Certificate number: 2022-IVDD/CE382

Certificate of CE-Notification

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

Monocent Inc.
9237 Eton Ave.,
Chatsworth, CA 91311
United States

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

IVD devices were registered with the Dutch Competent Authority with registration number:

IVD Devices groups:	Registration number:
CLIA Test Kits	NL-CA002-2020-50897
ELISA Test Kits	NL-CA002-2020-50898
IFA Test Kits	NL-CA002-2020-50899
Instruments	NL-CA002-2020-50900
PCR Test Kits	NL-CA002-2020-50901
Rapid Tests	NL-CA002-2020-50902
Serology Test Kits	NL-CA002-2020-50903

see appendix

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

Issue date: 2022-10-31

This Certificate of CE-Notification is valid until May 26, 2025

R. Nusselder
Sr. consultant CEpartner4U BV

CEpartner4U
Esdoornlaan13
3951 DB Maarn NL
tel: +31 (0)343 442 524
www.cepartner4u.nl

Digitally signed by Monastîrschii Viorica
Date: 2023.02.08 16:48:09 EET
Reason: MoldSign Signature
Location: Moldova

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

Appendix

List of devices.

CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Allergy Assays					
IgE	CL3-5055	Low Risk	C	30275	2020-04-14
Thyroid Assays					
T3	CL3-5028	Low Risk	C	30312	2020-04-14
T4	CL3-5029	Low Risk	C	30314	2020-04-14
TSH	CL2-5030	Low Risk	C	30318	2020-04-14
T3 Uptake	CL3-5072	Low Risk	C	30313	2020-04-14
FT3	CL3-5026	Low Risk	C	30309	2020-04-14
FT4	CL3-5027	Low Risk	C	30308	2020-04-14
Tg (Thyroglobulin)	CL3-5073	Low Risk	C	30490	2020-04-14
TBG	CL3-5074	Low Risk	C	30316	2020-04-14
Anti-Tg	CL3-5075	Low Risk	C	30490	2020-04-14
Anti-TPO	CL3-5076	Low Risk	C	30317	2020-04-14
Ultra-Sensitive TSH	CL2-5077	Low Risk	C	30318	2020-04-14
Fertility Assays					
LH	CL3-5006	Low Risk	C	38965	2020-04-14
FSH	CL3-5004	Low Risk	C	30322	2020-04-14
Prolactin	CL3-5008	Low Risk	C	30325	2020-04-14
hCG	CL2-5005	Low Risk	B	30513	2020-04-14
AMH	CL3-5069	Low Risk	C	43148	2020-04-14
Beta hCG	CL2-5055	Low Risk	B	30332	2020-04-14
HGH	CL3-5007	Low Risk	C	30333	2020-04-14
PAPP-A	CL3-5068	Low Risk	C	31533	2020-04-14
Diabetes Assays					
Insulin	CL2-5003	Low Risk	C	30338	2020-04-14
C-peptide	CL2-5002	Low Risk	C	30336	2020-04-14
Tumor Markers Assays					
AFP	CL3-5031	Low Risk	C	30295	2020-04-14
CEA	CL3-5036	Low Risk	C	30288	2020-04-14
Free Beta hCG	CL2-5037	Low Risk	C	30333	2020-04-14
Beta 2 Microglobulin	CL2-5032	Low Risk	C	30296	2020-04-14
NSE	CL2-5039	Low Risk	C	30301	2020-04-14
CA-12-5	CL3-5034	Low Risk	C	30283	2020-04-14
CA-19-9	CL2-5035	Low Risk	C	30280	2020-04-14
CA-15-3	CL2-5033	Low Risk	C	30279	2020-04-14
Ferritin	CL3-5001	Low Risk	C	30377	2020-04-14
Cyfra21-1	CL2-5079	Low Risk	C	44431	2020-04-14
Pro-GRP	CL2-5080	Low Risk	C	44438	2020-04-14
PAP	CL2-5081	Low Risk	C	34226	2020-04-14
Steroid Assays					
Progesterone	CL3-5021	Low Risk	C	30294	2020-04-14
Estradiol	CL3-5016	Low Risk	C	30321	2020-04-14
Testosterone	CL3-5022	Low Risk	C	30327	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Free Testosterone	CL9-5023	Low Risk	C	30327	2020-04-14
Testosterone (Saliva)	CL9-5025	Low Risk	C	30327	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a- Diol G)	CL9-5009	Low Risk	C	31533	2020-04-14
17 OH Progesterone	CL3-5010	Low Risk	C	30324	2020-04-14
Androstenedione	CL3-5070	Low Risk	C	30319	2020-04-14
Aldosterone	CL3-5011	Low Risk	C	31428	2020-04-14
Cortisol	CL3-5012	Low Risk	C	31394	2020-04-14
DHEA	CL3-5013	Low Risk	C	39894	2020-04-14
DHEA-S	CL3-5014	Low Risk	C	39894	2020-04-14
uE3	CL3-5041	Low Risk	C	30330	2020-04-14
Estriol (Saliva)	CL9-5018	Low Risk	C	30329	2020-04-14
Estrone (Saliva)	CL9-5019	Low Risk	C	33293	2020-04-14
Estrone	CL3-5020	Low Risk	C	33293	2020-04-14
Plasma Renin Activity (PRA)	CL9-5024	Low Risk	C	43444	2020-04-14
SHBG	CL3-5071	Low Risk	C	30326	2020-04-14
Procalcitonin	CL3-5067	Low Risk	C	12069016	2020-04-14
Infectious Disease Assays					
Digoxin	CL3-5059	Low Risk	C	30386	2020-04-14
hs-CRP	CL2-5060	Low Risk	C	30499	2020-04-14
CK-MB	CL3-5061	Low Risk	C	30499	2020-04-14
Myoglobin	CL3-5062	Low Risk	C	30264	2020-04-14
cTn I	CL2-5063	Low Risk	C	30266	2020-04-14
Bone Metabolism					
ACTH	CL3-5017	Low Risk	C	39005	2020-04-14
Calcitonin	CL3-5064	Low Risk	C	30342	2020-04-14
PTH	CL3-5065	Low Risk	C	30353	2020-04-14
Vitamin D	CL3-5066	Low Risk	C	30350	2020-04-14
Autoimmune Disease					
Cardiolipin IgA	CL2-5051	Low Risk	C	30475	2020-04-14
Cardiolipin IgG	CL2-5052	Low Risk	C	30475	2020-04-14
Cardiolipin IgM	CL2-5053	Low Risk	C	30475	2020-04-14
ds-DNA	CL2-5054	Low Risk	C	30458	2020-04-14
RF IgM	CL2-5114	Low Risk	C	30500	2020-04-14
B2GP1 IgA	CL2-5115	Low Risk	C	30478	2020-04-14
B2GP1 IgG	CL2-5116	Low Risk	C	30478	2020-04-14
B2GP1 IgM	CL2-5117	Low Risk	C	30478	2020-04-14
Thyroglobulin IgG	CL2-5118	Low Risk	C	30315	2020-04-14
Anti-CCP	CL2-5119	Low Risk	C	44202	2020-04-14
Anemia Assays					
Folate	CL3-5056	Low Risk	C	30378	2020-04-14
Vitamin B12	CL3-5057	Low Risk	C	30384	2020-04-14
Transferrin Soluble Receptor (sTfR)	CL3-5058	Low Risk	C	30253	2020-04-14
NeoNatal Assays					
Neonatal TSH	CL2-5078	Low Risk	C	30310	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Infectious Disease Assays					
H. pylori IgA	CL2-5048	Low Risk	B	30691	2020-04-14
H. pylori IgG	CL2-5049	Low Risk	B	30691	2020-04-14
H. pylori IgM	CL2-5050	Low Risk	B	30691	2020-04-14
H. pylori IgG (Quantitative)	CL2-5082	Low Risk	B	30691	2020-04-14
H. pylori Antigen	CL2-5083	Low Risk	B	30691	2020-04-14
EBV VCA IgA	CL2-5084	Low Risk	D	30809	2020-04-14
EBV VCA IgG	CL2-5085	Low Risk	D	30809	2020-04-14
EBV VCA IgM	CL2-5086	Low Risk	D	30809	2020-04-14
EBV EA-D IgA	CL2-5087	Low Risk	D	30809	2020-04-14
EBV EA-D IgG	CL2-5088	Low Risk	D	30809	2020-04-14
EBV EA-D IgM	CL2-5089	Low Risk	D	30809	2020-04-14
EBNA IgA	CL2-5090	Low Risk	D	30808	2020-04-14
EBNA IgG	CL2-5091	Low Risk	D	30808	2020-04-14
EBNA IgM	CL2-5092	Low Risk	D	30808	2020-04-14
Measles IgG	CL2-5093	Low Risk	C	44019	2020-04-14
Measles IgM	CL2-5094	Low Risk	C	44019	2020-04-14
VZV IgG	CL2-5095	Low Risk	C	44027	2020-04-14
VZV IgM	CL2-5096	Low Risk	C	44027	2020-04-14
Mumps IgG	CL2-5097	Low Risk	C	33908	2020-04-14
Mumps IgM	CL2-5098	Low Risk	C	33908	2020-04-14
Dengue IgG	CL2-5099	Low Risk	C	32481	2020-04-14
Dengue IgM	CL2-5100	Low Risk	C	32481	2020-04-14
HSV 1/2 IgG	CL2-5101	Low Risk	C	40176	2020-04-14
HSV 1/2 IgM	CL2-5102	Low Risk	C	40176	2020-04-14
HSV 1 IgA	CL2-5103	Low Risk	C	38870	2020-04-14
HSV 1 IgG	CL2-5104	Low Risk	C	38870	2020-04-14
HSV 1 IgM	CL2-5105	Low Risk	C	38870	2020-04-14
HSV 2 IgA	CL2-5106	Low Risk	C	38875	2020-04-14
HSV 2 IgG	CL2-5107	Low Risk	C	38875	2020-04-14
HSV 2 IgM	CL2-5108	Low Risk	C	38875	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Allergy					
Total Human IgE	EL1-1000, EL2-1000	Low Risk	B	30275	2020-04-14
Human Specific IgG	EL15-1001	Low Risk	C	44211	2020-04-14
Human Specific IgG4	EL15-1002	Low Risk	C	44211	2020-04-14
Histamine	EL30-1003	Low Risk	C	30274	2020-04-14
Anemia					
Vitamin B12	EL1-1007	Low Risk	B	30384	2020-04-14
Folate	EL1-1005	Low Risk	B	30378	2020-04-14
sTfR-Transferrin Soluble Receptor	EL3-1006	Low Risk	B	30253	2020-04-14
Ferritin	EL1-1004	Low Risk	B	30377	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Hepcidin	EL1-1008	Low Risk	B	12070190	2020-04-14
Autoimmune Disease					
Anti-CCP	EL2-1011	Low Risk	B	44202	2020-04-14
Anti-CP IgG	EL20-1288	Low Risk	B	44202	2020-04-14
Beta 2 Glycoprotein 1 IgA	EL2-1017	Low Risk	B	30478	2020-04-14
Beta 2 Glycoprotein 1 IgG	EL2-1018	Low Risk	B	30478	2020-04-14
Beta 2 Glycoprotein 1 IgM	EL2-1019	Low Risk	B	30478	2020-04-14
Anti-Tissue Transglutaminase IgG	EL20-1015	Low Risk	C	44385	2020-04-14
Anti-Tissue Transglutaminase IgA	EL20-1014	Low Risk	C	44385	2020-04-14
ANA Screen IgG	EL1-1009	Low Risk	B	30454	2020-04-14
ENA IgG Profile-6	EL10-1024	Low Risk	B	30455	2020-04-14
ENA Screen IgG	EL20-1025	Low Risk	B	30455	2020-04-14
Rheumatoid Factor (RF) IgA	EL15-1034	Low Risk	B	30500	2020-04-14
Rheumatoid Factor (RF) IgG	EL15-1035	Low Risk	B	30500	2020-04-14
Rheumatoid Factor (RF) IgM	EL2-1038	Low Risk	B	30500	2020-04-14
Sm/RNP IgG	EL1-1040	Low Risk	B	30464	2020-04-14
Sm IgG	EL1-1041	Low Risk	B	17276	2020-04-14
Jo-1 IgG	EL21-1029	Low Risk	C	30461	2020-04-14
Scl-70 IgG	EL1-1039	Low Risk	B	30463	2020-04-14
SS-A (Ro)	EL1-1042	Low Risk	B	44202	2020-04-14
SS-B (La)	EL1-1043	Low Risk	B	44202	2020-04-14
dsDNA	EL1-1023	Low Risk	B	30458	2020-04-14
Cardiolipin IgG	EL1-1021	Low Risk	C	30475	2020-04-14
Cardiolipin IgM	EL1-1022	Low Risk	C	30475	2020-04-14
Cardiolipin IgA	EL1-1020	Low Risk	C	30475	2020-04-14
Cardiolipin Total Ab	EL1-1044	Low Risk	C	30475	2020-04-14
Mitochondrial Antibody (MA)	EL1-1031	Low Risk	C	30476	2020-04-14
Thyroglobulin Antigen (Anti-Tg)	EL3-1016	Low Risk	C	30315	2020-04-14
PR3 (c-ANCA)	EL20-1033	Low Risk	B	30484	2020-04-14
ANCA screen IgG	EL10-1010	Low Risk	B	30483	2020-04-14
MPO, Myeloperoxidase (p-ANCA)	EL20-1032	Low Risk	B	30483	2020-04-14
Gliadin IgG	EL36-1026	Low Risk	C	30480	2020-04-14
Gliadin IgA	EL36-1027	Low Risk	C	30480	2020-04-14
TPO	EL1-1012	Low Risk	C	30317	2020-04-14
Anti-Phospholipids Screen	EL20-1013	Low Risk	B	30582	2020-04-14
ASMA	EL29-1302	Low Risk	B	30274	2020-04-14
Beta-2-Glycoprotein IgA	EL2-1017	Low Risk	B	30478	2020-04-14
Beta-2-Glycoprotein IgG	EL2-1018	Low Risk	B	30478	2020-04-14
Beta-2-Glycoprotein IgM	EL2-1019	Low Risk	B	30478	2020-04-14
Tumor markers					
Prostatic Acid Phosphatase (PAP)	EL2-1289	Low Risk	C	34226	2020-04-14
Beta-2-Microglobulin	EL2-1277	Low Risk	C	30296	2020-04-14
AFP (Alpha Fetoprotein)	EL1-1276	Low Risk	C	43480	2020-04-14
CEA	EL1-1283	Low Risk	C	30288	2020-04-14
CA-15-3	EL1-1279	Low Risk	C	30279	2020-04-14
CA-12-5	EL1-1278	Low Risk	C	30283	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
CA-19-9	EL1-1280	Low Risk	C	30280	2020-04-14
NSE	EL2-1286	Low Risk	C	30301	2020-04-14
Free Beta HCG	EL1-1284	Low Risk	C	30333	2020-04-14
Pro-GRP (Gastrin-Releasing Peptide)	EL2-1290	Low Risk	C	44438	2020-04-14
Chromogranin A	EL1-1281	Low Risk	C	30289	2020-04-14
HE4	EL1-1306	Low Risk	C	30289	2020-04-14
Cyfra21-1	EL2-1034	Low Risk	C	30289	2020-04-14
Bone Metabolism					
Intact PTH	EL3-1048	Low Risk	C	30353	2020-04-14
25-OH Vitamin D	EL1-1045	Low Risk	B	30350	2020-04-14
ACTH	EL3-1046	Low Risk	C	39005	2020-04-14
Cardiac					
Digoxin	EL3-1051	Low Risk	C	30386	2020-04-14
CK-MB	EL3-1050	Low Risk	C	30499	2020-04-14
Troponin I	EL1-1054	Low Risk	C	30266	2020-04-14
Myoglobin	EL6-1053	Low Risk	C	30264	2020-04-14
C-Reactive Protein (CRP)	EL1-1049	Low Risk	C	30499	2020-04-14
Diabetes					
Insulin	EL1-1058	Low Risk	C	30338	2020-04-14
C-peptide	EL1-1055	Low Risk	C	30336	2020-04-14
Leptin	EL9-1059	Low Risk	B	12069017	2020-04-14
Adiponectin	EL9-1056	Low Risk	B	12069017	2020-04-14
(IGFBP-1) Insulin-Like Growth Factor Binding Protein-1	EL9-1057	Low Risk	B	42852	2020-04-14
Anti-GAD	EL8-1060	Low Risk	B	30340	2020-04-14
IAA	EL8-1061	Low Risk	B	30339	2020-04-14
IGF-1	EL8-1062	Low Risk	B	30361	2020-04-14
Pro-Insulin	EL1-1063	Low Risk	C	42852	2020-04-14
Fertility					
Human Growth Hormone (HGH)	EL1-1083	Low Risk	B	30333	2020-04-14
hCG Visual	EL6-1082	Low Risk	B	30513	2020-04-14
Beta hCG (Total)	EL2-1078	Low Risk	B	30332	2020-04-14
FSH	EL1-1080	Low Risk	B	31533	2020-04-14
LH	EL1-1084	Low Risk	B	38246	2020-04-14
Prolactin	EL1-1086	Low Risk	B	30325	2020-04-14
PAPP-A	EL3-1085	Low Risk	B	31533	2020-04-14
SHBG	EL3-1261	Low Risk	B	30326	2020-04-14
AMH	EL3-1079	Low Risk	B	43148	2020-04-14
hCG	EL1-1081	Low Risk	B	30332	2020-04-14
Sperm Ab	EL8-1087	Low Risk	B	30486	2020-04-14
Infectious Diseases					
Adenovirus IgG	EL15-1102	Low Risk	C	39468	2020-04-14
Adenovirus IgA	EL15-1101	Low Risk	C	39468	2020-04-14
Adenovirus IgM	EL15-1103	Low Risk	C	39468	2020-04-14
Influenza A IgA	EL15-1365	Low Risk	B	39463	2020-04-14
Influenza A IgG	EL15-1366	Low Risk	B	39463	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Influenza A IgM	EL15-1367	Low Risk	B	39463	2020-04-14
Influenza B IgA	EL15-1368	Low Risk	B	39463	2020-04-14
Influenza B IgG	EL15-1369	Low Risk	B	39463	2020-04-14
Influenza B IgM	EL15-1370	Low Risk	B	39463	2020-04-14
Chikungunya IgG	EL4-1114	Low Risk	D	32481	2020-04-14
Chikungunya IgM	EL4-1113	Low Risk	D	32481	2020-04-14
COVID-19 IgA	EL45-1373	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL1-1360	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL1-1361	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL36-1360R	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL36-1361R	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL45-1360	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL45-1361	Low Risk	D	42994	2020-04-14
COVID-19 Total Ab	EL45-1379	Low Risk	D	42994	2020-12-06
Mycobacterium Tuberculosis (TB) IgA	EL15-1317	Low Risk	C	30635	2020-04-14
Mycobacterium Tuberculosis (TB) IgG	EL15-1201	Low Risk	C	30635	2020-04-14
Mycobacterium Tuberculosis (TB) IgM	EL15-1202	Low Risk	C	30635	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgA)	EL2-1162	Low Risk	C	38870	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgG)	EL1-1163	Low Risk	C	38870	2020-04-14
Herpes Simplex 1 IgM (HSV1 IgM)	EL1-1164	Low Risk	C	38870	2020-04-14
Herpes Simplex 2 IgG (HSV2 IgG)	EL1-1165	Low Risk	C	38875	2020-04-14
Herpes Simplex 2 IgM (HSV2 IgM)	EL1-1166	Low Risk	C	38875	2020-04-14
Herpes Simplex 1,2 IgG (HSV1,2 IgG)	EL1-1167	Low Risk	C	40176	2020-04-14
Herpes Simplex 1,2 IgM (HSV1,2 IgM)	EL1-1168	Low Risk	C	40176	2020-04-14
Epstein Barr Virus VCA IgA (EBV, VCA IgA)	EL2-1135	Low Risk	D	30809	2020-04-14
Epstein Barr Virus VCA IgG (EBV, VCA IgG)	EL1-1136	Low Risk	D	30809	2020-04-14
Epstein Barr Virus VCA IgM (EBV, VCA IgM)	EL1-1137	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgM	EL2-1134	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgG	EL2-1133	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgA	EL2-1132	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgG	EL2-1130	Low Risk	D	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgM	EL2-1131	Low Risk	D	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgA	EL2-1129	Low Risk	D	30808	2020-04-14
Measles IgG	EL1-1177	Low Risk	C	44019	2020-04-14
Measles IgM	EL1-1178	Low Risk	C	44019	2020-04-14
Mumps IgG	EL1-1179	Low Risk	C	33908	2020-04-14
Mumps IgM	EL1-1180	Low Risk	C	33908	2020-04-14
Mycoplasma pneumonia IgG	EL1-1181	Low Risk	C	30657	2020-04-14
Mycoplasma pneumonia IgM	EL1-1182	Low Risk	C	30657	2020-04-14
Syphilis (TPA) IgG	EL1-1195	Low Risk	C	30685	2020-04-14
Syphilis (TPA) IgM	EL1-1197	Low Risk	C	30685	2020-04-14
Legionela urine Ag detection	EL16-1175	Low Risk	C	30692	2020-04-14
H. pylori IgG	EL1-1140	Low Risk	B	30691	2020-04-14
H. pylori IgA	EL1-1139	Low Risk	B	30691	2020-04-14
H-Pylori IgM	EL1-1141	Low Risk	B	30691	2020-04-14
H. pylori Antigen	EL2-1138,	Low Risk	B	30691	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
	EL32-1138				
Varicella-Zoster IgG	EL1-1209	Low Risk	C	44027	2020-04-14
Varicella-Zoster IgM	EL1-1210	Low Risk	C	44027	2020-04-14
HEV IgG	EL13-1156	Low Risk	C	30757	2020-04-14
HEV IgM	EL13-1161	Low Risk	C	30758	2020-04-14
HAV Ab	EL7-1142	Low Risk	C	30721	2020-04-14
HAV IgM	EL7-1143	Low Risk	C	30722	2020-04-14
HDV IgG	EL7-1153	Low Risk	D	30750	2020-04-14
HDV IgM	EL7-1155	Low Risk	D	30752	2020-04-14
HDV Ab	EL13-1315	Low Risk	D	30750	2020-04-14
HDV Ag	EL13-1316, EL7-1154	Low Risk	D	30747	2020-04-14
HTLV 1 + 2 Ab	EL7-1160	Low Risk	C	30789	2020-04-14
Lyme Disease IgG	EL10-1171	Low Risk	C	30697	2020-04-14
Lyme Disease IgM	EL10-1172	Low Risk	C	30697	2020-04-14
Lyme Disease IgG, M	EL10-1173	Low Risk	C	30697	2020-04-14
Bordetella Pertussis IgA	EL15-1110	Low Risk	C	37723	2020-04-14
Bordetella Pertussis IgG	EL15-1111	Low Risk	C	37723	2020-04-14
Bordetella Pertussis IgM	EL15-1112	Low Risk	C	37723	2020-04-14
RSV IgA	EL15-1186	Low Risk	B	30814	2020-04-14
RSV IgG	EL15-1187	Low Risk	B	30814	2020-04-14
RSV IgM	EL15-1188	Low Risk	B	30814	2020-04-14
Tetanus	EL5-1205	Low Risk	C	38876	2020-04-14
Diphtheria IgG	EL5-1124	Low Risk	D	33499	2020-04-14
Salmonella typhi IgG	EL1-1193	Low Risk	C	30709	2020-04-14
Salmonella typhi IgM	EL1-1194	Low Risk	C	30709	2020-04-14
Salmonella Antigen detection	EL4-1192	Low Risk	C	30709	2020-04-14
Anthrax IgG	EL1-1105	Low Risk	C	32481	2020-04-14
Babesia IgG	EL4-1109	Low Risk	C	32481	2020-04-14
Dengue IgM	EL5-1127	Low Risk	C	32481	2020-04-14
Dengue IgG/IgM	EL5-1125	Low Risk	C	32481	2020-04-14
Dengue IgG	EL5-1126	Low Risk	C	32481	2020-04-14
Dengue NS1 Antigen	EL4-1128	Low Risk	C	32481	2020-04-14
Japanese Encephalitis IgG	EL4-1169	Low Risk	C	44321	2020-04-14
Japanese Encephalitis IgM	EL4-1170	Low Risk	C	44321	2020-04-14
Leprosy IgG/IgM	EL4-1176	Low Risk	C	32481	2020-04-14
Parvovirus B19 IgG	EL30-1183	Low Risk	C	40443	2020-04-14
Parvovirus B19 IgM	EL30-1184	Low Risk	C	40444	2020-04-14
Rotavirus (fecal)	EL16-1185	Low Risk	C	30815	2020-04-14
Scrub Typhus IgG	EL4-1199	Low Risk	C	44028	2020-04-14
Scrub Typhus IgM	EL4-1200	Low Risk	C	44028	2020-04-14
TB IgA	EL15-1317	Low Risk	C	30635	2020-04-14
TB IgG	EL15-1201	Low Risk	C	30635	2020-04-14
TB IgM	EL15-1202	Low Risk	C	30635	2020-04-14
Zika Virus IgG	EL1-1203	Low Risk	C	32481	2020-04-14
Zika Virus IgM	EL1-1204	Low Risk	C	32481	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
West Nile IgG	EL4-1211	Low Risk	C	42926	2020-04-14
West Nile IgM	EL4-1212	Low Risk	C	42926	2020-04-14
Parasitology					
Schistosoma IgG	EL5-1227	Low Risk	C	30824	2020-04-14
Chagas	EL5-1213	Low Risk	D	30820	2020-04-14
Cysticercosis IgG (T. solium)	EL5-1220	Low Risk	B	39979	2020-04-14
Campylobacter	EL16-1229	Low Risk	B	33948	2020-04-14
E. coli 0157 Ag detection	EL16-1232	Low Risk	B	37727	2020-04-14
E. histolytica IgG (Amebiasis)	EL5-1221	Low Risk	B	39979	2020-04-14
E. histolytica Dispar	EL16-1233	Low Risk	B	39979	2020-04-14
Echinococcus IgG	EL5-1222	Low Risk	B	30822	2020-04-14
Fasciola IgG	EL5-1216	Low Risk	B	34068	2020-04-14
Fasciola gigantica	EL5-1217	Low Risk	B	34068	2020-04-14
Filaria IgG4	EL4-1218	Low Risk	B	34068	2020-04-14
Leishmania	EL5-1223	Low Risk	C	30823	2020-04-14
Leptospira IgG	EL5-1224	Low Risk	C	30716	2020-04-14
Leptospira IgM	EL5-1226	Low Risk	C	30716	2020-04-14
Leptospira IgG/IgM	EL5-1225	Low Risk	C	30716	2020-04-14
Toxocara IgG	EL5-1228	Low Risk	C	34068	2020-04-14
Trichinella IgG	EL5-1215	Low Risk	C	33379	2020-04-14
Ascaris IgG	EL5-1219	Low Risk	B	39979	2020-04-14
Strongyloides IgG	EL5-1214	Low Risk	C	34068	2020-04-14
Crypto/Giardia Ag detection	EL16-1230	Low Risk	B	30675	2020-04-14
Cryptosporidium Ag detection	EL16-1231	Low Risk	B	30675	2020-04-14
Giardia antigen	EL16-1235	Low Risk	B	36173	2020-04-14
Giardia coprpantigen in stool	EL5-1361	Low Risk	B	36173	2020-04-14
Anti-Giardia IgA ELISA in saliva	EL5-1362	Low Risk	B	36173	2020-04-14
Entamoeba histolytica coproantigen in stool	EL5-1363	Low Risk	B	39979	2020-04-14
Adenovirus Antigen	EL16-1104	Low Risk	C	41274	2020-04-14
Steroid					
Aldosterone	EL3-1247	Low Risk	C	31428	2020-04-14
Cortisol	EL1-1249	Low Risk	C	31394	2020-04-14
Aldosterone	EL3-1247	Low Risk	B	31428	2020-04-14
Cortisol	EL1-1249	Low Risk	C	31394	2020-04-14
Cortisol Saliva	EL9-1250	Low Risk	C	31394	2020-04-14
Estradiol	EL1-1254	Low Risk	B	30321	2020-04-14
DHEA-S	EL1-1251	Low Risk	C	30320	2020-04-14
DHEA	EL3-1252	Low Risk	C	39894	2020-04-14
Progesterone	EL1-1259	Low Risk	C	30323	2020-04-14
Progesterone Saliva	EL9-1260	Low Risk	C	30294	2020-04-14
Testosterone	EL1-1263	Low Risk	B	30327	2020-04-14
Testosterone Saliva	EL9-1265	Low Risk	B	30327	2020-04-14
Free Testosterone	EL1-1264	Low Risk	B	30327	2020-04-14
Androstenedione	EL1-1248	Low Risk	C	30321	2020-04-14
Free Estriol	EL1-1257	Low Risk	B	30330	2020-04-14
Dihydrotestosterones (DHT)	EL9-1253	Low Risk	C	30327	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
17-OH Progesterone	EL1-1245	Low Risk	C	30324	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a- Diol G)	EL9-1246	Low Risk	C	31533	2020-04-14
Total Estrogen	EL9-1255	Low Risk	B	38858	2020-04-14
Estrone	EL3-1256	Low Risk	B	33293	2020-04-14
Pregnenolone	EL9-1258	Low Risk	B	33301	2020-04-14
Total Estriol	EL8-1266	Low Risk	B	30330	2020-04-14
Thyroid					
T3	EL1-1270	Low Risk	C	30314	2020-04-14
T4	EL1-1271	Low Risk	C	30312	2020-04-14
TSH	EL1-1273	Low Risk	C	30489	2020-04-14
U-TSH	EL6-1275	Low Risk	C	30489	2020-04-14
Free T4	EL1-1268	Low Risk	C	30308	2020-04-14
Free T3	EL1-1267	Low Risk	C	30309	2020-04-14
Reverse T3	EL9-1274	Low Risk	C	30311	2020-04-14
T Uptake	EL3-1269	Low Risk	C	30313	2020-04-14
Tg (Thyroglobulin)	EL1-1272	Low Risk	C	30490	2020-04-14
TBG (Thyroxine-Binding Globulin)	EL3-1262	Low Risk	C	30316	2020-04-14
Neo-Natal Panel					
Neo-Natal T4	EL1-1240	Low Risk	C	30273	2020-04-14
Neo-Natal TSH	EL1-1239	Low Risk	C	30310	2020-04-14
Neo-Natal TBG	EL3-1242	Low Risk	C	30316	2020-04-14
Neo-Natal 17-OH Progesterone	EL1-1236	Low Risk	C	30324	2020-04-14
Neo-Natal MSUD	EL1-1237	Low Risk	C	30273	2020-04-14
Neo-Natal PKU	EL1-1238	Low Risk	C	30273	2020-04-14
Neo-Natal IRT	EL1-1241	Low Risk	C	30273	2020-04-14
Neo-Natal Total Galactose	EL1-1243	Low Risk	C	30273	2020-04-14
G6PD	EL1-1303	Low Risk	C	30273	2020-04-14
Neo-Natal Biotinidase	EL1-1244	Low Risk	C	30273	2020-04-14
Others					
Procalcitonin	EL3-1309	Low Risk	C	12069016	2020-04-14
Calcitonin	EL3-1292	Low Risk	C	30342	2020-04-14
Renin	EL9-1300	Low Risk	B	43444	2020-04-14

IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Autoimmune Diseases and others					
ANA Rat Liver IFA Kit	IF17-4002, IF17-4019	Low Risk	C	41420	2020-04-14
ANA Mouse Kidney IFA Kit	IF17-4003	Low Risk	C	41420	2020-04-14
ANA Hep-2 IFA Kit	IF17-4004, IF17-4005, IF17-4018	Low Risk	C	17269	2020-04-14
AMA IFA Kit	IF17-4022, IF17-4023	Low Risk	C	17267	2020-04-14
AAS Rat Kidney Stomach Liver Tissue	IF17-4000	Low Risk	C	30274	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
ASMA IFA Kit	IF17-4006, IF17-4015	Low Risk	C	30274	2020-04-14
ATA IFA Kit	IF17-4030, IF174031	Low Risk	C	30274	2020-04-14
ASA IFA Kit	IF17-4008, IF17-4034	Low Risk	C	30274	2020-04-14
nDNA IFA Kit	IF17-4007, IF17-4051, IF17-4052	Low Risk	C	30274	2020-04-14
Endomysial (Primate Endomysial)	IF17-4032, IF17-4033	Low Risk	C	12109016	2020-04-14
Anti-Reticulin IgA	IF17-4041, IF17-4042	Low Risk	C	30526	2020-04-14
Anti-Reticulin IgG	IF17-4043, IF17-4044	Low Risk	C	30526	2020-04-14
C-ANCA	IF17-4059	Low Risk	C	30484	2020-04-14
P-ANCA	IF17-4060	Low Risk	C	30483	2020-04-14
Bacterial Diseases					
Legionella pneumophila 1-6 IFA Poly (HT)	IF17-4063, IF17-4064	Low Risk	C	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj/C Specimen	IF17-4061	Low Risk	C	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj DFA Screen	IF17-4062	Low Risk	C	30694	2020-04-14
FTA-ABS Double Stain (Syphilis) IFA Kit	IF17-4013, IF17-4066	Low Risk	C	32455	2020-04-14
FTA-ABS (T. pallidum)	IF17-4012, IF17-4067	Low Risk	C	32455	2020-04-14
FTA-ABS (Syphilis) Titrable IFA Kit	IF17-4014	Low Risk	C	32455	2020-04-14
Viral diseases					
HSV-1 IgG IFA Kit	IF17-4016	Low Risk	C	39502	2020-04-14
HSV-2 IgG IFA Kit	IF17-4080	Low Risk	C	39502	2020-04-14
HSV-1 IgM IFA Kit	IF17-4017	Low Risk	C	39502	2020-04-14
HSV-2 IgM IFA Kit	IF17-4081	Low Risk	C	39502	2020-04-14
HSV 1&2 IgG	IF17-4078	Low Risk	C	39502	2020-04-14
HSV 1&2 IgM	IF17-4079	Low Risk	C	39502	2020-04-14
EBV-VCA IgG IFA Kit	IF17-4074	Low Risk	C	33971	2020-04-14
EBV-VCA IgM IFA Kit	IF17-4075	Low Risk	C	33971	2020-04-14
EBV-EA IFA Kit	IF17-4077	Low Risk	C	33971	2020-04-14
EBNA IFA Kit	IF17-4076	Low Risk	C	33971	2020-04-14
RMSF Rocky Mountain Spotted Fever (R. ricketsii)	IF17-4065	Low Risk	C	32473	2020-04-14
Measles IgG IFA Kit	IF17-4092	Low Risk	C	44019	2020-04-14
Measles IgM IFA Kit	IF17-4093	Low Risk	C	44019	2020-04-14
Mumps IgG IFA Kit	IF17-4094	Low Risk	C	33908	2020-04-14
Mumps IgM IFA Kit	IF17-4095	Low Risk	C	33908	2020-04-14
RSV IgG (Respiratory Syncytial Virus)	IF17-4096	Low Risk	C	30814	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
RSV IgM (Respiratory Syncytial Virus)	IF17-4097	Low Risk	C	30814	2020-04-14
Varicella-Zoster Virus IgG IFA Kit	IF17-4098	Low Risk	C	44027	2020-04-14
Varicella-Zoster Virus IgM IFA Kit	IF17-4099	Low Risk	C	44027	2020-04-14
West Nile Virus IgG	IF17-4100	Low Risk	C	42926	2020-04-14
West Nile Virus IgG	IF17-4101	Low Risk	C	42926	2020-04-14

RT-PCR	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
SARS-CoV-2	PR31-8000	Low Risk	D	42994	2020-04-14
SARS-CoV-2	PR4-8000	Low Risk	D	42994	2020-04-14
SARS-CoV-2 pap-PCR	PR45-8000	Low Risk	D	42994	2020-12-06
SARS-CoV-2/Flu/RSV RT-PCR	PR31-8001	Low Risk	D	42994	2020-12-06

