLIA Microparticles	CMQA2001/ CMQA2002/ CMQA2003/ CMQA2004/ CMQA2005/ CMQA2006/ CMQA2007	697015090000251 HB	B	6	The t3 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum t3 IgE is used as an aid to diagnosis of Common silver birch allergy.
214	w22 CLIA Microparticles	CMQA2401/ CMQA2402/ CMQA2403/ CMQA2404/ CMQA2405/ CMQA2406/ CMQA2407	697015090000365 HT	B	6	The w22 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum w22 is used as an aid to diagnosis of humulus scandens allergy.

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215	f23 CLIA Microparticles	CMQA1201/ CMQA1202/ CMQA1203/ CMQA1204/ CMQA1205/ CMQA1206/ CMQA1207	697015090000243 HC	B	6	The f23 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f23 IgE is used as an aid to diagnosis of crab allergy.
216	f24 CLIA Microparticles	CMQA1301/ CMQA1302/ CMQA1303/ CMQA1304/ CMQA1305/ CMQA1306/ CMQA1307	697015090000244 HE	B	6	The f24 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f24 IgE is used as an aid to diagnosis of shrimp allergy.
217	f27 CLIA Microparticles	CMQA1401/ CMQA1402/ CMQA1403/ CMQA1404/ CMQA1405/ CMQA1406/ CMQA1407	697015090000245 HG	B	6	The f27 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of

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						albumen-specific IgE in human serum. Clinical determination of serum f27 IgE is used as an aid to diagnosis of beef allergy.
218	f88 CLIA Microparticles	CMQA1501/ CMQA1502/ CMQA1503/ CMQA1504/ CMQA1505/ CMQA1506/ CMQA1507	697015090000246 HJ	B	6	The f88 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f88 IgE is used as an aid to diagnosis of mutton allergy.
219	f3 CLIA Microparticles	CMQA0701/ CMQA0702/ CMQA0703/ CMQA0704/ CMQA0705/ CMQA0706/ CMQA0707	697015090000238 HK	B	6	The f3 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f3 IgE is used as an aid to diagnosis of fish(cob) allergy.

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220	f13 CLIA Microparticles	CMQA1001/ CMQA1002/ CMQA1003/ CMQA1004/ CMQA1005/ CMQA1006/ CMQA1007	697015090000241 H8	B	6	The f13 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f13 IgE is used as an aid to diagnosis of peanut allergy.
221	f14 CLIA Microparticles	CMQA1101/ CMQA1102/ CMQA1103/ CMQA1104/ CMQA1105/ CMQA1106/ CMQA1107	697015090000242 HA	B	6	The f14 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f14 IgE is used as an aid to diagnosis of soybean allergy.
222	f1 CLIA Microparticles	CMQA0501/ CMQA0502/ CMQA0503/ CMQA0504/ CMQA0505/ CMQA0506/ CMQA0507	697015090000236 HF	B	6	The f1 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of

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						albumen-specific IgE in human serum. Clinical determination of serum f1 IgE is used as an aid to diagnosis of egg white allergy.
223	f4 CLIA Microparticles	CMQA0801/ CMQA0802/ CMQA0803/ CMQA0804/ CMQA0805/ CMQA0806/ CMQA0807	697015090000239 HM	B	6	The f4 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f4 IgE is used as an aid to diagnosis of wheat allergy.
224	f10 CLIA Microparticles	CMQA0901/ CMQA0902/ CMQA0903/ CMQA0904/ CMQA0905/ CMQA0906/ CMQA0907	697015090000240 H6	B	6	The f10 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f10 IgE is used as an aid to diagnosis of sesame seed allergy.

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225	f2 CLIA Microparticles	CMQA0601/ CMQA0602/ CMQA0603/ CMQA0604/ CMQA0605/ CMQA0606/ CMQA0607	697015090000237 HH	B	6	The f2 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of albumen-specific IgE in human serum. Clinical determination of serum f2 IgE is used as an aid to diagnosis of milk allergy.
226	B19 IgG CLIA Microparticles	CMK1101/ CMK1102/ CMK1103/ CMK1104/ CMK1105/ CMK1106/ CMK1107/ CMK1108/ CMK1109/ CMK1110	697015090000275 HR	C	3 | e	The B19 IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of B19 IgG (IgG antibodies to Human Parvovirus B19) in human serum or plasma. B19 IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women.
227	B19 IgM CLIA Microparticles	CMK1201/ CMK1202/ CMK1203/ CMK1204/ CMK1205/ CMK1206/ CMK1207/ CMK1208/	697015090000276 HT	C	3 | e	The B19 IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system

