



global assurance

This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

For and on behalf of NQA, USA

Certificate Number: 16880
EAC Code: 34
Certified Since: March 22, 2012
Valid Until: March 19, 2024
Reissued: March 20, 2021
Cycle Issued: March 20, 2021



Declaration of CE conformity

Avantor Performance Materials B.V. reg. no. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20
7418 AM Deventer
The Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T.Baker[®] label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III. The BeneSphera[™] 3 Part Diff Analyzer H32 is in compliance with IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use.

The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self-registration.

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

January 6, 2015

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker® product list for CE marked products

Product no.	Product	Pack size
Hematology Analyzer		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
Clinical Chemistry Analyzer		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
Diluents		
3961	Diluid 100 Plus	20 liter
2990.9010PC	Diluid™ 22	10 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9020	Diluid Abacus	20 liter
3430.9010	Diluid Abacus	10 liter
3996	Diluid AC 900	20 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
2901.9010PC	Diluid BS34	10 liter
3963	Diluid III Diff	20 liter
3963.9010	Diluid III Diff	10 liter
3459.9020	Diluid Erma	20 liter
3419.9020PC	Diluid M5	20 liter
3439.9020PC	Diluid Mindray	20 liter
3483.9020PC	Diluid NR	20 liter
2987.9020PC	Diluid Ruby	20 liter
3832.9020	Diluid/Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3495.9010PC	Sheath D	10 liter
3471.9020PC	Sheath Fluid 3000/3500	20 liter
Lyses		
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet 1000 CN free	5 liter
2986.0500PE	CyMet™ 22	500 ml
3469.9010PC	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3839.5000PC	CyMet 3500	5 liter
3825	CyMet 3500 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3417.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
2950.2500PE	CyMet ASA	2.5 liter
2951.0500PE	CyMet ASB	500 ml
2952.9010PC	CyMet AS CN Free	10 liter
3755	CyMet Automated	5 liter
2982.0500PE	CyMet BS3 CN free	500 ml
2902.1000PE	CyMet BS34 CN Free	1 liter
3968.0500	CyMet III Diff	500 ml
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3511.1000	CyMet III Diff CN free	1 liter
3511.5000	CyMet III Diff CN free	5 liter

3416.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3853.1000	CyMet H20	1 liter
3425.0500	CyMet KX CN Free	500 ml
2985.1000PE	CyMet LH 53	1 liter
3489.1000PE	CyMet MBA	1 liter
3418.1000PE	CyMet MD(I)	1 liter
2984.1000PE	CyMet MD(I) 53	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3497.0500PE	CyMet MH CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3863.1000	CyMet Micro CN free	1L micros
3441.0500PE	CyMet Mindray	500 ml
3440.0500PE	CyMet Mindray CN Free	500 ml
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
2988.5000PC	CyMet Ruby CN Free	5 liter
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3788	CyMet STX/STL	1 liter
3475.5000PC	LeucoLyse	5 liter
2989.5000PC	LeucoLyse Ruby	5 liter
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3513.1000PE	RBCLyse™	1 liter
3518G.1000PE	RBCLyse G	1 liter
3514.0500PE	WBCStabilise™	500 ml
Reticulocyte Reagents		
3493.1000PE	RetiClear™ MHG	1 liter
3774	RetiCount™	30 ml
2953.0210PE	RetiCount AS	210 ml
3777	RetiCount CD	15 x 3.5 ml
3494.0200PE	RetiCount G	200 ml
Cleaners		
3507.9020	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3763	DetectoTerge™	5 liter
3766	DetectoTerge	1 liter
2970.0900PE	DetectoTerge BS	900 ml
3917	HypoChlorite	5 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3432.1000PE	ProClean Abacus	1 liter
3432.5000	ProClean Abacus	5 liter
3902.0100PE	ProClean CD	100 ml
3862.9020PC	ProClean Extra	20 liter
3862.5000	ProClean Extra	5 liter
3862.1000	ProClean Extra	1 liter
3867.1000PE	ProClean Extra	1L micros
3498.1000PE	ProClean MX5	1 liter
3901	ProClean Plus	100 ml
3442.5000PE	Rinse Mindray	5 liter

Product no.	Product	Pack size
Reagent Packs		
2910	Reagent Pack BS34	1 pack
Hematology Controls and Calibrators		
3427/3428/3429	8-Parameter Control L/N/H	2.5 ml
3463/3464/3465	8-Parameter Control L/N/H	2.5 ml
3701/3702/3703	8-Parameter Control L/N/H	4.5 ml
3746	8-Parameter Control L+N+H	3 x 2.5 ml
3747	8-Parameter Control 4xN	4 x 2.5 ml
3751	8-Parameter Control 1xL+4xN+1xH	6 x 2.5 ml
3633/3634/3635	8-Parameter Control ext L/N/H	2.5 ml
3433/3434/3435	3-Diff Control L/N/H	2.5 ml
3502/3503/3504	3-Diff Control L/N/H	4.5 ml
3466	3-Diff Control 4xL	4 x 2.5 ml
3467	3-Diff Control 4xN	4 x 2.5 ml
3468	3-Diff Control 4xH	4 x 2.5 ml
3421/3422/3423	3-Diff Control ext L/N/H	2.5 ml
3681/3682/3683	5D Control L/N/H	5.0 ml
3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3613/3614/3615	BC-Diff 5 Control L/N/H	4.5 ml
3940	Cal Set 1	2 x 2.5 ml
3452/3453/3454	CD-Diff Control L/N/H	3.0 ml
3838	CD-Diff Control 2xL+2xN+2xH	6 x 3.0 ml
3455/3456/3457	K-Diff Control L/N/H	2.5 ml
3424	Platelet Control Ext. value	5 x 3 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3652/3653/3654	XE-RET Control L/N/H	3.0 ml

Product no.	Product	Pack size
Stains and Dyes		
3800.1000PE	Eosin-Y Alcoholic	1 liter
3800.2500PE	Eosin-Y Alcoholic	2.5 liter
3800.9200	Eosin-Y Alcoholic	200 liter
3446.1000PE	Eosin Y 0.5% Aqueous	1 liter
3446.9200	Eosin Y 0.5% Aqueous	200 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3856.9180ST	Giemsa	180 liter
3870.1000	Hematoxyline (Mayer)	1 liter
3870.2500	Hematoxyline (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3873.9200	Hematoxyline (Harris, Gill II)	200 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	500 ml
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
Clearing agent		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
Mounting media		
3921.0500	UltraKitt™	500 ml
3921.0600	UltraKitt	6 x 100 ml
3921.9025ST	UltraKit	25 liter
3882.0500	Mounting Medium High	500 ml
3883.0500	Mounting Medium Low	500 ml
Fixatives		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010PE	10% v/v Buffered Formaldehyde	10 liter
3933.9020	10% v/v Buffered Formaldehyde	20 liter
3933.9200	10% v/v Buffered Formaldehyde	200 liter
3880.1000	Bouin's Fixative	1 liter
3869.1200	Cervix Fixative	12 x 125 ml
3884.9010PC	Cytology Fixative LBCM	10 liter
3409.9010	Immuno PBS 20x concentrated	10 liter
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter



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Conformity Declarations

Archem Diagnostics Systems

Declares in our own responsibility conformity of the products listed below according to the essential requirements in other IVD products the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive)



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REF No	Product Name
T1010	ADA Reagent
T1011	ADA Reagent
T2010	Albumin Reagent
T2011	Albumin Reagent
T2022	Alkaline Phosphatase Reagent
T2023	Alkaline Phosphatase Reagent
T2222	GPT (ALT) Reagent
T2223	GPT (ALT) Reagent
T2032M	Amylase Reagent
T2033M	Amylase Reagent
T2212	GOT (AST) Reagent
T2213	GOT (AST) Reagent
TBC20	Bicarbonate Reagent
T2040	Bilirubin Total Reagent
T2041	Bilirubin Total Reagent
T2050	Bilirubin Direct Reagent
T2051	Bilirubin Direct Reagent
T2062	Calcium Reagent
T2063	Calcium Reagent
T2060B	Calcium Reagent
T2061B	Calcium Reagent
TCL20	Chloride Reagent
T2092	Cholesterol Reagent
T2093	Cholesterol Reagent
TBC30	Cholinesterase Reagent
TCU20	Copper Reagent
TCU21	Copper Reagent
TCU22	Copper Reagent
T2142	CK-NAC Reagent
T2143	CK-NAC Reagent
T2162	Creatinine Reagent
T2163	Creatinine Reagent
T2172	Gamma-GT Reagent
T2173	Gamma-GT Reagent
T2192	Glucose Reagent
T2193	Glucose Reagent
T2242	Iron Reagent
T2243	Iron Reagent
T2260	LDH Reagent
T2261	LDH Reagent




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T2440	Lactate Acid
T2441	Lactate Acid
TLP22	Lipase Reagent
TLP23	Lipase Reagent
T2282	Magnesium Reagent
T2283	Magnesium Reagent
TMA71	Microalbumin II Reagent
T2290	Phosphorus Reagent
T2291	Phosphorus Reagent
TSP20	Protein HS (Microprotein) Reagent
TSP21	Protein HS (Microprotein) Reagent
T2300	Total Protein Reagent
T2312	Triglycerides Reagent
T2313	Triglycerides Reagent
T2232	Urea Reagent
T2233	Urea Reagent
T2342	Uric Acid Reagent
T2343	Uric Acid Reagent
TZN70	Zinc Reagent
TZN71	Zinc Reagent
TZN72	Zinc Reagent
TN13	HbA1c Reagent
TN14	HbA1c Reagent
TN15	HbA1c Reagent
TTH1	Ethanol Reagent
TTH2	Ethanol Reagent
TAB100	CRP Turbi Reagent
TAB101	CRP Turbi Reagent
TAB240	CRP HS Reagent
TAB122	RF Turbi Reagent
TAB123	RF Turbi Reagent
TAB124	RF Turbi Reagent
TAB130	Ferritin Reagent
TAB131	Ferritin Reagent
TAB133	CRP Turbi WR Reagent
TAB140	IgA Reagent
TAB150	IgG Reagent
TAB160	IgM Reagent
TAB170	Complement C3 Reagent
TAB180	Complement C4 Reagent
TAB190	Transferrin Reagent

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TAB220	Fructosamine Reagent
TAB230	D-Dimer Reagent
TAB231	D-Dimer Reagent
T2302	Procalcitonin Reagent
06T81-54	Amylase Reagent
06T81-55	Amylase Reagent
01R86-31	ASO Reagent
01R86-21	ASO Reagent
01R88-31	CK-MB Reagent
01R88-21	CK-MB Reagent
06R55-24	CK-NAC Reagent
06R55-25	CK-NAC Reagent
06T81-63	CRP Turbi WR Reagent
02R04-31	CRP WR Reagent
02R04-21	CRP WR Reagent
06T04-20	D-Dimer Reagent
06T04-25	D-Dimer Reagent
06R55-20	Iron Reagent
06R55-21	Iron Reagent
01R89-41	IgE Reagent
01R89-31	IgE Reagent
01R89-21	IgE Reagent
01R87-51	HbA1c Reagent
01R87-41	HbA1c Reagent
01R87-31	HbA1c Reagent
01R87-21	HbA1c Reagent
06R72-20	HbA1c II Reagent
02R06-31	HDL Cholesterol Direct Reagent
02R06-21	HDL Cholesterol Direct Reagent
02R05-31	LDL Cholesterol Direct Reagent
02R05-21	LDL Cholesterol Direct Reagent
06R55-22	Lipase Reagent
06R55-23	Lipase Reagent
06T81-58	RF Turbi Reagent
06T81-59	RF Turbi Reagent
06T81-60	RF Turbi Reagent
06T85-25	Triglycerides Reagent
06T85-35	Triglycerides Reagent
06T81-61	Urea Reagent
06T81-62	Urea Reagent
06T81-56	Uric Acid Reagent

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06T81-57	Uric Acid Reagent
01R85-41	UIBC Reagent
01R85-31	UIBC Reagent
01R85-21	UIBC Reagent
06R71-20	Zinc Reagent
01R95-01	HDL-LDL Calibrator (ARCAL Lipid)
01R90-01	ASO Calibrator
01R91-01	CRP WR Calibrator
06T81-64	CRP Turbi WR Calibrator Level 5
01R96-01	HbA1c Control Set
01R97-01	HbA1c Calibrator Set
01R98-01	IgE Control Set
01R99-01	IgE Calibrator Set
01R92-01	CK-MB Control Level I
01R93-01	CK-MB Control Level II
01R94-01	CK-MB Calibrator
06R56-01	Lipase Calibrator
06T04-02	D-Dimer Calibrator Set
06T04-10	D-Dimer Control Set
06R56-02	Multiconstituent Calibrator
06T81-65	Specific Protein Control Level I
06T81-66	Specific Protein Control Level II
06T81-67	Rheumatoid Control Level I
06T81-68	Rheumatoid Control Level II
06T81-69	RF Standard (Calibrator) Lyophilized
06R71-01	Zinc Calibrator
06R71-10	Zinc Control Level I
06R71-11	Zinc Control Level II
A2010B5	Albumin Reagent
A2010B10	Albumin Reagent
A2010B20	Albumin Reagent
A2020B1-R1	Alkaline Phosphatase Reagent
A2020B1-R2	Alkaline Phosphatase Reagent
A2020B5-R1	Alkaline Phosphatase Reagent
A2020B5-R2	Alkaline Phosphatase Reagent
A2020B10-R1	Alkaline Phosphatase Reagent
A2020B10-R2	Alkaline Phosphatase Reagent
A2020B25-R1	Alkaline Phosphatase Reagent
A2020B25-R2	Alkaline Phosphatase Reagent
ZA52B1-R1	ADA Reagent
ZA52B1-R2	ADA Reagent