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Tumor Markers Tests					
FOB Cassette	RT27-2182	Low Risk	C	38217	2020-04-14
FOB Strip	RT27-2181	Low Risk	C	38217	2020-04-14
CEA	RT27-2180	Low Risk	C	30288	2020-04-14
AFP	RT27-2179	Low Risk	C	30295	2020-04-14
Cardiac markers					
CK-MB Cassette (Serum/Plasma/Whole Blood)	RT27-2001	Low Risk	C	30499	2020-04-14
C-Reactive Protein (CRP) Cassette (Serum/Plasma/Whole Blood)	RT27-2003	Low Risk	C	30507	2020-04-14
C-Reactive Protein (CRP) Strip (Serum/Plasma/Whole Blood)	RT27-2002	Low Risk	C	30507	2020-04-14
D-Dimer Cassette (Plasma/Whole Blood)	RT27-2004	Low Risk	C	30576	2020-04-14
Myoglobin Cassette (Serum/Plasma/Whole Blood)	RT27-2005	Low Risk	C	30264	2020-04-14
Troponin I Cassette (Serum/Plasma/Whole Blood)	RT27-2007	Low Risk	C	30509	2020-04-14
3 in 1 Troponin I/Myoglobin/CKMB Cassette (Serum/Plasma/Whole Blood)	RT27-2006	Low Risk	C	42649	2020-04-14
Drug Test					
Alcohol Urine Strip	RT27-2010	Low Risk	B	30443	2020-04-14
Alcohol Saliva Strip	RT27-2009	Low Risk	B	30443	2020-04-14
Amphetamine Urine Cassette	RT27-2012	Low Risk	C	30516	2020-04-14
Amphetamine Urine Strip	RT27-2011	Low Risk	C	30516	2020-04-14
Barbiturates Urine Cassette	RT27-2014	Low Risk	C	30517	2020-04-14
Barbiturates Urine Strip	RT27-2013	Low Risk	C	30517	2020-04-14
Buprenorphine Urine Cassette	RT27-2016	Low Risk	C	31584	2020-04-14
Buprenorphine Urine Strip	RT27-2015	Low Risk	C	31584	2020-04-14
Benzodiazepine Urine Cassette	RT27-2018	Low Risk	C	30518	2020-04-14
Benzodiazepine Urine Strip	RT27-2017	Low Risk	C	30518	2020-04-14
Cocaine Urine Cassette	RT27-2022	Low Risk	C	30520	2020-04-14
Cocaine Urine Strip	RT27-2021	Low Risk	C	30520	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Cotinine Cassette	RT27-2024	Low Risk	C	37270	2020-04-14
Cotinine Strip	RT27-2023	Low Risk	C	37270	2020-04-14
EDDP Urine Cassette	RT27-2028	Low Risk	C	30521	2020-04-14
EDDP Urine Strip	RT27-2027	Low Risk	C	30521	2020-04-14
Fentanyl Urine Cassette	RT27-2030	Low Risk	C	31582	2020-04-14
Fentanyl Urine Strip	RT27-2029	Low Risk	C	31582	2020-04-14
Ketamine Urine Cassette	RT27-2032	Low Risk	C	31582	2020-04-14
Ketamine Urine Strip	RT27-2031	Low Risk	C	31582	2020-04-14
MDMA(Ecstasy) Cassette	RT27-2038	Low Risk	C	30423	2020-04-14
MDMA(Ecstasy) Strip	RT27-2037	Low Risk	C	30423	2020-04-14
Methadone (MTD) Urine Urine Cassette	RT27-2040	Low Risk	C	30521	2020-04-14
Methadone (MTD) Urine Urine Strip	RT27-2039	Low Risk	C	30521	2020-04-14
Methamphetamine Urine Cassette	RT27-2042	Low Risk	C	30423	2020-04-14
Methamphetamine Urine Strip	RT27-2041	Low Risk	C	30423	2020-04-14
Marijuana (THC) Urine Cassette	RT27-2057	Low Risk	C	30519	2020-04-14
Marijuana (THC) Urine Strip	RT27-2056	Low Risk	C	30519	2020-04-14
Opiates Urine Cassette	RT27-2044	Low Risk	C	30522	2020-04-14
Opiates Urine Strip	RT27-2043	Low Risk	C	30522	2020-04-14
Oxycodone Urine Cassette	RT27-2047	Low Risk	C	31584	2020-04-14
Oxycodone Urine Strip	RT27-2046	Low Risk	C	31584	2020-04-14
Phencyclidine (PCP) Urine Cassette	RT27-2049	Low Risk	C	30523	2020-04-14
Phencyclidine (PCP) Urine Strip	RT27-2048	Low Risk	C	30435	2020-04-14
Tricyclic Antidepressants (TCA) Cassette	RT27-2055	Low Risk	C	30524	2020-04-14
Tricyclic Antidepressants (TCA) Strip	RT27-2054	Low Risk	C	30523	2020-04-14
Tramadol Urine Cassette	RT27-2059	Low Risk	C	31582	2020-04-14
Tramadol Urine Strip	RT27-2058	Low Risk	C	31582	2020-04-14
2-Drug Cassette (Any Combination)	RT27-2060	Low Risk	C	30261	2020-04-14
3-Drug Cassette (Any Combination)	RT27-2061	Low Risk	C	30261	2020-04-14
4-Drug Cassette (Any Combination)	RT27-2062	Low Risk	C	30261	2020-04-14
5-Drug Cassette (Any Combination)	RT27-2063	Low Risk	C	30261	2020-04-14
6-Drug Cassette (Any Combination)	RT27-2064	Low Risk	C	30261	2020-04-14
7-Drug Cassette (Any Combination)	RT27-2065	Low Risk	C	30261	2020-04-14
8-Drug Cassette (Any Combination)	RT27-2066	Low Risk	C	30261	2020-04-14
9-Drug Cassette (Any Combination)	RT27-2067	Low Risk	C	30261	2020-04-14
10-Drug Cassette (Any Combination)	RT27-2068	Low Risk	C	30261	2020-04-14
11-Drug Cassette (Any Combination)	RT27-2069	Low Risk	C	30261	2020-04-14
12-Drug Cassette (Any Combination)	RT27-2070	Low Risk	C	30261	2020-04-14
2-Drug Strip (Any Combination)	RT27-2071	Low Risk	C	30261	2020-04-14
3-Drug Strip (Any Combination)	RT27-2072	Low Risk	C	30261	2020-04-14
4-Drug Strip (Any Combination)	RT27-2073	Low Risk	C	30261	2020-04-14
5-Drug Strip (Any Combination)	RT27-2074	Low Risk	C	30261	2020-04-14
6-Drug Strip (Any Combination)	RT27-2075	Low Risk	C	30261	2020-04-14
7-Drug Strip (Any Combination)	RT27-2076	Low Risk	C	30261	2020-04-14
8-Drug Strip (Any Combination)	RT27-2077	Low Risk	C	30261	2020-04-14
9-Drug Strip (Any Combination)	RT27-2078	Low Risk	C	30261	2020-04-14
10-Drug Strip (Any Combination)	RT27-2079	Low Risk	C	30261	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
11-Drug Strip (Any Combination)	RT27-2080	Low Risk	C	30261	2020-04-14
12-Drug Strip (Any Combination)	RT27-2081	Low Risk	C	30261	2020-04-14
Drug Test/Cup					
2-Drug Cup (Any Combination)	RT27-2082	Low Risk	C	30261	2020-04-14
3-Drug Cup (Any Combination)	RT27-2083	Low Risk	C	30261	2020-04-14
4-Drug Cup (Any Combination)	RT27-2084	Low Risk	C	30261	2020-04-14
5-Drug Cup (Any Combination)	RT27-2085	Low Risk	C	30261	2020-04-14
6-Drug Cup (Any Combination)	RT27-2086	Low Risk	C	30261	2020-04-14
7-Drug Cup (Any Combination)	RT27-2087	Low Risk	C	30261	2020-04-14
8-Drug Cup (Any Combination)	RT27-2088	Low Risk	C	30261	2020-04-14
9-Drug Cup (Any Combination)	RT27-2089	Low Risk	C	30261	2020-04-14
10-Drug Cup (Any Combination)	RT27-2090	Low Risk	C	30261	2020-04-14
11-Drug Cup (Any Combination)	RT27-2091	Low Risk	C	30261	2020-04-14
12-Drug Cup (Any Combination)	RT27-2092	Low Risk	C	30261	2020-04-14
Infectious Diseases and others					
Legionella Urinary Antigen Cassette	RT27-2147	Low Risk	C	30692	2020-04-14
Legionella Urinary Antigen Strip	RT27-2146	Low Risk	C	30692	2020-04-14
Adeno/Rotavirus Antigen Cassette	RT27-2131	Low Risk	C	42994	2020-04-14
Adeno Antigen Cassette	RT27-2132	Low Risk	C	42994	2020-04-14
Rotavirus Antigen Cassette	RT27-2161	Low Risk	C	30815	2020-04-14
Chagas Cassette	RT27-2133	Low Risk	C	30820	2020-04-14
Chikungunya IgG/IgM Cassette	RT27-2135	Low Risk	C	42994	2020-04-14
Gonorrhoea Cassette	RT27-2140	Low Risk	C	38851	2020-04-14
Influenza A&B Cassette	RT27-2145	Low Risk	C	39466	2020-04-14
Leishmania IgG/IgM Cassette	RT27-2149	Low Risk	C	30823	2020-04-14
Leishmania Cutaneous Strip	RT27-2148	Low Risk	C	30823	2020-04-14
Leptospira IgG/IgM	RT27-2150	Low Risk	C	30716	2020-04-14
Syphilis Cassette	RT27-2172	Low Risk	C	30687	2020-04-14
Syphilis Strip	RT27-2173, RT24-2173	Low Risk	C	30687	2020-04-14
Mononucleosis Cassette (Mono) (S/P)	RT27-2177	Low Risk	C	30826	2020-04-14
Strep A Cassette	RT27-2169	Low Risk	C	30826	2020-04-14
Strep A Strip	RT27-2168	Low Risk	C	30826	2020-04-14
Strep B Cassette	RT27-2171	Low Risk	C	30827	2020-04-14
Strep B Strip	RT27-2170	Low Risk	C	30827	2020-04-14
H1N1 Strip	RT40-2209	Low Risk	C	39461	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma)	RT27-2141	Low Risk	B	30825	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma/Whole Blood)	RT27-2142, RT24-2142	Low Risk	B	30825	2020-04-14
H. Pylori Antigen Cassette	RT27-2143, RT24-2203	Low Risk	B	30689	2020-04-14
HAV IgM	RT27-2108	Low Risk	C	30720	2020-04-14
Dengue IgG&IgM	RT27-2138, RT24-2197	Low Risk	C	42994	2020-04-14
Dengue NS1	RT24-2139	Low Risk	C	42994	2020-04-14
Dengue IgG/IgM/NS1	RT24-2208	Low Risk	C	42994	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Malaria P.f./Pv	RT24-2204	Low Risk	C	30674	2020-04-14
Malaria Pan	RT24-2206	Low Risk	C	30674	2020-04-14
Malaria P.f./Pan	RT24-2205, RT27-2154	Low Risk	C	30674	2020-04-14
Malaria P.f. Cassette	RT24-2207, RT27-2151	Low Risk	C	30674	2020-04-14
Malaria P.f. Strip	RT27-2152	Low Risk	C	30674	2020-04-14
Malaria P.f./vivax	RT27-2153	Low Risk	C	30674	2020-04-14
Norovirus	RT27-2156	Low Risk	C	32459	2020-04-14
Salmonella typhi Antigen Cassette	RT27-2163	Low Risk	C	30709	2020-04-14
Salmonella typhi IgG/IgM Cassette	RT27-2164	Low Risk	C	30709	2020-04-14
Salmonella typhi/paratyphi antigen	RT27-2165	Low Risk	C	30709	2020-04-14
Scrub typhus IgG Strip	RT4-2166	Low Risk	C	30717	2020-04-14
Scrub typhus IgM Strip	RT4-2167	Low Risk	C	30717	2020-04-14
Zika Virus IgG/IgM Cassette	RT27-2178	Low Risk	C	42994	2020-04-14
COVID-19 IgG/IgM	RT24-2198, RT28-2198, RT45-2198	Low Risk	D	44022	2020-04-14
SARS-CoV2 Antigen Rapid Test	RT45-2214	Low Risk	D	44022	2020-08-24
Tuberculosis (TB) Cassette	RT27-2175	Low Risk	C	44020	2020-04-14
Tuberculosis (TB) Strip	RT27-2174	Low Risk	C	44020	2020-04-14
HEV IgG/IgM	RT27-2119	Low Risk	D	30756	2020-04-14
Cryptococcus Ag	RT27-2137	Low Risk	C	37746	2020-04-14
Hantavirus IgG/IgM	RT27-2144	Low Risk	C	15048014	2020-04-14
Mycoplasma pneumoniae Ag	RT27-2155	Low Risk	C	17311	2020-04-14
Rickettsia IgG/IgM	RT24-2160	Low Risk	C	30717	2020-04-14
RSV	RT27-2162	Low Risk	C	30814	2020-04-14
Tetanus	RT27-2176	Low Risk	C	38876	2020-04-14
Fertility					
FSH Urine Cassette	RT27-2094	Low Risk	B	30512	2020-04-14
FSH Urine Strip	RT27-2093	Low Risk	B	30512	2020-04-14
Ovulation					
LH Urine Cassette	RT27-2106	Low Risk	B	30515	2020-04-14
LH Urine Strip	RT27-2105	Low Risk	B	30515	2020-04-14
Pregnancy					
hCG 10 mIU/ml Midstream	RT27-2099	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml Midstream	RT27-2102	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine Cassette	RT27-2095	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine Strip	RT27-2097	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine/serum	RT27-2098	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine Cassette	RT27-2101	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine Strip	RT27-2100	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine/serum/p	RT27-2096	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Cassette	RT27-2104	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Strip	RT27-2103	Low Risk	B	30513	2020-04-14
Others					

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Micro-Albumin (HAS) Strip	RT27-2197	Low Risk	C	30246	2020-04-14
Ferritin	RT27-2196	Low Risk	C	30377	2020-04-14
H-FABP	RT27-2107	Low Risk	C	1230190	2020-04-14
Nt-proBNP	RT27-1157	Low Risk	C	12130190	2020-04-14
Procalcitonin (S/P/WB)	RT27-2158	Low Risk	C	12069016	2020-04-14
Procalcitonin (S/P)	RT27-2159	Low Risk	C	12069016	2020-04-14
Urine Reagent Strips					
URS-1G	RT27-2185	Low Risk	B	17419	2020-04-14
URS-2PK	RT27-2186	Low Risk	B	30226	2020-04-14
URS-3 GKpH	RT27-2187	Low Risk	B	30226	2020-04-14
URS-4 GKpHB	RT27-2188	Low Risk	B	30226	2020-04-14
URS-5GKpHBP	RT27-2189	Low Risk	B	30226	2020-04-14
URS-6GKpHBPBili	RT27-2190	Low Risk	B	30226	2020-04-14
URS-7GKpHBPBiliU	RT27-2191	Low Risk	B	30226	2020-04-14
URS-8GKpHBPBiliUN	RT27-2192	Low Risk	B	30226	2020-04-14
URS-9GKpHBPBiliUNS	RT27-2193	Low Risk	B	30226	2020-04-14
URS-10GKpHBPBiliUNSL	RT27-2194	Low Risk	B	30226	2020-04-14
URS-11	RT27-2195	Low Risk	B	30226	2020-04-14

Serology Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
C- Reactive Protein (CRP)	SL25-3002, SL25-3003	Low Risk	C	30499	2020-04-14
RF	SL25-3008, SL25-3009	Low Risk	C	30500	2020-04-14
Anti- Streptolysin O(ASO)	SL25-3000, SL25-3001	Low Risk	C	30495	2020-04-14
Infectious Mononucleosis Screening (Mono)	SL25-3004, SL25-3005	Low Risk	C	30810	2020-04-14
RPR	SL25-3011, SL25-3012	Low Risk	C	17393	2020-04-14
Lupus Erythematosus (SLE)	SL25-3007	Low Risk	C	30487	2020-04-14
TPHA	SL25-3016	Low Risk	C	32453	2020-04-14
Rotavirus	SL25-3010	Low Risk	C	17381	2020-04-14
S. Aureus	SL25-3013	Low Risk	C	33887	2020-04-14
Streptococci Lancefield grouping	SL25-3015	Low Risk	C	17389	2020-04-14
VDRL Antigen	SL25-3017	Low Risk	C	17395	2020-04-14
PARATYPHOID A (Salmonella, flagellar a antigen)	SL25-3022	Low Risk	C	39453	2020-04-14
PARATYPHOID B (Salmonella, flagellar b antigen)	SL25-3023	Low Risk	C	39453	2020-04-14
PARATYPHOID C (Salmonella typhi, flagellar c antigen)	SL25-3024	Low Risk	C	39453	2020-04-14
SALMONELLA Group A Antigen (somatic antigen)	SL25-3028	Low Risk	C	39453	2020-04-14
SALMONELLA Group B Antigen (somatic antigen)	SL25-3029	Low Risk	C	39453	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

Serology Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
SALMONELLA Group C Antigen (somatic antigen)	SL25-3030	Low Risk	C	39453	2020-04-14
TYPHOID H (Salmonella typhi, flagellar d antigen)	SL25-3031	Low Risk	C	39453	2020-04-14
TYPHOID O (Salmonella typhi, somatic Group D antigen)	SL25-3032	Low Risk	C	39453	2020-04-14
Brucella Melitensis	SL25-3018	Low Risk	C	39536	2020-04-14
Brucella Abortus	SL25-3019	Low Risk	C	39536	2020-04-14
PROTEUS OX2 (somatic antigen)	SL25-3026	Low Risk	C	39543	2020-04-14
PROTEUS OX19 (somatic antigen)	SL25-3025	Low Risk	C	39543	2020-04-14
PROTEUS OXK (somatic antigen)	SL25-3027	Low Risk	C	39543	2020-04-14

AUTHORIZED REPRESENTATIVE AND CONSULTING SERVICE FOR CE MARKING **CEPARTNER4U BV,**
ESDOORNLAAN 13, 3951DB MAARN. THE NETHERLANDS. ☎:+31-(0)343.442.524; CELL PHONE: +31-(0)6.516.536.26;
FAX: +31-(0)343.442.162; E-MAIL: OFFICE@CEPARTNER4U.COM; WEBSITE: WWW.CEPARTNER4U.COM

Certificate of Registration

This is to certify the Quality Management System of:

MONOCENT, INC.
9237 Eton Avenue
Chatsworth, CA 91311

has been assessed and found to be in compliance with the requirements of

ISO 9001:2015

for the following scope:

Manufacturing and Distribution of IVD Products
(Serology, Rapid, ELISA, CLIA, IFA Test Systems and Instrumentation)

IAF Code: 31 & 35

Certificate Number: **SARA-2019-CA-0253-01-A**

Originally Registered:
January 10, 2020

Latest Issue:
December 20, 2022

Certification Cycle:
January 10, 2023 – January 9, 2026

Expiration Date:
January 9, 2026

President, SARA Registrar

MSCB-194

Certificate of Registration

This is to certify the Quality Management System of:

MONOCENT, INC.
9237 Eton Avenue
Chatsworth, CA 91311

has been assessed and found to be in compliance with the requirements of

ISO 13485:2016

for the following scope:

Manufacturing and Distribution of IVD Products
(Serology, Rapid, ELISA, CLIA, IFA Test Systems and Instrumentation)

ISO 13485:2016

Medical Device Code: In Vitro Dianostics (IVD) & Non-active Medical Device

Certificate Number: **SARA-2019-CA-0253-02-A**

Originally Registered:
January 10, 2020

Latest Issue:
December 20, 2022

Certification Cycle:
January 10, 2023 – January 9, 2026

Expiration Date:
January 9, 2026

President, SARA Registrar

MSCB-194

This registration is subject to the company maintaining its system to the required standard which will be monitored annually by SARA Registrar.
This certificate remains the property of Standards American Registrations Authority (SARA Registrar) and shall be returned immediately upon request.
SARA Registrar Headquarter Mailing: 1807H Santa Rita Road, #175, Pleasanton, CA 94566

MONOCENT
Innovation & Excellence

ENGLISH

ANA SCREEN IgG ELISA TEST SYSTEM

CE

REF EL1-1009 | Σ 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s ANA IgG ELISA Test System is an enzyme-linked immunosorbent assay (ELISA) for the detection of IgG class antibodies to ANA in human serum or plasma.

SUMMARY AND EXPLANATION

Antinuclear antibodies (ANA) are frequently present in patients with systemic lupus erythematosus (SLE) and, less commonly, in other autoimmune diseases Rheumatoid arthritis, Collagen vascular diseases, chronic liver diseases and systemic sclerosis (scleroderma). ANA bind to several nuclear antigens including DsDNA, SSDNA, RNP, Sm, SSA and SSB. ANA frequency increases with age in apparently healthy people, especially women after the age of 45 years. ANA ELISA is widely used as a screening procedure for different autoimmune diseases.

PRINCIPLE OF THE TEST

Diluted patient serum is added to wells coated with purified nuclear antigens. ANA IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample.

MATERIALS AND COMPONENTS

• Microwells coated with nuclear antigens	12x8x1
• Sample Diluent: 1 bottle (ready to use)	22ml
• Calibrator 1 Vial (ready to use)	1ml
• Positive Control 1 vial (ready to use)	1ml
• Negative Control 1 vial (ready to use)	1ml
• Enzyme conjugate: 1 bottle (ready to use)	12ml
• TMB Substrate: 1 bottle (ready to use)	12ml
• Stop Solution: 1 bottle (ready to use)	12ml
• Wash concentrate 20X: 1 bottle	25ml

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water.
- Precision pipettes.
- Disposable pipette tips.
- ELISA reader capable of reading absorbance at 450 nm.
- Absorbance paper or paper towel.

STORAGE CONDITIONS

- Store the kit at 2-8°C.
- Keep microwells sealed in a dry bag with desiccants.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun or strong light.

PRECAUTIONS

1. For Research Use Only. Not for use in diagnostic procedures.
2. For Laboratory use.
3. Not for Internal or External Use in Humans or Animals.
4. There should be no eating or drinking within work area.
5. Always wear gloves and a protective lab coat.
6. No pipetting should be done by mouth. Handle all specimens and reagents as potentially infectious and biohazardous.
7. Do not add sodium azide to samples as preservative.
8. Do not use external controls containing sodium azide.
9. Use disposable pipette tips to avoid contaminating chromogenic substrate reagent. Discard reagent if it turns blue.
10. Do not pour chromogenic substrate back into container after use.
11. Do not freeze reagents.
12. Do not mix reagents from different kit lot numbers.
13. Keep reagents out of direct sunlight.
14. Handle stop reagent with care, since it is corrosive.
15. Bring all reagents to room temperature.
16. Viscous forensic samples should always be diluted in phosphate buffered saline or distilled water prior to pipetting.
17. Ensure the bag containing the micro-plate strips and desiccant is sealed well, if only a few strips are used.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2-8°C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

REAGENT PREPARATION

Prepare 1x wash buffer by adding the contents of the bottle (25 ml, 20x) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

PREPARATION FOR TEST

Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

TEST PROCEDURE

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100 µl sample diluent in 1a well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1x wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1x wash buffer. Blot on absorbance paper or paper towel
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read OD at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.
2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

REFERENCES

1. Emlen w; o'neill l clinical significance of antinuclear antibodies: comparison of detection with immunofluorescence and enzyme-linked immunosorbent assays. Arthritis rheum 1997;40(9):1612-8.
2. Gonz´alez c; martin t; arroyo t; garc´ia-isidoro m; navajo ja; gonz´alez-buitrago jm. Comparison and variation of different methodologies for the detection of autoantibodies to nuclear antigens (ana). J clin lab anal 1997;11(6):388-92.
3. Parveen s; morshed sa; nishioka m. High prevalence of antibodies to recombinant cenp-b in primary biliary cirrhosis: nuclear immunofluorescence patterns and elisa reactivities. J gastroenterol hepatol 1995;10(4):438-45.
4. Welin henriksson e; hansson h; karlsson-parra a; pettersson i. Autoantibody profiles in canine ana-positive sera investigated by immunoblot and elisa. Vet immunol immunopathol 1998;61(2-4):157-70.
5. Koh wh; dunphy j; whyte j; dixey j; mchugh nj. Characterisation of anticytoplasmic antibodies and their clinical associations [see comments]. Ann rheum dis 1995;54(4):269-73.
6. Spronk pe; bootsma h; horst g; huitema mg; limburg pc; cohen tervaert jw; kallenberg cg. Antineutrophil cytoplasmic antibodies in systemic lupus erythematosus. Br j rheumatol 1996;35(7):625-31.

Manufactured by Monocent, Inc
9237 Eton Ave. Chatsworth, CA 91311, USA
Info@monocent.com | Tel: 424-310-0777
www.monocent.com

EC REP **CEpartner4U**
ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.
www.cepartner4u.com

Revision Date: 2017-04-13

MONOCENT
Innovation & Excellence

ENGLISH

CARDIOLIPIN IgG ELISA TEST SYSTEM

CE

REF EL1-1021 Σ 96 TESTS IVD

INTENDED USE

The Monocent, Inc.'s Cardiolipin IgG ELISA Test System is intended for the detection of IgG antibody to Cardiolipin in human serum or plasma.

SUMMARY AND EXPLANATION

Measurement of IgG, IgM and IgA cardiolipin autoantibodies (aCL) by EIA is the standard procedure for the detection of antiphospholipid antibodies (aPL) in patients with suspected antiphospholipid syndrome (APS). High aCL concentrations are associated with increased risk of venous and arterial thrombosis, recurrent pregnancy loss and thrombocytopenia. Patients with the anti-cardiolipin syndrome have one of the above clinical features and have antibodies to cardiolipin and/or a positive lupus anticoagulant test. The antibodies present to cardiolipin may be of the IgG, IgA, IgM isotypes. Testing for the various antibody isotypes to cardiolipin aid in diagnosis of the anti-phospholipid syndrome in patients with SLE or lupus-like disorders. Binding of aCL to CL in patients with autoimmune diseases is dependent on the presence of the cofactor *beta*-2-glycoprotein I (*beta2*-GPI); this binding is independent of *beta*-2-GPI in patients with infectious diseases (e.g., syphilis, tuberculosis). Recognition of the role of *beta*-2- GPI in the binding of aCL led to development of assay for direct measurement of *beta*-2-GPI autoantibodies using *beta*-2-GPI as antigen, allowing a clear distinction between *beta*-2-GPI autoantibodies and those that bind to CL alone.

PRINCIPLE OF THE TEST

Diluted patient serum is added to wells coated with purified aCL antigen. aCL specific IgG antibody, if present, binds to the antigen. All unbound materials are washed away, and the enzyme conjugate is added to bind to the antibody- antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of specific antibody in the sample.

MATERIALS AND COMPONENTS

- Microwells coated with Cardiolipin antigen (12x8x1)
- Sample Diluent: 1 bottle (ready to use) (22 ml)
- Calibrator: 1 vial (ready to use) (1ml)
- Positive Control: 1 vial (ready to use) (1ml)
- Negative Control: 1 vial (ready to use) (1ml)
- Enzyme conjugate: 1 bottle (ready to use) (12ml)
- TMB Substrate: 1 bottle (ready to use) (12ml)
- Stop Solution: 1 bottle (ready to use) (12ml)
- Wash concentrate 20X: 1 bottle (25ml)

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Precision pipettes
- Disposable pipette tips
- ELISA reader capable of reading absorbance at 450 nm
- Absorbance paper or paper towel
- Graph paper

STORAGE CONDITIONS

- Store the kit at 2-8°C.
- Keep microwells sealed in a dry bag with desiccants.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun or strong light.