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		CMK1209/ CMK1210				for the qualitative determination of B19 IgM (IgM antibodies to Human Parvovirus B19) in human serum or plasma. B19 IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women.
228	AutoLumo B19 IgG Calibrators	CA170101/ CA170102/ CA170103/ CA170104	697015090000275 HR	C	3 | e	AutoLumo B19 IgG Calibrators are used for calibrating the quantitative B19 IgG CLIA Microparticles assay on Autolumo immunoassay analyzers.
229	AutoLumo B19 IgM Calibrators	CA170201/ CA170202/ CA170203/ CA170204	697015090000276 HT	C	3 | e	AutoLumo B19 IgM Calibrators are used for calibrating the qualitative B19 IgM CLIA Microparticles assay on Autolumo immunoassay analyzers.
230	rT3 CLIA Microparticles	CME1101/ CME1102/ CME1103/ CME1104/ CME1105	697015090000264 HL	B	6	The rT3 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of rT3 (reverse thyronine) in human serum. Clinical determination of rT3 is used as an aid to diagnose euthyroid sick syndrome.

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231	Anti-TG CLIA Microparticles	CME0601/ CME0602/ CME0603/ CME0604/ CME0605/ CME0606/ CME0607/ CME0608/ CME0609/ CME0610	697015090000022 GS	B	6	The Anti-TG CLIA Microparticles assay is used based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative detection of Anti-TG (antibodies to thyroglobulin) in human serum or plasma. The determination of Anti-TG is used as an aid in the detection of autoimmune thyroid disease.
232	AutoLumo Anti-TG Calibrators	CA120501/ CA120502/ CA120503/ CA120504	697015090000022 GS	B	6	AutoLumo Anti-TG Calibrators are used for calibrating the quantitative Anti-TG CLIA Microparticles assay on AutoLumo immunoassay analyzers.
233	PINP CLIA Microparticles	CMS0701/ CMS0702/ CMS0703/ CMS0704/ CMS0705/ CMS0706/ CMS0707/ CMS0708/ CMS0709/ CMS0710	697015090000139 HG	B	6	The PINP CLIA Microparticles assay is used based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of PINP(procollagen type I N terminal propeptide) in human serum or plasma (EDTA or heparin).The determination of PINP is used as an aid to osteoporosis disease.

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234	AutoLumo PINP Calibrators	CA220101/ CA220102/ CA220103/ CA220104	697015090000139 HG	B	6	AutoLumo PINP Calibrators are used for calibrating the quantitative PINP CLIA Microparticles assay on AutoLumo immunoassay analyzers.
235	β-CTX CLIA Microparticles	CMS0801/ CMS0802/ CMS0803/ CMS0804/ CMS0805/ CMS0806/ CMS0807/ CMS0808/ CMS0809/ CMS0810	697015090000137 HC	B	6	The β-CTX CLIA Microparticles assay is used based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of β-CTX (Beta C-terminal cross-linked telopeptides of type I collagen) in human serum or plasma (EDTA or heparin).The determination of β-CTX is used as an aid to osteoporosis disease.
236	AutoLumo β-CTX Calibrators	CA220201/ CA220202/ CA220203/ CA220204	697015090000137 HC	B	6	AutoLumo β-CTX Calibrators are used for calibrating the quantitative β-CTX CLIA Microparticles assay on AutoLumo immunoassay analyzers.
237	CK-MB CLIA Microparticles	CMH0301/ CMH0302/ CMH0303/ CMH0304/ CMH0305/ CMH0306/ CMH0307/ CMH0308/ CMH0309/ CMH0310	697015090000037 H7	C	3 | g	The CK-MB CLIA Microparticles assay and AutoLumo CK-MB Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system

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						for the quantitative determination of CK-MB (Creatine Kinase-MB) in human serum and plasma. Clinical determination of CK-MB is used to assist diagnoses of an acute myocardial infarction.
238	AutoLumo CK-MB Calibrators	CA140201/ CA140202/ CA140203/ CA140204	697015090000037H7	C	3 | g	AutoLumo CK-MB Calibrators are used for calibrating the quantitative CK-MB CLIA Microparticles assay on Autolumo immunoassay analyzers
239	NT-proBNP CLIA Microparticles	CMH0401/ CMH0402/ CMH0403/ CMH0404/ CMH0405/ CMH0406/ CMH0407/ CMH0408/ CMH0409/ CMH0410	697015090000038H9	C	3 | g	The NT-proBNP CLIA Microparticles assay and AutoLumo NT-proBNP Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of NT-proBNP (N-terminal pro B-type natriuretic peptide) in human serum and plasma. Clinical determination of NT-proBNP is used to assist diagnoses of cardiac failure.
240	AutoLumo NT-proBNP Calibrators	CA140101/ CA140102/ CA140103/ CA140104	697015090000038H9	C	3 | g	AutoLumo NT-proBNP Calibrators are used for calibrating the quantitative NT-proBNP CLIA Microparticles assay on Autolumo