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ZA52B3-R1	ADA Reagent
ZA52B3-R2	ADA Reagent
ZA22B1-R1	Ethanol Reagent
ZA22B1-R2	Ethanol Reagent
ZA22B5-R1	Ethanol Reagent
ZA22B5-R2	Ethanol Reagent
ZA53B1	Aldolase Reagent
ZA57B1-R1	Ammonia Reagent
ZA57B1-R2	Ammonia Reagent
A2030B5	Amylase Reagent
A2030B10	Amylase Reagent
A2030B20	Amylase Reagent
ZA08B1-R1	Apolipoprotein A1 Reagent
ZA08B1-R2	Apolipoprotein A1 Reagent
ZA09B1-R1	Apolipoprotein B Reagent
ZA09B1-R2	Apolipoprotein B Reagent
TA110B5-R1	ASO Reagent
TA110B5-R2	ASO Reagent
TA110B10-R1	ASO Reagent
TA110B10-R2	ASO Reagent
TA110B25-R1	ASO Reagent
TA110B25-R2	ASO Reagent
A5010B1	Bicarbonate Reagent
A5010B5	Bicarbonate Reagent
A2040B1-R1	Bilirubin Total Reagent
A2040B1-R2	Bilirubin Total Reagent
A2040B5-R1	Bilirubin Total Reagent
A2040B5-R2	Bilirubin Total Reagent
A2040B10-R1	Bilirubin Total Reagent
A2040B10-R2	Bilirubin Total Reagent
A2040B25-R1	Bilirubin Total Reagent
A2040B25-R2	Bilirubin Total Reagent
A2050B5-R1	Bilirubin Direct Reagent
A2050B5-R2	Bilirubin Direct Reagent
A2050B10-R1	Bilirubin Direct Reagent
A2050B10-R2	Bilirubin Direct Reagent
A2050B25-R1	Bilirubin Direct Reagent
A2050B25-R2	Bilirubin Direct Reagent
A2060B5	Calcium Reagent
A2060B10	Calcium Reagent
A206MB8-R1	Calcium OCP Reagent

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A206MB8-R2	Calcium OCP Reagent
A206MB24-R1	Calcium OCP Reagent
A206MB24-R2	Calcium OCP Reagent
CL200B1	Chloride Reagent
A2090B5	Cholesterol Reagent
A2090B10	Cholesterol Reagent
A2090B25	Cholesterol Reagent
HD2210B4-R1	HDL Cholesterol Direct Reagent
HD2210B4-R2	HDL Cholesterol Direct Reagent
HD2210B12-R1	HDL Cholesterol Direct Reagent
HD2210B12-R2	HDL Cholesterol Direct Reagent
HD2210B20-R1	HDL Cholesterol Direct Reagent
HD2210B20-R2	HDL Cholesterol Direct Reagent
HD2210B40-R1	HDL Cholesterol Direct Reagent
HD2210B40-R2	HDL Cholesterol Direct Reagent
HD2210B80-R1	HDL Cholesterol Direct Reagent
HD2210B80-R2	HDL Cholesterol Direct Reagent
LD2600B4-R1	LDL Cholesterol Direct Reagent
LD2600B4-R2	LDL Cholesterol Direct Reagent
LD2600B12-R1	LDL Cholesterol Direct Reagent
LD2600B12-R2	LDL Cholesterol Direct Reagent
LD2600B20-R1	LDL Cholesterol Direct Reagent
LD2600B20-R2	LDL Cholesterol Direct Reagent
LD2600B80-R1	LDL Cholesterol Direct Reagent
LD2600B80-R2	LDL Cholesterol Direct Reagent
AB2130B1-R1	Cholinesterase Reagent
AB2130B1-R2	Cholinesterase Reagent
CU200B1	Copper Reagent
CU200B5	Copper Reagent
A2140B1-R1	CK-NAC Reagent
A2140B1-R2	CK-NAC Reagent
A2140B5-R1	CK-NAC Reagent
A2140B5-R2	CK-NAC Reagent
A2140B10-R1	CK-NAC Reagent
A2140B10-R2	CK-NAC Reagent
A2150B1-R1	CK-MB Reagent
A2150B1-R2	CK-MB Reagent
A2150B5-R1	CK-MB Reagent
A2150B5-R2	CK-MB Reagent
A2150B10-R1	CK-MB Reagent
A2150B10-R2	CK-MB Reagent

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TA170B1	Complement C3 Reagent
TA180B1	Complement C4 Reagent
A2160B1-R1	Creatinine Reagent
A2160B1-R2	Creatinine Reagent
A2160B5-R1	Creatinine Reagent
A2160B5-R2	Creatinine Reagent
A2160B10-R1	Creatinine Reagent
A2160B10-R2	Creatinine Reagent
A2160B25-R1	Creatinine Reagent
A2160B25-R2	Creatinine Reagent
TA101TB1-R1	CRP Turbi Reagent
TA101TB1-R2	CRP Turbi Reagent
TA101TB5-R1	CRP Turbi Reagent
TA101TB5-R2	CRP Turbi Reagent
TA101TB10-R1	CRP Turbi Reagent
TA101TB10-R2	CRP Turbi Reagent
TA101B5-R1	CRP WR Reagent
TA101B5-R2	CRP WR Reagent
TA101B10-R1	CRP WR Reagent
TA101B10-R2	CRP WR Reagent
TA101B50-R1	CRP WR Reagent
TA101B50-R2	CRP WR Reagent
ZA16B1-R1	Cystatin C Reagent
ZA16B1-R2	Cystatin C Reagent
TA130B1-R1	Ferritin Reagent
TA130B1-R2	Ferritin Reagent
TA130B3-R1	Ferritin Reagent
TA130B3-R2	Ferritin Reagent
TA130B5-R1	Ferritin Reagent
TA130B5-R2	Ferritin Reagent
TA131B12-R1	Ferritin Reagent
TA131B12-R2	Ferritin Reagent
A2191B1	Fructosamine Reagent
A2170B1-R1	Gamma-GT Reagent
A2170B1-R2	Gamma-GT Reagent
A2170B5-R1	Gamma-GT Reagent
A2170B5-R2	Gamma-GT Reagent
A2170B2-R1	Gamma-GT Reagent
A2170B2-R2	Gamma-GT Reagent
A2190B1	Glucose Reagent
A2190B5	Glucose Reagent

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A2190B10	Glucose Reagent
A2190B20	Glucose Reagent
A2210B5-R1	GOT (AST) Reagent
A2210B5-R2	GOT (AST) Reagent
A2210B10-R1	GOT (AST) Reagent
A2210B10-R2	GOT (AST) Reagent
A2210B25-R1	GOT (AST) Reagent
A2210B25-R2	GOT (AST) Reagent
A2220B5-R1	GPT (ALT) Reagent
A2220B5-R2	GPT (ALT) Reagent
A222B10-R1	GPT (ALT) Reagent
A222B10-R2	GPT (ALT) Reagent
A222B25-R1	GPT (ALT) Reagent
A222B25-R2	GPT (ALT) Reagent
A222B1-R1	GPT (ALT) Reagent
A222B1-R2	GPT (ALT) Reagent
A2340B2-R2	HbA1c II Reagent
A2340B4-R1	HbA1c II Reagent
A2340B4-R2	HbA1c II Reagent
A2340B20-R1	HbA1c II Reagent
A2340B20-R2	HbA1c II Reagent
A2341B20-R1	HbA1c Reagent
A2341B20-R2	HbA1c Reagent
ZA05B1-R1	(Alpha) HBDH Reagent
ZA05B1-R2	(Alpha) HBDH Reagent
ZA51B1-R1	Homocysteine Reagent
ZA51B1-R2	Homocysteine Reagent
TA140B1	IgA Reagent
TA200B1-R1	IgE Reagent
TA200B1-R2	IgE Reagent
TA200B3-R1	IgE Reagent
TA200B3-R2	IgE Reagent
TA150B1	IgG Reagent
TA160B1	IgM Reagent
ZA74B1-R1	Ischemia Modified Albumin (IMA) Reagent
ZA74B1-R2	Ischemia Modified Albumin (IMA) Reagent
A2240B1-R1	Iron Reagent
A2240B1-R2	Iron Reagent
A2240B5-R1	Iron Reagent
A2240B5-R2	Iron Reagent
A2240B10-R1	Iron Reagent

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A2240B10-R2	Iron Reagent
A2240B25-R1	Iron Reagent
A2240B25-R2	Iron Reagent
A2242B10	Iron Reagent
A2242B20	Iron Reagent
A229LB1	Lactate Acid
A229LB5	Lactate Acid
A2260B1-R1	LDH Reagent
A2260B1-R2	LDH Reagent
A2260B5-R1	LDH Reagent
A2260B5-R2	LDH Reagent
A226B10-R1	LDH Reagent
A226B10-R2	LDH Reagent
A226B25-R1	LDH Reagent
A226B25-R2	LDH Reagent
AD2270B1-R1	Lipase Reagent
AD2270B1-R2	Lipase Reagent
AD2270B3-R1	Lipase Reagent
AD2270B3-R2	Lipase Reagent
AD2270B4-R1	Lipase Reagent
AD2270B4-R2	Lipase Reagent
AD2270B5-R1	Lipase Reagent
AD2270B5-R2	Lipase Reagent
ZA31B1-R1	Lipoprotein A Reagent
ZA31B1-R2	Lipoprotein A Reagent
A2280B5	Magnesium Reagent
A2280B10	Magnesium Reagent
A2290B5	Phosphorus Reagent
A2290B10	Phosphorus Reagent
ZA66B1-R1	Potassium Enzymatic Reagent
ZA66B1-R2	Potassium Enzymatic Reagent
ZA38B1-R1	Prealbumin (Transthyretine) Reagent
ZA38B1-R2	Prealbumin (Transthyretine) Reagent
TA490B1	Protein HS (Microprotein) Reagent
A2300B5	Total Protein Reagent
A2300B10	Total Protein Reagent
A2300B20	Total Protein Reagent
TA120B1-R1	RF Turbi Reagent
TA120B1-R2	RF Turbi Reagent
TA120B5-R1	RF Turbi Reagent
TA120B5-R2	RF Turbi Reagent

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TA120B10-R1	RF Turbi Reagent
TA120B10-R2	RF Turbi Reagent
TA120B25-R1	RF Turbi Reagent
TA120B25-R2	RF Turbi Reagent
ZA65B1-R1	Sodium Enzymatic Reagent
ZA65B1-R2	Sodium Enzymatic Reagent
ZA13B1-R1	Total Bile Acids (TBA) Reagent
ZA13B1-R2	Total Bile Acids (TBA) Reagent
TA190B1	Transferrin Reagent
A2310B5	Triglycerides Reagent
A2310B10	Triglycerides Reagent
A2310B20	Triglycerides Reagent
A300GB1-R1	UIBC Reagent
A300GB1-R2	UIBC Reagent
A300GB5-R1	UIBC Reagent
A300GB5-R2	UIBC Reagent
A300GB10-R1	UIBC Reagent
A300GB10-R2	UIBC Reagent
A300GB50-R1	UIBC Reagent
A300GB50-R2	UIBC Reagent
A2330B1-R1	Urea Reagent
A2330B1-R2	Urea Reagent
A2330B5-R1	Urea Reagent
A2330B5-R2	Urea Reagent
A2330B10-R1	Urea Reagent
A2330B10-R2	Urea Reagent
A2330B25-R1	Urea Reagent
A2330B25-R2	Urea Reagent
A2340B5	Uric Acid Reagent
A2340B10	Uric Acid Reagent
ZN2270B1	Zinc Reagent
ZN2270B5	Zinc Reagent
ZN2270B10	Zinc Reagent
TA103B50-R1	CRP Turbi WR Reagent
ZA96B1	Lyse-Denaturant (Use with HbA1c)
ZA96B2	Lyse-Denaturant (Use with HbA1c)
ZA96B5	Lyse-Denaturant (Use with HbA1c)
ZA96B10	Lyse-Denaturant (Use with HbA1c)
ZA96B005	Lyse-Denaturant (Use with HbA1c)
ZA17B2-R1	D-Dimer Reagent
ZA17B2-R2	D-Dimer Reagent

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ZA17B4-R1	D-Dimer Reagent
ZA17B4-R2	D-Dimer Reagent
ZA17B20-R1	D-Dimer Reagent
ZA17B20-R2	D-Dimer Reagent
PR21B1-R1	Procalcitonin Reagent
PR21B1-R2	Procalcitonin Reagent
5110M	PlasmaDiluent III
5121M	StromaLyse III
5131M	CleanAr
5120R	StromaLyse
9020R	CleanAr
5310C	PlasmaDiluent C
5321C	StromaLyse C
5330C	CleanAr
5340C	Concentrated Cleanacer
5910MN	PlasmaDiluent III
5911MN	PlasmaDiluent III
5950MN	DS Diluent
5920MN	StromaLyse
5921MN	StromaLyse MN
5930MN	CleanAr
5931MN	CleanAr
5940MN	Concentrated Cleanacer
5941MN	PROBE CleanAr
5810AB	PlasmaDiluent
5811AB	PlasmaDiluent
5820AB	StromaLyse ABB
5821AB	StromaLyse ABB
5830AB	CleanAr
5831AB	CleanAr
5840AB	Concentrated Cleanacer
5611SW	PlasmaDiluent
5621SW	StromaLyse SW
5631SW	CleanAr
6410DN	PlasmaDiluent
6411DN	PlasmaDiluent
6420DN	StromaLyse DN
6421DN	StromaLyse DN
6430DN	CleanAr
6431DN	CleanAr
6440DN	Concentrated Cleanacer

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5410A	PlasmaDiluent A
5411A	PlasmaDiluent A
5420A	StromaLyse A
5421A	StromaLyse A
5430A	CleanAr
5431A	CleanAr
5440A	Concentrated Cleanacer
7310ER	PlasmaDiluent
7311ER	PlasmaDiluent
7320ER	StromaLyse E
7321ER	StromaLyse E
7322ER	StromaLyse E
7330ER	CleanAr
7340ER	Concentrated Cleanacer
6011MD	PlasmaDiluent III
6020MD	StromaLyse MD
6021MD	StromaLyse MD
6031MD	Cleaner MD Sample
6030MD	CleanAr
6040MD	Concentrated Cleanacer
6211HY	PlasmaDiluent
6220HY	StromaLyse HY
6221HY	StromaLyse HY
6231HY	CleanAr HY
6240HY	Concentrated Cleanacer
5211R	PlasmaDiluent
5220R	StromaLyse HY
5221R	StromaLyse HY
6510ML	PlasmaDiluent
6511ML	PlasmaDiluent
6520ML	StromaLyse DIFF
6521ML	M REF CONC
8111AR	PlasmaDiluent
8110AR	PlasmaDiluent
8112AR	PlasmaDiluent C
8120A	StromaLyse
8121A	StromaLyse
8130A	CleanAr
8131A	CleanAr
8132A	CleanAr
8140A	Concentrated Cleanacer