PRECAUTIONS

1. Potential biohazardous materials:
   The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent, these reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984
2. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
3. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
4. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
5. This product contains components preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2-8°C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing of serum sample.

REAGENT PREPARATION

Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

TEST PROCEDURE

Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.
2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

Example of typical results:
Calibrator mean OD = 0.8
Calibrator Factor (CF) = 0.5
Cut-off Value = 0.8 x 0.5= 0.400
Positive control O.D. = 1.2
Ab Index = 1.2 / 0.4 = 3
Patient sample O.D. = 1.6
Ab Index = 1.6 / 0.4 = 4.0

INTERPRETATION
The following is intended as a guide to interpretation of aCL antibody test results; each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

Antibody Index Interpretation

<0.9	No detectable aCL IgG antibody by ELISA.
0.9-1.1	Borderline positive. Follow-up testing is recommended if clinically indicated.
>1.1	Detectable aCL IgG antibody by ELISA.

Converting of Ab Index to GPL
As an option, Ab index may be converted to GPL units by multiplying Ab index value by 11. GPL units may then be interpreted as follows:

<10 GPL	Negative
10- 15 GPL	Borderline positive.
15-80 GPL	Low/Medium Positive
> 80 GPL	High Positive

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:

1. The O.D. of the Calibrator should be greater than 0.250.
2. The Ab index for Negative control should be less than 0.9.
3. The Ab Index for Positive control should fall within the range specified on the COA/label.

LIMITATIONS OF THE PROCEDURE

1. The test results obtained using this kit serve only as an aid to diagnosis and should be interpreted in relation to the patient's history, physical findings and other diagnostic procedures.
2. Lipemic or hemolyzed samples may cause erroneous results.

PERFORMANCE CHARACTERISTICS

1. SENSITIVITY AND SPECIFICITY

291 patient sera were tested by this ELISA and a reference ELISA method. 118 sera were positive, and 164 sera were negative by both methods. The agreement between the two methods was 96% (282/291). The results are summarized below:

		Monocent ELISA		
		+	–	Total
Reference ELISA kit	+	118	5	123
	–	4	164	168
	Total	122	169	291

2. PRECISION

Intra-Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	16	1.22	0.09	6.55
2	16	0.78	0.05	6.41
3	16	0.22	0.02	9.09

Inter-Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	10	1.17	0.1	8.54
2	10	0.84	0.09	10.8
3	10	0.27	0.04	14.8

REFERENCES

1. Barka N, Reagan K, Agopian M, Peter JB. Frequency of anticardiolipin and antiphosphatidylserine antibodies in patients with suspected antiphospholipid syndrome. Clin Chem 1995;41:5.
2. Khamashta MA, Hughes GRV. Detection and importance of anticardiolipin antibodies. J Clin Pathol 1993;46:104-7.
3. Reyes H, Dearing L, Bick RL, Shoenfeld Y, Peter JB. Laboratory diagnosis of antiphospholipid syndromes. Lab Clin North Am 1995;15:85-108.
4. Harris EN, Pierangeli S. Anticardiolipin antibodies: specificity and function. Lupus 1994;3:217-22.
5. Barka N. Phospholipid autoantibodies - phosphatidylserine. In: Peter JB, Shoenfeld Y, editors. Autoantibodies. Amsterdam: Elsevier 1996:630-4.
6. Triplett DA. Assays for detection of antiphospholipid antibodies. Lupus 1994;3:281-7.
7. Khamashta MA, Cuadrado MJ, Mujic F, et al. The management of thrombosis in the antiphospholipid antibody syndrome. N Engl J Med 1995;332:993-7.
8. Olee T, Pierangeli S, Handley H, et al. A monoclonal IgG anticardiolipin antibody from a
9. Hughes GRV. The antiphospholipid syndrome: ten years on. Lancet 1993;342:341-4.

Manufactured by Monocent, Inc.

9237 Eton Ave. Chatsworth, CA 91311, USA

Info@monocent.com | Tel: 424-310-0777

www.monocent.com

EC REP **CEpartner4U**

ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.

www.cepartner4u.com

Revision Date: 2016-07-06

MONOCENT
Innovation & Excellence

ENGLISH

CARDIOLIPIN IgM ELISA TEST SYSTEM

CE

REF **EL1-1022** Σ **96 TESTS** **IVD**

INTENDED USE

The Monocent, Inc.'s Cardiolipin IgM ELISA Test System is intended for the detection of IgM antibody to Cardiolipin in human serum or plasma.

SUMMARY AND EXPLANATION

Measurement of IgG, IgM and IgA cardiolipin autoantibodies (aCL) by EIA is the standard procedure for the detection of antiphospholipid antibodies (aPL) in patients with suspected antiphospholipid syndrome (APS). High aCL concentrations are associated with increased risk of venous and arterial thrombosis, recurrent pregnancy loss and thrombocytopenia. Patients with the anti-cardiolipin syndrome have one of the above clinical features and have antibodies to cardiolipin and/or a positive lupus anticoagulant test. The antibodies present to cardiolipin may be of the IgG, IgA, IgM isotypes. Testing for the various antibody isotypes to cardiolipin aid in diagnosis of the anti-phospholipid syndrome in patients with SLE or lupus-like disorders. Binding of aCL to CL in patients with autoimmune diseases is dependent on the presence of the cofactor *beta*-2-glycoprotein I (*beta2*-GPI); this binding is independent of *beta*-2-GPI in patients with infectious diseases (e.g., syphilis, tuberculosis). Recognition of the role of *beta*-2- GPI in the binding of aCL led to development of assay for direct measurement of *beta*-2-GPI autoantibodies using *beta*-2-GPI as antigen, allowing a clear distinction between *beta*-2-GPI autoantibodies and those that bind to CL alone.

PRINCIPLE OF THE TEST

Diluted patient serum (serum diluent contains sorbent to remove Rheumatoid Factor and human IgG interference) is added to wells coated with purified aCL antigen. aCL specific IgM antibody, if present, binds to the antigen. All unbound materials are washed away, and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of specific IgM antibody in the sample.

MATERIALS AND COMPONENTS

- Microwells coated with Cardiolipin antigen (12x8x1)
- Sample Diluent: 1 bottle (ready to use) (22 ml)
- Calibrator: 1 vial (ready to use) (1ml)
- Positive Control: 1 vial (ready to use) (1ml)
- Negative Control: 1 vial (ready to use) (1ml)
- Enzyme conjugate: 1 bottle (ready to use) (12ml)
- TMB Substrate: 1 bottle (ready to use) (12ml)
- Stop Solution: 1 bottle (ready to use) (12ml)
- Wash concentrate 20X: 1 bottle (25ml)

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Precision pipettes
- Disposable pipette tips
- ELISA reader capable of reading absorbance at 450 nm
- Absorbance paper or paper towel
- Graph paper

STORAGE CONDITIONS

- Store the kit at 2-8°C.
- Keep microwells sealed in a dry bag with desiccants.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun or strong light.

PRECAUTIONS

1. Potential biohazardous materials:
   The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent, these reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
2. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
3. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
4. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
5. This product contains components preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2-8°C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

REAGENT PREPARATION

Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

TEST PROCEDURE

Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.
2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

Example of typical results:
Calibrator mean OD = 0.8
Calibrator Factor (CF) = 0.5
Cut-off Value = 0.8 x 0.5= 0.400
Positive control O.D. = 1.2
Ab Index = 1.2 / 0.4 = 3
Patient sample O.D. = 1.6
Ab Index = 1.6 / 0.4 = 4.0

INTERPRETATION
The following is intended as a guide to interpretation of aCL antibody test results; each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

Antibody Index Interpretation

<0.9	No detectable IgM antibody.
0.9-1.1	Borderline positive. Follow-up testing is recommended if clinically indicated.
>1.1	Indicative of autoimmune disorder.

Converting of Ab Index to MPL
As an option, Ab index may be converted to MPL units by multiplying Ab index value by 17. MPL units may then be interpreted as follows:

<15 MPL	Negative
15- 20 MPL	Borderline positive.
21-80 MPL	Low/Medium Positive
> 80 MPL	High Positive

NOTE: Patient values above 80 MPL should be reported as > 80 MPL or retested after dilution. In case of dilution, final results must be multiplied by the dilution factor.

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:

1. The O.D. of the Calibrator should be greater than 0.250.
2. The Ab index for Negative control should be less than 0.9.
3. The Ab Index for Positive control should fall within the range specified on the COA/label.

LIMITATIONS OF THE PROCEDURE

1. The test results obtained using this kit serve only as an aid to diagnosis and should be interpreted in relation to the patient's history, physical findings and other diagnostic procedures.
2. Lipemic or hemolyzed samples may cause erroneous results.

PERFORMANCE CHARACTERISTICS

1. SENSITIVITY AND SPECIFICITY

291 patient sera were tested by this ELISA and a reference ELISA method. 118 sera were positive, and 164 sera were negative by both methods. The agreement between the two methods was 96% (282/291). The results are summarized below:

		Monocent ELISA		
		+	–	Total
Reference ELISA kit	+	118	5	123
	–	4	164	168
	Total	122	169	291

2. PRECISION

Intra-Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	16	1.22	0.09	6.55
2	16	0.78	0.05	6.41
3	16	0.22	0.02	9.09

Inter-Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	10	1.17	0.1	8.54
2	10	0.84	0.09	10.7
3	10	0.27	0.04	14.8

REFERENCES

1. Barka N, Reagan K, Agopian M, Peter JB. Frequency of anticardiolipin and antiphosphatidylserine antibodies in patients with suspected antiphospholipid syndrome. Clin Chem 1995;41:5.
2. Khamashta MA, Hughes GRV. Detection and importance of anticardiolipin antibodies. J Clin Pathol 1993;46:104-7.
3. Reyes H, Dearing L, Bick RL, Shoenfeld Y, Peter JB. Laboratory diagnosis of antiphospholipid syndromes. Lab Clin North Am 1995;15:85-108.
4. Harris EN, Pierangeli S. Anticardiolipin antibodies: specificity and function. Lupus 1994;3:217-22.
5. Barka N. Phospholipid autoantibodies - phosphatidylserine. In: Peter JB, Shoenfeld Y, editors. Autoantibodies. Amsterdam: Elsevier 1996:630-4.
6. Triplett DA. Assays for detection of antiphospholipid antibodies. Lupus 1994;3:281-7.
7. Khamashta MA, Cuadrado MJ, Mujic F, et al. The management of thrombosis in the antiphospholipid antibody syndrome. N Engl J Med 1995;332:993-7.
8. Olee T, Pierangeli S, Handley H, et al. A monoclonal IgG anticardiolipin antibody from a patient with the antiphospholipid syndrome is thrombogenic in mice. Proc Natl Acad Sci 1996;931:8606-11.
9. Hughes GRV. The antiphospholipid syndrome: ten years on. Lancet 1993;342:341-4.

Manufactured by
Monocent, Inc.
9237 Eton Ave. Chatsworth, CA 91311, USA
Info@monocent.com | Tel: 424-310-0777
www.monocent.com

EC REP **CEpartner4U**
ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.
www.cepartner4u.com

Revision Date: 2016-07-06

MONOCENT
Innovation & Excellence

ENGLISH

ScL-70 IgG
ELISA TEST SYSTEM

CE

REF EL1-1039 | Σ 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s Scl-70 ELISA Kit is intended for the detection of IgG antibody to Scl-70 in human serum or plasma.

SUMMARY AND EXPLANATION

Systemic autoimmune disease is characterized by the presence of circulating auto-antibodies directed to a wide variety of cellular antigens. Systemic lupus erythematosis (SLE), commonly referred to as Lupus is the best known of these diseases. Other possible connective tissue diseases include mixed connective tissue disease (MCTD), Sjogren syndrome, sclerodema, and polymyositis/dermatomyositis. The majority can be diagnosed by clinical presentation and their antibody profiles to the various antigens involved, which include dsDNA, SM, RNP, SSA, SSB Scl-70, Jo1 and Histones. Therefore, immunoassays for autoantibodies are useful for diagnostic and prognostic evaluations of autoimmune disease. Scl-70 IgG antibodies react with human topoisomerase I of 100 kd molecular weight as well as its 70 kd fragment. Scl-70 antibodies are present in 20-40% of diffuse scleroderma patients and in about 20% of patients with limited scleroderma. Scl-70 antibodies are sometimes reported in classical SLE without features of scleroderma, which may explain the unexpected co-existence of marker autoantibodies for SLE and scleroderma. Some patients with silica-associated systemic sclerosis (SSc) have Scl-70 antibodies.

PRINCIPLE OF THE TEST

Diluted patient serum is added to wells coated with purified antigen. IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample.

MATERIALS AND COMPONENTS

- Microwells coated with Scl-70 antigen - 12x8x1
- Sample Diluent: 1 bottle (ready to use) - 22ml
- Calibrator: 1 Vial (ready to use) - 1ml
- Positive Control: 1 vial (ready to use) - 1ml
- Negative Control: 1 vial (ready to use) - 1ml
- Enzyme conjugate: 1 bottle (ready to use) - 12ml
- TMB Substrate: 1 bottle (ready to use) - 12ml
- Stop Solution: 1 bottle (ready to use) - 12ml
- Wash concentrate 20X: 1 bottle - 25ml

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Precision pipettes
- Disposable pipette tips
- ELISA reader capable of reading absorbance at 450nm
- Absorbance paper or paper towel
- Graph paper

STORAGE CONDITIONS

- Store the kit at 2-8°C.
- Keep microwells sealed in a dry bag with desiccants.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun or strong light.

PRECAUTIONS

1. For Research Use Only. Not for use in diagnostic procedures.
2. For Laboratory Use.
3. Potential biohazardous materials:
   The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent. These reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories" 1984.
4. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
5. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
6. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
7. This product contains components preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2-8°C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

REAGENT PREPARATION

Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

TEST PROCEDURE

Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.
2. Calculate the cut-off value: Calibrator OD x Calibrator Factor(CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

LIMITATIONS OF THE TEST

Lipemic or hemolyzed samples may cause erroneous results.

REFERENCES

1. Hildebrandt S, Weiner ES, Senecal J-L, Noell GS, Earnshaw WC, Rothfield NF. Autoantibodies to topoisomerase I (Scl-70): analysis by gel diffusion, immunoblot, and enzyme-linked immunosorbent assay. Clin Immunol Immunopathol 1990;57:399-410.
2. Hildebrandt S, Weiner E, Senécal J, et al. The IgG, IgM, and IgA isotypes of anti- topoisomerase I and anticentromere autoantibodies. Arthritis Rheum 1990;33:724-7.
3. Steen VD, Powell DL, Medsger TA Jr. Clinical correlations and prognosis based on serum autoantibodies in patients with systemic sclerosis. Arthritis Rheum 1988;31:196-203.
4. Hildebrandt S, Jäckh G, Weber S, Peter H-H. A long-term longitudinal isotypic study of anti- topoisomerase I autoantibodies. Rheumatol Int 1993;12:321-4.
5. Briggs DC, Vaughan RW, Welsh KI, Myers A, DuBois RM, Black CM. Immunogenetic prediction of pulmonary fibrosis in systemic sclerosis. Lancet 1991;338:661-2.
6. Mukai M, Sagawa A, Atsumi T, et al. 3 cases of anti-Scl-70 (topoisomerase I) antibody associated with central nervous system lupus without renal disorder. J Rheumatol 1993;20:91594-7.
7. Stojanov L, Satoh M, Dooley MA, Kuwana M, Jennette JC, Reeves WH. Autoantibodies to topoisomerase I in a patient with systemic lupus erythematosus without features of scleroderma. Lupus 1995;4:314-7.
8. Juarez C, Vila JL, Gelpi C, et al. Characterization of the antigen reactive with anti-Scl-70 antibodies and its application in an enzyme-linked immunosorbent assay. Arthritis Rheum 1988;31:108-15.

Manufactured by Monocent, Inc.
9237 Eton Ave. Chatsworth, CA 91311, USA
Info@monocent.com | Tel: 424-310-0777
www.monocent.com

EC REP **CEpartner4U**
ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.
www.cepartner4u.com

Revision Date: 2017-04-17

MONOCENT
Innovation & Excellence

ENGLISH

ANTI-CCP ELISA TEST SYSTEM

CE

REF EL2-1011 Σ 96 TESTS IVD

INTENDED USE

The Monocent, Inc's Anti-CCP ELISA Test System is intended for the quantitative measurement of IgG class autoantibodies against cyclic citrullinated peptides present in human serum or plasma. It is intended for laboratory use only.

SUMMARY AND EXPLANATION

Rheumatoid arthritis (RA) is an inflammatory rheumatic disorder with a worldwide prevalence of about 0.5-1%. Although the course of RA varies widely among affected individuals, significant number of RA patients present with persistent pain and stiffness, progressive joint destruction, functional decline and premature mortality.

The serum of RA patients contains a variety of antibodies directed against self-antigens. The most widely known of these autoantibodies is the rheumatoid factor (RF) antibody directed against the constant domain of IgG molecules. The presence of RF is one of the American College of Rheumatology's (ACR) criteria for the classification of RA. Although the RF test has good sensitivity for RA, it is not very specific for the disease as it can also be detected in the serum of patients with other rheumatic or inflammatory diseases and even in a substantial percentage of the healthy (elderly) population. For several years it has been recognized that antibodies to anti-perinuclear factor (APF) and anti-keratin (AKA) are highly specific for RA. It was subsequently reported that both of these antibodies reacted with native filaggrin and are now referred to as anti-filaggrin antibodies (AFA). More recently it has been shown that all of these antibodies are directed to citrulline-containing epitopes. In order to correctly diagnose RA it is necessary to exclude other forms of arthritis. In such a diagnostic process, the laboratory plays an important role in the determination of IgM, detectable in 60-80% of the patients with RA. The RF antibodies are sensitive but not very specific markers; In contrast, Anti-CCPs are characterized by a specificity of over 90% in patients affected by RA, and are detectable in a very early asymptomatic stage in the approximately 70% of RA patients whereas only 2% of the control subjects resulted positive.

Therefore, the presence of Anti-CCP antibodies can be used in the diagnosis of RA, particularly in the case of erosive arthritis, in childhood in the case of juvenile RA. The Anti-CCP antibody test, together with the determination of RF, increases the ratio of sensitivity/specificity. 20% of the RAs are RF-negative and 15/20% of the RAs are positive only to RF. The simultaneous positive result of a sample to RF and CCP has a positive predictive value of about 100%.

The advantage of CCP antibodies is a higher sensitivity and specificity for the diagnosis of rheumatoid arthritis in comparison to the rheumatoid factors alone. Anti-CCP is often found at a very early state of the disease and it has a high predictive value for development of the disease.

PRINCIPLE OF THE TEST

Purified cyclic citrullinated peptides (CCP) is coated on the surface of microwells. Diluted patient serum is added to wells, and the specific antibody, if present, will binds to the antigen coated on the surface of the reaction well. All unbound materials are washed away. After adding enzyme conjugate, it binds to the antibody-antigen complex. Excess enzyme conjugate is washed off, and TMB Chromogenic Substrate is added. The enzyme conjugate catalytic reaction is stopped at a specific time. The intensity of the color generated is proportional to the amount of anti-CCP IgG antibodies in the sample. The concentration of the anti-CCP IgG antibodies in the sample is calculated through a standard curve.

MATERIALS AND COMPONENTS

- Microwell strips: Cyclical citrullinated peptides coated wells. 12x8 wells
- Sample Diluent: (1 bottle) 50 ml / bottle
- Standard set: 0, 10, 20, 50, 150 and 500 U/ml, in liquid form (ready to use) 1 ml/ vial
- Control set: Range stated on label, in liquid form (ready to use) 1 ml/ vial
- Washing Concentrate 20x (H). (1 bottle) 50 ml
- Enzyme Conjugate: Red color solution. (1 vial) 12 ml
- TMB Chromogenic Substrate: Amber bottle. (1 vial) 12 ml
- Stop Solution. (1 vial) 12 ml

STORAGE CONDITIONS

- Store the kit at 2-8°C.
- Always keep microwells tightly sealed in pouch with desiccants. It is recommended to use up all wells within 4 weeks after initial opening of the pouch.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun, or strong light during storage or usage.

PRECAUTIONS

For In Vitro Diagnostic Use

1. Potential biohazardous materials:
   The calibrator and controls contain human source components, which have been tested and found nonreactive for Hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus, or other infectious agents are absent, these reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control / National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984
2. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
3. Do not interchange kit components from different lots and products.
4. Do not re-use microplate wells
5. All materials must be at room temperature (20-25°C) and gently mix prior to use.
6. This product contains components preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Test serum should be clear and non-hemolyzed.
3. Specimens may be refrigerated at 2-8°C for up to five days or frozen for up to six months. Avoid repetitive freezing and thawing of serum sample.

REAGENT PREPARATION

1. Prepare 1x washing buffer:
   Prepare washing buffer by adding distilled or deionized water to 20x wash concentrate to make a final volume of 1 liter.
2. Sample dilution:
   Prepare 1:101 dilutions by adding 5 µl of the patient samples to 500 µl of sample diluent. Mix well.