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						immunoassay analyzers
241	H-FABP CLIA Microparticles	CMH1101/ CMH1102/ CMH1103/ CMH1104/ CMH1105/ CMH1106/ CMH1107/ CMH1108/ CMH1109/ CMH1110	697015090000259 HT	C	3 | g	The H-FABP CLIA Microparticles assay and AutoLumo H-FABP Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of H-FABP(Heart-type Fatty Acid-binding Protein) in human serum and plasma. Clinical determination of H-FABP is used to assist diagnoses of myocardial injury and AMI.
242	AutoLumo H-FABP Calibrators	CA140601/ CA140602/ CA140603/ CA140604	697015090000259 HT	C	3 | g	AutoLumo H-FABP Calibrators are used for calibrating the quantitative H-FABP CLIA Microparticles assay on Autolumo immunoassay analyzers
243	HS-cTnT CLIA Microparticles	CMH0601/ CMH0602/ CMH0603/ CMH0604/ CMH0605/ CMH0606/ CMH0607/ CMH0608/ CMH0609/ CMH0610	697015090000260 HC	C	3 | g	The HS-cTnT CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) for the high-sensitive quantitative determination of cTnT

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						(cardiac troponin T) in human serum and plasma (EDTA, heparin, sodium citrate). Clinical determination of the assay is used to assist diagnoses of myocardial injury, especially acute myocardial infarction.
244	AutoLumo HS-cTnT Calibrators	CA100701/ CA1100702 / CA100703/ CA100704	697015090000260HC	C	3 | g	AutoLumo HS-cTnT Calibrators are used for calibrating the quantitative HS-cTnT CLIA Microparticles assay on Autolumo immunoassay analyzers
245	Fungus AST	MD0401 / MD0402 / MD0403	697015090000067HG	C	Rule 3 | b	The Fungus AST (Antimicrobial Susceptibility test)is intended for in vitro determination of antimicrobial susceptibility of Fungus.Clinical determination of this assay is used as an aid to selection of clinical medication, drug resistance dymamics, and epidemiological tracking for Fungus infectious diseases.
246	Enterobacteriaceae AST	MD0501 / MD0502 / MD0503	697015090000071H7	C	Rule 3 | b	The Enterobacteriaceae AST (Antimicrobial Ausceptibility Test) is intended for in vitro determination of antimicrobial susceptibility of bacteria from pure culture belonging to the genera

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						Enterobacteriaceae.Clinical determination of this assay is used as an aid to selection of clinical medication, drug resistance dymamics, and epidemiological tracking for Enterobacteriaceae infectious diseases.
247	Streptococcus AST	MD0201 / MD0202 / MD0203	697015090000065HC	C	Rule 3 | b	The Streptococcus AST (Antimicrobial Susceptibility Test) is intended for in vitro determination of antimicrobial susceptibility of bacteria from pure culture belonging to the genera Streptococcus.Clinical determination of this assay is used as an aid to selection of clinical medication, drug resistance dymamics, and epidemiological tracking for Streptococcus infectious diseases.
248	Gram Positive bacteria AST	MD0301 / MD0302 / MD0303	697015090000066HE	C	Rule 3 | b	The Gram Positive bacteria AST (Antimicrobial Susceptibility test) is intended for in vitro determination of antimicrobial susceptibility of non-fastidious Gram Positive bacteria.Clinical determination of this assay is used as an aid to selection of clinical

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						medication, drug resistance dymamics, and epidemiological tracking for Gram Positive bacteria infectious diseases.
249	Non-fermenting bacteria AST	MD0101 / MD0102 / MD0103	697015090000064HA	C	Rule 3 | b	The Non-fermenting bacteria AST (Antimicrobial Susceptibility Test) is intended for in vitro determination of antimicrobial susceptibility of Non-fermenting bacteria.Clinical determination of this assay is used as an aid to selection of clinical medication, drug resistance dymamics, and epidemiological tracking for Non-fermenting bacteria infectious diseases.
250	Gram Positive bacteria ID/ AST	ME0101 / ME0102 / ME0103	697015090000068HJ	C	Rule 3 | b	The Gram Positive bacteria ID/ AST is intended for the in vitro identification (ID) and in vitro determination of minimal inhibitory concentration (MIC) for aerobic and facultative anaerobic Gram Positive bacteria.Clinical determination of this assay is used as an aid to diagnosis, selection of clinical medication,