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6710S	PlasmaDiluent
6711S	PlasmaDiluent
6720S	StromaLyse E
6721S	StromaLyse E
6730S	CleanAr
6740S	Concentrated Cleanacer
5111M	PlasmaDiluent III
5120M	StromaLyse III
5130M	CleanAr
5125B	StromaLyse B
5128B	StromaLyse EOS
5140M	Concentrated Cleanacer
7110N	PlasmaDiluent III
7111N	PlasmaDiluent III
7210N	StromaLyse
7211N	StromaLyse
7220N	CleanAr
7230N	Concentrated Cleanacer
7010P	PlasmaDiluent
7011P	PlasmaDiluent
7020P	StromaLyse
7021P	StromaLyse
7030P	CleanAr
7031P	CleanAr
7040P	Concentrated Cleanacer
5311C	PlasmaDiluent C
5320C	StromaLyse C
5325C	StromaLyse ALFA
5231R	CleanAr
5240R	Concentrated Cleanacer
7310S	PlasmaDiluent
7320S	StromaLyse
7321S	StromaLyse
7330S	CleanAr HY
7340S	Concentrated Cleanacer
8210DW	PlasmaDiluent
8220DW	StromaLyse
8221DW	StromaLyse
8230DW	CleanAr
8240DW	Concentrated Cleanacer
8310HX	PlasmaDiluent

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8320HX	StromaLyse H
8321HX	StromaLyse H
8330HX	CleanAr
8340HX	Concentrated Cleanacer
8410RP	PlasmaDiluent
8420RP	StromaLyse H
8421RP	StromaLyse H
8430RP	CleanAr
8440RP	Concentrated Cleanacer
H71264	Hemolysis Washing Solution
AA71264	HbA1c A Solution
AB71264	HbA1c B Solution
ACT71264	HbA1c C Solution AKRAY 8180T
ACV71264	HbA1c C Solution AKRAY 8180V
AH71264	HbA1c Hemolysis Solution
DW207	Deionized Water
DW208	Deionized Water
DW209	Deionized Water
ACD800	ACD80 Solution
MR760	ARMR Buffer Solution
TA71264	HbA1c A Solution
TB71264	HbA1c B Solution
TC71264	HbA1c C Solution
TH71264	HbA1c Hemolysis Solution
BA712	HbA1c A Solution
BB712	HbA1c B Solution
BC712	HbA1c C Solution
BW712	HbA1c Arwash Solution
ARXLW1	ARXL Wash Solution
ARCW10	Arcuvette Conditioner Solution
ARCW20	Arcuvette Wash Solution
ARCW50	ARDiluent
BAT4010	PlasmaDiluent
BAT4020	StromaLyse
8134A	Cleanar Solution
A3910	Arcon N Level I Control
A3920	Arcon P Level II Control
A3912	Arcon N Level I Control
A3922	Arcon P Level II Control
A39052	Arcal Auto (Calibrator) Lyophilized
A39053	Multiconstituent Calibrator

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A39048	HDL-LDL Calibrator (ARCAL Lipid)
AD2272S	Lipase Calibrator
TA112S	ASO Calibrator
TA101-3	CRP Standard (Calibrator) Liquid High
TA102S-4	CRP WR Calibrator
TA105S	CRP Turbi WR Calibrator
TA106S	CRP Turbi WR Calibrator Level 5
TA106	CRP HS Calibrator
TA107	CRP HS Control Level I
TA108	CRP HS Control Level II
TA120S	RF Standard (Calibrator) Lyophilized
TA122S	RF Standard (Calibrator) Lyophilized
TA124S	RF Standard (Calibrator) Lyophilized
TA125S	RF Standard (Calibrator) LIQUID
TA205	CRP HS Calibrator
TA210	CRP HS Control Level I
TA211	CRP HS Control Level II
RCN06	Specific Protein Control level I (Rheumatoid Control I) LIQUID
RCN07	Specific Protein Control level II (Rheumatoid Control II) LIQUID
RCN14	Specific Protein Control level I (Rheumatoid Control I) LIQUID
RCN15	Specific Protein Control level II (Rheumatoid Control II) LIQUID
RCN08	Specific Protein Control Level II (Rheumatoid Control I) Lyophilized
RCN09	Specific Protein Control Level I (Rheumatoid Control I) Lyophilized
RCN16	Specific Protein Control level I (Rheumatoid Control II) Lyophilized
RCN17	Specific Protein Control level II (Rheumatoid Control II) Lyophilized
TA130S	Ferritin Standard (Calibrator)
PC30	Protein Calibrator
PC31	Protein Calibrator
PCN01	Protein Control Serum I Lyophilized
PCN02	Protein Control Serum I Lyophilized
PCN05	Protein Control Serum II Lyophilized
PCN06	Protein Control Serum II Lyophilized
MACN1	Albumin Control Level I
MACN2	Albumin Control Level II
MACL4	Microalbumin Calibrator
HBCN01	HbA1c Control Set
HBCL04	HbA1c Calibrator Level 4
IGCN01	IgE Control Level I
IGCN02	IgE Control Level II
IGCN03	IgE Control Set
IGCL06	IgE Calibrator Set

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ACK3930	CK-MB Control Level I
ACK3940	CK-MB Control Level II
ACK3950	CK-MB Calibrator
ZNC05	Zinc Calibrator
ZNCR05	Zinc Calibrator
ZA75	Copper Control Level I
ZA76	Copper Control Level II
ZA77	Copper Calibrator
ZA96	Iron-Magnesium Standard (Calibrator)
A3025	UIBC Standard (Calibrator)
ZA78	Lipoprotein A Calibrator Set
ZA79	Lipoprotein A Control Set
ZB80	Apolipoprotein A1/B Calibrator Set
ELCN1	Ethanol Control Level I Liquid
ELCN2	Ethanol Control Level II Liquid
ZB81	Prealbumin (Transthyretine) Calibrator (Set)
ZB85	Total Bile Acids (TBA) Calibrator
ZA66	ADA Calibrator Set
ZA67	ADA Control Level I-II
ZB83	Sodium Calibrator
ZB82	Potassium Calibrator
ZA94	Procalcitonin Control Set
ZA95	Procalcitonin Calibrator Set
ZB86	Ischemia Modified Albumin (IMA) Control Set
ZB87	Ischemia Modified Albumin (IMA) Calibrator
ZA88	Cystatin C Calibrator
ZA89	Cystatin C Control
ZA99	D-Dimer Calibrator Set
ZA84	D-Dimer Control Set
ZA84B	D-Dimer Control Set
ZA101	Fructosamin Control Level I
ZA102	Fructosamin Control Level II
ZA103	Fructosamin Calibrator
PC01	Plasma Control Level I Lyophilized
PC02	Plasma Control Level II
PC03	Plasma Control Level III Lyophilized
HBC01	Hematology Control Level I
HBC02	Hematology Control Level II
MPCN1	Microprotein Control I (Protein HS)
MPCN2	Microprotein Control II (Protein HS)
MPCL4	Microprotein Calibrator (Protein HS)

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ZA68	Homocysteine Calibrator Set
ZA69	Homocysteine Control Level I-II Set
ZA92	Ammonia/Ethanol/Bicarbonate Calibrator
A201S	Albumin Standard-Calibrator
A201D	Albumin Standard-Calibrator
A206S	Calcium Standard-Calibrator
A206D	Calcium Standard-Calibrator
A209S	Cholesterol Standard-Calibrator
A209D	Cholesterol Standard-Calibrator
A216S	Creatinine Standard-Calibrator
A216D	Creatinine Standard-Calibrator
A217D	Creatinine Standard-Calibrator
A217S	Creatinine Standard-Calibrator
A218S	Creatinine Standard-Calibrator
A219S	Glucose Standard-Calibrator
A219D	Glucose Standard-Calibrator
ZA96S	Iron-Magnesium Standard (Calibrator)
ZA96D	Iron-Magnesium Standard (Calibrator)
A301S	UIBC Standard (Calibrator)
A301D	UIBC Standard (Calibrator)
A229D	Phosphorus Standard (Calibrator)
A230S	Total Protein Standard-Calibrator
A231D	Triglyceride Standard (Calibrator)
A232S	Triglyceride Standard (Calibrator)
A233S	Urea Standard-Calibrator
A233D	Urea Standard-Calibrator
A234S	Uric Acid Standard-Calibrator
A234D	Uric Acid Standard-Calibrator
A235S	Creatinine Standard Level I-Calibrator
A236S	Creatinine Standard Level II-Calibrator
A237S	Creatinine Enzymatic Standard Calibrator SET
A238S	Creatinine Enzymatic Calibrator
SG0102	Specific Gravity Calibrator
SG0102-1	Specific Gravity Calibrator (LOW)
SG0102-2	Specific Gravity Calibrator (HIGH)
ZNC06	Zinc Calibrator
A216	Creatinine Standard-Calibrator
A219	Glucose Standard-Calibrator
ZA94-1	Procalcitonin Control Set
ZA95-1	Procalcitonin Calibrator Set
ZA107	UIBC Standard (Calibrator)

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ZA52	ADA Reagent
ZA01	Acid Phosphatase Reagent
ZA01-1	Acid Phosphatase Reagent
A2011N	Albumin Reagent
A2012N	Albumin Reagent
A2013N	Albumin Reagent
A2014N	Albumin Reagent
ZA21	Ethanol Reagent
ZA23	Ethanol Reagent
ZA02	Acetaminophen Assay Reagent
ZA03	Alpha-1 Glicoprotein Assay Reagent
ZA04	Alpha-1 Antitrypsin Assay Reagent
ZA10	B-2 Microglobulin Assay Reagent
ZA53	Aldolase Reagent
ZA06	Amikacin Assay Reagent
ZA07	AMPHETAMİNES/METAMPHETAMİNES Assay Reagent
A2020N	Alkaline Phosphatase Reagent
A2021N	Alkaline Phosphatase Reagent
A2022N	Alkaline Phosphatase Reagent
A2023N	Alkaline Phosphatase Reagent
ZA57	Ammonia Reagent
A2031N	Amylase Reagent
A2032N	Amylase Reagent
A2033N	Amylase Reagent
A2036N	Amylase Reagent
A2037N	Amylase Reagent
ZA08	Apolipoprotein A1 Reagent
ZA09	Apolipoprotein B Reagent
TA111N	ASO Reagent
TA112N	ASO Reagent
TA113N	ASO Reagent
ZA11	Barbiturates Assay Reagent
ZA12	Benzodiazepines Assay Reagent
A5010	Bicarbonate Reagent
A2050N	Bilirubin Direct Reagent
A2051N	Bilirubin Direct Reagent
A2052N	Bilirubin Direct Reagent
A2053N	Bilirubin Direct Reagent
A2040N	Bilirubin Total Reagent
A2041N	Bilirubin Total Reagent
A2042N	Bilirubin Total Reagent

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A2043N	Bilirubin Total Reagent
A2060N	Calcium Reagent
A2061N	Calcium Reagent
A2063	Calcium Reagent
A2064N	Calcium Reagent
A2065N	Calcium Reagent
A2066N	Calcium Reagent
ZA49	Ceruloplasmin Assay Reagent
CL200N	Chloride Reagent
CL201N	Chloride Reagent
A2091N	Cholesterol Reagent
A2092N	Cholesterol Reagent
A2093N	Cholesterol Reagent
A2094N	Cholesterol Reagent
HD2211	HDL Cholesterol Direct Reagent
HD2211N	HDL Cholesterol Direct Reagent
HD2213N	HDL Cholesterol Direct Reagent
HD2215N	HDL Cholesterol Direct Reagent
LD2600	LDL Cholesterol Direct Reagent
LD2600N	LDL Cholesterol Direct Reagent
LD2602N	LDL Cholesterol Direct Reagent
LD2604N	LDL Cholesterol Direct Reagent
AB2130N	Cholinesterase Reagent
AB2131N	Cholinesterase Reagent
ZA59	Citric Acid
CU200N	Copper Reagent
CU201N	Copper Reagent
A2140N	CK-NAC Reagent
A2141N	CK-NAC Reagent
A2150N	CK-MB Reagent
A2151N	CK-MB Reagent
A2152N	CK-MB Reagent
ZA15	Cocaine Assay Reagent
TA170N	Complement C3 Reagent
TA171N	Complement C3 Reagent
TA180N	Complement C4 Reagent
TA181N	Complement C4 Reagent
A2560N	Creatinine Enzymatic Reagent
A2561N	Creatinine Enzymatic Reagent
A2562N	Creatinine Enzymatic Reagent
A2160N	Creatinine Reagent

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A2161N	Creatinine Reagent
A2162N	Creatinine Reagent
A2163N	Creatinine Reagent
ZA48	CRP HS Reagent
TW101N	CRP WR Reagent
TW102N	CRP WR Reagent
TW103N	CRP WR Reagent
TA101N	CRP Turbi Reagent
TA102N	CRP Turbi Reagent
TA103N	CRP Turbi Reagent
TA104N	CRP Turbi Reagent
TB101N	CRP Turbi WR Reagent
TB102N	CRP Turbi WR Reagent
TB103N	CRP Turbi WR Reagent
ZA16	Cystatin C Reagent
ZA16-1	Cystatin C Reagent
ZA16N	Cystatin C Reagent
ZA17	D-Dimer Reagent
ZA108	D-Dimer Reagent
ZA14	Dibucaine CHE Assay Reagent
ZA19	Digoxin Assay Reagent
ZA18	Digitoxin Assay Reagent
ZA20	Ecstasy Assay Reagent
ZA29	Ethyl Glucuronid Assay Reagent
TA130N	Ferritin Reagent
TA131N	Ferritin Reagent
TA132N	Ferritin Reagent
TF130	Ferritin Reagent
TF131	Ferritin Reagent
TF132	Ferritin Reagent
A2196	Fructosamine Reagent
A2174N	Gamma-GT Reagent
A2173N	Gamma-GT Reagent
A2170N	Gamma-GT Reagent
A2172N	Gamma-GT Reagent
A2191N	Glucose Reagent
A2192N	Glucose Reagent
ZA50	G6PDH (Glucose Reagent) Determination Test
A2210N	GOT (AST) Reagent
A2211N	GOT (AST) Reagent
A2212N	GOT (AST) Reagent