TEST PROCEDURE

1. Place the desired number of coated strips into the holder.
2. Dispense 100 µl of standards, controls and pre-diluted patient samples into the appropriate wells. For the reagent blank, dispense 100 µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 30 minutes at room temperature.
3. Remove liquid from all wells. Repeat washing three times with washing buffer.
4. Dispense 100 µl of enzyme conjugate to each well and incubate for 30 minutes at room temperature.
5. Remove enzyme conjugate from all wells. Repeat washing three times with washing buffer.
6. Dispense 100 µl of TMB Chromogenic Substrate to each well and incubate for 15 minutes at room temperature.
7. Add 100 µl of Stop solution to stop reaction. (Make sure there are no air bubbles).
8. Read O.D. at 450 nm with a microwell reader.

CALCULATION OF RESULTS

For the anti-CCP test the method of choice for treatment of results is a 4-parameter-fit with axes Lin-Log for optical density and concentration, respectively.

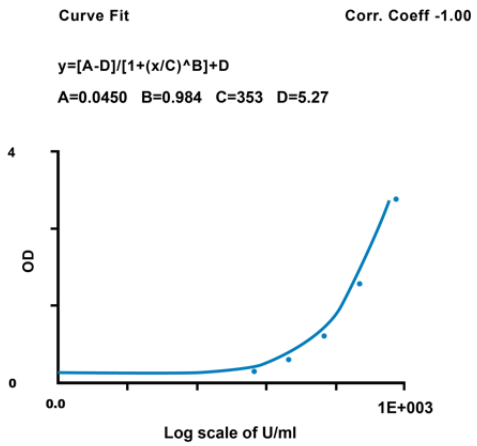
First calculate the average optical density with standards. Use a sheet of paper with Lin-Log axes and plot averaged optical density of each standard versus their concentration. Draw the best fitting curve approximating the path of all calibrator points. The standard points may also be connected with straight line segments. The concentration of unknowns may then be estimated from the standard curve by interpolation.

Typical results (to consider only as an example)

EXAMPLE OF RESULTS AND CALCULATIONS

The below reported table shows the typical results for the anti-CCP test. The data are to be considered as example only and not be used for the calculation of results.

	u/ml	O.D. 450 nm	O.D. 450 nm	Average OD
Standard 1	0	0.050	0.051	0.051
Standard 2	10	0.197	0.196	0.197
Standard 3	20	0.321	0.320	0.328
Standard 4	50	0.728	0.727	0.728
Standard 5	150	1.612	1.610	1.611
Standard 6	500	3.100	3.090	3.095



QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:

1. The O.D. value of the reagent blank against air from a microwell reader should be less than 0.150.
2. If the O.D. value of the standard 6 is lower than 1.0, the test is not valid and must be repeated.
3. The concentration of controls should be in the range stated on the labels.
4. The samples having an OD value higher the Standard 6 (500 U/mL) should be subsequently diluted and the concentration of Anti CCP antibodies should be calculated applying the dilution factor.

INTERPRETATION OF RESULTS

In a normal range study with samples from 183 healthy blood donors the following ranges have been established with this ELISA assay:

Cut-off:	10 U/ml
Negative:	< 10 U/ml
Positive:	≥ 10 U/ml

1. LINEARITY

Patient samples containing high levels of specific antibody were serially diluted in sample diluent to demonstrate the dynamic range of the assay and the upper/ lower end of linearity.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E %
1	1:100	353.6	350	101%
	1:200	151.7	175	87%
	1:400	89.2	87.5	102%
	1:800	45.24	43.75	103%
	1:1600	21.76	21.88	99%
2	1:100	291.4	300	97%
	1:200	150.5	150	100.3%
	1:400	71.79	75	96%
	1:800	37.37	37.5	99.7%
	1:1600	19.38	18.75	103%

2. DETECTION LIMIT

The analytical sensitivity (lower detection limit, 0 + 2SD) was established to be 1.9 U/ml.

3. REPRODUCIBILITY

Intra-assay Precision:

Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single assay.
Results are shown in the table below:

Sample	Average (U/ml)	CV %
1	58.15	4.05
2	60.51	3.74
3	75.04	6.13

Inter-assay Precision:

Coefficient of variation (CV) was calculated for each of three samples from the results of 4 determinations in 5 different assays. Results are shown in the table below.

Sample	Average (U/ml)	CV %
1	5.58	2.61
2	47.51	1.84
3	132.93	3.52

LIMITATIONS OF THE TEST

1. This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of patient. Also, every decision for therapy should be taken individually.
2. The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establish its own ranges according to an applicable laboratory guideline.
3. This kit is designed for professional use only.

PERFORMANCE CHARACTERISTICS

1. SENSITIVITY AND SPECIFICITY

Sensitivity, specificity and accuracy were evaluated using a commercially available ELISA kit on 191 specimens. The correlation results are summarized in the following table:

		Reference ELISA (1)		
		N	P	Total
Monocent ELISA	N	183 (D)	2 (B)	185
	P	0 (C)	6 (A)	6
	Total	183	8	191

Sensitivity = A / (A+B)= 6/(6+2)=75%
Specificity = D/(C+D) = 183/183 = 100%
Accuracy (Overall agreement) = (A+D) / (A+B+C+D) = 189/191=98.9%

2. HIGH DOSE HOOK

High dose hook is a phenomenon whereby very high-level specimens may read within the dynamic range of the assay. For the Anti-CCP ELISA assay, no high dose hook effect was observed when a sample containing approximately 6000 U/mL of Anti-CCP antibody was assayed

3. INTERFERENCE

Potential Interfering Substance	No Interference Found up to the Following Concentration
Bilirubin	40 mg/dl
Hemoglobin	200 mg/dl

REFERENCES

1. Arnett FC, Edworthy SM, Bloch DA, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988;31(3):315-24.
2. van Venrooij WJ, Hazes JM, Visser H. Anticitrullinated protein/peptide antibody and its role in the diagnosis and prognosis of early rheumatoid arthritis. Neth J Med 2002;60(10):383-8.
3. Nienhuis RL, Mandema E, Smids C. A new serum factor in patients with rheumatoid arthritis. The antiperinuclear factor. Ann Rheum Dis 1964;23:302-05.
4. Young BJ, Mallya RK, Leslie RD, et al. Anti-keratin antibodies in rheumatoid arthritis. Br Med J 1979;2:97-9.
5. Hoet RM, Boerbooms AM, Arends M, et al. Antiperinuclear factor, a marker autoantibody for rheumatoid arthritis: colocalisation of the perinuclear factor and profilaggrin. Ann Rheum Dis 1991;50:611-8.
6. Sebbag M, Simon M, Vincent C, et al. The antiperinuclear factor and the so-called antikeratin antibodies are the same rheumatoid arthritisspecific autoantibodies. J Clin Invest 1995;95:2672-9.
7. Bizzaro N. et al. Diagnostic Accuracy of the anticitrulline antibody assay for rheumatoid arthritis. Clin Chem 47:6, 1089-1093,2001
8. Schellekens G. et al. The diagnostic properties of rheumatoid arthritis antibodies recognizing a cyclic citrullinated peptide. Arthritis Rheum 43:155-163 (2000)
9. Baeten D. et al. Specific presence of intracellular citrullinated proteins in rheumatoid arthritis synovium. Arthritis Rheum 44:2255-2262 (2001)
10. del Val del Amo N, Ibanez Bosch R, Fito Manteca C, et al. Anti-cyclic citrullinated peptide antibody in rheumatoid arthritis: relation with disease aggressiveness. Clin Exp Rheumatol. 2006;24(3):281-6
11. Samanci N, Ozdem S, Akbas H, et al. Diagnostic value and clinical significance of Anti CCP in patients with advanced rheumatoid arthritis. J Natl Med Assoc. 005;97(8):1120-6
12. Matsui T, Shimada K, Ozawa N, et al. Diagnostic utility of anti-cyclic citrullinated peptide antibodies for very early rheumatoid arthritis. J Rheumatol. 2006;33(12):2390-7
13. Bizzaro N, Villalta D, Tozzoli R, et al. Validazione del primo Calibrator internazionale WHO per gli anticorpi anti-Peptidi Citrullinati RiMEL/IJLaM 2008; 4(suppl): F23 – 203
14. Kroot EJ, De Jong BA, Van Leeuwen MA, Swinkels H, Van den Hoogen FH, Van't Hof M, et al. The prognostic value of anti-cyclic citrullinate peptide antibody in patients with recent- onset rheumatoid arthritis. Arthritis Rheum 2000; 43: 1831-5.

Manufactured by Monocent, Inc.
9237 Eton Ave. Chatsworth, CA 91311, USA
Info@monocent.com | Tel: 424-310-0777
www.monocent.com

EC REP **CEpartner4U**
ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.
www.cepartner4u.com

Revision Date: 2019-03

MONOCENT
Innovation & Excellence

ENGLISH

MPO (p-ANCA) ELISA TEST SYSTEM

CE

REF EL20-1032 Σ 96 TESTS IVD

INTENDED USE

The Monocent, Inc.'s MPO (p-ANCA) ELISA Test System is an indirect solid phase enzyme immunoassay (ELISA) for the quantitative measurement of IgG class autoantibodies against myeloperoxidase (MPO) in human serum or plasma. The assay is intended for in vitro diagnostic use only as an aid in the diagnosis of certain autoimmune vasculitites such as Wegener´s granulomatosis.
Anti MPO (p-ANCA) kit is intended for laboratory use only.

SUMMARY AND EXPLANATION

Anti-neutrophilic-cytoplasm antibodies (ANCA) represent a group of autoantibodies directed towards the cytoplasmatic components of the neutrophilic granulocytes and monocytes. The classical methods for the determination of ANCA are the immunofluorescent methods. With these indirect immunofluorescence techniques two main patterns are recognized, a cytoplasmatic (c-ANCA) and a perinuclear (p-ANCA) type. The main antigen for the c-ANCA is the proteinase 3 (PR3), which is a serine proteinase of the present in primary granules. Antibodies of p-ANCA positive sera are mainly directed to myeloperoxidase (MPO). Antibodies to other antigens e.g. lactoferrin, elastase, cathepsin-G and also lysozyme often result in a similar p-ANCA pattern. Beside different untypical variants of p- ANCA IF patterns granulocyte specific antinuclear antibodies (GS-ANA) is indistinguishable from p-ANCA. This makes a clear interpretation and classification of the IF patterns difficult.
Therefore, every positive IF-ANCA findings esp. p-ANCA should be differentiated by ELISA techniques using purified antigens. A survey of documented clinical indications of specific ANCA is given in the table below. PR3- ANCA and MPO-ANCA are reliable serologic markers in the diagnostics of vasculitides.
PR3- ANCA is the classical autoantigen in Wegener´s granulomatosis with a clinical specificity of more than 95%. c-ANCA is documented to be present in different diseases. Anti-MPO antibodies are highly specific for idiopathic and vasculitis associated crescentic glomerulonephritis and also for classic polyarteritis nodosa, Churg-Strauss syndrome and the polyangitis overlap syndrome without renal involvement.7-10 With respect to sensitivity, either MPO or PR-3 antibodies were found in 77 to 100% of patients with idiopathic and vasculitis associated crescentic glomerulonephritis. In WG, anti-MPO antibodies were detected only occasionally and generally in patients negative for PR-3 antibodies.
The MPO and PR-3 specific ELISA methods can provide an important confirmatory result for two of the more important of the identified antigens. ELISA is also useful for interpreting "difficult" samples by IFA such as those which exhibit several antibodies simultaneously or those with high background fluorescence.

PRINCIPLE OF THE TEST

Anti MPO (p-ANCA) test is based on the binding of the antibodies in the sample to the human neutrophil myeloperoxidase coated on the microplates. In the first step the antibodies in calibrators, controls or prediluted patient samples bind to the inner surface of the wells. After a 60 minutes incubation the microplate is washed with a wash buffer to remove the non-reactive serum components. In the second step an anti-human-IgG horseradish peroxidase conjugated solution recognizes the IgG class antibodies bound to the immobilized antigens. After a 30 minutes incubation any excess of enzyme conjugate which is not specifically bound is washed away with the wash buffer. Then a chromogenic substrate solution containing TMB is dispensed into the wells. After 15 minutes of incubation the color development is stopped by adding the stop solution. The solutions color change into yellow. The amount of color is directly proportional to the concentration of IgG antibodies present in the original sample. The concentration of IgG antibodies in the sample is calculated through a calibration curve.

MATERIALS AND COMPONENTS

Reagents and materials supplied in the kit

- **Calibrators** (5 vials, 1.2 mL each)
  Phosphate buffer 0,1M, NaN_3 < 0,1%, human serum
- **Controls** (2 vials, 1.2 mL each)
  Phosphate buffer 0,1M, NaN_3 < 0,1%, human serum
  Negative control
  Positive control
- **Sample Diluent** (1 vial, 100 mL)
  Phosphate buffer 0,1 M NaN_3 < 0,1%
- **Conjugate** (1 vial, 15 mL)
  Anti h-IgG conjugated with horseradish peroxidase (HRP), BSA 0,1%, Proclin < 0,0015%
- **Coated Microplate** (1 breakable microplate)
  Microplate coated with human neutrophil myeloperoxidase
- **TMB Substrate** (1 vial, 15 mL)
  H_2O_2-TMB 0.26 g/L *(avoid any skin contact)*
- **Stop Solution** (1 vial, 15 mL)
  Sulphuric acid 0.15M *(avoid any skin contact)*
- **10X Conc. Wash Solution** (1 vial, 50 mL)
  Phosphate buffer 0,2M, pH 7.4

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled water
- Automatic dispenser.
- Microplate reader (450 nm, 620-630 nm).

STORAGE CONDITIONS

- Store all reagents between 2-8°C in the dark.
- Open the bag of reagent 5 (Coated Microplate) only when it is at room temperature and close it immediately after use; once opened, it is stable until expiry date of the kit.

PRECAUTIONS

- Please adhere strictly to the sequence of pipetting steps provided in this protocol. The performance data represented here were obtained using specific reagents listed in this Instruction. For Use.
- All reagents should be stored refrigerated at 2-8°C in their original container. Any exceptions are clearly indicated. The reagents are stable until the expiry date when stored and handled as indicated.
- Allow all kit components and specimens to reach room temperature (22-28°C) and mix well prior to use.
- Do not interchange kit components from different lots. The expiry date printed on box and vials labels must be observed. Do not use any kit component beyond their expiry date.
- **WARNING: the conjugate reagent is designed to ensure maximum dose sensitivity and may be contaminated by external agents if not used properly;** therefore, it is recommended to use disposable consumables (tips, bottles, trays, etc.). For divided doses, take the exact amount of conjugate needed and do not re-introduce any waste product into the original bottle. In addition, **for doses dispensed with the aid of automatic and semi-automatic devices,** before using the conjugate, it is advisable to clean the fluid handling system, ensuring that the procedures of washing, deproteinization and decontamination are effective in avoiding contamination of the conjugate; this procedure is highly recommended when the kit is processed using analyzers which are not equipped with disposable tips.
  For this purpose, Monocent supplies a separate decontamination reagent for cleaning needles.
- If you use automated equipment, the user has the responsibility to make sure that the kit has been appropriately tested.
- The incomplete or inaccurate liquid removal from the wells could influence the assay precision and/or increase the background. To improve the performance of the kit on automatic systems is recommended to increase the number of washes.
- It is important that the time of reaction in each well is held constant for reproducible results. Pipetting of samples should not extend beyond ten minutes to avoid assay drift. If more than 10 minutes are needed, follow the same order of dispensation. If more than one plate is used, it is recommended to repeat the dose response curve in each plate
- Addition of the TMB Substrate solution initiates a kinetic reaction, which is terminated by the addition of the Stop Solution. Therefore, the TMB Substrate and the Stop Solution should be added in the same sequence to eliminate any time deviation during the reaction.
- Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera.
- Maximum precision is required for reconstitution and dispensation of the reagents.
- Samples microbiologically contaminated, highly lipemeic or haemolysed should not be used in the assay.
- Plate readers measure vertically. Do not touch the bottom of the wells.

WARNINGS

1. This kit is intended for in vitro use by professional persons only. Not for internal or external use in Humans or Animals.
2. Use appropriate personal protective equipment while working with the reagents provided.
3. Follow Good Laboratory Practice (GLP) for handling blood products.
4. All human source material used in the preparation of the reagents has been tested and found negative for antibody to HIV 1&2, HbsAg, and HCV. No test method however can offer complete assurance that HIV, HBV, HCV or other infectious agents are absent. Therefore, Calibrators and Controls should be handled in the same manner as potentially infectious material.

5. Material of animal origin used in the preparation of the kit has been obtained from animals certified as healthy and the bovine protein has been obtained from countries not infected by BSE, but these materials should be handled as potentially infectious.
6. Some reagents contain small amounts of Sodium Azide (NaN_3) or Proclin 300® as preservatives. Avoid the contact with skin or mucosa.
7. Sodium Azide may be toxic if ingested or absorbed through the skin or eyes; moreover, it may react with lead or copper plumbing to form potentially explosive metal azides. If you use a sink to remove the reagents, allow scroll through large amounts of water to prevent azide build-up.
8. The TMB Substrate contains an irritant, which may be harmful if inhaled, ingested or absorbed through the skin. To prevent injury, avoid inhalation, ingestion or contact with skin and eyes.
9. The Stop Solution consists of a diluted sulfuric acid solution. Sulfuric acid is poisonous and corrosive and can be toxic if ingested. To prevent chemical burns, avoid contact with skin and eyes.
10. Avoid the exposure of reagent TMB/H_2O_2 to directed sunlight, metals or oxidants. Do not freeze the solution.

REAGENT PREPARATION

Preparation of the Calibrators (C_0…C_4)
Since no international reference preparation for Anti-myeloperoxidase antibodies is available, the assay system is calibrated in relative arbitrary units. The Calibrators are to use and have the following concentration:

	C_0	C_1	C_2	C_3	C_4
AU/mL	0	10	20	40	160

Once opened, the Calibrators are stable 6 months at 2-8°C.

Preparation of the Sample
Either human serum or plasma samples can be used for the test execution. Test samples should be clear. Contamination by lipemia is best avoided but does not interfere with this assay.
Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months. Avoid repetitive freezing and thawing of serum samples. This may result in variable loss of autoantibody activity.
Testing of heat-inactivated sample is not recommended.
All serum and plasma samples must be prediluted 1:100 with sample diluents; for example, 10 µL of sample should be diluted with 990 µL of sample diluent.
The Controls are ready to use.

Preparation of the Wash Solution
Dilute the content of each vial of the "10X Conc. Wash Solution" with distilled water to a final volume of 500 mL prior to use. For smaller volumes respect the 1:10 dilution ratio. The diluted wash solution is stable for 30 days at 2-8°C.
In concentrated wash solution is possible to observe the presence of crystals; in this case mix at room temperature until the complete dissolution of crystals; for greater accuracy, dilute the whole bottle of concentrated wash solution to 500 mL, taking care to transfer completely the crystals, then mix until crystals are completely dissolved.

TEST PROCEDURE

- **Allow all reagents to reach room temperature (22-28°C) for at least 30 minutes.** At the end of the assay store immediately the reagents at 2-8°C: avoid long exposure to room temperature.
- Unused coated microwell strips should be released securely in the foil pouch containing desiccant and stored at 2-8°C.
- To avoid potential microbial and/or chemical contamination, unused reagents should never be transferred into the original vials.
- As it is necessary to perform the determination in duplicate in order to improve accuracy of the test results, prepare two wells for each point of the calibration curve (C_0-C_4), two for each Control, two for each sample, one for Blank.

Reagent	Calibrator	Sample/ Controls	Blank
Calibrator C_0-C_4	**100 µL**		
Controls		**100 µL**	
Diluted Sample		**100 µL**	
Incubate 60 minutes at room temperature (22-28°C). Remove the contents from each well, wash the wells 3 times with 300 µL of diluted wash solution. **Important note**: during each washing step, gently shake the plate for 5 seconds and remove excess solution by tapping the inverted plate on an absorbent paper towel. **Automatic washer**: if you use automated equipment, wash the wells at least 5 times.			
Conjugate	**100 µL**	**100 µL**	
Incubate 30 minutes at room temperature (22-28°C). Remove the contents from each well, wash the wells 3 times with 300 µL of diluted wash solution. **Washing**: follow the same indications of the previous point.			
TMB Substrate	**100 µL**	**100 µL**	**100 µL**
Incubate 15 minutes in the dark at room temperature (22-28°C).			
Stop Solution	**100 µL**	**100 µL**	**100 µL**
Shake the microplate gently. Read the absorbance (E) at 450 nm against a reference wavelength of 620-630 nm or against Blank within 5 minutes.			

QUALITY CONTROL

- The MPO IgG Positive and Negative Control should be run with every batch of samples to ensure that all reagents and procedures perform properly.
- Because Positive and the Negative Control are prediluted, they do not control for procedural methods associated with dilution of specimens.
- Additional suitable control sera may be prepared by aliquoting pooled human serum specimens and storing at < -20°C.
- In order for the test results to be considered valid, all of the criteria listed below must be met. If any of these are not met, the test should be considered invalid and the assay repeated:
  - The absorbance of the prediluted MPO IgG Positive must be greater than the absorbance of the prediluted Negative Control.
  - The Negative and Positive Control are intended to monitor for substantial reagent failure, and they will not ensure precision at the assay cutoff.
  - This test is only valid if the optical density at 450 nm for Positive Control (1) and Negative Control (2) as well as for the Calibrator S0-S5 complies with the respective range indicated on the Quality Control Certificate enclosed to each test kit: If any of these criteria is not met, the results are invalid and the test should be repeated.