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						drug resistance dymamics, and epidemiological tracking for Gram Positive bacteria infectious diseases.
251	YEAST ID/ AST	ME0301 / ME0302 / ME0303	697015090000070H5	C	Rule 3 | b	The YEAST ID/ AST is intended for the in vitro identification (ID) and in vitro determination of minimal inhibitory concentration (MIC) for yeast-like organisms.Clinical determination of this assay is used as an aid to diagnosis, selection of clinical medication,drug resistance dymamics, and epidemiological tracking for yeast-like organisms infectious diseases.
252	Gram Negative bacteria ID/ AST	ME0201 / ME0202 / ME0203	697015090000069HL	C	Rule 3 | b	The Gram Negative bacteria ID/ AST is intended for the in vitro identification (ID) and in vitro determination of minimal inhibitory concentration (MIC) for aerobic and facultative anaerobic Gram Negative bacteria.Clinical determination of this assay is used as an aid to diagnosis, selection of clinical medication , drug resistance

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						dymamics, and epidemiological tracking for Gram Negative bacteria infectious diseases.
253	Gram Positive bacteria ID	ME0501/ ME0502/ ME0503/ ME0504/ ME0505/ ME0506	697015090000331HA	C	Rule 3 | b	The Gram Positive bacteria ID is intended for the in vitro identification (ID)for aerobic and facultative anaerobic Gram Positive bacteria. Clinical determination of this assay is used as an aid to diagnosis, selection of clinical medication and epidemiological tracking for Gram Positive bacteria infectious diseases.
254	Gram Negative bacteria ID	ME0601/ ME0602/ ME0603/ ME0604/ ME0605/ ME0606	697015090000332HC	C	Rule 3 | b	The Gram Negative bacteria ID is intended for the in vitro identification (ID) for aerobic and facultative anaerobic Gram Negative bacteria.Clinical determination of this assay is used as an aid to diagnosis, selection of clinical medication and epidemiological tracking for Gram Negative bacteria infectious diseases.
255	Mycoplasma (UU-MH) Culture Broth	M0204	697015090000054H7	C	Rule 3 | b	Mycoplasma (UU-MH) Culture Broth is intend for the qualitative

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						detection of Mycoplasma (the combination of UU and MH) in human urogenital tract
256	CA50 CLIA Microparticles	CMB0401 / CMB0402 / CMB0403 / CMB0404/ CMB0405/ CMB0406/ CMB0407/ CMB0408/ CMB0409/ CMB0410	697015090000225HA	C	3 | h	The CA50 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of CA50 (Carbohydrate Antigen 50) in human serum. Clinical determination of CA50 is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of digestive tract malignant tumors such as pancreas.
257	CYFRA21-1 CLIA Microparticles	CMB1201 / CMB1202 / CMB1203 / CMB1204/ CMB1205/ CMB1206/ CMB1207/ CMB1208/ CMB1209/ CMB1210	697015090000226HC	C	3 | h	The CYFRA21-1 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of CYFRA 21-1 in human serum. Clinical determination of CYFRA 21-1 is used for treatment observation and recurrent monitoring of non-small cell lung cancer.

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258	Pepsinogen I CLIA Microparticles	CMB1501 / CMB1502 / CMB1503 / CMB1504/ CMB1505/ CMB1506/ CMB1507/ CMB1508/ CMB1509/ CMB1510	697015090000229HJ	C	3 | h	The Pepsinogen I CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of Pepsinogen I (PG I) in human serum. Clinical determination of PG I is used for monitoring of gastric mucosal function changes. The joint detection of PG I and PG II can be used to monitor the severity of gastric mucosal atrophy, and works as an aid of gastric cancer diagnosis.
259	Pepsinogen II CLIA Microparticles	CMB1601 / CMB1602 / CMB1603 / CMB1604/ CMB1605/ CMB1606/ CMB1607/ CMB1608/ CMB1609/ CMB1610	697015090000230H3	C	3 | h	The Pepsinogen II CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of Pepsinogen II (PG II) in human serum. Clinical determination of PG II is used for monitoring of gastric mucosal function changes. The joint detection of PG I and PG II can be used to monitor the severity of gastric mucosal atrophy, and works as an aid of

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						gastric cancer diagnosis.
260	G-17 CLIA Microparticles	CMB2101 / CMB2102 / CMB2103 / CMB2104/ CMB2105/ CMB2106/ CMB2107/ CMB2108/ CMB2109/ CMB2110	697015090000231H5	B	6	The G-17 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of gastrins-17 (G-17) in human serum. Clinical determination of G-17 is used for an aid of atrophic gastritis diagnosis.
261	HE4 CLIA Microparticles	CMB1801 / CMB1802 / CMB1803 / CMB1804/ CMB1805/ CMB1806/ CMB1807/ CMB1808/ CMB1809/ CMB1810	697015090000227HE	C	3 | h	The HE4 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of HE4 (human epididymal protein 4) in human serum. Clinical determination of HE4 is used as an aid in disease progression or treatment effectiveness, through the dynamic