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A2213N	GOT (AST) Reagent
A2220N	GPT (ALT) Reagent
A2221N	GPT (ALT) Reagent
A2222N	GPT (ALT) Reagent
A2223N	GPT (ALT) Reagent
HG700	HbA1c Reagent
HG702	HbA1c Reagent
ZA58	Beta Hydroxy Butiric Acid
ZA25	ISE Reagent A Assay Reagent
ZA24	Haptoglobin Assay Reagent
ZA05	(Alpha) HBDH Reagent
ZA51	Homocysteine Reagent
ZA74	Ischemia Modified Albumin (IMA) Reagent
ZA74-1	Ischemia Modified Albumin (IMA) Reagent
TA140N	IgA Reagent
TA141N	IgA Reagent
TA200	IgE Reagent
TA201	IgE Reagent
TA150N	IgG Reagent
TA151N	IgG Reagent
TA160N	IgM Reagent
TA161N	IgM Reagent
A2240N	Iron Reagent
A2241N	Iron Reagent
A2242N	Iron Reagent
A300N	UIBC Reagent
A301N	UIBC Reagent
ZA27	Kappa Light Ring Assay Reagent
ZA30	Lactate Acid
ZA30-1	Lactate Acid
A2260N	LDH Reagent
A2261N	LDH Reagent
A2262N	LDH Reagent
A2263N	LDH Reagent
AD2272	Lipase Reagent
AD2270	Lipase Reagent
AD2271	Lipase Reagent
ZA31	Lipoprotein A Reagent
A2280N	Magnesium Reagent
A2281N	Magnesium Reagent
A2282N	Magnesium Reagent

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A2283N	Magnesium Reagent
ZA32	Methadone Assay Reagent
A2296	Microalbumin II Reagent
ZA54	Mucoprotein Assay Reagent
ZA33	Myoglobin Assay Reagent
ZA34	Opiates Assay Reagent
ZA36	Phenobarbital Assay Reagent
ZA37	Phenytoin Assay Reagent
ZA35	Phencyclidine Assay Reagent
ZA39	Propoxyphene Assay Reagent
ZA61	Pyruvate Kinase Reagent
A2291N	Phosphorus Reagent
A2292N	Phosphorus Reagent
A2293N	Phosphorus Reagent
A2294N	Phosphorus Reagent
ZA104	Potassium Enzymatic Reagent
ZA38	Prealbumin (Transthyretine) Reagent
A2300N	Total Protein Reagent
A2301N	Total Protein Reagent
A2302N	Total Protein Reagent
A2303N	Total Protein Reagent
TA490	Protein HS (Microprotein) Reagent
ZA40	Quinidine Assay Reagent
TA120	RF Turbi Reagent
TA121N	RF Turbi Reagent
TA122N	RF Turbi Reagent
ZA41	Salicylate Assay Reagent
ZA65	Sodium Enzymatic Reagent
ZA42	TC-Antidepressant Assay Reagent
ZA43	Theophylline Assay Reagent
ZA44	Tobramycin Assay Reagent
ZA63	TAS Assay Reagent
ZA64	TOS Assay Reagent
ZA13	Total Bile Acids (TBA) Reagent
ZA13-1	Total Bile Acids (TBA) Reagent
TA190N	Transferrin Reagent
TA191N	Transferrin Reagent
A2311N	Triglycerides Reagent
A2312N	Triglycerides Reagent
A2313N	Triglycerides Reagent
A2314N	Triglycerides Reagent

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A2330N	Urea Reagent
A2331N	Urea Reagent
A2332N	Urea Reagent
A2340N	Uric Acid Reagent
A2341N	Uric Acid Reagent
A2342N	Uric Acid Reagent
ZA45	Valproic Acid
ZA46	Vancomycin Assay Reagent
ZN2270N	Zinc Reagent
ZN2271N	Zinc Reagent
ZA55	Procalcitonin Reagent
S2012	Albumin Reagent
S2061	Calcium Reagent
S2092	Cholesterol Reagent
S2112	LDL Cholesterol Direct Reagent
S2561	Creatinine Enzymatic Reagent
S2191	Glucose Reagent
S2430	Potassium Enzymatic Reagent
S2480	Sodium Enzymatic Reagent
S2301	Total Protein Reagent
S2312	Triglycerides Reagent
S2331	Urea Reagent
S2341	Uric Acid Reagent
5051SH	Arsheat Solution
5050SH	Arsheat Solution
M1526C	Isotonic Diluent
M1527C	Isotonic Diluent
M1528C	Isotonic Diluent
ARSH20	Arsheat Solution
ARAWS	Acid Washing Solution
ARBWS	Base Washing Solution
ARSRF	Surfactant
ARCL01	ARClean Reagent
A71262	ELUENT 80A Reagent
A71263	ELUENT 80B Reagent
5060SH	MAGNESIUM SOLUTION Reagent
L2110	CRP HS Reagent
LMA72	Microalbumin II Reagent
LM060	Calcium Reagent
LM144	CK-NAC Reagent
LM156	CK-MB Reagent

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LM163	HDL Cholesterol Direct Reagent
LM164	HDL Cholesterol Direct Reagent
LM165	HDL Cholesterol Direct Reagent
LM173	LDL Cholesterol Direct Reagent
LM174	LDL Cholesterol Direct Reagent
LM175	LDL Cholesterol Direct Reagent
LM187	IgE Reagent
LM189	IgE Reagent
LM208	HbA1c Reagent
LM209	HbA1c Reagent
LM212	HbA1c Reagent
LM224	ASO Reagent
LM225	ASO Reagent
LM233	RF Turbi Reagent
LM234	RF Turbi Reagent
LM242	Ferritin Reagent
LM243	Ferritin Reagent
LM244	Ferritin Reagent
LM240	Zinc Reagent
LM241	Zinc Reagent
LM249	D-Dimer Reagent
LM246	Creatinine Reagent
LM247	Creatinine Reagent
LM255	Creatinine Enzymatic Reagent
LM256	Creatinine Enzymatic Reagent
LM260	Magnesium Reagent
LM261	Magnesium Reagent
LM267	Iron Reagent
LM268	Iron Reagent
LM275	CRP HS Reagent
LM50	Bilirubin Direct Reagent
LM51	Bilirubin Direct Reagent
LM54	Bilirubin Total Reagent
LM257	CRP Turbi WR Reagent
LM258	CRP Turbi WR Reagent
LM43	Albumin Reagent
LM35	Alkaline Phosphatase Reagent
LM36	Alkaline Phosphatase Reagent
LM70	GOT (AST) Reagent
LM80	GPT (ALT) Reagent
LM45	Amylase Reagent

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LM46	Amylase Reagent
LM155	Glucose Reagent
LM157	Gamma-GT Reagent
LM158	Gamma-GT Reagent
LM188	LDH Reagent
LM067	Phosphorus Reagent
LM068	Total Protein Reagent
LM238	Uric Acid Reagent
LM71	Triglycerides Reagent
LM73	Urea Reagent
LM227	Lipase Reagent
LM228	Lipase Reagent
LM440	IgA Reagent
LM442	IgG Reagent
LM444	IgM Reagent
LM446	Complement C3 Reagent
LM448	Complement C4 Reagent
LM450	Transferrin Reagent
LM38	Bicarbonate Reagent
LM069	Procalcitonin Reagent
LM248	Ethanol Reagent
LM070	Protein HS (Microprotein) Reagent
LM460	Sodium Enzymatic Reagent
LM462	Potassium Enzymatic Reagent
LM464	Chloride Reagent
LM270	Copper Reagent
LB57	Iron Reagent
LB235	LDL Cholesterol Direct Reagent
LB140	CK-NAC Reagent
LB150	CK-MB Reagent
LB111	CRP TURBI Reagent
LB163	D-Dimer Reagent
LB126	Ferritin Reagent
LB260	LDH Reagent
LB280	Magnesium Reagent
LB410	IgM Reagent
LB080	IgE Reagent
LB400	IgA Reagent
LB122	Procalcitonin Reagent
LB120	RF Turbi Reagent
LB112	CRP Turbi WR Reagent

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LB425	Transferrin Reagent
LB80	HbA1c Reagent
LB81	HbA1c Reagent
LB82	HbA1c Reagent
LB094	Copper Reagent
LB075	Zinc Reagent
BZ2010	Albumin Reagent
BZ2015	Alkaline Phosphatase Reagent
BZ2020	Amylase Reagent
BZ2030	Bilirubin Total Reagent
BZ2035	Bilirubin Direct Reagent
BZ2040	Calcium Reagent
BZ2050	Cholesterol Reagent
BZ2055	HDL Cholesterol Direct Reagent
BZ2060	LDL Cholesterol Direct Reagent
BZ2065	Cholinesterase Reagent
BZ2075	CK-NAC Reagent
BZ2080	CK-MB Reagent
BZ2095	Creatinine Reagent
BZ2097	Creatinine Enzymatic Reagent
BZ2100	Gamma-GT Reagent
BZ2105	Glucose Reagent
BZ2110	GOT (AST) Reagent
BZ2115	GPT (ALT) Reagent
BZ2120	HbA1c Reagent
BZ2125	Iron Reagent
BZ2135	LDH Reagent
BZ2140	Lipase Reagent
BZ2145	Magnesium Reagent
BZ2155	Phosphorus Reagent
BZ2160	Protein HS (Microprotein) Reagent
BZ2165	Total Protein Reagent
BZ2170	Triglycerides Reagent
BZ2180	Urea Reagent
BZ2185	Uric Acid Reagent
BZ2200	CRP Turbi WR Reagent
BZ2210	ASO Reagent
BZ2215	RF Turbi Reagent
BZ2220	Ferritin Reagent
BZ2225	IgA Reagent
BZ2230	IgG Reagent

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BZ2235	IgM Reagent
BZ2240	Complement C3 Reagent
BZ2245	Complement C4 Reagent
BZ2250	Transferrin Reagent
D2010	Albumin Reagent
D2011	Albumin Reagent
D2020	Alkaline Phosphatase Reagent
D2021	Alkaline Phosphatase Reagent
D2031	Amylase Reagent
DBC20	Bicarbonate Reagent
D2040	Bilirubin Total Reagent
D2041	Bilirubin Total Reagent
D2050	Bilirubin Direct Reagent
D2051	Bilirubin Direct Reagent
D2061	Calcium Reagent
D2062	Calcium Reagent
DCL20	Chloride Reagent
D2090	Cholesterol Reagent
D2091	Cholesterol Reagent
DBC30	Cholinesterase Reagent
DCU20	Copper Reagent
D2140	CK-NAC Reagent
D2141	CK-NAC Reagent
D2150	CK-MB Reagent
D2151	CK-MB Reagent
D2160	Creatinine Reagent
D2161	Creatinine Reagent
D2162	Creatinine Reagent
D2170	Gamma-GT Reagent
D2171	Gamma-GT Reagent
D2190	Glucose Reagent
D2191	Glucose Reagent
D2192	Glucose Reagent
D2210	GOT (AST) Reagent
D2211	GOT (AST) Reagent
D2220	GPT (ALT) Reagent
D2221	GPT (ALT) Reagent
D2230	HDL Cholesterol Direct Reagent
D2231	HDL Cholesterol Direct Reagent
D2240	Iron Reagent
D2241	Iron Reagent

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D2260	LDH Reagent
D2261	LDH Reagent
D2251	LDL Cholesterol Direct Reagent
D2252	LDL Cholesterol Direct Reagent
D2255	Lipase Reagent
D2256	Lipase Reagent
D2280	Magnesium Reagent
D2281	Magnesium Reagent
DMA70	Microalbumin Reagent
DMA71	Microalbumin Reagent
DMA72	Microalbumin Reagent
D2290	Phosphorus Reagent
D2291	Phosphorus Reagent
D2400	Protein HS (Microprotein) Reagent
D2402	Protein HS (Microprotein) Reagent
D2403	Protein HS (Microprotein) Reagent
D2300	Total Protein Reagent
D2301	Total Protein Reagent
D2310	Triglycerides Reagent
D2311	Triglycerides Reagent
D2320	UIBC Reagent
D2321	UIBC Reagent
D2330	Urea Reagent
D2331	Urea Reagent
D2333	Uric Acid Reagent
DZN70	Zinc Reagent
DZN71	Zinc Reagent
D2340	IgE Reagent
D2341	IgE Reagent
D2342	IgE Reagent
D2350	HbA1c Reagent
D2351	HbA1c Reagent
DDH1	Ethanol Reagent
DDH2	Ethanol Reagent
D2360	CRP WR Reagent
D2361	CRP WR Reagent
D2370	ASO Reagent
D2371	ASO Reagent
D2380	RF Turbi Reagent
D2381	RF Turbi Reagent
D2390	Ferritin Reagent

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D2391	Ferritin Reagent
DAB140	IgA Reagent
DAB150	IgG Reagent
DAB160	IgM Reagent
DAB170	Complement C3 Reagent
DAB180	Complement C4 Reagent
DAB190	Transferrin Reagent
ER2020	Alkaline Phosphatase Reagent
ER2021	Alkaline Phosphatase Reagent
ER2030	Creatinine Reagent
ER2040	Copper Reagent
ER2050	ASO Reagent
ER2060	Calcium Reagent
ER2061	Calcium Reagent
ER2070	Zinc Reagent
ER2080	RF Turbi Reagent
ER2090	Cholesterol Reagent
ER2091	Cholesterol Reagent
ER2100	Lipase Reagent
ER2130	CRP Turbi WR Reagent
ERD20	HDL Cholesterol Direct Reagent
ERD21	HDL Cholesterol Direct Reagent
ERD40	LDL Cholesterol Direct Reagent
ERD41	LDL Cholesterol Direct Reagent
ER110	CRP Turbi WR Reagent
ER160	D-Dimer Reagent
ER2110	GOT (AST) Reagent
ER2111	GOT (AST) Reagent
ER2120	GPT (ALT) Reagent
ER2121	GPT (ALT) Reagent
ERL20	Lipase Reagent
ER4310	Triglycerides Reagent
ER4311	Triglycerides Reagent
ER4232	Urea Reagent
RD2010	Albumin Reagent
RD2020	Alkaline Phosphatase Reagent
RD2021	Alkaline Phosphatase Reagent
RD2022	Alkaline Phosphatase Reagent
RD2030	Amylase Reagent
RD2031	Bicarbonate Reagent
RD2040	Bilirubin Total Reagent