CALCULATION OF RESULTS

For Anti MPO (p-ANCA) test a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice. Smoothed-Spline Approximation and log-log coordinates are also suitable. Recommended Lin-Log Plot
First calculate the averaged optical densities for each calibrator well. Use lin-log graph paper and plot the averaged optical density of each calibrator versus the concentration. Draw the best fitting curve approximating the path of all calibrator points. The calibrator points may also be connected with straight line segments. The concentration of unknowns may then be estimated from the calibration curve by interpolation.

EXPECTED VALUES

In a normal range study with serum samples from healthy blood donors the following ranges have been established with the Anti MPO (p-ANCA) tests:

	Anti MPO (p-ANCA)
Cut-off	20 AU/mL

Please pay attention to the fact that the determination of a range of expected values for a "normal" population in a given method is dependent on many factors, such as specificity and sensitivity of the method used and type of population under investigation. Therefore, each laboratory should consider the range given by the Manufacturer as a general indication and produce their own range of expected values based on the indigenous population where the laboratory works.
Positive results should be verified concerning the entire clinical status of the patient. Also, every decision for therapy should be taken individually. It is recommended that each laboratory establishes its own normal and pathological ranges of serum Anti-MPO.

PERFORMANCE CHARACTERISTICS

1. Specificity
Comparison test against a commercial reference kit, performed on 32 sera (8 of them positive sera and 24 negative sera) showed a 100% specificity.

2. Sensitivity
Comparison test against a commercial reference kit, performed on 32 sera (8 of them positive sera and 24 negative sera) showed a 100% sensitivity.

3. Detection Limit
The lowest concentration of anti MPO antibodies that can be distinguished from the Calibrator 0 is about 0.73 AU/mL with a confidence limit of 98%.

4. Precision and reproducibility
i. Intra-Assay
Within run variation was determined by replicate the measurements of three different sera with values in the range of the calibration curve. The within assay variability is ≤ 6.1%.
ii. Inter-Assay
Between run variation was determined by replicate the measurements of two different control sera with different lots of kits and/or different mix of lots of reagents. The between assay variability is ≤ 12.3%.

LIMITATIONS OF PROCEDURE

The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay.

WASTE MANAGEMENT

Reagents must be disposed of in accordance with local regulations.

REFERENCES

1. Jennette, J.C. and Falk, R.J. Antineutrophil Cytoplasmic Autoantibodies and Associated Diseases: a Review. Am. J. Kidney Dis. 1990,Vol. XV,No. 6: 517 - 529.
2. Gross, W.L. et al. Antineutrophil Cytoplasmic Autoantibody-Associated Diseases: A Rheumatologist`s Perspective. Am. J. Kidney Dis. 1991,Vol. XVIII, No. 2: 175 - 179.
3. Wieslander, J.How are Antineutrophil Cytoplasmic Autoantibodies Detected ? Am.J.Kidney Dis. 1991,Vol. XVIII, No. 2: 154 - 158.
4. Lesavre, P. Antineutrophil cytoplasmic antibodies antigen specificity. Am. J. Kidney Dis. 1991,Vol. XVIII, No. 2: 159 - 163.
5. Hagen, E.C. et al. Antineutrophil cytoplasmic autoantibodies: a review of the antigens involved, the assays, and the clinical and possible pathogenic consequences.Blood 1993,Vol.81: 1996 - 2000.
6. Gross,W.L. et al.Immunodiagnostische und immunopathogenetische Bedeutung von Anti- Neutrophilen-Cytoplasma-Antikörpern. Deutsche Medizinische Wochenschrift 1993, Vol. 118: 191 - 199.

Manufactured by
Monocent, Inc.
9237 Eton Ave. Chatsworth, CA 91311, USA
Info@monocent.com | Tel: 424-310-0777
www.monocent.com

EC REP **CEpartner4U**
ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.
www.cepartner4u.com

Revision Date: 2018/09

MONOCENT
Innovation & Excellence

ENGLISH

PR-3 (c-ANCA) ELISA TEST SYSTEM

CE

REF EL20-1033 Σ 96 TESTS IVD

INTENDED USE

The Monocent, Inc.'s PR-3 (c-ANCA) Test System is an indirect solid phase enzyme immunoassay (ELISA) for the quantitative measurement of IgG class autoantibodies against proteinase 3 (PR-3) in human serum or plasma. The assay is intended for in vitro diagnostic use only as an aid in the diagnosis of certain autoimmune vasculitides such as Wegener´s granulomatosis.
Anti-PR-3 (c-ANCA) kit is intended for laboratory use only.

SUMMARY AND EXPLANATION

Anti-neutrophilic-cytoplasm antibodies (ANCA) represents a group of autoantibodies directed towards the cytoplasmatic components of the neutrophilic granulocytes and monocytes. The classical methods for the determination of ANCA are the immunofluorescent methods. With these indirect immunofluorescence techniques two main patterns are recognized, a cytoplasmatic (c-ANCA) and a perinuclear (p-ANCA) type. The main antigen for the c-ANCA is the proteinase 3 (PR-3), which is a serine proteinase present in primary granules. Antibodies of p-ANCA positive sera are mainly directed to myeloperoxidase (MPO). Antibodies to other antigens e.g. lactoferrin, elastase, cathepsin-G and also lysozyme often result in a similar p-ANCA pattern. Beside different untypical variants of p-ANCA IF patterns granulocyte specific antinuclear antibodies (GS-ANA) is indistinguishable from p-ANCA. This makes a clear interpretation and classification of the IF patterns difficult.
Therefore, every positive IF-ANCA findings esp. p-ANCA should be differentiated by ELISA techniques using purified antigens. A survey of documented clinical indications of specific ANCA is given in the table below. PR-3- ANCA and MPO-ANCA are reliable serologic markers in the diagnostics of vasculitides.
PR-3- ANCA is the classical autoantigen in Wegener´s granulomatosis with a clinical specificity of more than 95%. c-ANCA is documented to be present in different diseases. Anti-MPO antibodies are highly specific for idiopathic and vasculitis associated crescentic glomerulonephritis and also for classic polyarteritis nodosa, Churg-Strauss syndrome and the polyangiitis overlap syndrome without renal involvement. With respect to sensitivity, either MPO or PR-3 antibodies were found in 77 to 100% of patients with idiopathic and vasculitis associated crescentic glomerulonephritis. In WG, anti-MPO antibodies were detected only occasionally and generally in patients negative for PR-3 antibodies.
The MPO and PR-3 specific ELISA methods can provide an important confirmatory result for two of the more important of the identified antigens. ELISA is also useful for interpreting "difficult" samples by IFA such as those which exhibit several antibodies simultaneously or those with high background fluorescence.

PRINCIPLE OF THE TEST

Anti-PR-3 (c-ANCA) test is based on the binding of the antibodies in the sample with human neutrophil proteinase 3 coated into the microplates. In the first step the antibodies in calibrators, controls or prediluted patient samples bind to the inner surface of the wells. After a 60 minutes incubation the microplate is washed with wash buffer for removing non-reactive serum components. In the second step an anti-human-IgG horseradish peroxidase conjugated solution recognizes the IgG class antibodies bound to the immobilized antigens. After a 30 minutes incubation any excess enzyme conjugate which is not specifically bound is washed away with the wash buffer.
Then a chromogenic substrate solution containing TMB is dispensed into the wells. After 15 minutes of incubation the color development is stopped by adding the Stop Solution. The solution color change into yellow. The amount of color is directly proportional to the concentration of IgG antibodies present in the original sample.
The concentration of IgG antibodies in the sample is calculated through a calibration curve.

MATERIALS AND COMPONENTS

Reagents and materials supplied in the kit

- **Calibrators** (5 vials, 1.2 mL each)
  Phosphate buffer 0,1M, NaN_3 < 0,1%, human serum
- **Controls** (2 vials, 1.2 mL each)
  Phosphate buffer 0,1M, NaN_3 < 0,1%, human serum
  Negative control
  Positive control
- **Sample Diluent** (1 vial, 100 mL)
  Phosphate buffer 0,1 M NaN_3 < 0,1%
- **Conjugate** (1 vial, 15 mL)
  Anti h-IgG conjugated with horseradish peroxidase (HRP), BSA 0,1%, Proclin < 0,0015%
- **Coated Microplate** (1 breakable microplate)
  Microplate coated with human neutrophil proteinase 3
- **TMB Substrate** (1 vial, 15 mL)
  H_2O_2-TMB 0.26 g/L *(avoid any skin contact)*
- **Stop Solution** (1 vial, 15 mL)
  Sulfuric acid 0.15M *(avoid any skin contact)*
- **10X Conc. Wash Solution** (1 vial, 50 mL)
  Phosphate buffer 0,2M, pH 7.4

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled water
- Automatic dispenser
- Microplate reader (450 nm, 620-630 nm)

STORAGE CONDITIONS

- Store all reagents between 2-8°C in the dark.
- Open the bag of reagent 5 (Coated Microplate) only when it is at room temperature and close it immediately after use; once opened, it is stable until expiry date of the kit.

PRECAUTIONS

1. Please adhere strictly to the sequence of pipetting steps provided in this protocol. The performance data represented here were obtained using specific reagents listed in this Instruction For Use.
2. All reagents should be stored refrigerated at 2-8°C in their original container. Any exceptions are clearly indicated. The reagents are stable until the expiry date when stored and handled as indicated.
3. Allow all kit components and specimens to reach room temperature (22-28°C) and mix well prior to use.
4. Do not interchange kit components from different lots. The expiry date printed on box and vials labels must be observed. Do not use any kit component beyond their expiry date.
5. **WARNING: the conjugate reagent is designed to ensure maximum dose sensitivity and may be contaminated by external agents if not used properly;** therefore, it is recommended to use disposable consumables (tips, bottles, trays, etc.). For divided doses, take the exact amount of conjugate needed and do not re-introduce any waste product into the original bottle. In addition, for doses dispensed with the aid of automatic and semi-automatic devices, before using the conjugate, it is advisable to clean the fluid handling system, ensuring that the procedures of washing, deproteinization and decontamination are effective in avoiding contamination of the conjugate; this procedure is highly recommended when the kit is processed using analysers which are not equipped with disposable tips.
6. For this purpose, Monocent supplies a separate decontamination reagent for cleaning needles.
7. If you use automated equipment, the user has the responsibility to make sure that the kit has been appropriately tested.
8. The incomplete or inaccurate liquid removal from the wells could influence the assay precision and/or increase the background. To improve the performance of the kit on automatic systems is recommended to increase the number of washes.
9. It is important that the time of reaction in each well is held constant for reproducible results. Pipetting of samples should not extend beyond ten minutes to avoid assay drift. If more than 10 minutes are needed, follow the same order of dispensation. If more than one plate is used, it is recommended to repeat the dose response curve in each plate
10. Addition of the TMB Substrate solution initiates a kinetic reaction, which is terminated by the addition of the Stop Solution. Therefore, the TMB Substrate and the Stop Solution should be added in the same sequence to eliminate any time deviation during the reaction.
11. Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera.
12. Maximum precision is required for reconstitution and dispensation of the reagents.
13. Samples microbiologically contaminated, highly lipemic or haemolysed should not be used in the assay.
14. Plate readers measure vertically. Do not touch the bottom of the wells.

WARNINGS

- This kit is intended for in vitro use by professional persons only. Not for internal or external use in Humans or Animals.
- Use appropriate personal protective equipment while working with the reagents provided.
- Follow Good Laboratory Practice (GLP) for handling blood products.
- All human source material used in the preparation of the reagents has been tested and found negative for antibody to HIV 1&2, HbsAg, and HCV. No test method however can offer complete assurance that HIV, HBV, HCV or other infectious agents are absent. Therefore, Calibrators and Controls should be handled in the same manner as potentially infectious material.

- Material of animal origin used in the preparation of the kit has been obtained from animals certified as healthy and the bovine protein has been obtained from countries not infected by BSE, but these materials should be handled as potentially infectious.
- Some reagents contain small amounts of Sodium Azide (NaN3) or Proclin 300R as preservatives. Avoid the contact with skin or mucosa.
- Sodium Azide may be toxic if ingested or absorbed through the skin or eyes; moreover, it may react with lead or copper plumbing to form potentially explosive metal azides. If you use a sink to remove the reagents, allow scroll through large amounts of water to prevent azide build-up.
- The TMB Substrate contains an irritant, which may be harmful if inhaled, ingested or absorbed through the skin. To prevent injury, avoid inhalation, ingestion or contact with skin and eyes.
- The Stop Solution consists of a diluted sulphuric acid solution. Sulphuric acid is poisonous and corrosive and can be toxic if ingested. To prevent chemical burns, avoid contact with skin and eyes.
- Avoid the exposure of reagent TMB/H2O2 to directed sunlight, metals or oxidants. Do not freeze the solution.

REAGENT PREPARATION

Preparation of the Calibrators (C_0…C_4)
Since no international reference preparation for Anti-proteinase 3 antibodies is available, the assay system is calibrated in relative arbitrary units. The Calibrators are ready to use and have the following concentration:

	C_0	C_1	C_2	C_3	C_4
AU/mL	0	10	20	40	160

Once opened, the Calibrators are stable 6 months at 2-8°C.

Preparation of the Sample
Either human serum or plasma samples can be used for the test execution. Test samples should be clear. Contamination by lipemia is best avoided but does not interfere with this assay.
Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months. Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of autoantibody activity.
Testing of heat-inactivated serum or plasma samples is not recommended.
All serum or plasma samples must be prediluted 1:100 with sample diluent; for example, 10 µL of sample should be diluted with 990 µL of sample diluent.
The Controls are ready to use.

Preparation of the Wash Solution
Dilute the content of each vial of the "10X Conc. Wash Solution" with distilled water to a final volume of 500 mL prior to use. For smaller volumes respect the 1:10 dilution ratio. The diluted wash solution is stable for 30 days at 2-8°C.
In concentrated wash solution is possible to observe the presence of crystals; in this case mix at room temperature until the complete dissolution of crystals; for greater accuracy, dilute the whole bottle of concentrated wash solution to 500 mL, taking care to transfer completely the crystals, then mix until crystals are completely dissolved.

TEST PROCEDURE

- **Allow all reagents to reach room temperature (22-28°C) for at least 30 minutes.** At the end of the assay store immediately the reagents at 2-8°C: avoid long exposure to room temperature.
- Unused coated microwell strips should be released securely in the foil pouch containing desiccant and stored at 2-8°C.
- To avoid potential microbial and/or chemical contamination, unused reagents should never be transferred into the original vials.
- As it is necessary to perform the determination in duplicate in order to improve accuracy of the test results, prepare two wells for each point of the calibration curve (C_0-C_4), two for each Control, two for each sample, one for Blank.

Reagent	Calibrator	Sample/ Controls	Blank
Calibrator C_0-C_4	**100 µL**		
Controls		**100 µL**	
Diluted Sample		**100 µL**	
Incubate 60 minutes at room temperature (22-28°C). Remove the content from each well, wash the wells 3 times with 300 µL of diluted wash solution. **Important note**: during each washing step, gently shake the plate for 5 seconds and remove excess solution by tapping the inverted plate on an absorbent paper towel. **Automatic washer**: if you use automated equipment, wash the wells at least 5 times.			
Conjugate	**100 µL**	**100 µL**	
Incubate 30 minutes at room temperature (22-28°C). Remove the contents from each well, wash the wells 3 times with 300 µL of diluted wash solution. **Washing**: follow the same indications of the previous point.			
TMB Substrate	**100 µL**	**100 µL**	**100 µL**
Incubate 15 minutes in the dark at room temperature (22-28°C).			
Stop Solution	**100 µL**	**100 µL**	**100 µL**
Shake the microplate gently. Read the absorbance (E) at 450 nm against a reference wavelength of 620-630 nm or against Blank within 5 minutes.			

QUALITY CONTROL

- The PR-3 IgG Positive and the Negative Control should be run with every batch of samples to ensure that all reagents and procedures perform properly.
- Because Positive and the Negative Control are prediluted, they do not control for procedural methods associated with dilution of specimens.
- Additional suitable control sera may be prepared by aliquoting pooled human serum specimens and storing at < -20°C.
- In order for the test results to be considered valid, all of the criteria listed below must be met. If any of these are not met, the test should be considered invalid and the assay repeated:
  - The absorbance of the prediluted PR-3 IgG Positive must be greater than the absorbance of the prediluted Negative Control.
  - The Negative and Positive Control are intended to monitor for substantial reagent failure, and they will not ensure precision at the assay cutoff.
  - This test is only valid if the optical density at 450 nm for Negative Control (1) and Positive Control (2) as well as for the Calibrator S_0-S_4 complies with the respective range indicated on the Quality Control Certificate enclosed to each test kit: if any of these criteria is not met, the results are invalid and the test should be repeated.

CALCULATION OF RESULTS

For the Anti PR-3 (c-ANCA) test a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice. Smoothed-Spline Approximation and log-log coordinates are also suitable. We recommend using a Lin-Log curve.
First calculate the averaged optical densities for each calibrator well. Use lin-log graph paper and plot the averaged optical density of each calibrator versus the concentration. Draw the best fitting curve approximating the path of all calibrator points. The calibrator points may also be connected with straight line segments. The concentration of unknowns may then be estimated from the calibration curve by interpolation.

EXPECTED VALUES

In a normal range study with serum samples from healthy blood donors the following ranges have been established with the Anti PR-3 (c-ANCA) test:

	Anti-PR-3 (c-ANCA)
Cut-off	20 AU/mL

Please pay attention to the fact that the determination of a range of expected values for a "normal" population in a given method is dependent on many factors, such as specificity and sensitivity of the method used and type of population under investigation. Therefore, each laboratory should consider the range given by the Manufacturer as a general indication and produce their own range of expected values based on the indigenous population where the laboratory works.
Positive results should be verified concerning the entire clinical status of the patient. Also, every decision for therapy should be taken individually. It is recommended that each laboratory establishes its own normal and pathological ranges of serum anti PR-3 antibodies.

PERFORMANCE CHARACTERISTICS

Precision and reproducibility
Precision and reproducibility are evaluated by eight reply of two positive samples by two different runs with two different lots.
Dispensing and washing operations were performed manually by an operator.
The results in terms of Calibrator deviation and coefficient of variation were below:

Sample	1		2	
	SD	CV%	SD	CV%
Intra-test	0.16	4.2	3.1	4.9
Inter-test	0.35	7.5	5.68	7.4

Specificity
Comparison test against a commercial reference kit, performed on 32 sera (3 of them positive sera and 29 negative sera) showed a 100% specificity.

Sensitivity
Comparison test against a commercial reference kit, performed on 32 sera (3 of them positive sera and 29 negative sera) showed a 100% sensibility.

Detection Limit
The lowest concentration of anti-PR-3 antibodies that can be distinguished from the Calibrator 0 is about 0.13 AU/mL with a confidence limit of 98%.

LIMITATIONS OF PROCEDURE

The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay.

WASTE MANAGEMENT

Reagents must be disposed of in accordance with local regulations.

REFERENCES

1. Jennette, J.C. and Falk, R.J. Antineutrophil Cytoplasmic Autoantibodies and Associated Diseases: a Review. Am. J. Kidney Dis. 1990,Vol. XV,No. 6: 517 - 529.
2. Gross, W.L. et al. Antineutrophil Cytoplasmic Autoantibody-Associated Diseases: A Rheumatologist`s Perspective. Am. J. Kidney Dis. 1991,Vol. XVIII, No. 2: 175 - 179.
3. Wieslander, J.How are Antineutrophil Cytoplasmic Autoantibodies Detected ? Am.J.Kidney Dis. 1991,Vol. XVIII, No. 2: 154 - 158.
4. Lesavre, P. Antineutrophil cytoplasmic antibodies antigen specificity. Am. J. Kidney Dis. 1991,Vol. XVIII, No. 2: 159 - 163.
5. Hagen, E.C. et al. Antineutrophil cytoplasmic autoantibodies: a review of the antigens involved, the assays, and the clinical and possible pathogenic consequences.Blood 1993,Vol.81: 1996 - 2000.

Manufactured by
Monocent, Inc.
9237 Eton Ave. Chatsworth, CA 91311, USA
Info@monocent.com | Tel: 424-310-0777
www.monocent.com

EC REP **CEpartner4U**
ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.
www.cepartner4u.com

Revision Date: 2018/09

2021 CATALOG

100%

QUALITY GUARANTEE

USA

MADE IN USA

MONOCENT®

Innovation & Excellence

About **monocent**

Monocent, Inc. is a U.S-based developer, manufacturer and distributor of innovative In-Vitro Diagnostics and Research products with a comprehensive array of superior offerings at competitive pricing. We also provide a verity of Analyzers, Automations & series of instruments that work and complements our test systems.

We have the capacity to continuously excel in groundbreaking development in the realm of IVD. All our products, services and business models exceed the needs of our customers, which can be delivered in a scalable way. We strive to provide our products and solutions worldwide to Hospitals, Research Institutes and Distributors.

We conform to the highest Quality Management System in compliance to FDA regulations, ISO 13485-2016 & ISO 9001-2015 standards and we are committed to quality, customer care and manufacturing excellence. Our products are CE Marked and many are FDA approved. As a major contributor in international IVD field, we continuously seek to provide solutions to the unmet medical needs of the world.

TIMELESS
INNOVATIONS
Constantly developing and enhancing IVD products to provide superior solutions for the laboratory needs.

EXTENSIVE
CATALOG
Providing a comprehensive and growing list of high quality test systems in various methods.