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						monitoring of patients with ovarian malignant tumors.
262	ProGRP CLIA Microparticles	CMB1901 / CMB1902 / CMB1903 / CMB1904/ CMB1905/ CMB1906/ CMB1907/ CMB1908/ CMB1909/ CMB1910	697015090000228HG	C	3 | h	The ProGRP CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of ProGRP (Pro-Gastrin-Releasing Peptide) in human serum. Clinical determination of ProGRP is used for an aid in differential diagnosis of lung cancer, and also management of small cell lung cancer (SCLC) patients.
263	HER-2/ neu CLIA Microparticles	CMB2201 / CMB2202 / CMB2203 / CMB2204/ CMB2205/ CMB2206/ CMB2207/ CMB2208/ CMB2209/ CMB2210	697015090000132H2	C	3 | h	The HER-2/ neu CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of human epidermal growth factor receptor 2 (HER-2/ neu) protein in human serum. HER-2/ neu is used for dynamic monitoring of

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						patients, which acts as an aid of disease progression or treatment determination of breast cancer.
264	S100 CLIA Microparticles	CMB2301 / CMB2302 / CMB2303 / CMB2304/ CMB2305/ CMB2306/ CMB2307/ CMB2308/ CMB2309/ CMB2310	697015090000133H4	C	3 | h	The S100 CLIA Microparticles assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the quantitative determination of S100 protein in human serum. Clinical determination of S100 is used for disease progression or treatment determination of melanoma, it also works as an aid of cerebral damage diagnosis.
265	AutoLumo CA50 Calibrators	CA061701/ CA061702/ CA061703/ CA061704	697015090000225HA	C	3 | h	AutoLumo CA50 Calibrators are used for calibrating the quantitative CA50 CLIA Microparticles assay on Autolumo immunoassay analyzers.
266	AutoLumo CYFRA21-1 Calibrators	CA061801/ CA061802/ CA061803/ CA061804	697015090000226HC	C	3 | h	AutoLumo CYFRA21-1 Calibrators are used for calibrating the quantitative CYFRA21-1 CLIA Microparticles assay on Autolumo immunoassay analyzers.

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267	AutoLumo Pepsinogen I Calibrators	CA061501/ CA061502/ CA061503/ CA061504	697015090000229 HJ	C	3 | h	AutoLumo Pepsinogen Ⅰ Calibrators are used for calibrating the quantitative Pepsinogen Ⅰ CLIA Microparticles assay on Autolumo immunoassay analyzers.
268	AutoLumo Pepsinogen II Calibrators	CA061601/ CA061602/ CA061603/ CA061604	697015090000230 H3	C	3 | h	AutoLumo Pepsinogen Ⅱ Calibrators are used for calibrating the quantitative Pepsinogen Ⅱ CLIA Microparticles assay on Autolumo immunoassay analyzers.
269	AutoLumo G-17 Calibrators	CA061901/ CA061902/ CA061903/ CA061904	697015090000231 H5	B	6	AutoLumo G-17 Calibrators are used for calibrating the quantitative G-17 CLIA Microparticles assay on Autolumo immunoassay analyzers.
270	AutoLumo HE4 Calibrators	CA062001/ CA062002/ CA062003/ CA062004	697015090000227 HE	C	3 | h	AutoLumo HE4 Calibrators are used for calibrating the quantitative HE4 CLIA Microparticles assay on Autolumo immunoassay analyzers.
271	AutoLumo ProGRP Calibrators	CA062101/ CA062102/ CA062103/ CA062104	697015090000228 HG	C	3 | h	AutoLumo ProGRP Calibrators are used for calibrating the quantitative ProGRP CLIA Microparticles assay on Autolumo immunoassay analyzers.
272	AutoLumo HER-2/ neu Calibrators	CA062201/ CA062202/ CA062203/ CA062204	697015090000132 H2	C	3 | h	AutoLumo HER-2/ neu Calibrators are used for calibrating the quantitative HER-2/ neu CLIA Microparticles assay on Autolumo immunoassay analyzers.