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RD2041	Bilirubin Total Reagent
RD2050	Bilirubin Direct Reagent
RD2051	Bilirubin Direct Reagent
RD2060	Calcium Reagent
RD2090	Cholesterol Reagent
RD2091	Cholesterol Reagent
RDA220	HDL Cholesterol Direct Reagent
RDA221	HDL Cholesterol Direct Reagent
RDA222	HDL Cholesterol Direct Reagent
RD2600	LDL Cholesterol Direct Reagent
RD2601	LDL Cholesterol Direct Reagent
RD2130	Cholinesterase Reagent
RD200	Copper Reagent
RD2140	CK-NAC Reagent
RD2150	CK-MB Reagent
RD2160	Creatinine Reagent
RD2170	Gamma-GT Reagent
RD2171	Gamma-GT Reagent
RD2190	Glucose Reagent
RD2210	GOT (AST) Reagent
RD2211	GOT (AST) Reagent
RD2212	GOT (AST) Reagent
RD2220	GPT (ALT) Reagent
RD2221	GPT (ALT) Reagent
RD2222	GPT (ALT) Reagent
RDB3	HbA1c II Reagent
RDB4	HbA1c Reagent
RD2240	Iron Reagent
RD2241	Iron Reagent
RDA20	IgE Reagent
RD2260	LDH Reagent
RD2261	LDH Reagent
RD2275	Lipase Reagent
RD2280	Magnesium Reagent
RD2290	Phosphorus Reagent
RD2297	Protein HS (Microprotein) Reagent
RD2300	Total Protein Reagent
RD2310	Triglycerides Reagent
RD2311	Triglycerides Reagent
RDU300	UIBC Reagent
RDU301	UIBC Reagent

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RD2331	Urea Reagent
RD2332	Urea Reagent
RD2341	Uric Acid Reagent
RD2270	Zinc Reagent
RD102	CRP Turbi Reagent
RD103	CRP Turbi Reagent
RD112	ASO Reagent
RD113	ASO Reagent
RD121	RF Turbi Reagent
RD122	RF Turbi Reagent
RD131	Ferritin Reagent
RD140	IgA Reagent
RD150	IgG Reagent
RD160	IgM Reagent
RD170	Complement C3 Reagent
RD180	Complement C4 Reagent
RD190	Transferrin Reagent
RD104	CRP Turbi WR Reagent
RD193	D-Dimer Reagent
M2010	Albumin Reagent
M2011	Albumin Reagent
M2020	Alkaline Phosphatase Reagent
M2021	Alkaline Phosphatase Reagent
M2030	Amylase Reagent
M2031	Amylase Reagent
M2032	Amylase Reagent
M2033	Amylase Reagent
MBC20	Bicarbonate Reagent
M2042	Bilirubin Total Reagent
M2052	Bilirubin Direct Reagent
M2060	Calcium Reagent
M2061	Calcium Reagent
MCL20	Chloride Reagent
M2091	Cholesterol Reagent
MBC30	Cholinesterase Reagent
MCU20	Copper Reagent
M2140	CK-NAC Reagent
M2141	CK-NAC Reagent
M2150	CK-MB Reagent
M2151	CK-MB Reagent
M2160	Creatinine Reagent

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M2161	Creatinine Reagent
ME110	Ethanol Reagent
ME111	Ethanol Reagent
M2170	Gamma-GT Reagent
M2171	Gamma-GT Reagent
M2192	Glucose Reagent
M2210	GOT (AST) Reagent
M2211	GOT (AST) Reagent
M2220	GPT (ALT) Reagent
M2221	GPT (ALT) Reagent
MHD20	HDL Cholesterol Direct Reagent
MHD21	HDL Cholesterol Direct Reagent
M2241	Iron Reagent
M2260	LDH Reagent
M2261	LDH Reagent
MLD20	LDL Cholesterol Direct Reagent
MLD21	LDL Cholesterol Direct Reagent
MLP20	Lipase Reagent
MLP22	Lipase Reagent
MLP23	Lipase Reagent
MLP24	Lipase Reagent
M2280	Magnesium Reagent
M2281	Magnesium Reagent
M2290	Phosphorus Reagent
M2291	Phosphorus Reagent
MSP20	Protein HS (Microprotein) Reagent
MSP21	Protein HS (Microprotein) Reagent
M2300	Total Protein Reagent
M2301	Total Protein Reagent
M2311	Triglycerides Reagent
MUIB10	UIBC Reagent
MUIB11	UIBC Reagent
M2232	Urea Reagent
M2340	Uric Acid Reagent
M2341	Uric Acid Reagent
MZN70	Zinc Reagent
MIGE20	IgE Reagent
MIGE21	IgE Reagent
MHB1	HbA1c II Reagent
MHB2	HbA1c II Reagent
MAB100	CRP WR Reagent

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MAB101	CRP WR Reagent
MAB103	CRP Turbi WR Reagent
MAB110	ASO Reagent
MAB111	ASO Reagent
MAB120	RF Turbi Reagent
MAB121	RF Turbi Reagent
MAB130	Ferritin Reagent
MAB131	Ferritin Reagent
MAB140	IgA Reagent
MAB141	IgA Reagent
MAB150	IgG Reagent
MAB151	IgG Reagent
MAB160	IgM Reagent
MAB161	IgM Reagent
MAB170	Complement C3 Reagent
MAB171	Complement C3 Reagent
MAB180	Complement C4 Reagent
MAB181	Complement C4 Reagent
MAB190	Transferrin Reagent
MAB191	Transferrin Reagent
M2164	D-Dimer Reagent
M3092	Sodium Enzymatic Reagent
M3095	Potassium Enzymatic Reagent
M2293	Procalcitonin Reagent
M3010	Albumin Reagent
M3011	Albumin Reagent
M3020	Alkaline Phosphatase Reagent
M3021	Alkaline Phosphatase Reagent
M3022	Alkaline Phosphatase Reagent
M3030	Amylase Reagent
M3031	Amylase Reagent
M3032	Amylase Reagent
M3C20	Bicarbonate Reagent
M3040	Bilirubin Total Reagent
M3041	Bilirubin Total Reagent
M3042	Bilirubin Total Reagent
M3050	Bilirubin Direct Reagent
M3051	Bilirubin Direct Reagent
M3052	Bilirubin Direct Reagent
M3060	Calcium Reagent
M3061	Calcium Reagent

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M3062	Calcium Reagent
MD120	Chloride Reagent
MD121	Chloride Reagent
M3090	Cholesterol Reagent
M3091	Cholesterol Reagent
M3C30	Cholinesterase Reagent
M3U20	Copper Reagent
M3140	CK-NAC Reagent
M3141	CK-NAC Reagent
M3142	CK-NAC Reagent
M3150	CK-MB Reagent
M3151	CK-MB Reagent
M3160	Creatinine Reagent
M3162	Creatinine Reagent
M3110	Ethanol Reagent
M3170	Gamma-GT Reagent
M3171	Gamma-GT Reagent
M3190	Glucose Reagent
M3191	Glucose Reagent
M3210	GOT (AST) Reagent
M3211	GOT (AST) Reagent
M3212	GOT (AST) Reagent
M3220	GPT (ALT) Reagent
M3221	GPT (ALT) Reagent
M3222	GPT (ALT) Reagent
M3D20	HDL Cholesterol Direct Reagent
M3D21	HDL Cholesterol Direct Reagent
M3D22	HDL Cholesterol Direct Reagent
M3240	Iron Reagent
M3241	Iron Reagent
M3260	LDH Reagent
M3261	LDH Reagent
M3262	LDH Reagent
M3D40	LDL Cholesterol Direct Reagent
M3D41	LDL Cholesterol Direct Reagent
M3D42	LDL Cholesterol Direct Reagent
M3L20	Lipase Reagent
M3280	Magnesium Reagent
M3281	Magnesium Reagent
M3290	Phosphorus Reagent
M3291	Phosphorus Reagent

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M3P20	Protein HS (Microprotein) Reagent
M3300	Total Protein Reagent
M3301	Total Protein Reagent
M3310	Triglycerides Reagent
M3312	Triglycerides Reagent
M3IB10	UIBC Reagent
M3IB11	UIBC Reagent
M3IB12	UIBC Reagent
M3230	Urea Reagent
M3231	Urea Reagent
M3232	Urea Reagent
M3340	Uric Acid Reagent
M3341	Uric Acid Reagent
M3342	Uric Acid Reagent
M3N70	Zinc Reagent
M3GE20	IgE Reagent
M3B1	HbA1c II Reagent
M3B2	HbA1c II Reagent
M3B100	CRP WR Reagent
M3B101	CRP WR Reagent
M3B102	CRP Turbi WR Reagent
M3B103	CRP Turbi WR Reagent
M3B105	CRP Turbi Reagent
M3B110	ASO Reagent
M3B111	ASO Reagent
M3B120	RF Turbi Reagent
M3B121	RF Turbi Reagent
M3B130	Ferritin Reagent
M3B140	IgA Reagent
M3B150	IgG Reagent
M3B160	IgM Reagent
M3B170	Complement C3 Reagent
M3B180	Complement C4 Reagent
M3B190	Transferrin Reagent
M3D143	Sodium Enzymatic Reagent
M3D145	Potassium Enzymatic Reagent
M3161	D-Dimer Reagent
M3A71	Microalbumin Reagent
MD010	Albumin Reagent
MD011	Albumin Reagent
MD020	Alkaline Phosphatase Reagent

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MD030	Amylase Reagent
MD031	Amylase Reagent
MDC20	Bicarbonate Reagent
MD040	Bilirubin Total Reagent
MD050	Bilirubin Direct Reagent
MD060	Calcium Reagent
MD090	Cholesterol Reagent
MD091	Cholesterol Reagent
MDC30	Cholinesterase Reagent
MDU20	Copper Reagent
MD140	CK-NAC Reagent
MD150	CK-MB Reagent
MD160	Creatinine Reagent
MD110	Ethanol Reagent
MD170	Gamma-GT Reagent
MD190	Glucose Reagent
MD191	Glucose Reagent
MD210	GOT (AST) Reagent
MD220	GPT (ALT) Reagent
MDD20	HDL Cholesterol Direct Reagent
MDD21	HDL Cholesterol Direct Reagent
MD240	Iron Reagent
MD260	LDH Reagent
MDD40	LDL Cholesterol Direct Reagent
MDD41	LDL Cholesterol Direct Reagent
MDL20	Lipase Reagent
MDL21	Lipase Reagent
MD280	Magnesium Reagent
MD281	Magnesium Reagent
MD290	Phosphorus Reagent
MD291	Phosphorus Reagent
MDP21	Protein HS (Microprotein) Reagent
MD300	Total Protein Reagent
MD301	Total Protein Reagent
MD310	Triglycerides Reagent
MD311	Triglycerides Reagent
MDIB10	UIBC Reagent
MD230	Urea Reagent
MD340	Uric Acid Reagent
MD341	Uric Acid Reagent
MDN70	Zinc Reagent

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MDGE20	IgE Reagent
MDB1	HbA1c II Reagent
MDB100	CRP WR Reagent
MDB200	CRP Turbi Reagent
MDB110	ASO Reagent
MDB120	RF Turbi Reagent
MDB130	Ferritin Reagent
MDB140	IgA Reagent
MDB141	IgA Reagent
MDB150	IgG Reagent
MDB151	IgG Reagent
MDB160	IgM Reagent
MDB161	IgM Reagent
MDB170	Complement C3 Reagent
MDB171	Complement C3 Reagent
MDB180	Complement C4 Reagent
MDB181	Complement C4 Reagent
MDB190	Transferrin Reagent
MDB191	Transferrin Reagent
MDB105	CRP Turbi WR Reagent
M4010	Albumin Reagent
M4011	Albumin Reagent
M4020	Alkaline Phosphatase Reagent
M4021	Alkaline Phosphatase Reagent
M4030	Amylase Reagent
M4031	Amylase Reagent
M4C20	Bicarbonate Reagent
M4042	Bilirubin Total Reagent
M4041	Bilirubin Total Reagent
M4052	Bilirubin Direct Reagent
M4051	Bilirubin Direct Reagent
M4060	Calcium Reagent
M4061	Calcium Reagent
M4L25	Chloride Reagent
M4092	Cholesterol Reagent
M4091	Cholesterol Reagent
M4C30	Cholinesterase Reagent
M4U20	Copper Reagent
M4140	CK-NAC Reagent
M4141	CK-NAC Reagent
M4150	CK-MB Reagent

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DIAGNOSTICS

M4151	CK-MB Reagent
M4160	Creatinine Reagent
M4110	Ethanol Reagent
M4170	Gamma-GT Reagent
M4171	Gamma-GT Reagent
M4192	Glucose Reagent
M4191	Glucose Reagent
M4210	GOT (AST) Reagent
M4211	GOT (AST) Reagent
M4220	GPT (ALT) Reagent
M4221	GPT (ALT) Reagent
M4D20	HDL Cholesterol Direct Reagent
M4D21	HDL Cholesterol Direct Reagent
M4242	Iron Reagent
M4241	Iron Reagent
M4260	LDH Reagent
M4261	LDH Reagent
M4D40	LDL Cholesterol Direct Reagent
M4D41	LDL Cholesterol Direct Reagent
M4L20	Lipase Reagent
M4L21	Lipase Reagent
M4280	Magnesium Reagent
M4281	Magnesium Reagent
M4290	Phosphorus Reagent
M4291	Phosphorus Reagent
M4P20	Protein HS (Microprotein) Reagent
M4P21	Protein HS (Microprotein) Reagent
M4300	Total Protein Reagent
M4301	Total Protein Reagent
M4312	Triglycerides Reagent
M4311	Triglycerides Reagent
M4IB10	UIBC Reagent
M4IB11	UIBC Reagent
M4232	Urea Reagent
M4231	Urea Reagent
M4340	Uric Acid Reagent
M4341	Uric Acid Reagent
M4N70	Zinc Reagent
M4GE20	IgE Reagent
M4GE21	IgE Reagent
M4B1	HbA1c II Reagent

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M4B2	HbA1c II Reagent
M4B100	CRP WR Reagent
M4B101	CRP WR Reagent
M4B110	ASO Reagent
M4B111	ASO Reagent
M4B120	RF Turbi Reagent
M4B121	RF Turbi Reagent
M4B130	Ferritin Reagent
M4B131	Ferritin Reagent
M4B140	IgA Reagent
M4B141	IgA Reagent
M4B150	IgG Reagent
M4B151	IgG Reagent
M4B160	IgM Reagent
M4B161	IgM Reagent
M4B170	Complement C3 Reagent
M4B171	Complement C3 Reagent
M4B180	Complement C4 Reagent
M4B181	Complement C4 Reagent
M4B190	Transferrin Reagent
M4B191	Transferrin Reagent
M4D162	D-Dimer Reagent
PL2011	Albumin Reagent
PL2012	Albumin Reagent
PL2020	Alkaline Phosphatase Reagent
PL2031	Amylase Reagent
PL2032	Amylase Reagent
PL2037	Bicarbonate Reagent
PL2038	Bicarbonate Reagent
PL2040	Bilirubin Total Reagent
PL2050	Bilirubin Direct Reagent
PL2060	Calcium Reagent
PL2061	Calcium Reagent
PL2065	Chloride Reagent
PL2066	Chloride Reagent
PL2090	Cholesterol Reagent
PL2091	Cholesterol Reagent
PL2106	LDL Cholesterol Direct Reagent
PL2605	Cholinesterase Reagent
PL2607	Copper Reagent
PL2140	CK-NAC Reagent