RELIABLE
RESOURCES
Having local offices in multiple territories with familiarity in governments and their regulations.

GROUNDBREAKING
SOLUTIONS
Introducing and promoting new technologies that can elevate laboratory diagnosis to a much higher capabilities.

GLOBAL
COLLABORATION
Cooperation with our subsidiaries & developers across the world for a successful and seemless alliance.

TRUE
PARTNERSHIP
Treating our distributors and customers as a business partner with full transparency for mutual success.

ELISA
RAPID
IFA
CLIA
SEROLOGY
VET
PCR
NGS
INSTRUMENTS

ELISA

Enzyme-Linked Immunosorbent Assays

» ALLERGY

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL46-1003	Histamine	96	EL15-1002	IgG4 Food Allergy	96
EL15-1001	IgG Food Allergy	96	EL1-1000	Total IgE	96

» ANEMIA

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL30-1390	Anti-Parietal Cell	96	EL1-1008	Hepcidin	96
EL1-1004	Ferritin	96	EL3-1006	sTfR	96
EL1-1005	Folate	96	EL1-1007	Vitamin B12	96

» AUTOIMMUNE DISEASE

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL30-1391	AMA-M2	96	EL36-1027	Gliadin IgA	96
EL30-1375	ANA profile	96	EL36-1026	Gliadin IgG	96
EL1-1009	ANA Screen IgG	96	EL10-1029	Jo-1	96
EL10-1010	ANCA Screen	96	EL1-1031	Mitochondrial Ab	96
EL2-1011	Anti-CCP	96	EL20-1032	MPO (p-ANCA)	96
EL20-1288	Anti-CP IgG	96	EL20-1033	PR-3 (C-ANCA)	96
EL20-1013	Anti-Phospholipids Screen	96	EL15-1034	RF IgA	96
EL3-1016	Anti-Tg	96	EL15-1035	RF IgG	96
EL20-1014	Anti-tTG IgA	96	EL2-1038	RF IgM	96
EL20-1015	Anti-tTG IgG	96	EL1-1039	Scl-70 IgG	96
EL29-1302	ASMA	96	EL1-1041	Sm IgG	96
EL1-1020	Cardiolipin IgA	96	EL1-1040	Sm/RNP IgG	96
EL1-1021	Cardiolipin IgG	96	EL1-1042	SSA IgG	96
EL1-1022	Cardiolipin IgM	96	EL1-1043	SSB(La) IgG	96
EL1-1044	Cardiolipin Total	96	EL1-1012	TPO IgG	96
EL1-1023	ds-DNA	96	EL2-1017	β-2-Glycoprotein 1 IgA	96
EL30-1024	ENA IgG profile-6	96	EL2-1018	β-2-Glycoprotein 1 IgG	96
EL30-1392	ENA profile-4	96	EL2-1019	β-2-Glycoprotein 1 IgM	96
EL30-1025	ENA Screen IgG	96	EL20-1406	β-2-Glycoprotein 1 Total	96

» BONE METABOLISM

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL1-1045	25(OH) Vitamin D	96	EL1-1048	Intact PTH	96
EL3-1046	ACTH	96			

» CARDIAC MARKERS

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL3-1050	CKMB	96	EL3-1051	Digoxin	96
EL3-1430	D-Dimer	96	EL1-1049	hs-CRP	96
EL3-1053	Myoglobin	96	EL1-1054	Troponin I	96

» DIABETES

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL9-1056	Adiponectin	96	EL20-1062	IGF-1	96
EL20-1060	Anti-GAD	96	EL9-1057	IGFBP-1	96
EL1-1055	C-peptide	96	EL1-1058	Insulin	96
EL20-1405	IA2	96	EL9-1059	Leptin	96
EL8-1061	IAA	96	EL1-1063	Pro-Insulin	96
EL20-1404	IgA Saliva	96			

» FERTILITY

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL3-1079	AMH	96	EL45-1084	LH	96
EL45-1080	FSH	96	EL2-1085	PAPP-A	96
EL45-1394	hCG Qualitative	96	EL45-1086	Prolactin	96
EL6-1082	hCG visual	96	EL8-1087	Sperm Ab	96
EL1-1083	HGH	96	EL45-1081	Total B-hCG	96

» INFECTIOUS DISEASE

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL5-1104	Adenovirus Ag	96	EL45-1379	COVID-19 Total Ab	96
EL15-1101	Adenovirus IgA	96	EL46-1388	Dengue IgA	96
EL15-1102	Adenovirus IgG	96	EL46-1126	Dengue IgG	96
EL15-1103	Adenovirus IgM	96	EL46-1127	Dengue IgM	96
EL15-1110	B. pertussis IgA	96	EL4-1128	Dengue Virus NS1	96
EL15-1111	B. pertussis IgG	96	EL46-1129	EBNA IgA	96
EL15-1112	B. pertussis IgM	96	EL46-1130	EBNA IgG	96
EL1-1107	Brucella IgG	96	EL46-1131	EBNA IgM	96
EL1-1108	Brucella IgM	96	EL46-1132	EBV EA IgA	96
EL4-1114	Chikungunya IgG	96	EL46-1133	EBV EA IgG	96
EL4-1113	Chikungunya IgM	96	EL46-1134	EBV EA IgM	96
EL1-1117	Chlamydia P. IgA	96	EL46-1135	EBV VCA IgA	96
EL1-1115	Chlamydia P. IgG	96	EL1-1136	EBV VCA IgG	96
EL1-1116	Chlamydia P. IgM	96	EL1-1137	EBV VCA IgM	96
EL1-1118	Chlamydia T. IgA	96	EL45-1138	H. pylori Antigen	96
EL1-1119	Chlamydia T. IgG	96	EL1-1139	H. pylori IgA	96
EL1-1120	Chlamydia T. IgM	96	EL1-1140	H. pylori IgG	96
EL1-1121	CMV IgA	96	EL1-1141	H. pylori IgM	96
EL1-1122	CMV IgG	96	EL13-1142	HAV Ab	96
EL1-1123	CMV IgM	96	EL45-1381	HAV IgG	96
EL45-1373	COVID-19 IgA	96	EL45-1143	HAV IgM	96
EL45-1360	COVID-19 IgG	96	EL13-1144	HBcAb	96
EL45-1442	COVID-19 IgG Quantitative	96	EL13-1150	HBcAb IgM	96
EL45-1361	COVID-19 IgM	96	EL13-1415	HBeAb	96

EL13-1148	HBeAb/Ag	96
EL13-1416	HBeAg	96
EL45-1145	HBsAb	96
EL45-1151	HBsAg	96
EL45-1157	HCV Ab	96
EL45-1382	HCV IgG	96
EL13-1152	HCV IgM	96
EL13-1428	HDV Ab	96
EL13-1316	HDV Ag	96
EL13-1315	HDV IgG	96
EL13-1396	HDV IgM	96
EL13-1156	HEV IgG	96
EL13-1161	HEV IgM	96
EL45-1158	HIV 1+2	96
EL13-1378	HIV Ag p24	96
EL13-1376	HIV Ag/Ab	96
EL8-1427	HPV IgG	96
EL1-1163	HSV 1 IgG	96
EL1-1164	HSV 1 IgM	96
EL1-1167	HSV 1&2 IgG	96
EL1-1168	HSV 1&2 IgM	96
EL2-1162	HSV 1+2 IgM	96
EL1-1165	HSV 2 IgG	96
EL1-1166	HSV 2 IgM	96
EL13-1160	HTLV 1/2 Ab	96
EL15-1365	Influenza A IgA	96
EL15-1366	Influenza A IgG	96
EL15-1367	Influenza A IgM	96
EL15-1368	Influenza B IgA	96
EL15-1369	Influenza B IgG	96
EL15-1370	Influenza B IgM	96
EL4-1169	JE IgG	96
EL4-1170	JE IgM	96
EL5-1175	Legionella urine Ag	96
EL4-1176	Leprosy IgG/IgM	96
EL30-1440	Lyme IgG	96
EL30-1441	Lyme IgM	96
EL46-1389	Malaria Screen	96
EL1-1177	Measles IgG	96
EL1-1178	Measles IgM	96
EL1-1179	Mumps IgG	96
EL1-1180	Mumps IgM	96
EL1-1181	Mycoplasma IgG	96
EL45-1182	Mycoplasma IgM	96
EL30-1383	Parainfluenza 1/2/3 IgA	96
EL30-1384	Parainfluenza 1/2/3 IgG	96
EL30-1385	Parainfluenza 1/2/3 IgM	96
EL30-1183	Parvovirus B19 IgG	96
EL30-1184	Parvovirus B19 IgM	96
EL5-1185	Rotavirus	96
EL15-1186	RSV IgA	96
EL15-1187	RSV IgG	96
EL15-1188	RSV IgM	96
EL1-1190	Rubella IgG	96
EL1-1191	Rubella IgM	96
EL4-1192	Salmonella Antigen	96
EL1-1193	Salmonella IgG	96
EL1-1194	Salmonella IgM	96
EL45-1387	SARS-CoV-2 Antigen	96
EL45-1439	SARS-CoV2 Neutralization Ab	96
EL4-1199	Scrub Typhus IgG	96
EL4-1200	Scrub Typhus IgM	96
EL46-1195	Syphilis IgG	96
EL46-1197	Syphilis IgM	96
EL46-1374	Syphilis Total	96
EL46-1201	TB IgG	96
EL46-1202	TB IgM	96
EL5-1205	Tetanus	96
EL2-1206	Toxoplasma IgA	96
EL1-1207	Toxoplasma IgG	96
EL1-1208	Toxoplasma IgM	96
EL1-1209	VZV IgG	96
EL1-1210	VZV IgM	96
EL4-1211	West Nile IgG	96
EL4-1212	West Nile IgM	96
EL1-1203	Zika Virus IgG	96
EL1-1204	Zika Virus IgM	96

» NEONATAL

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL1-1236	17OH progesterone	96	EL1-1238	PKU	96
EL1-1244	Biotinidase	96	EL1-1240	T4	96
EL1-1303	G6PD	96	EL3-1242	TBG	96
EL1-1241	IRT	96	EL1-1243	Total Galactose	96
EL1-1237	MSUD	96	EL1-1239	TSH	96

» PARASITOLOGY

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL5-1362	Anti-Giardia IgA saliva	96	EL5-1411	Fasciola IgM	96
EL5-1219	Ascaris IgG	96	EL4-1218	Filaria IgG4	96
EL5-1408	Ascaris IgM	96	EL5-1235	Giardia Ag 2nd generation	96
EL5-1229	Campylobacter	96	EL5-1372	Giardia coprpantigen Ag	96
EL5-1213	Chagas IgG	96	EL5-1223	Leishmania IgG	96
EL5-1429	Chagas IgM	96	EL5-1431	Leishmania IgM	96
EL5-1230	Crypto/Giardia Ag	96	EL5-1224	Leptospira IgG	96
EL5-1231	Cryptosporidium Ag	96	EL5-1225	Leptospira IgG/IgM	96
EL5-1220	Cysticercosis IgG	96	EL5-1226	Leptospira IgM	96
EL5-1417	Cysticercosis IgM	96	EL5-1444	Paragonimus IgG	96
EL5-1232	E. coli 0157 Ag	96	EL5-1445	Paragonimus IgM	96
EL5-1233	E. histolytica (Dispar)	96	EL5-1227	Schistosoma IgG	96
EL5-1221	E. histolytica Ab	96	EL5-1412	Schistosoma IgM	96
EL5-1363	E. histolytica Ag	96	EL5-1214	Strongyloids IgG	96
EL5-1410	E. histolytica IgM	96	EL5-1413	Strongyloids IgM	96
EL5-1222	Echinococcus IgG	96	EL5-1228	Toxocara IgG	96
EL5-1409	Echinococcus IgM	96	EL5-1418	Toxocara IgM	96
EL5-1217	F. gigantica IgG	96	EL5-1215	Trichinella IgG	96
EL5-1432	F. gigantica IgM	96	EL5-1419	Trichinella IgM	96
EL5-1216	Faciola IgG	96			

» STEROIDS

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL1-1245	17 OH progesterone	96	EL1-1254	Estradiol	96
EL9-1246	3a-Diol G	96	EL3-1256	Estrone	96
EL3-1247	Aldosterone	96	EL1-1257	Free Estriol (uE3)	96
EL1-1248	Androstenedione	96	EL9-1258	Pregnenolone	96
EL1-1249	Cortisol	96	EL1-1259	Progesterone	96
EL20-1250	Cortisol Saliva	96	EL9-1260	Progesterone Saliva	96
EL3-1252	DHEA	96	EL3-1261	SHBG	96
EL1-1251	DHEA-S	96	EL1-1263	Testosterone	96
EL9-1253	DHT	96	EL1-1264	Testosterone (Free)	96

EL20-1265	Testosterone Saliva	96	EL9-1255	Total Estrogen	96
EL20-1266	Total Estriol	96	EL20-1401	Urinary Cortisol	96

» THYROID

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL1-1267	FT3	96	EL3-1262	TBG	96
EL1-1268	FT4	96	EL1-1272	Tg Ab (Thyroglobulin)	96
EL9-1274	Reverse T3 (rT3)	96	EL49-1437	Thyroglobulin,TG	96
EL1-1270	T3	96	EL1-1273	TSH	96
EL3-1269	T3 uptake	96	EL6-1275	Ultra-TSH	96
EL1-1271	T4	96			

» TUMOR MARKERS

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL1-1276	AFP	96	EL1-1284	FFree beta hCG	96
EL2-1277	Beta-2-microglobulin	96	EL1-1285	Free PSA	96
EL30-1407	CA 72-4	96	EL1-1306	HE4	96
EL1-1278	CA-125	96	EL20-1403	HS-NSE	96
EL1-1279	CA-153	96	EL2-1286	NSE	96
EL1-1280	CA-199	96	EL2-1289	PAP	96
EL1-1283	CEA	96	EL2-1290	Pro-GRP	96
EL20-1397	CH50	96	EL1-1291	PSA	96
EL2-1034	Cyfra21-1	96			

» OTHER

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
EL1-1298	ACT	96	EL3-1309	Procalcionin	96
EL3-1292	Calcitonin	96	EL9-1300	Renin	96
EL36-1293	Calprotectin	96	EL9-1299	Resistin	96
EL20-1398	CIC C1q	96	EL1-1297	Secretory IgA	96
EL20-1399	CIC C3d	96	EL22-1305	Tacrolimus FK506	96
EL8-1294	FABP	96	EL30-1377	TNF alpha ELISA	96
EL23-1314	GIF (Anti-intrinsic Factor)	96	EL20-1400	TRAb	
EL36-1295	HAMA	96			
EL29-1313	Human CGRP	96			
EL30-1378	IL-1 Beta ELISA	96			
EL2-1364	IL-6	96			
EL39-1446	Inhibin	96			
EL30-1380	LKM	192			
EL1-1395	Lysozyme	96			
EL6-1308	PD-1	96			

RAPID

Immunochromatography Assays

» ALLERGY

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT48-2000	Total IgE	cassette	S/P/WB	25

» CARDIAC MARKERS

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT48-2264	D-Dimer	cassette	P/WB	25
RT48-2107	H-FABP	cassette	S/P/WB	25
RT48-2003	hs-CRP	cassette	S/P/WB	25
RT48-2005	Myoglobin	cassette	S/P/WB	25
RT28-2006	Tn I/CK-MB/Myo	cassette	serum/WB	25
RT48-2217	Troponin I	cassette	serum/WB	25

» DRUG OF ABUSE

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT35-2240	1 Panel Saliva Drug Test	cassette	saliva	25
RT35-2241	2 Panel Saliva Drug Test	cassette	saliva	25
RT35-2242	3 Panel Saliva Drug Test	cassette	saliva	25
RT35-2243	4 Panel Saliva Drug Test	cassette	saliva	25
RT35-2244	5 Panel Saliva Drug Test	cassette	saliva	25
RT35-2245	6 Panel Saliva Drug Test	cassette	saliva	25
RT24-2227	6-MAM (Heroin)	cassette	urine	25
RT24-2226	6-MAM (Heroin)	strip	urine	25
RT35-2246	7 Panel Saliva Drug Test	cassette	saliva	25
RT35-2247	8 Panel Saliva Drug Test	cassette	saliva	25
RT35-2248	9 Panel Saliva Drug Test	cassette	saliva	25
RT35-2249	10 Panel Saliva Drug Test	cassette	saliva	25
RT35-2250	11 Panel Saliva Drug Test	cassette	saliva	25
RT35-2251	12 Panel Saliva Drug Test	cassette	saliva	25
RT27-2215	Adultration	strip	urine	25
RT28-2009	Alcohol saliva	strip	saliva	25
RT35-2010	Alcohol urine	strip	urine	25
RT48-2061	Amphetamine	cassette	urine	25
RT48-2060	Amphetamine	strip	urine	25
RT48-2014	Barbiturate	cassette	urine	25
RT48-2013	Barbiturate	strip	urine	25
RT48-2018	Benzodiazepine	cassette	urine	25
RT48-2017	Benzodiazepine	strip	urine	25
RT48-2016	Buprenorphine	cassette	urine	25
RT48-2015	Buprenorphine	strip	urine	25
RT24-2020	Clonazepam (CLO)	cassette	urine	25
RT24-2019	Clonazepam (CLO)	strip	urine	25
RT48-2022	Cocaine	cassette	urine	25

RT48-2021	Cocaine	stip	urine	25
RT35-2071	Combo Any 2 Drug Test	strip	urine	25
RT35-2072	Combo Any 3 Drug Test	strip	urine	25
RT35-2073	Combo Any 4 Drug Test	strip	urine	25
RT35-2074	Combo Any 5 Drug Test	strip	urine	25
RT35-2075	Combo Any 6 Drug Test	strip	urine	25
RT35-2076	Combo Any 7 Drug Test	strip	urine	25
RT35-2077	Combo Any 8 Drug Test	strip	urine	25
RT35-2078	Combo Any 9 Drug Test	strip	urine	25
RT35-2079	Combo Any 10 Drug Test	strip	urine	25
RT35-2080	Combo Any 11 Drug Test	strip	urine	25
RT35-2081	Combo Any 12 Drug Test	strip	urine	25
RT48-2024	Cotinine	cassette	urine	25
RT48-2023	Cotinine	Strip	urine	25
RT28-2026	Diazapam	cassette	urine	25
RT28-2025	Diazepam	strip	urine	25
RT48-2028	EDDP	cassette	urine	25
RT48-2027	EDDP	Strip	urine	25
RT48-2029	Fentanyl	cassette	urine	25
RT48-2008	Fentanyl	strip	urine	25
RT48-2032	Ketamine	cassette	urine	25
RT48-2031	Ketamine	strip	urine	25
RT28-2034	LSD	cassette	urine	25
RT35-2033	LSD	strip	urine	25
RT48-2038	MDMA (Ecstasy)	cassette	urine	25
RT48-2037	MDMA (Ecstasy)	strip	urine	25
RT48-2040	Methadone	cassette	urine	25
RT48-2039	Methadone	strip	urine	25
RT48-2042	Methamphetamine	cassette	urine	25
RT48-2041	Methamphetamine	strip	urine	25
RT48-2044	Morphine/Heroin/Opiate	cassette	urine	25
RT48-2043	Morphine/Heroin/Opiate	strip	urine	25
RT48-2047	Oxycodone	cassette	urine	25
RT48-2046	Oxycodone	strip	urine	25
RT48-2049	PCP	cassette	urine	25
RT48-2048	PCP	strip	urine	25
RT48-2055	TCA	cassette	urine	25
RT48-2054	TCA	strip	urine	25
RT48-2057	THC	cassette	urine	25
RT48-2056	THC	strip	urine	25
RT28-2059	Tramadol	cassette	urine	25
RT28-2058	Tramadol	strip	urine	25

» FERTILITY

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT48-2094	FSH	cassette	urine	25
RT48-2093	FSH	strip	urine	25
RT48-2096	hCG 10 mIU/ml	cassette	urine	25
RT48-2099	hCG 10 mIU/ml	midstream	urine	25
RT48-2101	hCG 20 mIU/ml	cassette	urine	25
RT48-2102	hCG 20 mIU/ml	midstream	urine	25
RT48-2103	hCG 20 mIU/ml	strip	urine	25
RT48-2212	hCG Combo	cassette	urine/serum	25
RT48-2217	hCG Combo	strip	urine/serum	25
RT48-2106	LH	strip	urine	25
RT48-2105	LH	cassette	urine	25
RT48-3234	LH	midstream	urine	25

» INFECTIOUS DISEASE

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT48-2131	Adeno/Rota Antigen combo	cassette	stool	25
RT48-2132	Adenovirus Antigen	cassette	stool	25
RT31-2272	Astrovirus	cassette	stool	25
RT48-2136	Chlamydia Trachomatis	cassette	swab	25
RT31-2275	Clostridium Difficile	cassette	stool	25
RT45-2262	COVID-19 Antigen Microfluidic	cassette	swab	25
RT45-2263	COVID-19 Antigen/FluA/FluB Microfluidic	cassette	swab	25
RT45-2198	COVID-19 IgG/IgM	cassette	serum/P/WB	25
RT45-2276	COVID-19 IgG/IgM Microfluidic	cartridge	serum/P/WB	25
RT48-2138	Dengue IgG/IgM	cassette	serum/WB	25
RT48-2215	Dengue NS1	cassette	S/P	25
RT24-2208	Dengue Virus IgG/IgM/NS1	cassette	serum/WB/p	25
RT31-2273	Enterovirus	cassette	stool	25
RT48-2140	Gonorrhoea	Cassette	swab	25
RT28-2142	H. pylori	cassette	serum/WB	25
RT28-2143	H. pylori Antigen	cassette	stool	25
RT31-2274	H. pylori + Transferrin	cassette	stool	25
RT48-2115	HBsAg	cassette	serum/P/WB	25
RT48-2118	HCV	cassette	S/P	25
RT48-2121	HIV (1+2)	cassette	serum/plasma	25
RT48-2267	Influenza A/B	cassette/Pan	swab	25
RT4-2148	Leishmania (Cutaneous)	strip	skin	25
RT4-2149	Leishmania IgG/IgM	strip	serum	25
RT48-2207	Malaria pf	cassette	WB	25
RT48-2204	Malaria pf/pv	cassette	WB	25

RT48-2161	Rotavirus	cassette	stool	25
RT48-2162	RSV	cassette	swab	25
RT45-2214	SARS-CoV2 Antigen	cassette	swab	25
RT45-2211	SARS-CoV2 Neutralizing Ab	cassette	swab	25
RT4-2166	Scrub Typhus IgG	strip	serum/WB	25
RT4-2167	Scrub Typhus IgM	strip	serum/WB	25
RT48-2168	Strep A	cassette	swab	25
RT48-2171	Strep B	cassette	swab	25
RT48-2172	Syphilis	cassette	S/P/WB	25
RT48-2175	TB	cassette	S/P/WB	25

» TUMOR MARKERS

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT48-2179	AFP	cassette	serum/WB/P	25
RT27-2197	Albumin	cassette	urine	25
RT31-2269	Calprotectin	cassette	stool	20
RT48-2180	CEA	cassette	serum/WB/P	25
RT48-2196	Ferritin	cassette	serum/WB	25
RT24-2182	FOB	cassette	stool	25
RT31-2271	FOB/Transferrin/Calprotectin/Lactoferrin	cassette	stool	20
RT31-2270	Lactoferrin	cassette	stool	20
RT48-2183	PSA	cassette	serum/WB	25

» URINE STRIP REAGENTS

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT48-2185	URS-1 G	strip	urine	25
RT48-2256	URS-2 G/K	strip	urine	25
RT48-2187	URS-3 GKpH	strip	urine	25
RT48-2188	URS-4 GKpHB	strip	urine	25
RT48-2189	URS-5 GKpHBP	strip	urine	25
RT48-2190	URS-6 GKpHBPBili	strip	urine	25
RT48-2191	URS-7 GKpHBPBiliU	strip	urine	25
RT48-2192	URS-8 GKpHBPBiliUN	strip	urine	25
RT48-2193	URS-9 GKpHBPBiliUNS	strip	urine	25
RT48-2194	URS-10 GKpHBPBiliUNSL	strip	urine	25
RT35-2195	URS-11	strip	urine	25
RT35-2239	URS-12	strip	urine	25

» OTHER

CAT#	PRODUCT	FORMAT	SPECIMEN	TESTS
RT24-2228	Vitamin D	cassette	S/P	25

SARS-CoV2
ANTIGEN RAPID TEST SYSTEM
CAT# RT45-2214

- 98% Sensitivity & 100% specificity
- 0.1 Ng/Ml limit of detection
- Validated with anterior nasal collection method
- Software integration available
- Validated with all certified SARS-CoV2 variants

COMPONENTS

- 25 Test Cassettes
- 25 Tubes with Extraction Buffer & Droppers
- 25 Sterilized Anterior Nasal Swabs
- Tube Rack Positive & Negative Control Swabs
- IFU

COVID-19
ANTIBODY IgG/IgM RAPID TEST SYSTEM
CAT# RT45-2198

- 98% Sensitivity & 100% specificity
- 100% Agreement with finger-stick external clinical trial with PCR confirmed SARS-CoV-2
- Targets both virus spike protein and nucleocapsid protein to cover all epitopes for a strong detection
- Detect low levels of COVID-19 IgG with samples diluted at 1:5, 1:50, 1:500 and 1:1000 folds

COMPONENTS

- 25 Test Cassettes
- One Vial of Extraction Buffer
- 25 Pipettes
- 25 Alcohol Pads
- 25 Lancets
- IFU


IFA
Immunofluorescence Assays

» AUTOIMMUNE DISEASE

CAT#	PRODUCT	TESTS
IF17-4001	AAS Rat Kidney/Stomach	96
IF17-4107	AMA (Mouse Kidney)	96
IF17-4023	AMA (Rat Kidney)	96
IF17-4018	ANA Hep-2	120
IF17-4005	ANA Hep-2	60
IF17-4105	ANA Mouse Liver	96
IF17-4019	ANA Rat Liver Tissue	96
IF17-4054	Anti-Adrenal (Monkey)	96
IF17-4056	Anti-Ovary (Monkey)	96
IF17-4042	Anti-Reticulin IgA Antibody	96
IF17-4044	Anti-Reticulin IgG Antibody	96
IF17-4058	Anti-Testes (Monkey)	96
IF17-4034	ASA Antibody	96
IF17-4109	ASMA (Mouse Stomach)	96
IF17-4015	ASMA (Rat Stomach)	96
IF17-4031	ATA (Primate Thyroid)	96
IF17-4021	Autoscreen I (ANA, AMA, PCA, ASMA) (Rat Kidney/Stomach)	96
IF17-4027	Autoscreen II (ANA, AMA, PCA, ASMA) (Rat Kidney/Stomach)	96
IF17-4025	Autoscreen II (ANA, AMA, PCA, ASMA) (Rat Kidney/Stomach)	96
IF17-4059	C-ANCA	60
IF17-4115	C-ANCA	120
IF17-4036	CMA (Primate Heart)	96
IF17-4111	CMA (Rat Heart)	96
IF17-4033	Endomysial (Primate)	96
IF17-4040	GBM (Primate Kidney)	96
IF17-4038	ICA (Primate Pancreas)	96
IF17-4051	nDNA	100
IF17-4060	P-ANCA	60
IF17-4029	PCA (Rat Stomach)	96
IF17-4050	Primate Submaxillary	96
IF17-4046	SM Striated Muscle (Monkey)	96
IF17-4048	SM Striated Muscle (Rat)	96

» INFECTIOUS DISEASE

CAT#	PRODUCT	TESTS
IF17-4068	Chlamydia T. IgG	120
IF17-4069	Chlamydia T. IgM	120
IF17-4072	CMV IgG	120
IF17-4073	CMV IgM	120
IF17-4114	EBV EA IgG	120
IF17-4074	EBV VCA IgG	120
IF17-4012	EBV VCA IgM	120
IF17-4075	FTA-ABS (T. pallidum)	100
IF17-4067	FTA-ABS (T. pallidum)	400
IF17-4013	FTA-ABS Double Stain	100
IF17-4066	FTA-ABS Double Stain	400
IF17-4016	HSV 1 IgG	120
IF17-4017	HSV 1 IgM	120
IF17-4078	HSV 1&2 IgG	120
IF17-4079	HSV 1&2 IgM	120
IF17-4080	HSV 2 IgG	120
IF17-4081	HSV 2 IgM	120
IF17-4113	Legionela p. Gr. 1 (HT)	180
IF17-4112	Legionella p. 1-6 Poly (HT)	60
IF17-4092	Measles IgG	120
IF17-4093	Measles IgM	120
IF17-4094	Mumps IgG	120
IF17-4095	Mumps IgM	120
IF17-4065	Rocky Mountain Spotted Fever	30
IF17-4096	RSV IgG	120
IF17-4097	RSV IgM	120
IF17-4070	Toxoplasma IgG	120
IF17-4071	Toxoplasma IgM	120
IF17-4098	VZV IgG	120
IF17-4099	VZV IgM	120


CLIA
Chemiluminescent Assays

» ALLERGY

CAT#	PRODUCT	TESTS
CL3-5055	Total IgE	96

» AUTOIMMUNE DISEASE

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL2-5119	Anti-CCP	96	CL2-5052	Cardioipin IgG	96
CL2-5115	B2GP1 IgA	96	CL2-5053	Cardioipin IgM	96
CL2-5116	B2GP1 IgG	96	CL2-5054	ds-DNA	96
CL2-5117	B2GP1 IgM	96	CL2-5114	RF IgM	96
CL2-5051	Cardioipin IgA	96	CL2-5118	Thyroglobulin IgG	96

» ANEMIA

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL3-5001	Ferritin	96	CL3-5058	sTfR	96
CL3-5056	Folate	96	CL3-5057	Vitamin B12	96

» BONE METABOLISM

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL3-5017	ACTH	96	CL3-5065	PTH	96
CL3-5064	Calcitonin	96	CL3-5066	Vitamin D	96

» CARDIAC MARKERS

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL3-5061	CK-MB	96	CL2-5060	hs-CRP	96
CL2-5063	cTnI	96	CL3-5062	Myoglobin	96
CL3-5059	Digoxin	96			

» DIABETES

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL2-5002	C-peptide	96	CL2-5003	Insulin	96

» FERTILITY

CAT#	PRODUCT	TESTS
CL3-5069	AMH	96
CL2-5055	Beta hCG	96
CL2-5004	FSH	96
CL2-5005	hCG	96
CL3-5007	HGH	96
CL2-5006	LH	96
CL3-5068	PAPP-A	96
CL2-5008	Prolactin	96

» INFECTIOUS DISEASE

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL2-5042	Chalmydia Trachomatis IgA	96	CL46-5104	HSV 1 IgG	96
CL2-5043	Chalmydia Trachomatis IgG	96	CL46-5105	HSV 1 IgM	96
CL2-5044	Chalmydia Trachomatis IgM	96	CL46-5101	HSV 1/2 IgG	96
CL2-5111	CMV IgA	96	CL46-5102	HSV 1/2 IgM	96
CL46-5112	CMV IgG	96	CL2-5106	HSV 2 IgA	96
CL46-5113	CMV IgM	96	CL46-5107	HSV 2 IgG	96
CL46-5134	COVID Antigen	96	CL46-5108	HSV 2 IgM	96
CL46-5120	COVID-19 IgG	96	CL46-5125	Malaria Screen	96
CL46-5133	COVID-19 IgM	96	CL46-5093	Measles IgG	96
CL46-5123	Dengue IgA	96	CL46-5094	Measles IgM	96
CL46-5099	Dengue IgG	96	CL46-5097	Mumps IgG	96
CL46-5100	Dengue IgM	96	CL46-5098	Mumps IgM	96
CL46-5090	EBNA IgA	96	CL46-5126	Mycoplasma IgG	96
CL46-5091	EBNA IgG	96	CL46-5127	Mycoplasma IgM	96
CL46-5092	EBNA IgM	96	CL3-5067	PCT	96
CL46-5087	EBV EA IgA	96	CL46-5109	Rubella IgG	96
CL46-5088	EBV EA IgG	96	CL46-5110	Rubella IgM	96
CL46-5089	EBV EA IgM	96	CL46-5130	Schistosoma IgG	96
CL46-5084	EBV VCA IgA	96	CL46-5128	Syphilis IgG	96
CL46-5085	EBV VCA IgG	96	CL46-5129	Syphilis IgM	96
CL46-5086	EBV VCA IgM	96	CL46-5135	Syphilis Total	96
CL2-5083	H. pylori Antigen	96	CL46-5046	Toxoplasma IgG	96
CL46-5048	H. pylori IgA	96	CL46-5047	Toxoplasma IgM	96
CL46-5049	H. pylori IgG	96	CL46-5131	Tuberculosis IgG	96
CL46-5050	H. pylori IgM	96	CL46-5132	Tuberculosis IgM	96
CL46-5124	Histamine	96	CL46-5095	VZV IgG	96
CL2-5103	HSV 1 IgA	96	CL46-5096	VZV IgM	96

» NEONATAL

CAT#	PRODUCT	TESTS
CL2-5078	Neonatal TSH	96

» STEROIDS

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL9-5009	(3a-Diol G)	96	CL3-5013	DHEA	96
CL3-5010	17 OH progesterone	96	CL3-5014	DHEA-S	96
CL3-5122	17 OH progesterone SI	96	CL3-5016	Estradiol	96
CL3-5011	Aldosterone	96	CL9-5018	Estriol (Saliva)	96
CL3-5070	Androstenedione	96	CL3-5020	Estrone	96
CL3-5012	Cortisol	96	CL9-5019	Estrone (Saliva)	96

CL3-5023	Free Testosterone	96	CL3-5022	Testosterone	96
CL9-5024	Plsama Renin Activity	192	CL9-5025	Testosterone (Saliva)	96
CL3-5021	Progesterone	96	CL3-5041	uE3	96
CL3-5071	SHBG)	96			

» THYROIDS

CAT#	PRODUCT	TESTS	CAT#	PRODUCT	TESTS
CL3-5075	Anti-Tg	96	CL3-5029	T4	96
CL3-5076	Anti-TPO	96	CL3-5074	TBG	96
CL3-5026	FT3	96	CL3-5073	Tg	96
CL2-5027	FT4	96	CL2-5030	TSH	96
CL3-5028	T3	96	CL2-5077	Ultra-Sensitive TSH	96
CL3-5072	T3 Uptake	96			

» TUMOR MARKERS

CAT#	PRODUCT	TESTS
CL3-5031	AFP	96
CL2-5032	Beta 2 microglobulin	96
CL3-5034	CA-125	96
CL2-5033	CA-153	96
CL2-5035	CA-19-9	96
CL3-5036	CEA	96
CL2-5079	Cyfra21-1	96
CL2-5037	Free Beta hCG	96
CL2-5038	Free PSA	96
CL2-5039	NSE	96
CL2-5081	PAP	96
CL2-5080	Pro-GRP	96
CL3-5040	PSA	96
CL3-5121	PSA High Sensitivity	96

SEROLOGY

Test Kits

» LATEX AGGULTINATION

CAT#	PRODUCT	TESTS
SL25-3000	ASO	50
SL25-3001	ASO	100
SL26-3038	Control Serum Kit	500
SL25-3002	CRP	50
SL25-3003	CRP	100
SL25-3004	Mono	50
SL25-3005	Mono	100
SL25-3008	RF	50
SL25-3009	RF	100
SL26-3033	Rose Bengal Brucella Antigen/dropper	3ml
SL26-3034	Rose Bengal Brucella Antigen/dropper	5ml
SL26-3035	Rose Bengal Brucella Antigen/cap	10ml
SL26-3036	Rose Bengal Brucella Antigen/dropper	10ml
SL25-3010	Rotovirus	50
SL25-3011	RPR	100
SL25-3012	RPR	500
SL25-3007	SLE	100
SL25-3016	TPHA	100
SL26-3039	VDRL Antigen & buffer	500
SL26-3017	VDRL Complete Kit	500
SL26-3042	VDRL Non-Reactive Control	5ml
SL26-3040	VDRL Reactive Control	5ml
SL26-3041	VDRL Weakly Reactive Control	5ml

» FEBRILE ANTIGENS

CAT#	PRODUCT	TESTS
SL25-3019	Brucella Abortus	5ml
SL25-3018	Brucella Melitensis	5ml
SL25-3021	Febrile Negative Control	5ml
SL25-3020	Febrile Positive Control	5ml
SL25-3022	Paratyphoid A	5ml
SL25-3023	Paratyphoid B	5ml
SL25-3024	Paratyphoid C	5ml
SL25-3025	Proteus Ox19	5ml
SL25-3026	Proteus OX2	5ml
SL25-3027	Proteus OXK	5ml
SL25-3028t	Salmonella Group A Antigen	5ml
SL25-3029	Salmonella Group B Antigen	5ml
SL25-3030	Salmonella Group C Antigen	5ml
SL25-3031	Typhoid H	5ml
SL25-3032	Typhoid O	5ml

VETERINARY

Test Kits

» ELISA FORMAT

CAT#	PRODUCT	SPECIMEN	TESTS
VE39-7030	Activin	Mouse	96
VE39-7022	AMH	Bovine	96
VE39-7023	AMH	Canine	96
VE39-7024	AMH	Caprine	96
VE39-7025	AMH	Equine	96
VE39-7026	AMH	Ovine	96
VE39-7027	AMH	Porcine	96
VE39-7028	AMH	Primate	96
VE39-7029	AMH	Rat/Mouse	96
VE39-7032	IGFs	Rat/Mouse Free IGF-I	96
VE39-7031	IGFs	Rat/Mouse Total IGF-I	96
VE39-7033	Inhibins	Equine/Canine/Rodent Inhibin A	96
VE39-7034	Inhibins	Equine/Canine/Rodent Inhibin B	96
VE30-7020	Insulin	Mouse	96
VE30-7019	Insulin	Rat	96
VE22-7021	LH	Rat	96
VE39-7035	Oxyntomodulin	Rat/Mouse	96
VE39-7036	PAPP-A	Mouse	96
VE48-7037	SARS-Cov-2	Multi-Species	192
VE39-7038	SARS-Cov-2	Multi-Species	480

INSTRUMENTS

MONOLYZE VX1000

ELISA 1 PLATE ANALYZER

- Batch work
- 1 microplate + 1 prediluition plate
- From a single strip up to a maximum of 12 (1 microplate)
- Disposable tips

MONOLYZE VX3000

ELISA 3 PLATE ANALYZER

- Fully automated random access analyzer
- Continuous loading
- 3 indipendent microplates + 1 prediluition microplate
- From a single strip up to a maximum of 36 (3 microplates)
- Disposable Tips

MONOLYZE AX1100

ELISA & CLIA COMBO 1 PLATE ANALYZER

- Fully automated ELISA and CLIA Analyzer
- Microwell CLIA and ELISA assays occur on the same plate
- Reactions take place in standard plastic microwells/strips, opaque white for CLIA and transparent for ELISA
- Spectral range for CLIA (300-650 peak wavelength of 400 nm)
- Absorbance 4 filter wheel (405, 450, 492, 630 nm)
- Patented dual-function reader, which automatically switches between absorbance and chemiluminescence reading
- QC Tracking SW enables controls and calibrators to be tracked using Levey-Jennings graph
- Performs dilutions and pre-dilutions; dispense volumes range from 2 µL to 1.95 mL

MONOZYME AX9200
ELISA MIXER/INCUBATOR

- Holds two 96-well microplates.
- Digitally controlled 8-speed mixer with orbital mixing from 575 to 1500 rpm.
- Temperature adjustable from ambient to 40°C with resolution of 0.1°C
- Digital timer controls mixing or can be operated independently, solely as a timer.
- Compact and easy to operate
- Outer tinted cover provides further insulation and protection from light.

MONOZYME AX9600
ELISA WASHER

- Washes flat or round bottom microwells
- Automatically positions each row for washing
- Stores 50 user programmable wash protocols
- 6 Factory-programmed wash/rinse modes
- Aerosol shield & aerosol line filter (bio-hazard protection)
- Strip selection for partial plate washing
- Low-maintenance
- Economical open system/compact design
- (Optional extra wash bottle)

MONOZYME AX9300
ELISA READER

- Economical open system & compact design
- Reads a 96 microwell plate in 12 seconds
- Multiple calculation modes
- Dependable performance
- Custom filter configurations available
- Intuitive software, designed for ease of use

MONOZYME VX5000

ELISA COMBO WASHER/INCUBATOR/READER

- Washer, Incubator, Linear Shaker and Reader.
- External connection to PC for instrument control
- Touch screen on board (optional)
- Up to 4 usable wavelengths

MONOFLOW ZX5100

MICROFLUIDIC ANALYZER

- Micro channel designed for micro sampling
- Observed results in 4 MIN
- CV < 5%
- Continuous operations & simultaneous reactions outside the analyzer
- Light, handy, and portable
- Diagnose with only 35μL sample volume
- 3 simple step to quick result

MONOZYME TX2000

URINE ANALYZER

The Monozyme TX2000 Analyzer is a desktop analyzer designed to read Monocent's proprietary urinalysis strips. The instrument is intended to be used together with the Monocent Urine Reagent Strips as a system for semi- quantitative detection of Microalbumin, Creatinine, Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

The Monozyme TX2000 analyzer uses a touch screen to display user options, results, settings and diagnostics. All user input occurs via touch screen, though a bar code reader attachment may also be enabled for identifying test strip bottles.

GLOBAL REACH

Monocent has a wide variety of IVD products and instruments. We have connections and resources across the globe with a team of experts who can accommodate you as a distributor or a customer.

Contact us for orders and inquiries. Our Sales Specialists and Technicians are always available to assist you.

Monocent conforms to the highest Quality Management System in compliance to FDA regulations, ISO 13485-2016, and ISO 9001-2015 standards.

MADE IN USA · ISO 13485-2016 · ISO 9001-2015 · FDA · CE

Monocent, Inc.

+1 424 310 0777

+1 424 310 0777

info@monocent.com

www.monocent.com

9237 Eton Ave., Chatsworth, CA 91311 USA

We Are

A California Based Medical Device Manufacturer and a Core Provider of In-Vitro Diagnostic Solutions, Instruments & High Quality Test Systems in Variety of Methods: & Platforms

ELISA RAPID CLIA IFA SEROLOGY PCR NGS VETERINARY

Monocent, Inc.

+1.424.310.0777
+1.424.310.0777
info@monocent.com
www.monocent.com
9237 Eton Ave.
Chatsworth, CA 91311, USA