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273	AutoLumo S100 Calibrators	CA062301/ CA062302/ CA062303/ CA062304	697015090000133 H4	C	3 | h	AutoLumo S100 Calibrators are used for calibrating the quantitative S100 CLIA Microparticles assay on Autolumo immunoassay analyzers.
274	MN CLIA Microparticles	CMD0601/ CMD0602/ CMD0603/ CMD0604/ CMD0605/ CMD0606/ CMD0607/ CMD0608/ CMD0609/ CMD0610	697015090000134 H6	B	6	The MN CLIA Microparticles assay and AutoLumo MN Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Metanephrine (MN) in human plasma or urine. Clinical determination of MN is used as an aid in the diagnosis of secondary hypertension.
275	AutoLumo MN Calibrators	CA030701/ CA030702/ CA030703/ CA030704	697015090000134 H6	B	6	The MN CLIA Microparticles assay and AutoLumo MN Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Metanephrine (MN) in human plasma or urine. Clinical determination of MN is used as an aid in the diagnosis of secondary hypertension.

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276	NMN CLIA Microparticles	CMD0701/ CMD0702/ CMD0703/ CMD0704/ CMD0705/ CMD0706/ CMD0707/ CMD0708/ CMD0709/ CMD0710	697015090000135H8	B	6	The NMN CLIA Microparticles assay and AutoLumo NMN Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Normetanephrine (NMN) in human plasma or urine. Clinical determination of NMN is used as an aid in the diagnosis of secondary hypertension.
277	AutoLumo NMN Calibrators	CA030801/ CA030802/ CA030803/ 4	697015090000135H8	B	6	The NMN CLIA Microparticles assay and AutoLumo NMN Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Normetanephrine (NMN) in human plasma or urine. Clinical determination of NMN is used as an aid in the diagnosis of secondary hypertension.
278	3-MT CLIA Microparticles	CMD0801/ CMD0802/ CMD0803/ CMD0804/ CMD0805/ CMD0806/ CMD0807/ CMD0808/	697015090000136HA	B	6	The 3-MT CLIA Microparticles assay and AutoLumo 3-MT Calibrators are used together based on the fully automated chemiluminescent microparticle

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		CMD0809/ CMD0810				immunoassay (CLIA Microparticles) system for the quantitative determination of 3-methoxytyramine (3-MT) in human plasma or urine. Clinical determination of 3-MT is used as an aid in the diagnosis of secondary hypertension.
279	AutoLumo 3-MT Calibrators	CA030901/ CA030902/ CA030903/ CA030904	697015090000136 HA	B	6	The 3-MT CLIA Microparticles assay and AutoLumo 3-MT Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of 3-methoxytyramine (3-MT) in human plasma or urine. Clinical determination of 3-MT is used as an aid in the diagnosis of secondary hypertension.
280	Aldosterone CLIA Microparticles	CMD0101/ CMD0102/ CMD0103/ CMD0104/ CMD0105/ CMD0106/ CMD0107/ CMD0108/ CMD0109/ CMD0110	697015090000017 GZ	B	6	The Aldosterone CLIA Microparticles assay and AutoLumo Aldosterone Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of ALD

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						(Aldosterone) in human serum, plasma or urine. Clinical determination of ALD is used as an aid in the diagnosis of hypertension, hypokalemia, primary aldosteronism, and secondary aldosteronism.
281	AutoLumo Aldosterone Calibrators	CA030401/ CA030402/ CA030403/ CA030404	697015090000017 GZ	B	6	The Aldosterone CLIA Microparticles assay and AutoLumo Aldosterone Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of ALD (Aldosterone) in human serum, plasma or urine. Clinical determination of ALD is used as an aid in the diagnosis of hypertension, hypokalemia, primary aldosteronism, and secondary aldosteronism.
282	IGFBP-3 CLIA Microparticles	CML0301/ CML0302/ CML0303/ CML0304/ CML0305/ CML0306/ CML0307/ CML0308/ CML0309/ CML0310	697015090000263 HT	B	6	The IGFBP-3 CLIA Microparticles assay and AutoLumo IGFBP-3 Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of IGFBP-3

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						(Insulin Like Growth Factor Binding Protein 3) in human serum or plasma. Clinical determination of IGFBP-3 is used as an aid in the diagnosis of growth disorders.
283	AutoLumo IGFBP-3 Calibrators	CA040301/ CA040302/ / CA040303/ CA040304	697015090000263 HT	B	6	The IGFBP-3 CLIA Microparticles assay and AutoLumo IGFBP-3 Calibrators are used together based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of IGFBP-3 (Insulin Like Growth Factor Binding Protein 3) in human serum or plasma. Clinical determination of IGFBP-3 is used as an aid in the diagnosis of growth disorders.
284	Aerobic culture bottle SA	MC0304/ MC0307	697015090000138 HE	A	5	Aerobic Culture Bottle SA (Standard Aerobic) is for the qualitative recovery and detection of aerobic, facultative anaerobic microorganisms (bacteria and fungus) from blood and other normally sterile body fluids in human.