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PL2150	CK-MB Reagent
PL2160	Creatinine Reagent
PL2170	Gamma-GT Reagent
PL2190	Glucose Reagent
PL2191	Glucose Reagent
PL2210	GOT (AST) Reagent
PL2220	GPT (ALT) Reagent
PL2226	HbA1c II Reagent
PL2240	Iron Reagent
PL2246	IgE Reagent
PL2260	LDH Reagent
PL2270	Lipase Reagent
PL2280	Magnesium Reagent
PL2281	Magnesium Reagent
PL2285	Microalbumin Reagent
PL2290	Phosphorus Reagent
PL2291	Phosphorus Reagent
PL2297	Protein HS (Microprotein) Reagent
PL2298	Protein HS (Microprotein) Reagent
PL2300	Total Protein Reagent
PL2301	Total Protein Reagent
PL2310	Triglycerides Reagent
PL2311	Triglycerides Reagent
PL2316	UIBC Reagent
PL2330	Urea Reagent
PL2340	Uric Acid Reagent
PL2341	Uric Acid Reagent
PL2271	Zinc Reagent
PL2350	CRP WR Reagent
PL2351	CRP Turbi Reagent
PL2355	ASO Reagent
PL2358	RF Turbi Reagent
PL2360	Ferritin Reagent
PL2365	IgA Reagent
PL2367	IgG Reagent
PL2369	IgM Reagent
PL2371	Complement C3 Reagent
PL2375	Complement C4 Reagent
PL2380	Transferrin Reagent
PL2390	CRP Turbi WR Reagent
PL2248	D-Dimer Reagent

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PL2268	Sodium Enzymatic Reagent
PL2269	Potassium Enzymatic Reagent
RC220	HDL Cholesterol Direct Reagent
RC223	HDL Cholesterol Direct Reagent
RC2600	LDL Cholesterol Direct Reagent
RC2140	CK-NAC Reagent
RC2150	CK-MB Reagent
RCU300	UIBC Reagent
RC2270	Zinc Reagent
RC2271	Zinc Reagent
RC2272	Zinc Reagent
RCC200	Copper Reagent
RCL2270	Lipase Reagent
RC2030M	Amylase Reagent
RC2603	Procalcitonin Reagent
RC2604	D-Dimer Reagent
RC2605	D-Dimer Reagent
RC130	Ferritin Reagent
8A2010	Albumin Reagent
8A2011	Albumin Reagent
8A2020	Alkaline Phosphatase Reagent
8A2021	Alkaline Phosphatase Reagent
8A2030	Amylase Reagent
8A2031	Amylase Reagent
8A2030M	Amylase Reagent
8A2031M	Amylase Reagent
8A2034	Bicarbonate Reagent
8A2040	Bilirubin Total Reagent
8A2041	Bilirubin Total Reagent
8A2050	Bilirubin Direct Reagent
8A2051	Bilirubin Direct Reagent
8A2060	Calcium Reagent
8A2061	Calcium Reagent
8A2062	Calcium Reagent
8A200	Chloride Reagent
8A2090	Cholesterol Reagent
8A2091	Cholesterol Reagent
8AH220	HDL Cholesterol Direct Reagent
8AH221	HDL Cholesterol Direct Reagent
8A2600	LDL Cholesterol Direct Reagent
8A2601	LDL Cholesterol Direct Reagent

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8A2610	LDL Cholesterol Direct Reagent
8A2611	LDL Cholesterol Direct Reagent
8AC2130	Cholinesterase Reagent
8AC200	Copper Reagent
8AC201	Copper Reagent
8A2140	CK-NAC Reagent
8A2141	CK-NAC Reagent
8A2150	CK-MB Reagent
8A2151	CK-MB Reagent
8A2160	Creatinine Reagent
8A2161	Creatinine Reagent
8A2170	Gamma-GT Reagent
8A2171	Gamma-GT Reagent
8A2190	Glucose Reagent
8A2191	Glucose Reagent
8A2210	GOT (AST) Reagent
8A2211	GOT (AST) Reagent
8A2220	GPT (ALT) Reagent
8A2221	GPT (ALT) Reagent
8A9000	HbA1c Reagent
8A9001	HbA1c Reagent
8A9500	IgE Reagent
8A9501	IgE Reagent
8A2240	Iron Reagent
8A2241	Iron Reagent
8A2260	LDH Reagent
8A2261	LDH Reagent
8AL2271	Lipase Reagent
8A2280	Magnesium Reagent
8A2281	Magnesium Reagent
8A2290	Phosphorus Reagent
8A2291	Phosphorus Reagent
8A2305	Protein HS (Microprotein) Reagent
8A2300	Total Protein Reagent
8A2301	Total Protein Reagent
8A2310	Triglycerides Reagent
8A2311	Triglycerides Reagent
8AU300	UIBC Reagent
8AU301	UIBC Reagent
8A2330	Urea Reagent
8A2331	Urea Reagent

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DIAGNOSTICS

8A2340	Uric Acid Reagent
8A2341	Uric Acid Reagent
8A2270	Zinc Reagent
8A2271	Zinc Reagent
8A101	CRP WR Reagent
8A102	CRP WR Reagent
8A11T	CRP Turbi WR Reagent
8A101T	CRP Turbi Reagent
8A102T	CRP Turbi Reagent
8A111	ASO Reagent
8A112	ASO Reagent
8A120	RF Turbi Reagent
8A121	RF Turbi Reagent
8A130	Ferritin Reagent
8A131	Ferritin Reagent
8A132	Ferritin Reagent
8A141	IgA Reagent
8A151	IgG Reagent
8A161	IgM Reagent
8A171	Complement C3 Reagent
8A181	Complement C4 Reagent
8A191	Transferrin Reagent
8A114	Procalcitonin Reagent
8A11D	D-Dimer Reagent
8A2163	Ethanol Reagent
BY2010	Albumin Reagent
BY2011	Albumin Reagent
BY2020	Alkaline Phosphatase Reagent
BY2021	Alkaline Phosphatase Reagent
BY2030	Amylase Reagent
BY2031	Amylase Reagent
BY2030M	Amylase Reagent
BY2031M	Amylase Reagent
BY2034	Bicarbonate Reagent
BY2040	Bilirubin Total Reagent
BY2041	Bilirubin Total Reagent
BY2050	Bilirubin Direct Reagent
BY2051	Bilirubin Direct Reagent
BY2060	Calcium Reagent
BY2061	Calcium Reagent
BY2062	Calcium Reagent

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DIAGNOSTICS

BY200	Chloride Reagent
BY2090	Cholesterol Reagent
BY2091	Cholesterol Reagent
BYH220	HDL Cholesterol Direct Reagent
BYH221	HDL Cholesterol Direct Reagent
BY2600	LDL Cholesterol Direct Reagent
BY2601	LDL Cholesterol Direct Reagent
BY2610	LDL Cholesterol Direct Reagent
BY2611	LDL Cholesterol Direct Reagent
BYC2130	Cholinesterase Reagent
BYC200	Copper Reagent
BYC201	Copper Reagent
BY2140	CK-NAC Reagent
BY2141	CK-NAC Reagent
BY2150	CK-MB Reagent
BY2151	CK-MB Reagent
BY2160	Creatinine Reagent
BY2161	Creatinine Reagent
BY2170	Gamma-GT Reagent
BY2171	Gamma-GT Reagent
BY2190	Glucose Reagent
BY2191	Glucose Reagent
BY2210	GOT (AST) Reagent
BY2211	GOT (AST) Reagent
BY2220	GPT (ALT) Reagent
BY2221	GPT (ALT) Reagent
BY9000	HbA1c Reagent
BY9001	HbA1c Reagent
BY9500	IgE Reagent
BY9501	IgE Reagent
BY2240	Iron Reagent
BY2241	Iron Reagent
BY2260	LDH Reagent
BY2261	LDH Reagent
BYL2270	Lipase Reagent
BY2280	Magnesium Reagent
BY2281	Magnesium Reagent
BY2290	Phosphorus Reagent
BY2291	Phosphorus Reagent
BY2305	Protein HS (Microprotein) Reagent
BY2300	Total Protein Reagent

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DIAGNOSTICS

BY2301	Total Protein Reagent
BY2310	Triglycerides Reagent
BY2311	Triglycerides Reagent
BYU300	UIBC Reagent
BYU301	UIBC Reagent
BY2330	Urea Reagent
BY2331	Urea Reagent
BY2340	Uric Acid Reagent
BY2270	Zinc Reagent
BY2271	Zinc Reagent
BY101	CRP WR Reagent
BY102	CRP WR Reagent
BY101T	CRP Turbi Reagent
BY102T	CRP Turbi Reagent
BY111	ASO Reagent
BY112	ASO Reagent
BY120	RF Turbi Reagent
BY121	RF Turbi Reagent
BY130	Ferritin Reagent
BY131	Ferritin Reagent
BY132	Ferritin Reagent
BY141	IgA Reagent
BY151	IgG Reagent
BY161	IgM Reagent
BY171	Complement C3 Reagent
BY181	Complement C4 Reagent
BY191	Transferrin Reagent
At220	HDL Cholesterol Direct Reagent
At2600	LDL Cholesterol Direct Reagent
AT2610	LDL Cholesterol Direct Reagent
At2140	CK-NAC Reagent
At2150	CK-MB Reagent
At305	UIBC Reagent
At2270	Zinc Reagent
At101	CRP WR Reagent
At111	ASO Reagent
At120	RF Turbi Reagent
At2265	Lipase Reagent
At103	CRP Turbi WR Reagent
At141	IgA Reagent
At2292	Procalcitonin Reagent

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DIAGNOSTICS

At2297	D-Dimer Reagent
At9500	IgE Reagent
At130	Ferritin Reagent
DM2010	Albumin Reagent
DM2020	Alkaline Phosphatase Reagent
DM2030	Amylase Reagent
DM2040	Bilirubin Total Reagent
DM2050	Bilirubin Direct Reagent
DM2060	Calcium Reagent
DMCL20	Chloride Reagent
DM2090	Cholesterol Reagent
DMC20	Copper Reagent
DM2140	CK-NAC Reagent
DM2150	CK-MB Reagent
DM3010	Cholinesterase Reagent
DM2160	Creatinine Reagent
DM2170	Gamma-GT Reagent
DM2171	Gamma-GT Reagent
DM2190	Glucose Reagent
DM2210	GOT (AST) Reagent
DM2220	GPT (ALT) Reagent
DMHD20	HDL Cholesterol Direct Reagent
DM2240	Iron Reagent
DM2260	LDH Reagent
DML20	LDL Cholesterol Direct Reagent
DMLP20	Lipase Reagent
DMLP21	Lipase Reagent
DM2280	Magnesium Reagent
DMM70	Microalbumin II Reagent
DM2290	Phosphorus Reagent
DM2300	Total Protein Reagent
DM2310	Triglycerides Reagent
DM2315	Protein HS (Microprotein) Reagent
DMU10	UIBC Reagent
DM2230	Urea Reagent
DM2340	Uric Acid Reagent
DMZ70	Zinc Reagent
DMT100	CRP Turbi Reagent
DMT101	CRP WR Reagent
DMT102	CRP WR Reagent
DMT110	ASO Reagent

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DIAGNOSTICS

DMT120	RF Turbi Reagent
DMT130	Ferritin Reagent
DMT140	IgA Reagent
DMT150	IgG Reagent
DMT160	IgM Reagent
DMT170	Complement C3 Reagent
DMT180	Complement C4 Reagent
DMT190	Transferrin Reagent
DME20	IgE Reagent
DM2162	D-Dimer Reagent
DMHB10	HbA1c II Reagent
A39051	Arcal Auto (Calibrator) Lyophilized
A3911	Arcon N Level I Control
A3921	Arcon P Level II Control
A39047	HDL-LDL Calibrator (ARCAL Lipid)
TA111S	ASO Calibrator
TA104S	CRP Turbi WR Calibrator
TA121S	RF Standard (Calibrator) Lyophilized
RCN01	Romatoid Control Level I
RCN05	Romatoid Control Level II
A300S	UIBC Standard (Calibrator)
L2010	Albumin Reagent
L2011	Albumin Reagent
L2012	Albumin Reagent
L2020	Alkaline Phosphatase Reagent
L2021	Alkaline Phosphatase Reagent
L2022	Alkaline Phosphatase Reagent
L2030	Amylase Reagent
L2031	Amylase Reagent
L2032	Amylase Reagent
LBC20	Bicarbonate Reagent
L2040	Bilirubin Total Reagent
L2041	Bilirubin Total Reagent
L2042	Bilirubin Total Reagent
L2050	Bilirubin Direct Reagent
L2051	Bilirubin Direct Reagent
L2052	Bilirubin Direct Reagent
L2060	Calcium Reagent
L2061	Calcium Reagent
L2062	Calcium Reagent
LCL20	Chloride Reagent

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DIAGNOSTICS

L2090	Cholesterol Reagent
L2091	Cholesterol Reagent
L2092	Cholesterol Reagent
LBC30	Cholinesterase Reagent
LCU20	Copper Reagent
L2140	CK-NAC Reagent
L2141	CK-NAC Reagent
L2142	CK-NAC Reagent
L2144	CK-NAC Reagent
L2150	CK-MB Reagent
L2151	CK-MB Reagent
L2152	CK-MB Reagent
L2154	CK-MB Reagent
L2160	Creatinine Reagent
L2161	Creatinine Reagent
L2162	Creatinine Reagent
L2163	Creatinine Enzymatic Reagent
L2167	Procalcitonin Reagent
L2170	Gamma-GT Reagent
L2171	Gamma-GT Reagent
L2172	Gamma-GT Reagent
L2190	Glucose Reagent
L2191	Glucose Reagent
L2192	Glucose Reagent
L2210	GOT (AST) Reagent
L2211	GOT (AST) Reagent
L2212	GOT (AST) Reagent
L2220	GPT (ALT) Reagent
L2221	GPT (ALT) Reagent
L2222	GPT (ALT) Reagent
LHD20	HDL Cholesterol Direct Reagent
LHD21	HDL Cholesterol Direct Reagent
LHD22	HDL Cholesterol Direct Reagent
LHD23	HDL Cholesterol Direct Reagent
L2240	Iron Reagent
L2241	Iron Reagent
L2242	Iron Reagent
L2260	LDH Reagent
L2261	LDH Reagent
L2262	LDH Reagent
LLD20	LDL Cholesterol Direct Reagent