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285	Aerobic culture bottle SP	MC0305/ MC0308	697015090000148 HH	A	5	Aerobic Culture Bottle SP (Standard Aerobic) is for the qualitative recovery and detection of aerobic, facultative anaerobic microorganisms (bacteria and fungus) from blood and other normally sterile body fluids in children.
286	Anaerobic culture bottle SN	MC0306/ MC0309	697015090000149 HK	A	5	Anaerobic Culture Bottle SN (Standard Anaerobic) is for the qualitative recovery and detection of anaerobic and facultative anaerobic microorganisms from blood and other normally sterile body fluids in human.
287	Anti-β2-GP1 CLIA Microparticles	CMQ2901/ CMQ2902/ CMQ2903/ CMQ2904/ CMQ2905/ CMQ2906/ CMQ2907/ CMQ2908/ CMQ2909/ CMQ2910	697015090000321 H7	C	3k	This Anti-β2-GP1 CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-β2-GP1 in human serum and plasma. This assay is to be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.
288	AutoLumo Anti-β2-GP1 Calibrators	CA012501/ CA012502/ CA012503/ CA012504	697015090000321 H7	C	3k	AutoLumo Anti-β2-GP1 Calibrators are used for calibrating the quantitative Anti-β2-

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						GP1 CLIA Microparticles assay on AutoLumo immunoassay analyzers.
289	Anti-β2-GP1 IgA CLIA Microparticles	CMQ3001/ CMQ3002/ CMQ3003/ CMQ3004/ CMQ3005/ CMQ3006/ CMQ3007/ CMQ3008/ CMQ3009/ CMQ3010	697015090000322H9	C	3k	This Anti-β2-GP1 IgA CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-β2-GP1 IgA in human serum and plasma. This assay is to be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.
290	AutoLumo Anti-β2-GP1 IgA Calibrators	CA012601/ CA012602/ CA012603/ CA012604	697015090000322H9	C	3k	AutoLumo Anti-β2-GP1 IgA Calibrators are used for calibrating the quantitative Anti-β2-GP1 IgA CLIA Microparticles assay on AutoLumo immunoassay analyzers.
291	Anti-β2-GP1 IgG CLIA Microparticles	CMQ3101/ CMQ3102/ CMQ3103/ CMQ3104/ CMQ3105/ CMQ3106/ CMQ3107/ CMQ3108/ CMQ3109/ CMQ3110	697015090000323HB	C	3k	This Anti-β2-GP1 IgG CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-β2-GP1 IgG in human serum and plasma. This assay is

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						to be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.
292	AutoLumo Anti-β2-GP1 IgG Calibrators	CA012701/ CA012702/ CA012703/ CA012704	697015090000323 HB	C	3k	AutoLumo Anti-β2-GP1 IgG Calibrators are used for calibrating the quantitative Anti-β2-GP1 IgG CLIA Microparticles assay on AutoLumo immunoassay analyzers.
293	Anti-β2-GP1 IgM CLIA Microparticles	CMQ3201/ CMQ3202/ CMQ3203/ CMQ3204/ CMQ3205/ CMQ3206/ CMQ3207/ CMQ3208/ CMQ3209/ CMQ3210	697015090000324 HD	C	3k	This Anti-β2-GP1 IgM CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-β2-GP1 IgM in human serum and plasma. This assay is to be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.
294	AutoLumo Anti-β2-GP1 IgM Calibrators	CA012801/ CA012802/ CA012803/ CA012804	697015090000324 HD	C	3k	AutoLumo Anti-β2-GP1 IgM Calibrators are used for calibrating the quantitative Anti-β2-GP1 IgM CLIA Microparticles assay on AutoLumo immunoassay analyzers.

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295	Anti-CL CLIA Microparticles	CMQ3401/ CMQ3402/ CMQ3403/ CMQ3404/ CMQ3405/ CMQ3406/ CMQ3407/ CMQ3408/ CMQ3409/ CMQ3410	697015090000327 HK	C	3k	This Anti-CL CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-CL in human serum and plasma. This assay is to be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.
296	AutoLumo Anti-CL Calibrators	CA013101/ CA013102/ CA013103/ CA013104	697015090000327 HK	C	3k	AutoLumo Anti-CL Calibrators are used for calibrating the quantitative Anti-CL CLIA Microparticles assay on AutoLumo immunoassay analyzers.
297	Anti-CL IgG CLIA Microparticles	CMQ3501/ CMQ3502/ CMQ3503/ CMQ3504/ CMQ3505/ CMQ3506/ CMQ3507/ CMQ3508/ CMQ3509/ CMQ3510	697015090000328 HM	C	3k	This Anti-CL IgG CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-CL IgG in human serum and plasma.This assay is to be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.