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LLD21	LDL Cholesterol Direct Reagent
LLD22	LDL Cholesterol Direct Reagent
LLP20	Lipase Reagent
L2280	Magnesium Reagent
L2281	Magnesium Reagent
L2282	Magnesium Reagent
LMA71	Microalbumin II Reagent
L2290	Phosphorus Reagent
L2291	Phosphorus Reagent
L2292	Phosphorus Reagent
LSP20	Protein HS (Microprotein) Reagent
L2300	Total Protein Reagent
L2301	Total Protein Reagent
L2302	Total Protein Reagent
L2310	Triglycerides Reagent
L2311	Triglycerides Reagent
L2312	Triglycerides Reagent
LUIB10	UIBC Reagent
LUIB11	UIBC Reagent
LUIB12	UIBC Reagent
L2230	Urea Reagent
L2231	Urea Reagent
L2232	Urea Reagent
L2340	Uric Acid Reagent
L2341	Uric Acid Reagent
L2342	Uric Acid Reagent
LZN70	Zinc Reagent
LHB1	HbA1c Reagent
LHB2	HbA1c Reagent
LHB4	HbA1c Reagent
LHB5	HbA1c Reagent
LTH1	Ethanol Reagent
LTH2	Ethanol Reagent
LAB100	CRP WR Reagent
LAB101	CRP WR Reagent
LAB102	CRP Turbi Reagent
LAB110	ASO Reagent
LAB111	ASO Reagent
LAB112	ASO Reagent
LAB120	RF Turbi Reagent
LAB121	RF Turbi Reagent

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DIAGNOSTICS

LAB122	RF Turbi Reagent
LAB130	Ferritin Reagent
LAB132	Ferritin Reagent
LAB133	Ferritin Reagent
LAB140	IgA Reagent
LAB150	IgG Reagent
LAB160	IgM Reagent
LAB170	Complement C3 Reagent
LAB180	Complement C4 Reagent
LAB190	Transferrin Reagent
LAB200	Homocysteine Reagent
LAB201	Homocysteine Reagent
LSP21	Protein HS (Microprotein) Reagent
L2164	D-Dimer Reagent
L3210	Sodium Enzymatic Reagent
L3212	Potassium Enzymatic Reagent
LM061	Calcium Reagent
LM143	CK-NAC Reagent
LM153	CK-MB Reagent
LM160	HDL Cholesterol Direct Reagent
LM161	HDL Cholesterol Direct Reagent
LM162	HDL Cholesterol Direct Reagent
LM170	LDL Cholesterol Direct Reagent
LM171	LDL Cholesterol Direct Reagent
LM172	LDL Cholesterol Direct Reagent
LM183	UIBC Reagent
LM185	IgE Reagent
LM186	IgE Reagent
LM205	HbA1c II Reagent
LM206	HbA1c II Reagent
LM207	HbA1c II Reagent
LM210	CRP WR Reagent
LM211	CRP WR Reagent
LM250	CRP Turbi Reagent
LM251	CRP Turbi Reagent
LM220	ASO Reagent
LM221	ASO Reagent
LM230	RF Turbi Reagent
LM231	RF Turbi Reagent
LM235	Ferritin Reagent
LM236	Ferritin Reagent

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LM245	D-Dimer Reagent
LM265	Iron Reagent
LM266	Iron Reagent
LM53	Bilirubin Total Reagent
LM065	Cholesterol Reagent
LM254	CRP Turbi WR Reagent
LM253	CRP Turbi WR Reagent
LM72	Urea Reagent
LM182	UIBC Reagent
LM223	ASO Reagent
LB230	HDL Cholesterol Direct Reagent
LB160	Creatinine Reagent
LB265	Lipase Reagent
HN010	Albumin Reagent
HN011	Albumin Reagent
HN020	Alkaline Phosphatase Reagent
HN021	Alkaline Phosphatase Reagent
HN030	Amylase Reagent
HN031	Amylase Reagent
HN320	Bicarbonate Reagent
HN040	Bilirubin Total Reagent
HN041	Bilirubin Total Reagent
HN050	Bilirubin Direct Reagent
HN051	Bilirubin Direct Reagent
HN060	Calcium Reagent
HN061	Calcium Reagent
HN325	Chloride Reagent
HN090	Cholesterol Reagent
HN091	Cholesterol Reagent
HN330	Cholinesterase Reagent
HN335	Copper Reagent
HN140	CK-NAC Reagent
HN141	CK-NAC Reagent
HN142	CK-NAC Reagent
HN150	CK-MB Reagent
HN151	CK-MB Reagent
HN160	Creatinine Reagent
HN170	Gamma-GT Reagent
HN171	Gamma-GT Reagent
HN190	Glucose Reagent
HN191	Glucose Reagent

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HN210	GOT (AST) Reagent
HN211	GOT (AST) Reagent
HN220	GPT (ALT) Reagent
HN221	GPT (ALT) Reagent
HN240	Iron Reagent
HN241	Iron Reagent
HN242	Iron Reagent
HN260	LDH Reagent
HN261	LDH Reagent
HN345	LDL Cholesterol Direct Reagent
HN346	LDL Cholesterol Direct Reagent
HN350	Lipase Reagent
HN280	Magnesium Reagent
HN281	Magnesium Reagent
HN290	Phosphorus Reagent
HN291	Phosphorus Reagent
HN360	Protein HS (Microprotein) Reagent
HN361	Protein HS (Microprotein) Reagent
HN300	Total Protein Reagent
HN301	Total Protein Reagent
HN365	Triglycerides Reagent
HN366	Triglycerides Reagent
HN370	UIBC Reagent
HN371	UIBC Reagent
HN230	Urea Reagent
HN231	Urea Reagent
HN375	Uric Acid Reagent
HN376	Uric Acid Reagent
HN380	Zinc Reagent
HN385	IgE Reagent
HN386	IgE Reagent
HN390	HbA1c Reagent
HN391	HbA1c Reagent
HN392	HbA1c Reagent
HN395	Ethanol Reagent
HN396	Ethanol Reagent
HN400	CRP WR Reagent
HN401	CRP WR Reagent
HN402	CRP Turbi Reagent
HN403	CRP Turbi Reagent
HN400S	CRP Turbi HS Reagent (High Sensitive-Micro CRP)

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HN401S	CRP Turbi HS Reagent (High Sensitive-Micro CRP)
HN405	ASO Reagent
HN406	ASO Reagent
HN410	RF Turbi Reagent
HN411	RF Turbi Reagent
HN412	Ferritin Reagent
HN413	Ferritin Reagent
HN415	IgA Reagent
HN417	IgG Reagent
HN419	IgM Reagent
HN421	Complement C3 Reagent
HN422	Complement C4 Reagent
HN424	Transferrin Reagent
HN154	D-Dimer Reagent
HN294	Procalcitonin Reagent
K2010	Albumin Reagent
K2011	Albumin Reagent
K2020	Alkaline Phosphatase Reagent
K2021	Alkaline Phosphatase Reagent
K2030	Amylase Reagent
K2031	Amylase Reagent
KBC20	Bicarbonate Reagent
K2040	Bilirubin Total Reagent
K2041	Bilirubin Total Reagent
K2050	Bilirubin Direct Reagent
K2051	Bilirubin Direct Reagent
K2060	Calcium Reagent
K2061	Calcium Reagent
KCL20	Chloride Reagent
K2090	Cholesterol Reagent
K2091	Cholesterol Reagent
KBC30	Cholinesterase Reagent
KCU20	Copper Reagent
K2140	CK-NAC Reagent
K2141	CK-NAC Reagent
K2150	CK-MB Reagent
K2151	CK-MB Reagent
K2160	Creatinine Reagent
K2161	Creatinine Reagent
KE110	Ethanol Reagent
K2170	Gamma-GT Reagent

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K2171	Gamma-GT Reagent
K2190	Glucose Reagent
K2191	Glucose Reagent
K2210	GOT (AST) Reagent
K2211	GOT (AST) Reagent
K2220	GPT (ALT) Reagent
K2221	GPT (ALT) Reagent
KHD20	HDL Cholesterol Direct Reagent
KHD21	HDL Cholesterol Direct Reagent
K2240	Iron Reagent
K2241	Iron Reagent
K2260	LDH Reagent
K2261	LDH Reagent
KLD20	LDL Cholesterol Direct Reagent
KLD21	LDL Cholesterol Direct Reagent
KLP20	Lipase Reagent
KLP21	Lipase Reagent
K2280	Magnesium Reagent
K2281	Magnesium Reagent
K2290	Phosphorus Reagent
K2291	Phosphorus Reagent
KSP20	Protein HS (Microprotein) Reagent
KSP21	Protein HS (Microprotein) Reagent
K2300	Total Protein Reagent
K2301	Total Protein Reagent
K2310	Triglycerides Reagent
K2311	Triglycerides Reagent
KUIB10	UIBC Reagent
KUIB11	UIBC Reagent
K2230	Urea Reagent
K2231	Urea Reagent
K2340	Uric Acid Reagent
K2341	Uric Acid Reagent
KZN70	Zinc Reagent
KIGE20	IgE Reagent
KIGE21	IgE Reagent
KHB1	HbA1c II Reagent
KHB2	HbA1c II Reagent
KHB3	HbA1c II Reagent
KAB100	CRP WR Reagent
KAB101	CRP WR Reagent


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KAB140	CRP Turbi WR Reagent
KAB110	ASO Reagent
KAB111	ASO Reagent
KAB120	RF Turbi Reagent
KAB121	RF Turbi Reagent
KAB130	Ferritin Reagent
KAB131	Ferritin Reagent
TB1010	ADA Reagent
TB1011	ADA Reagent
TB2010	Albumin Reagent
TB2011	Albumin Reagent
TB2020	Alkaline Phosphatase Reagent
TB2021	Alkaline Phosphatase Reagent
TB2030	Amylase Reagent
TB2031	Amylase Reagent
TBC210	Carbondioxide Reagent
TB2040	Bilirubin Total Reagent
TB2041	Bilirubin Total Reagent
TB2050	Bilirubin Direct Reagent
TB2051	Bilirubin Direct Reagent
TB2060	Calcium Reagent
TB2061	Calcium Reagent
TB2090	Cholesterol Reagent
TB2091	Cholesterol Reagent
TBCU20	Copper Reagent
TBCU21	Copper Reagent
TB2140	CK-NAC Reagent
TB2141	CK-NAC Reagent
TB2150	CK-MB Reagent
TB2151	CK-MB Reagent
TB2160	Creatinine Reagent
TB2161	Creatinine Reagent
TB2170	Gamma-GT Reagent
TB2171	Gamma-GT Reagent
TB2190	Glucose Reagent
TB2191	Glucose Reagent
TB2210	GOT (AST) Reagent
TB2211	GOT (AST) Reagent
TB2220	GPT (ALT) Reagent
TB2221	GPT (ALT) Reagent
TBHD20	HDL Cholesterol Direct Reagent


SAĞLIK SAN. VE TİC. ANONİM ŞTİ.
Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST. Tel:444 08 92 Fax:0212 629 98 89
Güneşli V.D.:0730790980



archem
DIAGNOSTICS

Archem Sağlık San. ve Tic. A.Ş.
Mahmutbey Mah. Halkalı Cad.
No:124 Bağcılar/İstanbul
Tel : 444 08 92 Pbx
Fax: +90 (212) 629 98 89
info@archem.com.tr
www.archem.com.tr

TBHD21	HDL Cholesterol Direct Reagent
TB2240	Iron Reagent
TB2241	Iron Reagent
TB2260	LDH Reagent
TB2261	LDH Reagent
TB2440	Lactate Acid
TB2441	Lactate Acid
TBLD20	LDL Cholesterol Direct Reagent
TBLD21	LDL Cholesterol Direct Reagent
TBLP20	Lipase Reagent
TBLP21	Lipase Reagent
TB2280	Magnesium Reagent
TB2281	Magnesium Reagent
TB2290	Phosphorus Reagent
TB2291	Phosphorus Reagent
TBSP20	Protein HS (Microprotein) Reagent
TBSP21	Protein HS (Microprotein) Reagent
TB2300	Total Protein Reagent
TB2301	Total Protein Reagent
TB2310	Triglycerides Reagent
TB2311	Triglycerides Reagent
TBUIB10	UIBC Reagent
TBUIB11	UIBC Reagent
TB2230	Urea Reagent
TB2231	Urea Reagent
TB2340	Uric Acid Reagent
TB2341	Uric Acid Reagent
TBZN70	Zinc Reagent
TBZN71	Zinc Reagent
TBIGE20	IgE Reagent
TBIGE21	IgE Reagent
TBHB1	HbA1c Reagent
TBHB2	HbA1c Reagent
TBHB3	HbA1c Reagent
TBHB4	HbA1c Reagent
TBAB100	CRP WR Reagent
TBAB101	CRP WR Reagent
TBAB110	ASO Reagent
TBAB111	ASO Reagent
TBAB120	RF Turbi Reagent
TBAB121	RF Turbi Reagent

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SAĞLIK SAN. VE TİC. ANONİM ŞTİ.
Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST. Tel:444 08 92 Fax:0212 629 98 89
Güneşli V.D.:0730790900



archem
DIAGNOSTICS

TBAB130	Ferritin Reagent
TBAB131	Ferritin Reagent
TBAB140	IgA Reagent
TBAB150	IgG Reagent
TBAB160	IgM Reagent
TBAB170	Complement C3 Reagent
TBAB180	Complement C4 Reagent
TBAB190	Transferrin Reagent
VT020	IgE Reagent
VT030	D-Dimer Reagent
MMA70	Microalbumin

Archem Sağlık San. ve Tic. A.Ş.
Mahmutbey Mah. Halkalı Cad.
No:124 Bağcılar/Istanbul
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info@archem.com.tr
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SAĞLIK SAN. VE TİC. ANONİM ŞTİ.
Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST. Tel: 444 08 92 Fax:0212 629 98 89
Güneşli V.D.:0730790980



archem
DIAGNOSTICS

Appendix to
Conformity Declarations
Archem Diagnostic Systems



Archem Sağlık San. ve Tic. A.Ş.
Mahmutbey Mah. Halkalı Cad.
No:124 Bağcılar/İstanbul
Tel : 444 08 92 Pbx
Fax: +90 (212) 629 98 89
info@archem.com.tr
www.archem.com.tr

Conformity also declared with all applicable harmonized standards, especially the following:

EN ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purpose.

EN ISO 14971: Medical devices — Application of risk management to medical devices.

EN ISO 17511: In vitro diagnostic medical devices — Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials.

EN ISO 18113-1: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements.

EN ISO 18113-2: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for Professional use.

Other standards applied:

EN ISO 9001: Quality management systems

Note: Standards are used in this issue that is valid at date of issue of this conformity declaration.

Commercial Director

Erkan Uca
06.10.2022


SAĞLIK SAN. VE TİC. ANONİM ŞTİ.
Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST. Tel: +90 212 444 08 92 Fax:0212 629 98 89
Gözetim Y.LL:0730790980



Archem Diagnostic Industry Inc.

Mahmutbey Mah. Halkalı Cad. No:124 Bağcılar, İSTANBUL TURKEY
Tlf: + 90 212 444 08 92 Fax: +90 212 629 98 89 info@archem.com.tr www.archem.com.tr

EC Certificate



Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valenciennes Str. 11
52355 Düren
Germany

Products: Products for self-testing
- Single and multi-parameter disposable test strips for urine analysis
- Indicator test strips and papers for measurement of pH in urine

Replaces Certificate, Registration No.: HL 60119814 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate



Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valenciennner Str. 11
52355 Düren
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MACHEREY-NAGEL GmbH & Co. KG Valenciennner Str. 11 52355 Düren Germany	Design and development, manufacture and quality control
/02	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

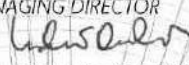
Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR


Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

1998-07-23

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2020-10-30

Data di Scadenza
Expiration Date

2023-10-29

Settore IAF 14 - 29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.

Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.

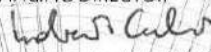
Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi
del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in
Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of
invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile).
Marketing of medical and diagnostic devices in vitro.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR


Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date
2007-10-30

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT
2011-10-30

Data di Rinnovo
Renewal Date
2020-10-30

Data di Scadenza
Expiration Date
2023-10-29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

**DICHIARA
DECLARES**

Che i Dispositivi Medici di seguito descritti:
That Medical Devices described as follows:

**TAMPONI PER LA RACCOLTA E LA CONSERVAZIONE DI CAMPIONI
BIOLOGICI, ANCHE IN AMBITO CHIRURGICO, CON O SENZA TERRENO DI
TRASPORTO**

**MEDICAL SWABS AND APPLICATORS FOR BIOLOGICAL SAMPLE
COLLECTION AND PRESERVATION, ALSO FOR SURGERY USE, WITH OR
WITHOUT TRANSPORT MEDIUM**

PRODOTTI STERILI – STERILE PRODUCTS

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- Sono conformi ai requisiti essenziali di cui all'allegato I della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE.
They are conform to the essential requirements of Annex I of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC
- Sono classificati di Classe IIa sterile in base all'Allegato IX - regola 6 - p.to 2.2. della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE.
They are classified as Class IIa sterile according to Annex IX - Rule 6 - p.t 2.2. of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC
- Sono soggetti a marcatura CE rilasciata dall'Organismo Notificato n° 0426 Italcert Srl
They are subject to CE mark issued by the Notified Body n° 0426 Italcert Srl
- Sono prodotti con un Sistema Qualità della produzione conforme all'Allegato V della Direttiva 93/42/CE
They are manufactured with a production quality system in accordance with Annex V of Directive 93/42/EC

Tale dichiarazione è supportata dalla certificazione del Sistema Qualità Nuova Aptaca secondo gli standard UNI EN ISO 9001 e UNI EN ISO 13485

This statement is supported by the New Aptaca Quality System Certification according to UNI EN ISO 9001 and UNI EN ISO 13485

**Rilasciato / Released
Canelli, 13.05.2014**

Dulio BUONO
Responsabile Assicurazione Qualità



ALLEGATO 1 alla Dichiarazione di Conformità Tamponi sterili

Annex 1 to Declaration of Conformity Sterile Swabs

COD.	DESCRIZIONE	DESCRIPTION
2150/SG	Tamponi sterili puntale in cotone ed asta in legno, in provetta PP, sterili	<i>Sterile swabs cotton tip and wooden stick, in PP test tubes, sterile</i>
2150/SG/CS	Tamponi sterili puntale in cotone ed asta in legno, in provetta PP, sterili in confezione singola	<i>Sterile swabs cotton tip and wooden stick, in PP test tubes, sterile individually wrapped</i>
2160/SG	Tamponi sterili puntale in viscosa ed asta in plastica, in provetta PP, sterili	<i>Sterile swabs rayon tip and plastic stick, in PP test tubes, sterile</i>
2160/SG/CS	Tamponi sterili puntale in viscosa ed asta in plastica, in provetta PP, sterili in confezione singola	<i>Sterile swabs rayon tip and plastic stick, in PP test tubes, sterile individually wrapped</i>
2170/SG	Tamponi sterili puntale in viscosa ed asta in alluminio, in provetta PP, sterili	<i>Sterile swabs rayon tip and aluminium stick, in PP test tubes, sterile</i>
2170/SG/CS	Tamponi sterili puntale in viscosa ed asta in alluminio, in provetta PP, sterili in confezione singola	<i>Sterile swabs rayon tip and aluminium stick, in PP test tubes, sterile individually wrapped</i>
301/SG	Tamponi sterili con terreno di trasporto Amies senza carbone, asta in plastica, in provetta PP	<i>Sterile swabs with clear Amies medium, plastic stick, in PP test tubes</i>
301/AL/SG	Tamponi sterili con terreno di trasporto Amies senza carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with clear Amies medium, aluminium stick, in PP test tubes</i>
303/SG	Tamponi sterili con terreno di trasporto Amies con carbone, asta in plastica, in provetta PP	<i>Sterile swabs with Amies medium with charcoal, plastic stick, in PP test tubes</i>
303/AL/SG	Tamponi sterili con terreno di trasporto Amies con carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with Amies medium with charcoal, aluminium stick, in PP test tubes</i>
305/SG	Tamponi sterili con terreno di trasporto Stuart senza carbone, asta in plastica, in provetta PP	<i>Sterile swabs with clear Stuart medium, plastic stick, in PP test tubes</i>
305/AL/SG	Tamponi sterili con terreno di trasporto Stuart senza carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with clear Stuart medium, aluminium stick, in PP test tubes</i>
307/SG	Tamponi sterili con terreno di trasporto Stuart con carbone, asta in plastica, in provetta PP	<i>Sterile swabs with Stuart medium with charcoal, plastic stick, in PP test tubes</i>
307/AL/SG	Tamponi sterili con terreno di trasporto Stuart con carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with Stuart medium with charcoal, aluminium stick, in PP test tubes</i>
309/SG	Tamponi sterili con terreno di trasporto Cary Blair, asta in plastica, in provetta PP	<i>Sterile swabs with Cary Blair medium, plastic stick, in PP test tubes</i>

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28





Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



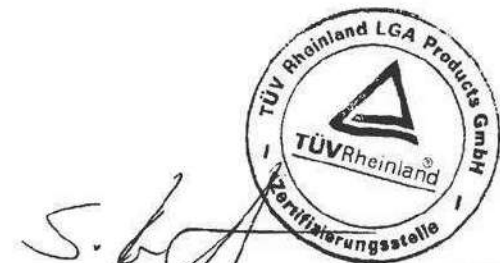
Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valenciener Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90
Effective date: 2020-05-29
Expiry date: 2023-05-28
Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number:

MD 69326

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 69326**

Location

Registered Activities

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Sunderland Enterprise Park
Colima Avenue
Sunderland
SR5 3XB
United Kingdom

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



Original Registration Date: 2002-10-25

Effective Date: 2021-04-14

Latest Revision Date: 2021-04-13

Expiry Date: 2024-04-13

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 11 января 2017 года № ФСР 2010/08997

На медицинское изделие

Набор контрольных растворов белков мочи "БМ-контроль"
по ТУ 9398-269-52208224-2010

Настоящее регистрационное удостоверение выдано

Общество с ограниченной ответственностью "Медлакор С.-П."
(ООО "Медлакор С.-П."), Россия,

194100, Санкт Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П, офис 212

Производитель

Общество с ограниченной ответственностью "Медлакор С.-П."
(ООО "Медлакор С.-П."), Россия,

194100, Санкт Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П, офис 212

Место производства медицинского изделия

ООО "Медлакор С.-П.", Россия, 194100, Санкт-Петербург, ул. А. Матросова, д. 4,
корп. 2, Лит. П

Номер регистрационного досье № РД-14955/64156 от 20.12.2016

Вид медицинского изделия **206630**

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 11 января 2017 года № 80
допущено к обращению на территории Российской Федерации.

**Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения**



Д.Ю. Павлюков

0024833

**ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**

от 11 января 2017 года № ФСР 2010/08997

Лист 1

На медицинское изделие

Набор контрольных растворов белков мочи "БМ-контроль"

по ТУ 9398-269-52208224-2010:

- комплект 1 «БМ-контроль-ССК»;
- комплект 2 «БМ-контроль-ССК + глюкоза и рН»;
- комплект 3 «БМ-контроль-ССК с калибратором»;
- комплект 4 «БМ-контроль-ССК + глюкоза и рН с калибратором»;
- комплект 5 «БМ-контроль-ПГК»;
- комплект 6 «БМ-контроль-ПГК + глюкоза и рН».

7



Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения

Д.Ю. Павлюков

0026953

АНАЛИТИЧЕСКИЙ ПАСПОРТ

Набор контрольных растворов белков мочи «БМ-контроль-ССК + глюкоза и рН»

Код ОКП 93 9816

Регистрационное удостоверение № ФСР 2010/08997

ТУ 9398-269-52208224-2010

Кат № 04.01.04

Номер серии ПВ 13 -22

Срок годности до: 26.10.2023 г.

НАЗНАЧЕНИЕ

Набор «БМ-контроль-ССК + глюкоза и рН» предназначен для контроля правильности и воспроизводимости результатов определения в моче

- белков** - по их реакции с сульфосалициловой кислотой
- с помощью диагностических полосок
- глюкозы** - ферментативным методом (глюкозоксидазным)
- качественным по реакции Бенедикта
- с помощью диагностических полосок
- рН** - с помощью диагностических полосок

СОСТАВ НАБОРА

Набор «БМ-контроль-ССК + глюкоза и рН» содержит 8 флаконов контрольных растворов:

- 4 флакона уровень №1 по 10 мл
- 4 флакона уровень №2 по 10 мл

В паспорте набора указывается среднее значение концентрации белка мочи и глюкозы с контрольными пределами ($X \pm 2S$).

Технические характеристики набора:

- | | | |
|---|---------|---------------|
| - коэффициент вариации результатов измерения концентрации белков, %, не более | 10 | Соответствует |
| - коэффициент вариации результатов измерения концентрации глюкозы, %, не более | 5 | Соответствует |
| - межфлаконная вариация, %, не более | 5 | Соответствует |
| - допустимый разброс результатов определения концентрации белков в разных наборах одной серии, %, не более | 10 | Соответствует |
| - допустимый разброс результатов определения концентрации глюкозы в разных наборах одной серии, %, не более | 5 | Соответствует |
| - срок хранения набора, мес | 12 | |
| - температура хранения, °С | 2 - 8°С | |
| - после вскрытия флакона раствор можно хранить, дней, не более | 14 | |

Начальник отдела
Технического контроля



Краснопольская Е.В.

« 26 » октября 2022г



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060

Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru



№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970


НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:


(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.




(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU 32028.04EAC1

ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU 32028

ИНН 7717616798 ОГРН 1087746489060

Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17

Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru



РАЗРЕШЕНИЕ на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ
СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключаяющей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа
по сертификации:

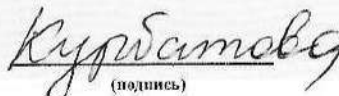

(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.




(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
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РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО


Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



(подпись)

В. И. Погодин

Председатель
экспертной комиссии:
М.П.





(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА
Регистрационный номер № 04EAC1.CM.03842-03
НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



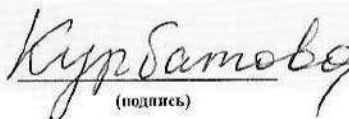
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.





(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «EAC AUDIT» И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



Клиническая
биохимия

ООО «Агат-Мед»
105173, г. Москва, ул. Главная, 6-12
тел. (495) 777-41-92
agat@agat.ru www.agat.ru

ПАСПОРТ

Набор реагентов для определения гемоглобина в крови
гемиглобинцианидным методом
«Гемоглобин-АГАТ»
(600 опр. х 5 мл)

Серия 17/110222 Дата выпуска 02.2022 Годен до 03.2024
Количество наборов в серии 50000

Наименование показателя	Характеристика и норма по ТУ 9398-280-11498242-00	Результаты анализа
1. Внешний вид		
1.1 Трансформирующий реагент	Порошок желто-оранжевого цвета или смесь белых и оранжевых кристаллов	Смесь белых и оранжевых кристаллов
1.2 Ацетонциангидрин	Бесцветная прозрачная жидкость	Бесцветная прозрачная жидкость
1.3 Калибровочный раствор гемоглобина	Прозрачная жидкость от темно-красного до темно-коричневого цвета	Прозрачная жидкость темно-красного цвета
2. Технические характеристики		
2.1 Тест на соответствие калибратора контрольному лабораторному раствору гемоглобина 120 г/л, отклонение в %, не более	2	Соответствует
2.2 Чувствительность, г/л, не более	10	Соответствует
3. Показатели правильности определения		
3.1 Тест на "линейность" в диапазоне концентраций от 20 до 200 г/л, отклонение в %, не более	2	Соответствует
3.2 Тест на "открытие", отклонение в %, не более	2	Соответствует
3.3 Коэффициент вариации результатов определения, %, не более	2	Соответствует
3.4 Допустимый разброс результатов при параллельных определениях одной пробы разными наборами одной серии, %, не более	2	Соответствует
3.5 Время выхода оптической плотности на устойчивые показатели после добавления анализируемой пробы, мин, не более	20	Соответствует

Заключение ОКК ООО «Агат-Мед»:

Серия 17/110222 соответствует требованиям ТУ 9398-280-11498242-00

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.
«01» февраля 2022г.