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298	AutoLumo Anti-CL IgG Calibrators	CA013201/ CA013202/ CA013203/ CA013204	697015090000328 HM	C	3k	AutoLumo Anti-CL IgG Calibrators are used for calibrating the quantitative Anti-CL IgG CLIA Microparticles assay on AutoLumo immunoassay analyzers.
299	Anti-CL IgM CLIA Microparticles	CMQ3601/ CMQ3602/ CMQ3603/ CMQ3604/ CMQ3605/ CMQ3606/ CMQ3607/ CMQ3608/ CMQ3609/ CMQ3610	697015090000329 HP	C	3k	This Anti-CL IgM CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-CL IgM in human serum and plasma. This assay is to be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.
300	AutoLumo Anti-CL IgM Calibrators	CA013301/ CA013302/ CA013303/ CA013304	697015090000329 HP	C	3k	AutoLumo Anti-CL IgM Calibrators are used for calibrating the quantitative Anti-CL IgM CLIA Microparticles assay on AutoLumo immunoassay analyzers.
301	Anti-CL IgA CLIA Microparticles	CMQ3701/ CMQ3702/ CMQ3703/ CMQ3704/ CMQ3705/ CMQ3706/ CMQ3707/ CMQ3708/ CMQ3709/ CMQ3710	697015090000330 H8	C	3k	This Anti-CL IgA CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Anti-CL IgA in human serum and plasma. This assay is to

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						be used as an aid in the diagnosis of antiphospholipid antibody syndrome and systemic lupus erythematosus.
302	AutoLumo Anti-CL IgA Calibrators	CA013401/ CA013402/ CA013403/ CA013404	697015090000330H8	C	3k	AutoLumo Anti-CL IgA Calibrators are used for calibrating the quantitative Anti-CL IgA CLIA Microparticles assay on AutoLumo immunoassay analyzers.
303	Sputum Processing Reagent	AS030101/ AS030102/ AS030103	697015090000170HA	A	5	This assay is used for the dilution and liquidation of sputum samples to homogenize sputum before culture, which facilitates the detection of sputum samples and analysis.
304	HIV Ag/ Ab Combo CLIA Microparticles	CMJ0104/ CMJ0103/ CMJ0105/ CMJ0106/ CMJ0107	697015090000257HP	D	Rule 1 | 1st Indent	HIV Ag/ Ab Combo CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1) and/ or type 2(HIV-2) in human serum and plasma. This assay is intended to be used as a screening assay for blood donation. This

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						test reactive result does not distinguish between the detection of HIV p24 antigen, HIV-1 antibody, or HIV-2 antibody. Clinical determination of HIV Ag/ Ab Combo is used as an aid to diagnosis the presence of HIV infection.
305	HIV Control	ZKN0101/ ZKN0102/ ZKN0103/ ZKN0104/ ZKN0201/ ZKN0202/ ZKN0203/ ZKN0204/ ZKN0301/ ZKN0302/ ZKN0303/ ZKN0304	697015090000257HP	D	Rule 1 | 1st Indent	HIV Control is intended for use as an assayed quality control to monitor the precision of HIV Ag/ Ab Combo CLIA Microparticles.
306	Anti-HCV CLIA Microparticles	CMC0601/ CMC0602/ CMC0603/ CMC0604/ CMC0605	697015090000256HM	D	Rule 1 | 1st Indent	Anti-HCV CLIA Microparticles is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the qualitative determination of Anti-HCV (IgG antibodies to hepatitis C virus) in human serum or plasma. Clinical determination of Anti-HCV is used as an aid to diagnosis the presence of HCV

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						infection. This assay can also be used as a screening assay for blood donation. The chemiluminescence microparticle immunoassay (CLIA Microparticles) is intended for use on AutoLumo immunoassay analyzers.
307	Anti-HCV Control	ZKF0101/ ZKF0102/ ZKF0103/ ZKF0104/ ZKF0201/ ZKF0202/ ZKF0203/ ZKF0204/ ZKF0301/ ZKF0302/ ZKF0303/ ZKF0304	697015090000256HM	D	Rule 1 | 1st Indent	Anti-HCV Control is intended for use as an assayed quality control to monitor the precision of Anti-HCV CLIA Microparticles on AutoLumo immunoassay analyzers.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (Annex VIII of Regulation (EU) 2017/ 746).

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Manufacturer's Name

AUTOBIO DIAGNOSTICS CO., LTD.

Signature: _____

Date: ***March 24, 2025***

Stamp: