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

Digitally signed by Ceaicovschi Tudor
Date: 2023.03.16 12:31:04 EET
Reason: MoldSign Signature
Location: Moldova

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии _____ (подпись) **Е. Д. Курбатова**

М.П.

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

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«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)

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**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей 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: _____ (подпись) **Е. Д. Курбатова**

М.П.

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

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

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: _____ (подпись) **Е. Д. Курбатова**

М.П.

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

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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: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

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

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard.
This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
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

Gliwice, Poland

January 25, 2019

Anna Szuba
Quality Director

NIP 631-010-13-07
Numer w KRS: 0000010108
Sąd rejestrowy: Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 360 793,00 zł
Regon: 271563380

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430,9020	20 L
	3430,9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459,9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832,9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823,1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431,1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511,1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416,0500	500 ml
CyMet™ H20	3853,1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425,0500	500 ml
CyMet™ Micro	3852,1000	1 L
CyMet™ Micro CN free	3863,1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

J.T.Baker product list for CE marked products

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768,1000	1 L micros
ProClean™ Abacus	3432,5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862,5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control extented L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
Fixatives		
Cervix Spray Fixative	3869,1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933,1000	1 L
	3933.5000PC	5 L
	3933,9010	10 L
	3933,9020	20 L
	3933.1000MB	1000 L
	3933.9020PE	20 L
	3933.9010JL	10 L
	3933.9020JL	20 L
Clearing agents		
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS		
PBS	3059	20 L
	3059.9010PC	10 L

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 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.
22 November 2011

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker product list for CE marked products

Prod.no.	Product	Pack size
Reagents for diluting and lysing		
3961	Diluid™ 100 Plus	20 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9010	Diluid Abacus	10 liter
3430.9020	Diluid Abacus	20 liter
3996	Diluid AC 900	20 liter
3996.9010PC	Diluid AC 900	10 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
3958	Diluid Azide free	10 liter
3963.9010	Diluid III Diff	10 liter
3963	Diluid III Diff	20 liter
3974	Diluid III Diff Seaccontainer	20 liter
3459.9020	Diluid Erma	20 liter
3483.9020PC	Diluid NR	20 liter
3439.9020PC	Diluid Mindray	20 liter
3832.9020	Diluid Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3496.9020PC	Diluid M5	20 liter
3495.9010PC	Sheath D	10 liter
3826	Sheath Fluid 3000/3500	20 liter
3826.5000	Sheath Fluid 3000/3500	5 liter
3827.5000PC	LeucoLyse	5 liter
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet™ 1000 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3824	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3825	CyMet 3500 CN free	5 liter
3839.5000PC	CyMet 3500	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
3918.5000	CyMet 9000 CN free	5 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3477.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3755	CyMet Automated	5 liter
3757	CyMet Automated	500 ml
3780	CyMet Automated CN Free	1 liter
3460.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3842.1000	EO Reagent Autocounter	1 liter
3853.1000	CyMet H20	1 liter
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3972.1000	CyMet III Diff CN free	1 liter
3972.5000	CyMet III Diff CN free	5 liter
3740.0500	CyMet KX CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3852.0500	CyMet Micro	500 ml
3857.1000	CyMet Micro CN free	1 liter
3857.0500	CyMet Micro CN free	500 ml
3863.1000	CyMet Micro CN free	1L micros
3440.0500PE	CyMet Mindray CN Free	500 ml
3441.0500PE	CyMet Mindray	500 ml
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
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3788	CyMet STX/STL	1 liter
3919	CyMet STX/STL	5 liter
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III, CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
3497.0500PE	CyMet MH CN Free	500 ml
3489.1000PE	CyMet MBA	1 liter
3487.1000PE	CyMet MD(I)	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3770	LyzerGlobin II	10 x 10 ml
3850	LyzerGlobin CN free	6 x 15 ml
Cleaners		
3766.0500	DetectoTerge	500 ml
3763	DetectoTerge	5 liter
3766	DetectoTerge	1 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3867.1000PE	ProClean Extra	1L micros
3862.1000	ProClean Extra	1 liter
3862.5000	ProClean Extra	5 liter
3901	ProClean Plus	100 ml
3902.0100PE	ProClean CD	100 ml
3432.5000	ProClean Abacus	5 liter
3946	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3917	Hypochlorite 0.5%	1liter
3917.5000	Hypochlorite 0.5%	5 liter
3936.1000	Hypochlorite 5%	1liter
3442.5000PE	Rinse Mindray	5 liter
3915	Rinsing Solution Serono 9000	20 liter
3941.1000PE	HypoChlorite NR	1 liter
3941.5000PC	HypoChlorite NR	5 liter
3498.1000PE	ProClean MX5	1 liter
Reagents for 5-part WBC diff. on STKS and MaxM.		
3938	RBCLyse™	1 liter
3938G.1000PE	RBCLyse G	1 liter
3939	WBCStabilise™	500 ml
3492.0090	RetiCount MH	6 x 15 ml
3493.0500PE	RetiClear MHG	500 ml
3493.1000PE	RetiClear MHG	1 liter
3494.0200PE	RetiCount G	200 ml
3774	Reticount™	30 ml
3777	Reticount CD	15 x 3.5 ml

Hematology Controls		
3721/3722/3723	8 PMC Low/Normal/High	8 ml
3724/3725/3726	8 PMC Low/Normal/High	2.5 ml
3633/3634/3635	8 PMC Low/Normal/High ext	2.5 ml
3701/3702/3703	8 PMC Low/Normal/High	4.5 ml
3922/3923/3924	8 PMC L/N/H Swelab	4.5 ml
3746	8 PMC 1 x L,1 x N,1 x H	3 x 2.5 ml
3747	8 PMC 4 x Normal	4 x 2.5 ml
3748	8 PMC 4 x Normal	4 x 8 ml
3749	8 PMC 4 x Low	4 x 2.5 ml
3751	8 PMC 1x L, 4 x N, 1x H	6 x 2.5 ml
3734/3735/3736	3-Diff Control L/N/H	2.5 ml
3630/3631/3632	3-Diff Control L/N/H ext	2.5 ml
3820/3821/3822	3-Diff Control L/N/H	4.5 ml
3752	3-Diff Control 4 x Low	4 x 2.5 ml
3753	3-Diff Control 4 x Norm	4 x 2.5 ml
3754	3-Diff Control 4 x High	4 x 2.5 ml
3782/3783/3784	CA-Diff Control L/N/H	4.5 ml
3607/3608/3609	CA-Diff Control L/N/H	2.5 ml
3610/3611/3612	DIA Diff 5 Control L/N/H	4.5 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3613/3614/3615	BC Diff 5 Control L/N/H	4.5 ml

3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3690/3691/3692	ADV Retic 1/2/3	4.0 ml
3828/3829/3830	CD-Diff Control	3.0 ml
3838	CD-Diff Control 2x L,N,H	6 x 3.0 ml
3687/3688	CD 4K Retic 1/2	3.0 ml
3892/3893/3894	AC-Diff Control	2.5 ml
3896/3897/3898	K-Diff Control	2.5 ml
3696/3697	WBC reduced Plt Control L/H	3.0 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
Laser controls for Coulter MaxM, GenS and STKS		
3681/3682/3683	5D Control Low /N /H	5.0 ml
Calibration Set for Cell Analysers.		
3940	Cal Set 1	2 x 2.5 ml
3720	Platelet Control Ext. value	5 x 3 ml
Phosphate Buffered Saline.		
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Number	Product	Content
	Stains and Dyes	
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
3800.1000PE	Eosine-Y Alcoholic	1 liter
3800.2500PE	Eosine-Y Alcoholic	2.5liter
3801.1000PE	Eosin Y 0.5% Aqueous	1 liter
3801.2500PE	Eosin Y 0.5% Aqueous	2.5liter
3871.1000	Eosine Solution 0.2% ready to use	1 liter
3871.2500	Eosine Solution 0.2% ready to use	2.5 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3870.1000	Hematoxyline er (Mayer)	1 liter
3870.2500	Hematoxyline er (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	0.5 liter
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter

3864.1000	Papanicolaou 2A OG6	1 liter
3864.2500	Papanicolaou 2A OG6	2.5 liter
3865.1000	Papanicolaou 2B Orange II	1 liter
3865.2500	Papanicolaou 2B Orange II	2,5 liter
3866.1000	Papanicolaou 3B EA 50	1 liter
3866.2500	Papanicolaou 3B EA 50	2,5 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
	Fixatives	
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010 (PE)	10% v/v Buffered Formaldehyde	10 liter (PE)
3933.9020 (PE)	10% v/v Buffered Formaldehyde	20 liter (PE)
3869.1200	Cervix Fixative	12 x 125 ml
3880.1000	Bouin's Fixative	1 liter
3058.9010	Immuno PBS 20x concentrated	10 liter

22 November 2011

To whom this may concern

Date: March 01, 2021 Letter of Authorization

Avantor Performance Materials Poland S.A., reg. No. 0000010108 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histology located at:

Sowińskiego 11
44-101 Gliwice
Poland

herewith confirms that:

I.M Global Biomarketing Group Moldova S.R.L
Republic of Moldova
MD-2001, Chisinau
Tighina str. 65, 607 office
Tel (373 22) 549 120, 549 121
Fax (373 22) 547 373

is authorized to act as our distributor for our hematology/histology reagents and controls (Products) in Moldova
.
We declare that we will supply the Products for the needs of tenders.
We declare that we will supply the Products for tenders with warranty as per the Avantor General Conditions of Sale.

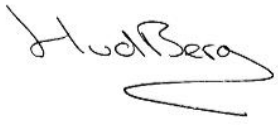
Furthermore I.M Global Biomarketing Group is duly entitled to:

- Register, promote, offer, negotiate prices and sell our Products in Moldova;
- carry out the required product training of the medical and technical personnel who will use these products.

The product specialists of I.M Global Biomarketing Group have been duly trained and are qualified for providing all services in regards to consulting, sales, maintenance and training.

In all the above activities I.M Global Biomarketing Group is acting in its own name and on its own account.
This authorization letter is valid until about 1 year after date.

Avantor Performance Materials S.A.
Poland



H van den Berg,
Marketing Product Manager Diagnostics

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

Hiroshi Shimosaka
President
ERMA INC.

BeneSphera™

3 PART DIFFERENTIAL

Hematology Analyzer

BeneSphera™ **TRAINING**

Mr / ~~Ms~~ **Sergiu Sorocovici**

Global Biomarketing Group

str. Tighina 65, of. 607

2001 Chisinau, Moldau

has attended a 2-days training on goods manufactured or distributed by us.

April 12th – April 13th, 2012

Deventer, The Netherlands

Place, Date 13.04.2012

P.O. Box 1 - 0570-687500
AVANTOR PERFORMANCE MATERIALS B.V.
7400 AA DEVENTER - Holland

BeneSphera™ | AVANTOR™ PERFORMANCE MATERIALS

CERTIFICATE

This is to certify that

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope:
Sales and supply of branded and private label chemicals, consumables, laboratory equipment, furniture, and medical devices from global leading developers and manufacturers of those products to customers in biopharma, healthcare, advanced technology and applied materials, education and government; manufacture of private label products, primarily laboratory and production chemicals including custom manufacturing solutions used in biopharmaceutical and industrial applications and production processes; provide value-added service offerings such as client outsourced activities: including sourcing and procurement, logistics, chemical and equipment tracking, lab and production services, scientific services and sample management; technical services in-house and at customer sites including installation, maintenance, qualification, calibration and repair of laboratory equipment

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	530840 QM15
Valid from	2021-08-04
Valid until	2024-06-28
Date of certification	2021-08-04

DAkkS Deutsche Akkreditierungsstelle D-ZM-16074-01-00

DQS GmbH

Markus Bleher
Managing Director

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530842 **VWR International GmbH** **Graumanngasse 7** **1150 Wien** **Austria**	Sales and supply; Lab and Production Services
530843 **VWR International GmbH** **Zimbagasse 5** **1210 Wien** **Austria**	Distribution; Technical Services
530841 **VWR International bv** **Researchpark Haasrode 2020** **Geldenaaksebaan 464** **3001 Leuven** **Belgium**	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531223 **VWR International GmbH** **Rue de Rive 18** **1260 Nyon** **Switzerland**	Sales and supply
531224 **VWR International GmbH** **Grabenstraße 1** **8952 Schlieren** **Switzerland**	Sales and supply; Distribution; Lab and Production Services; Technical services
531221 **VWR International GmbH** **Lerzenstraße 16 / 18** **8953 Dietikon** **Switzerland**	Sales and supply

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530844 **VWR International s.r.o.** **Praská 442** **281 67 Stribrná Skalice** **Czech Republic**	Sales and supply; Distribution; Kitting Services; Technical services
530847 **VWR International s.r.o.** **Pivovarská 30** **75661 Rožnov prod Radhoštêm** **Czech Republic**	Sales and supply
530868 **VWR International GmbH** **Großenhainer Straße 99** **01127 Dresden** **Germany**	Sales and supply
530869 **VWR International GmbH** **Wöhlerstraße 42** **30163 Hannover** **Germany**	Sales and supply
530867 **VWR International GmbH** **Hilpertstraße 20A** **64295 Darmstadt** **Germany**	Sales and supply; Lab and Production Services; Technical services
539946 **VWR International GmbH** **Heinrich-Blanc-Straße 40** **76646 Bruchsal** **Germany**	Distribution

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530865 **VWR International GmbH** **John-Deere-Straße 5** **76646 Bruchsal** **Germany**	Sales and supply; Distribution
530866 **VWR International GmbH** **Vichystraße 2** **76646 Bruchsal** **Germany**	Distribution
530870 **VWR International GmbH** **Fraunhoferstr.11** **85737 Ismaning** **Germany**	Sales and supply
530871 **VWR International GmbH** **James-Franck-Ring 9** **89081 Ulm** **Germany**	Sales and supply
530859 **VWR International A/S** **Tobaksvejen 21** **2860 Søborg** **Denmark**	Sales and supply; Distribution; Lab and Production Services; Technical services
531213 **VWR International Eurolab, S.L.** **C/ De la Technología, 5-17A7 - Llinars Park** **08450 Llinars Del Vallès Barcelona** **Spain**	Sales and supply; Distribution; Lab and Production Services; Technical services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530860 **VWR International Oy** **Valimotie 9** **00380 Helsinki** **Finland**	Sales and supply; Distribution; Lab and Production Services; Technical services
530863 **VWR International S.A.S.** **Europarc** **26 Avenue Leonard de Vinci** **33608 Pessac Cedex** **France**	Sales and supply
530861 **VWR International S.A.S** **Chemin de la Croix Saint-Marc** **Z.I. de Vaugereeau** **45250 Briare-le-Canal** **France**	Distribution; Manufacture
530862 **VWR International S.A.S** **Immeuble Estréo,** **1-3 Rue d'Aurion** **93110 Rosny-sous-Bois** **France**	Sales and supply; Lab and Production Services; Technical services
531226 **VWR International Ltd** **VWR House** **Warren Court** **Feldspar Close** **Enderby** **LE19 4SD** **Leicester** **United Kingdom**	Sales and supply

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531228 **LAB3 Service** **1 Dragon Court** **Crofts End Road** **St George** **Bristol** **BS5 7XX** **United Kingdom**	Lab and Production Services; Technical services
531225 **VWR International Ltd.** **Customer Service Centre** **Hunter Boulevard** **Magna Park** **Lutterworth, Leicestershire** **LE17 4 XN** **United Kingdom**	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531227 **VWR International Ltd.** **14 Media Village** **Liscombe Park** **Soulbury** **Leighton Buzzard** **LU7 0GA** **United Kingdom**	Sales and supply
540366 **VWR International** **Medical Equipment Supplies and Management** **The Solutions Buckshaw Village, Chorley** **Chorley** **PR7 7EL** **United Kingdom**	Sales and supply; Distribution; Technical Services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531229 **Basan - the cleanroom division of VWR** **Units 2 & 3 Newton Court** **Basingstoke** **RG24 8GF** **United Kingdom**	Sales and supply; Distribution; Manufacture
546015 **Hichrom Ltd** **1-3 The Markham Centre, Station Road,** **Theale,** **Reading, Berkshire** **RG7 4AB** **United Kingdom**	Manufacture of UHPLC and HPLC columns with lot traceability. Procurement and distributor for UHPLC and HPLC columns and associated solvents, packing materials and accessories with lot traceability
531198 **VWR International Kft.** **Simon László utca 4** **4034 Debrecen** **Hungary**	Sales and supply; Distribution; Lab and Production Services; Technical services
531199 **VWR International Ltd** **Orion Business Campus** **Northwest Business Park** **Ballycoolin, Blanchardstown** **Dublin 15** **Ireland**	Sales and supply; Distribution; Lab and Production Services; Technical services
531200 **VWR International (Northern Ireland) Ltd** **19 Clarendon Street** **Derry BT4 87EP** **Ireland**	Sales and supply

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531201 **VWR International s.r.l.** **Via San Giusto 85** **20153 Milano** **Italy**	Sales and supply; Lab and Production Services; Technical Services; Manufacture
531203 **VWR International B.V.** **Orlyplein 85** **1043 AP Amsterdam** **Netherlands**	Sales and supply; Lab and Production Services; Technical services
531205 **VWR International AS** **Brynsalleen 4** **0667 Oslo** **Norway**	Sales and supply; Lab and Production Services; Technical services
531206 **VWR International AS** **Kokstadtflaten 35** **5152 Bønes (Bergen)** **Norway**	Sales and supply
531207 **VWR International AS** **Leirfossvegen 27** **7038 Trondheim** **Norway**	Sales and supply
531211 **VWR International Sp. z. o.o.** **Limbowa 5** **80-175 Gdańsk** **Poland**	Sales and supply; Lab and Production Services; Technical services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531212 **VWR International Sp. z. o.o.** **Aleja Niepodległości 606/610** **81-879 Sopot** **Poland**	Distribution
531208 **VWR International** **Material De Laboratorio, LDA** **Centro Empresarial de Alfragide** **Rua da Industria, nº 6** **2610-088 Alfragide** **Portugal**	Sales and supply; Distribution; Lab and Production Services; Technical services
531217 **VWR International AB** **Fagerstagatan 18A** **163 94 Stockholm** **Sweden**	Sales and supply; Lab and Production Services; Technical services
531220 **VWR International AB** **Skiffervägen 12** **224 78 Lund** **Sweden**	Sales and supply
531218 **VWR International AB** **Varbergsgatan 2** **412 65 Göteborg** **Sweden**	Sales and supply
531219 **VWR International AB** **Nordiskt Centrallager** **Gjuterigatan 3 (Bofors Industriområde)** **691 50 Karlskoga** **Sweden**	Distribution

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.

Certificate of Registration

nqa 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

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

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:
9362-8

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
March 24, 2021

Issuing Date:
March 27, 2021

Valid Until:
March 27, 2024

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

Certificate JP06/040143

The management system of

ERMA INC.

3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers
2. Distribution of in-vitro diagnostic products for hemoglobin measurement

This certificate is valid from 16 November 2021 until 16 November 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 10. Certified since 16 November 2006

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

21HC 13485 2016 0421

Certificate of Registration of Quality Management System to ISO 13485:2016

Brazil - RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada - Medical Devices Regulations – Part 1- SOR 98/282
United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 - Quality System Regulation,

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

Facility ID: F002818
has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4585)

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4585 / Rev 2
Certification Granted: 2019/09/25
Effective Date: 2022/09/25
Expiry Date: 2025/09/24

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412
All valid certifications are listed on NSAI's website – www.nsaiinc.com The continued validity of this certificate may be verified under "Approved Client Listing

Annex to Certificate Number: MP19.4585 / Rev 2

Scope of Registration:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Activity	Location
Headquarters, Design, Manufacture	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MP19.4585 Facility ID: F002818
Manufacture, Distribution	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MP19.4585/A Facility ID: F002818

Verified by:
Director of Certification

CERTIFICATE

EC Certificate No. 1434-IVDD-075/2022

Full Quality Assurance System
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT, UNITED KINGDOM

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

The list of medical devices covered by this certificate is provided
in the Annex 1 to EC Design-examination Certificate No. 1434-IVDD-074/2022

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Issued under the Contract No. MD-004/2022
Application No: 505/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022
Module H7

President

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
LE Latex test kit	840050

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

_____

Eddy Velthuis
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CERTIFICATE OF REGISTRATION

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UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

UKAS MANAGEMENT SYSTEMS
4426

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC

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File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

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LORNE LABORATORIES LTD.

GREAT BRITAIN

RAPID LATEX KIT

DIRECTIONS FOR USE

LE Latex Test Kit: For Identification Of Anti-DNP.

SUMMARY

In LE (Lupus Erythmatosis), autoantibodies directed against native deoxyribonucleic acid (DNA) and other nuclear constituents are produced. It is classed as the prototype of severe autoimmune diseases, involving a variety of tissues and associated with a wide range of antibodies in the circulation. Characteristics of the disease are antibodies against native DNA, nucleoprotein, denatured DNA and other extractable nuclear antigens. LE also affects a wide range of tissues. Organs affected are, in decreasing incidence, joints, skin, kidney, central nervous system, heart and lungs. One other important feature is the high frequency of the disease in women, approximately 3 to 4 times more frequent than in men. The high incidence of LE between monozygous twins (70-80%) and of close relatives (5-10%) indicates that LE may be a hereditary disease.

INTENDED PURPOSE

The reagent is a latex test reagent intended to be used to qualitatively and semi-quantitatively determine the presence or absence of antibodies against native DNA and other nuclear constituents in the serum or plasma of patients when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

When used by recommended techniques, latex particles in reagent will agglutinate (clump) in presence of Anti-DNA. No agglutination generally indicates the absence of Anti-DNA (see **Limitations**).

KIT DESCRIPTION

Lorne LE Rapid Latex Kit is for the identification of Anti-DNA. The test reagent consists of latex particles coated with DNA extracted from foetal calf thymus. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. All the reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. Reagent will remain stable for up to 7 days when subjected to temperatures not exceeding 30ºC.

SPECIMEN COLLECTION

Specimens should be drawn without anticoagulant, using an aseptic phlebotomy technique. If testing is delayed, store specimens at 2-8ºC for up to 48 hours. For longer storage, remove serum from clot by centrifugation and freeze at or below –20ºC. Avoid repeated freeze thawing of specimens. Do not use visibly haemolysed serum as this may cause false-positive reactions.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents contain less than 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
5. The reagents in this kit have been processed to reduce the bio-burden, but are not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date.
6. Materials used to produce the kit were tested at source and found to be negative for HTLV-1 and HBsAg using approved microbiological tests. However, no known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended that LE Positive and Negative Controls be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25ºC before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. The reusable agglutination slide must be washed in a suitable mild disinfectant after use and then rinsed twice with deionised water to remove any residue.
6. The use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the kit is in use.
7. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

- LE Latex Reagent (Yellow label).
- LE Positive Control (Red label/cap).
- LE Negative Control (Blue label/cap).
- Reusable agglutination slide.
- Pipette-Stirrers.

RECOMMENDED QUALITATIVE TECHNIQUE

1. Place in separate test circles of the same slide one drop of undiluted serum, one drop of positive control and one drop of negative control using the disposable pipettes provided.
2. Add one of LE Latex reagent next to each test circle.
3. Using the broad end of a pipette spread the latex reagent and specimen over entire area of the test circle.
4. Gently tilt agglutination slide backwards and forwards for 3 minutes whilst observing for agglutination.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Positive:** Agglutination of latex reagent constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of Anti-DNA, LE positive.
2. **Negative:** No agglutination of latex reagent constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of Anti-DNA, LE negative.

RECOMMENDED SEMI-QUANTITATIVE TECHNIQUE

1. Using saline, dilute the specimen(s) 1:2, 1:4, 1:8, 1:16, 1:32 and 1:64.
2. Place one drop of each dilution on successive fields of the agglutination slide.
3. Add one drop of LE latex reagent to each test field and using stirrers spread the reaction mixture over the entire test field.
4. Rotate the slide for 3 minutes whilst observing for agglutination.

INTERPRETATION OF SEMI-QUANTITATIVE RESULTS

The serum LE antibody titre is the highest dilution of serum showing agglutination of the latex reagent, 3 minutes after mixing.

STABILITY OF THE REACTIONS

Slide tests should be interpreted immediately after the 3-minute rotation period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. Freezing the LE Latex Reagent will cause it to agglutinate.
2. Intensity of agglutination is not necessarily indicative of relative LE titres; therefore screening reactions should not be graded.
3. Anti-DNA may be found in diseases other than LE. Low titres have been detected in rheumatoid arthritis, chronic hepatitis, periarteritis nodosa, dermatomyositis, scleroderma, atypical pneumonia, tuberculosis and lymphoma.
4. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper incubation time or temperature
   - Improper storage of test materials or omission of reagents
   - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne LE Latex Test Kit is tested by **Recommended Techniques** to ensure suitable reactivity.
3. The LE latex test has been compared with a standard LE cell preparation test as well as a fluorescent ANA test. The three tests showed excellent agreement on serum from clinically active LE patients: LE latex 82% positive, LE cell prep 86% positive, ANA test 82% positive. Serum from clinically inactive LE patients: positive reactions, were LE latex 19%, ANA test 71%. Patients with connective tissue disease showed no positive reactions with the LE latex tests, but 17% and 50% positive reactions with the LE cell prep and ANA test, respectively.
4. Additional published studies have confirmed the sensitivity and specificity of the LE latex test.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. David S.Jacobs et al. Laboratory Test Handbook, 3rd edition, Lexi-Comp Inc, 1994.

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
50 Tests Per Kit	840050

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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

от 05 ноября 2009 года

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью «Медиклон»,
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Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1
и подтверждает, что медицинское изделие
Набор реагентов для определения групп крови человека систем АВО, Резус и Kell (Цоликлоны анти-А, анти-В, анти-АВ, анти-А1, анти-Ас1, анти-D супер, анти-D (IgG), анти-С супер, анти-с супер, анти-Е супер, анти-е супер, анти-Kell супер) по ТУ 9398-101-51203590-2009
производства
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класс потенциального риска **2а** ОКП **93 9816**

вид медицинского изделия –

соответствующее регистрационному досье № 67875 от 22.09.2009

приказом Росздравнадзора от 05 ноября 2009 года № 8861-Пр/09

и приказом от 17 июля 2013 года № 3237-Пр/13 с замене
допущено к обращению на территории Российской Федерации.

Приложение: на 1 листе

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

0001849

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

Лист 1

- цоликлон анти-А - моноклональные антитела (IgM) к антигену А;
- цоликлон анти-В - моноклональные антитела (IgM) к антигену В;
- цоликлон анти-АВ - моноклональные антитела (IgM) к антигенам А и В;
- цоликлон анти-А1 - фитогемагглютинин к антигену А1;
- цоликлон анти-Ас1 - моноклональные антитела (IgM) к антигенам А1 и А2;
- цоликлон анти-D супер - моноклональные антитела (IgM) к антигену D;
- цоликлон анти-D (IgG) - моноклональные антитела (IgG) к антигену D;
- цоликлон анти-С супер - моноклональные антитела (IgM) к антигену С;
- цоликлон анти-с супер - моноклональные антитела (IgM) к антигену с;
- цоликлон анти-Е супер - моноклональные антитела (IgM) к антигену Е;
- цоликлон анти-е супер - моноклональные антитела (IgM) к антигену е;
- цоликлон анти-Kell супер - моноклональные антитела (IgM) к антигену К;

Приказом от 17 июля 2013 года № 3237-Пр/13 с замене допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
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05 ноября 2009 года

0001890

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
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СЕРТИФИКАТ СООТВЕТСТВИЯ

Рег.№ VCS-IST.SS.RU.0214.04.20

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО
СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА
СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ
(область сертификации указана в приложении №1. Приложение является неотъемлемой частью сертификата)
ГОСТ Р ИСО 9001-2015 (ISO 9001:2015)

СЕРТИФИКАТ ВЫДАН

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Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:
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Эксперт:
Анафиев А.Р.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМ СТАНДАРТОМ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «МТС» И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ИНСПЕКЦИОННОГО КОНТРОЛЯ

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
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Приложение № 1
к сертификату соответствия **№ VCS-IST.SS.RU.0214.04.20**
Область сертификации системы менеджмента качества:

21.20.2 Производство материалов, применяемых в медицинских целях

Руководитель органа:
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СЕРТИФИКАТ СООТВЕТСТВИЯ ПЕРСОНАЛА

Рег.№ VCS-IST.EXP.RU.1136.04.20

Настоящий сертификат удостоверяет, что

Викторов Николай Александрович

Соответствует требованиям СДС «МТС» предъявляемым к

ВНУТРЕННИМ АУДИТОРАМ

по направлению
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Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:
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Сертификат выдан на основании решения комиссии в системе добровольной сертификации «Международные Технологии Стандартизации» от 27.04.2020
Зарегистрирован в Реестре аудиторов внутренних проверок системы добровольной сертификации «Международные Технологии Стандартизации» Протокол № 04 от 28.04.2020

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
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ВНУТРЕННИМ АУДИТОРАМ

по направлению
ГОСТ Р ИСО 9001-2015 (ISO 9001:2015)
Настоящий сертификат предоставляет право на проведение внутренних проверок систем менеджмента качества

Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:
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СЕРТИФИКАТ СООТВЕТСТВИЯ ПЕРСОНАЛА

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Ющенко Кристина Валерьевна

Соответствует требованиям СДС «МТС» предъявляемым к

ВНУТРЕННИМ АУДИТОРАМ

по направлению
ГОСТ Р ИСО 9001-2015 (ISO 9001:2015)
Настоящий сертификат предоставляет право на проведение внутренних проверок систем менеджмента качества

Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:

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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«МЕЖДУНАРОДНЫЕ ТЕХНОЛОГИИ СТАНДАРТИЗАЦИИ»
Зарегистрирована в едином реестре систем добровольной сертификации
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РАЗРЕШЕНИЕ

№ VCS-IST.RZ.RU.0214.04.20

НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ
СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«МЕЖДУНАРОДНЫЕ ТЕХНОЛОГИИ СТАНДАРТИЗАЦИИ»

РАЗРЕШЕНИЕ ВЫДАНО

ООО «Медиклон»
Адрес: 127276 Москва, Ботаническая ул, дом 35
ИНН 7719191607 ОГРН 1027700153766

НА ОСНОВАНИИ СЕРТИФИКАТА
№ VCS-IST.SS.RU.0214.04.20

Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Условия применения Знака соответствия:
Фирменные бланки предприятия, договоры, рекламные и печатные издания

Руководитель органа _____ Малиновский Э.Г.

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) Product(s) *(name, type or model/batch number, etc.)*:

Immunoassay products;
AccuBind® ELISA,
AccuLite® CLIA,
QSure® Control,
Instruments
see appendix

4) The product(s) described above is in conformity with:

Document No.	Title
98/79/EC	*In vitro* Diagnostic Medical Devices Directive

5) Additional information *(Conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2021-09-20 — A Shatola

(Place & date of issue (yyyy-mm-dd))

Tony Shatola; QA Director, Monobind Inc.
(name, function and signature of manufacturer)

Appendix

Date: 2021-09-20

List of devices.

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Allergy & Anemia							
Ferritin Test System	2825-300A 2825-300B	2875-300A 2875-300B			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300A 7525-300B	7575-300A 7575-300B			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300A 2525-300B	2575-300A 2575-300B			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300A 8625-300B	8675-300A 8675-300B			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (Vit B12) Test System	7625-300A 7625-300B	7675-300A 7675-300B			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (Anemia Panel VAST) Test System	7825-300A 7825-300B	7875-300A 7875-300B			12.07.01.00.00	Low	2013-09-16
Autoimmune							
Anti-Cyclic Citrullinated Peptide IgG (Anti-CCP IgG) Test System	12725-300A 12725-300B	12775-300A 12775-300B			12.11.01.90.00	Low	2019-04-03
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300A 1025-300B	1075-300A 1075-300B			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300A 1125-300B	1175-300A 1175-300B			12.10.03.01.00	Low	2005-11-11
Bone Metabolism & Growth							
Calcitonin Test System	9325-300A 9325-300B	9375-300A 9375-300B			12.06.03.02.00	Low	2019-04-03
Growth Hormone (hGH) Test System	1725-300A 1725-300B	1775-300A 1775-300B			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9025-300A 9025-300B	9075-300A 9075-300B			12.06.03.13.00	Low	2011-09-26
Parathyroid Hormone (PTH) 3rd & 2nd Gen (VAST) Test System	10025-300A 10025-300B	10075-300A 10075-300B			12.06.03.13.00	Low	2019-04-03
25(OH) Vitamin D Total Direct (Vit D-Direct) Test System	7725-300A 7725-300B	7775-300A 7775-300B			12.06.03.10.00	Low	2017-07-05
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300A 1925-300B	1975-300A 1975-300B			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300A 3025-300B	3075-300A 3075-300B			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300A 5625-300B	5675-300A 5675-300B			12.03.01.02.00	Low	2010-06-29
CA 19-9 Test System	3925-300A 3925-300B	3975-300A 3975-300B			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300A 1825-300B	1875-300A 1875-300B			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen	4625-300A	4675-300A			12.03.01.31.00	Low	2010-06-29

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
(CEA-Next Gen) Test System	4625-300B	4675-300B					
Free β-Subunit Human Chorionic Gonadotropin (Free Beta hCG) Test System	2025-300A 2025-300B	2075-300A 2075-300B			12.03.01.90.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300A 2925-300B	2975-300A 2975-300B			12.13.01.02.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300A 925-300B	975-300A 975-300B			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300A 3125-300B	3175-300A 3175-300B			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300A 3225-300B	3275-300A 3275-300B			12.13.01.05.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300A 3825-300B	3875-300A 3875-300B			12.13.01.07.00	Low	2005-11-11
Diabetes							
C-Peptide Test System	2725-300A 2725-300B	2775-300A 2775-300B			12.06.01.01.00	Low	2005-11-11
Insulin Test System	2425-300A 2425-300B	2475-300A 2475-300B			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300A 5825-300B				12.06.01.03.00	Low	2010-06-29
Insulin - C-Peptide (Diabetes Panel VAST)	7325-300A 7325-300B	7375-300A 7375-300B			12.06.01.03.00	Low	2005-11-11
Endocrine							
ACTH Test System	10625-300	10675-300			12.06.04.01.00	Low	2019-04-03
Aldosterone Test System	10125-300	10175-300			12.06.02.01.00	Low	2019-04-03
Leptin Test System	10925-300	10975-300			12.06.90.17.00	Low	2019-04-03
Fertility & Prenatal							
Anti-Müllerian Hormone (AMH) Test System	9725-300A 9725-300B	9775-300A 9775-300B			12.05.02.16.00	Low	2019-04-03
Folicle Stimulating Hormone (FSH) Test System	425-300A 425-300B	475-300A 475-300B			12.05.01.04.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300A 825-300B	875-300A 875-300B			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (hCG-XR) Test System	8825-300A 8825-300B	8875-300A 8875-300B			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid -hCG) Test System	3325-300A 3325-300B				12.05.02.05.00	Low	2005-11-11
Inhibin A Test System	9525-300A 9525-300B	9575-300A 9575-300B			12.05.01.90.00	Low	2019-04-03
Inhibin B Test System	9625-300A 9625-300B	9675-300A 9675-300B			12.05.01.90.00	Low	2019-04-03
Luteinizing Hormone (LH) Test System	625-300A 625-300B	675-300A 675-300B			12.05.01.05.00	Low	2005-11-11
Pregnancy Associated Plasma Protein – A Mass Units (PAPP-A Mass Units) Test System	12625-300A 12625-300B	12675-300A 12675-300B			12.05.02.10.00	Low	2017-07-05
Prolactin Hormone (PRL) Test System	725-300A 725-300B	775-300A 775-300B			12.05.01.08.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Prolactin Hormone Sequential (PRLs) Test System	4425-300A 4425-300B	4475-300A 4475-300B			12.05.01.08.00	Low	2005-11-11
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) (Fertility Panel VAST) Test System	8325-300B 8325-300D 8325-300E	8375-300B 8375-300D 8375-300E			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (Triple Screen Panel VAST) Test System	8525-300A 8525-300B	8575-300A 8575-300B			12.05.01.90.00	Low	2010-06-29
Infectious Diseases							
Anti-H. Pylori IgG (H. Pylori Ab IgG) Test System	1425-300A 1425-300B	1475-300A 1475-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM (H. Pylori Ab IgM) Test System	1525-300A 1525-300B	1575-300A 1575-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA (H. Pylori Ab IgA) Test System	1625-300A 1625-300B	1675-300A 1675-300B			15.01.04.03.00	Low	2005-11-11
Anti-SARS-CoV-2 (COVID-19) IgG Test System	11925-300A 11925-300B	11975-300A 11975-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgM Test System	11725-300A 11725-300B	11775-300A 11775-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgA Test System	11825-300A 11825-300B	11875-300A 11875-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System	12025-300A 12025-300B	12075-300A 12075-300B			15.04.80.90.00	Low	2021-09-20
D-Dimer Test System	9225-300A 9225-300B	9275-300A 9275-300B			13.02.05.03.00	Low	2020-08-25
Procalcitonin (PCT) Test System	1425-300A 1425-300B	1475-300A 1475-300B			12.06.90.16.00	Low	2017-07-05
Neonatal							
Neonatal 17OHP (N-17OHP) Test System	5525-300A 5525-300B				12.05.01.07.00	Low	2008-02-01
Neonatal (N-T4) Thyroxine Test System	2625-300A 2625-300B				12.04.01.12.00	Low	2005-11-11
Neonatal TBG (N-TBG) Test System	8925-300A 8925-300B				12.04.01.09.00	Low	2013-09-16
Neonatal TSH (N-TSH) Test System	3425-300A 3425-300B 3425-300D 3425-300E				12.04.01.90.00	Low	2005-11-11
Steroid							
Androstenedione (ANST) Test System	12425-300A 12425-300B	12475-300A 12475-300B			12.05.01.01.00	Low	2021-09-20
Cortisol Test System	3625-300A 3625-300B	3675-300A 3675-300B			12.06.02.04.00	Low	2005-11-11
Dehydroepiandrosterone (DHEA) Test System	7425-300A 7425-300B	7475-300A 7475-300B			12.05.01.02.00	Low	2011-09-26
Dehydroepiandrosterone Sulfate (DHEA-S) Test System	5125-300A 5125-300B	5175-300A 5175-300B			12.05.01.02.00	Low	2010-06-29
Estrone (E1) Test System	10325-300A 10325-300B	10375-300A 10375-300B			12.05.02.04.00	Low	2019-04-03

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Estradiol (E2) Test System	4925-300A 4925-300B	4975-300A 4975-300B			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300A 5025-300B	5075-300A 5075-300B			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300A 4825-300B	4875-300A 4875-300B			12.05.01.06.00	Low	2010-06-29
17-OH Progesterone (17-OHP) Test System	5225-300A 5225-300B	5275-300A 5275-300B			12.05.01.07.00	Low	2010-06-29
17-OH Progesterone SI (17-OHP-SI) Test System	9925-300A 9925-300B	9975-300A 9975-300B			12.05.01.07.00	Low	2010-10-18
Sex Hormone Binding Globulin (SHBG) Test System	9125-300A 9125-300B	9175-300A 9175-300B			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300A 3725-300B	3775-300A 3775-300B			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300A 5325-300B	5375-300A 5375-300B			12.05.01.10.00	Low	2010-06-29
Thyroid							
Total Triidothyronine (tT3) Test System	125-300A 125-300B 125-300D 125-300E	175-300A 175-300B 175-300D 175-300E			12.04.01.05.00	Low	2005-11-11
Free Triidothyronine (fT3) Test Stystem	1325-300A 1325-300B 1325-300A 1325-300B	1375-300A 1375-300B 1375-300D 1375-300E			12.04.01.01.00	Low	2005-11-11
Total Triidothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Triidothyronine (Rapid -tT3) Test System	11225-300A 11225-300B				12.04.01.01.00	Low	2017-07-05
T3-Uptake (T3U) Test System	525-300A 525-300B	575-300A 575-300B			12.04.01.06.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300A 225-300B 225-300D 225-300E	275-300A 275-300B 275-300D 275-300E			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300A 1225-300B 1225-300D 1225-300E	1275-300A 1275-300B 1275-300D 1275-300E			12.04.01.02.00	Low	2005-11-11
Total Thyroxine (tT4 SBS) Test System	8225-300A 8225-300B	8275-300A 8275-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Thyroxine (Rapid -tT4) Test System	11125-300A 11125-300B				12.04.01.01.00	Low	2017-07-05
Thyrotropin (TSH) Test System	325-300A 325-300B 325-300D 325-300E	375-300A 375-300B 375-300D 375-300E			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300A 6025-300B	6075-300A 6075-300B			12.04.01.11.00	Low	2010-06-29
Thyroxine-Binding Globulin (TBG) Test System	3525-300A 3525-300B	3575-300A 3575-300B			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300A	2275-300A			12.04.01.08.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triidothyronine (tT3) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E			12.04.01.01.00	Low	2005-11-11
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E			12.04.01.01.00	Low	2010-06-29
Miscellaneous Controls							
Anti-H. Pylori Control (IgA, IgG, IgM) – Positive & Negative			HPC-300		12.50.01.16.00	Low	2013-09-16
Anti-Tg & Anti-TPO Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level			MC-300		12.50.01.16.00	Low	2010-06-29
TBG Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Tg Control – Tri-Level			TG-300		12.50.01.16.00	Low	2010-06-29
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level			TMC-300		12.50.01.16.00	Low	2013-09-16
Miscellaneous Instruments							
Autoplex® ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex® G2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Autoplex® G3 ELISA & CLIA Analyzer				IN006-3	21.02.10.01	Low	2017-07-05
NeoEldex® ELISA Analzyer				IN009	21.02.10.01	Low	2011-09-26
Impulse® 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
NeoLumax® CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26
LuMatic® CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
PrisMatic® ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
PlateWash - Immunoassay Washer				IN002	21.02.10.01	Low	2010-06-29
TITIN® ELISA & CLIA Analyzer				IN015-EC	21.02.10.01	Low	2017-07-05
TITIN® ELISA Analyzer				IN015-E	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA & CLIA Analyzer				IN016-EC	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA Analyzer				IN016-E	21.02.10.01	Low	2017-07-05

Monobind Inc.
Lake Forest, CA 92630, USA

AccuBind
ELISA Microwells

Anti-SARS-CoV-2 (COVID-19) IgM Test System

Product Codes: 11725-300

1.0 INTRODUCTION

Intended Use: The Qualitative Determination of Anti-SARS-CoV-2 Specific Antibodies of the IgM type in Human Serum or Plasma by Microplate Enzyme Immunoassay

2.0 SUMMARY AND EXPLANATION OF THE TEST

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), discovered at the end of 2019, is the cause of the disease COVID-19.[1-2] Both SARS-CoV-2 and SARS-CoV, the cause of the 2002 SARS epidemic, are of the genus betacoronavirus and are closely related.[2] Transmission of SARS-CoV-2 is primarily through close contact with infected patients via expelled respiratory droplets, usually from coughing or sneezing.[1-2]

Due to its high transmission rate and severeness, COVID-19 has emerged as a global pandemic that has forced lockdowns and quarantine protocols from countries all over the world.[3] Though diagnoses are primarily conducted using viral nucleic acid detection via real-time reverse transcriptase PCR, many false negatives have been reported and there is urgent need for serological antibody screening as a more robust and reliable test methodology.[4-5]

Tests for immunoglobulin M (IgM) antibodies are of importance as as an early detection of infection.[6] The body's primary defense against a pathogen (antigen) is to produce antibodies. Specifically, IgM appears first and wanes over time as IgG antibodies begin to rise and appear at detectable levels 10-20 days after symptom onset.[7-8]

The Anti-SARS-CoV-2 (COVID-19) IgM AccuBind® ELISA test kit is a qualitative test designed to produce highly sensitive and specific results with a simple and brief protocol. The test utilizes a recombinant nucleocapsid protein (rNCP) in the Enzyme Reagent and Anti-human IgM antibodies coated on microwells to capture native antibodies in the sample. In the first step, prediluted samples are added directly to the wells. After the first incubation, excess sample material is washed out and a rNCP labeled with an enzyme is added to the wells to detect IgM against SARS-CoV-2. After the second incubation, excess material is washed out again and substrate is added to produce a measurable color through the reaction with the enzyme and hydrogen peroxide.

3.0 PRINCIPLE

Sequential Sandwich ELISA Method (TYPE 10):

The reagents required for the sequential ELISA assay include immobilized antibody, circulating antibody to SARS-CoV-2, and enzyme-linked SARS-CoV-2 antigen.

Upon adding a sample containing the anti-SARS-CoV-2 antibody, reaction results between the antibody that has been immobilized on the microwell and the antibody to form an immune-complex. The interaction is illustrated by the following equation:

$$\text{h-Ab}_{(\text{IgM})} + \text{Ab}_{(\text{x-IgM})} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} \text{h-Ab}_{(\text{IgM})} - \text{Ab}_{(\text{x-IgM})}$$

$\text{Ab}_{(\text{x-IgM})}$ = Immobilized Antibody (Constant Quantity)
$\text{h-Ab}_{(\text{IgM})}$ = Human Antibody (Variable Quantity)
$\text{h-Ab}_{(\text{IgM})} - \text{Ab}_{(\text{x-IgM})}$ = Immune Complex (Variable Quantity)
k_a = Rate Constant of Association
k_{-a} = Rate Constant of Disassociation

After the incubation time, the well is washed to separate the unbound components by aspiration and/or decantation. The enzyme linked SARS-CoV-2 antigen is then added to the microwells. This conjugate binds to the immune complex that formed.

$$\text{IC}_{(\text{h-IgM.})} + {}^{\text{ENZ}}\text{Ag}_{(\text{SARS-CoV-2})} \Rightarrow {}^{\text{ENZ}}\text{Ag}_{(\text{X-SARS-CoV-2})} - \text{IC}_{(\text{h-IgM})}$$

$\text{IC}_{(\text{h-IgM})}$ = Immobilized Immune complex (Variable Quantity)

${}^{\text{ENZ}}\text{Ab}_{(\text{X-SARS-CoV-2})}$ = Enzyme-antibody Conjugate (Constant Quantity)

${}^{\text{ENZ}}\text{Ab}_{(\text{X-SARS-CoV-2})} - \text{I.C.}_{(\text{h-IgM})}$ = Ag-Ab Complex (Variable)

The anti-h-IgM enzyme conjugate that binds to the immune complex in a second incubation is separated from unreacted material by a wash step. The enzyme activity in this fraction is directly proportional to the antibody concentration in the specimen. By utilizing a serum reference equivalent to the positive-negative cut-off value, the absorbance value can be compared to the cut-off to determine a positive or negative result.

4.0 REAGENTS

Materials provided:

A. Anti-SARS-CoV-2 IgM Controls – 1ml/vial - Icons PC, NC, CC
Three (3) vials of ready-to-use references for anti-SARS-CoV-2 at positive, negative, and cut-off levels of IgM. Store at 2-8°C. A preservative has been added.

B. SARS-CoV-2 IgM Enzyme Reagent – 12 ml/vial - Icon
One (1) vial of nucleocapsid protein from SARS-CoV-2 labeled with horseradish peroxides (HRP) in a buffering matrix. A preservative has been added. Store at 2-8°C.

C. Anti hIgM Antibody Coated Plate – 96 wells - Icon
One 96-well microplate coated with anti-human IgM antibody and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

D. Serum Diluent Concentrate – 20ml
One (1) vial of concentrated serum diluent containing buffer salts and a dye. Store at 2-8°C.

E. Wash Solution Concentrate – 20ml - Icon
One (1) vial containing a surfactant in buffered saline. A preservative has been added. Store at 2-8°C

F. Substrate – 12ml/vial - Icon S^N
One (1) vial containing tetramethylbenzidine (TMB) and hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C.

G. Stop Solution – 8ml/vial - Icon
One (1) vial contains a strong acid (0.5 M H_2SO_4). Store at 2-8°C.

H. Product Instructions.

Note 1: Do not use reagents beyond the kit expiration date.

Note 2: Avoid extended exposure to heat and light. **Opened reagents are stable for sixty (60) days when stored at 2-8°C. Kit and component stability are identified on the label.**

Note 3: Above reagents are for a single 96-well microplate.

4.1 Required But Not Provided:

1. Fixed volume or variable volume pipette capable of delivering volumes ranging from 10 to 1000 µl with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.050 ml, 0.100 ml, and 0.350 ml volumes with a precision of better than 1.5%.
3. Microplate washers or a squeeze bottle (optional).
4. Microplate Reader with 450nm and 620nm wavelength absorbance capability.
5. Absorbent Paper for blotting the microplate wells.
6. Plastic wrap or microplate cover for incubation steps.
7. Vacuum aspirator (optional) for wash steps.
8. Timer.
9. Quality control materials.

5.0 PRECAUTIONS

For In Vitro Diagnostic Use
Not for Internal or External Use in Humans or Animals

Any components containing human serum from COVID-19 patients have been heat inactivated prior to handling and manufacturing. All products that contain human serum have been found to be non-reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV Antibodies by FDA licensed reagents. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

Safe Disposal of kit components must be according to local regulatory and statutory requirement.

6.0 SPECIMEN COLLECTION AND PREPARATION

The specimens shall be blood; serum or plasma in type and the usual precautions in the collection of venipuncture samples should be observed. The blood should be collected in a plain redtop venipuncture tube without additives or anti-coagulants (for serum) or evacuated tube(s) containing EDTA or heparin (for plasma) Allow the blood to clot for serum samples. Centrifuge the specimen to separate the serum or plasma from the cells.

Please note that there has been no evidence of COVID-19 transmission through blood handling, but technicians should always exercise caution and treat all patient samples as potentially hazardous.[9]

Samples may be refrigerated at 2-8°C for a maximum period of seven (7) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20°C for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing. When assayed in duplicate, 0.200ml of the diluted specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the normal, borderline and elevated range for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. The individual laboratory should set acceptable assay performance limits. In addition, maximum absorbance should be consistent with past experience. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

8.0 REAGENT PREPARATION

1. **Serum Diluent**
   Dilute contents of Serum Diluent Concentrate to 200ml (1:10 Dilution) in a suitable container with distilled or deionized water. Store at 2-8°C.
2. **Wash Buffer**
   Dilute contents of wash solution concentrate to 1000 ml with distilled or deionized water in a suitable storage container. Store at 2-30°C for up to 60 days.
3. **Patient Sample Dilution (1/100)**
   For example, dispense 0.010ml (10µl) of each patient specimen into 0.990 ml (990 µl) of serum diluent or 0.0101 ml (10.1 µl) into 1 ml (1000 µl). Cover and vortex or mix thoroughly by inversion. Store at 2-8°C for up to forty-eight (48) hours.

Note : Do not use reagents that are contaminated or have bacteria growth.

9.0 TEST PROCEDURE

Before proceeding with the assay, bring all reagents, serum references and controls to room temperature (20-27°C).
*****Test Procedure should be performed by a skilled individual or trained professional*****

1. Format the microplates' wells for each control sample and patient specimen to be assayed in duplicate. Dilute the patient or any external control samples 1/100 (see Reagent Preparation **Section 8.0)** **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.**
2. Pipette 0.100 ml (100µl) of the appropriate control or diluted patient specimen into the assigned well for IgM determination.
   DO NOT SHAKE THE PLATE AFTER SAMPLE ADDITION
3. Cover and incubate 30 minutes at room temperature**.**
4. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.
5. Add 350µl of wash buffer (see Reagent Preparation Section 8.0), decant (blot) or aspirate. Repeat two (4) additional times for a total of five (5) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat two (2) additional times.**
6. Add 0.100 ml (100µl) of SARS-CoV-2 IgM Enzyme Reagent to all wells. **Always add reagents in the same order to minimize reaction time differences between wells.**
   DO NOT SHAKE THE PLATE AFTER ENZYME ADDITION
7. Cover and incubate for thirty (30) minutes at room temperature.
8. Wash the wells five (5) times with 350 µl wash buffer by repeating steps (4 & 5) as explained above.
9. Add 0.100 ml (100µl) of Substrate Reagent to all wells. **Always add reagents in the same order to minimize reaction time differences between wells. Do not use the Substrate Reagent if it looks blue.**
   DO NOT SHAKE THE PLATE AFTER SUBSTRATE ADDITION
10. Incubate at room temperature for twenty (20) minutes to develop sufficient color.
11. Add 0.050ml (50µl) of stop solution to each well and swirl the microplate gently for 15-20 seconds to mix. **Always add reagents in the same order to minimize reaction time differences between wells.**
12. Read the absorbance in each well at 450nm (using a reference wavelength of 620-630nm to minimize well imperfections) in a microplate reader. **The results should be read within fifteen (15) minutes of adding the stop solution.**

Note: The relationship of absorbance to cut-off value is not necessarily linear so samples need not be diluted further if the absorbance is higher than the plate reader's capability (usually 3.0). However, these samples should be interpreted as strongly positive.

10.0 INTERPRETATION OF RESULTS

A Cut-Off Control is used to ascertain the positivity or negativity of samples. Follow the following procedure to interpret the sample results.

1. Record the absorbance of all samples obtained from the printout of the microplate reader as outlined in Example 1.
2. Multiply the average absorbance of the Cut-Off Control by the Cut-Off Factor to obtain the Cut-Off Value.
2. Divide the average absorbance of each sample by the Cut-Off Value and multiply by 10 to obtain the relative value unit (RV).
3. If RV <9, the sample is negative for Anti-SARS-CoV-2 IgM and if RV >10, the sample is positive for Anti-SARS-CoV-2 IgM
4. Samples with RV that fall within the range of 9-10 are considered borderline and should be retested with a new blood draw within 4-7 days for reevaluation.

Note: Computer data reduction software designed for ELISA assay may also be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

EXAMPLE 1
(Cut-Off Factor = 1.0)

COV = MeanCC x COF
COV = Cut-Off Value
MeanCC = Mean Absorbance of Cut-Off Control
COF = Cut-Off Factor (See Certificate of Analysis)
COV = 0.230 x 1.0 = 0.230

Sample I.D.	Abs	Mean Abs	RV	Pos/Neg
Negative	0.059	0.060	÷0.230 x 10 =2.6	Negative
	0.061			
Cut Off	0.216	0.230	÷0.230 x 10 =10	Cut-Off
	0.244			
Positive	2.805	2.845	÷0.230 x 10 =124	Positive
	2.884			
Patient 1	0.104	0.105	***÷0.230 x 10 =4.6***	***Negative***
	0.106			
Patient 2	1.534	1.603	***÷0.230 x 10 =69.7***	***Positive***
	1.671			
Patient 3	0.225	0.217	***÷0.230 x 10 =9.4***	***Borderline***
	0.209			

*The data presented in Example 1 is for illustration only and **should not** be used in lieu of a Cut-Off sample run with each assay. **In this example, since the Cut-Off Factor = 1.0, the average absorbance of the Cut-Off Control = Cut-Off Value**

11.0 Q.C. PARAMETERS

In order for the assay results to be considered valid the following criteria should be met:

1. Maximum Absorbance (Positive control) > 1.5
2. Positive control RV > 15
3. Negative control RV < 6

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product is available on request from Monobind Inc.

12.1 Assay Performance

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the Cut-Off control.
5. The addition of substrate solution initiates a kinetic reaction, which is terminated by the addition of the stop solution. Therefore, the substrate and stop solution should be added in the same sequence to eliminate any time-deviation during reaction.
6. Plate readers measure vertically. Do not touch the bottom of the wells.
7. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
8. Use components from the same lot. No intermixing of reagents from different batches.
9. Very high concentration of anti-SARS-CoV-2 in patient specimens can contaminate samples immediately following these extreme levels. Bad duplicates are indicative of cross contamination. Repeat any sample, which follows any patient specimen with over 3.0 units of absorbance.
10. The Anti-SARS-CoV-2 (COVID-19) IgM AccuBind® ELISA Test System is a qualitative assay and does not necessarily give an indication of quantities of IgM antibodies.
11. Samples, which are contaminated microbiologically, should not be used.
12. Any patient samples used in manufacturing have been heat inactivated prior to handling. However, treat all samples, including the control samples, as potentially hazardous or infectious.
13. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from Monobind's IFU may yield inaccurate results.
14. All applicable national standards, regulations and laws, including, but not limited to, good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
15. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.
16. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.

12.2 Interpretation

1. ***Measurements and interpretation of results must be performed by a skilled individual or trained professional.***
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
4. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
5. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.
6. The clinical significance of the result should be used in evaluating the possible presence of SARS-CoV-2 infection or COVID-19. However, **clinical inferences should not be solely based on this test** but rather as an adjunct to the clinical manifestations of the patient and other relevant tests such as Histology, nasophyrangeal swab, etc. A positive result does not indicate COVID-19 and does not distinguish between infection or contagiousness of COVID-19. Similarly, a negative result does not eliminate the absence COVID-19 infection but rather a very low titer of antibody that may be related to the early stages of disease.

13.0 EXPECTED RANGES OF VALUES

A study of apparently healthy population (n=154) from prior to December 2019 was undertaken to determine expected values for the Anti-SARS-CoV-2 Accubind® ELISA test system. Based on the data, the following cut-off point was established.

Presence of SARS-CoV-2 antibodies Confirmed

IgM > 10 RV

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precision of the Anti-SARS-CoV-2 (COVID-19) AccuBind® ELISA Test System were determined by analyses on two different levels of pool control sera. The number, mean value, standard deviation (σ) and coefficient of variation for each of these control sera are presented below.

TABLE 1
Within Assay Precision (Values in RV)

Sample	N	X	σ	C.V.
Negative	20	2.1	0.11	5.24%
Borderline	20	9.2	0.23	2.50%
Positive	20	30.5	0.54	1.77%

TABLE 2*
Between Assay Precision (Values in RV)

Sample	N	X	σ	C.V.
Negative	16	1.9	0.16	8.42%
Borderline	16	9.3	0.45	4.84%
Positive	16	29.6	1.38	4.66%

*As measured in eight experiments in duplicate.

14.2 Sensitivity

The sensitivity of the Anti-SARS-CoV-2 IgM AccuBind® ELISA Test System was determined by testing samples from 30 patients who had previously tested positive for SARS-CoV-2 via RT-PCR. The patient samples were sourced from three different blood banks. 25* out of the 30 patients tested positive indicating that the sensitivity of the test is at least 83.3% True Positive Rate.

*Since IgM antibodies decrease over time, some patients may not have been drawn early enough in the disease state to detect IgM antibodies.

14.3 Accuracy

The Anti-SARS-CoV-2 (COVID-19) IgM AccuBind® ELISA test system was used to test samples drawn at subsequent time intervals from 90 patients who tested PCR and IgM positive for SARS-CoV-2. The data is shown in Table 3 below.

TABLE 3

*Time Interval listed is in days after first hospital visit and is not indicative of date of symptom onset.

		Candidate Test Results		
Days from Hospitalization	Number of Subjects Tested	Total Antibody Positive results	Total Antibody PPA	95% CI
0-7 days	72	71	98.6%	92.5%-99.8%
8-14 days	11	10	90.9%	62.3%-98.4%
15-30 days	4	4	100%	51%-100%
≥31 days	3	3	100%	43.9%-100%
Total Subjects	90	N/A	N/A	N/A

14.4 Specificity

>150 different patient samples drawn prior to December 2019 were assayed to determine the prevalence of false positives. No false positive samples were detected indicating the Anti-SARS-CoV-2 (COVID-19) IgM AccuBind® ELISA Test System has a 100% Specificity.

16.0 REFERENCES

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MP11725 Product Code: 11725-300

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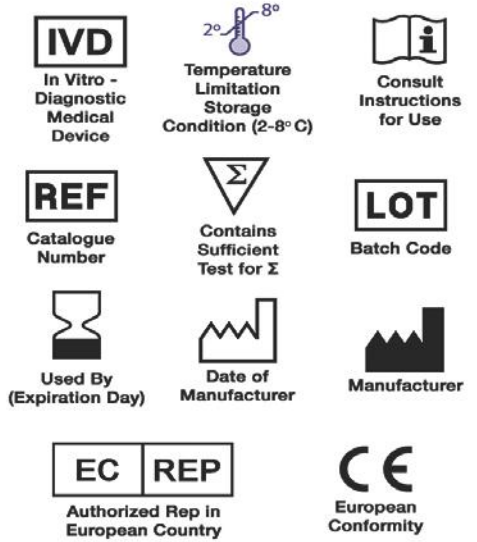
Glossary of Symbols
(EN 980/ISO 15223)



Monobind Inc.
Lake Forest, CA 92630, USA

AccuBind
ELISA Microwells

Anti-SARS-CoV-2 (COVID-19) IgG Test System

Product Codes: 11925-300

1.0 INTRODUCTION

Intended Use: The Qualitative Determination of Anti-SARS-CoV-2 Specific Antibodies of the IgG type in Human Serum or Plasma by Microplate Enzyme Immunoassay

2.0 SUMMARY AND EXPLANATION OF THE TEST

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), discovered at the end of 2019, is the cause of the disease COVID-19.[1-2] Both SARS-CoV-2 and SARS-CoV, the cause of the 2002 SARS epidemic, are of the genus betacoronavirus and are closely related.[2] Transmission of SARS-CoV-2 is primarily through close contact with infected patients via expelled respiratory droplets, usually from coughing or sneezing.[1-2]

Due to its high transmission rate and severeness, COVID-19 has emerged as a global pandemic that has forced lockdowns and quarantine protocols from countries all over the world.[3] Though diagnoses are primarily conducted using viral nucleic acid detection via real-time reverse transcriptase PCR, many false negatives have been reported and there is urgent need for serological antibody screening as a more robust and reliable test methodology.[4-5]

Tests for immunoglobulin G (IgG) antibodies are of particular interest since they are produced in high amounts and indicate previous or recovering infection of pathogens. High levels of IgG are also known to mark immunity to a pathogen.[6] Additionally, IgG antibodies can be a good marker for efficacy of treatment of COVID-19 and successful immunization against SARS-CoV-2. However, IgG antibodies to SARS-CoV-2 do not usually appear in detectable levels until 10-20 days after symptom onset.[7-8] Therefore it is recommended that patient samples be repeated on a weekly basis to monitor the increase and stabilization of anti-SARS-CoV-2 IgG antibodies.

The Anti-SARS-CoV-2 (COVID-19) IgG AccuBind® ELISA test kit is a qualitative test designed to produce highly sensitive and specific results with a simple and brief protocol. The test utilizes a recombinant nucleocapsid protein (rNCP) from SARS-CoV-2 coated on microwells to capture native antibodies in the sample. In the first step, prediluted samples are added directly to the wells. After the first incubation, excess sample material is washed out and an anti-human IgG (anti-hIgG) antibody labeled with an enzyme is added to the wells. After the second incubation, excess material is washed out again and substrate is added to produce a measurable color through the reaction with the enzyme and hydrogen peroxide.

3.0 PRINCIPLE

Sequential Sandwich ELISA Method (TYPE 10):

The reagents required for the sequential ELISA assay include immobilized antigen, circulating antibody to SARS-CoV-2, and enzyme-linked human IgG-specific antibody.

Upon adding a sample containing the anti-SARS-CoV-2 antibody, reaction results between the antigen that has been immobilized on the microwell and the antibody to form an immune-complex. The interaction is illustrated by the following equation:

$$h\text{-}Ab_{(X\text{-}SARS\text{-}CoV\text{-}2)} + Ag_{(rNCP)} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} h\text{-}Ab_{(X\text{-}SARS\text{-}CoV\text{-}2)} - Ag_{(rNCP)}$$

$Ag_{(rNCP)}$ = Immobilized Antigen (Constant Quantity)
$h\text{-}Ab_{(X\text{-}SARS\text{-}CoV\text{-}2)}$ = Human Antibody (Variable Quantity)
$h\text{-}Ab_{(X\text{-}SARS\text{-}CoV\text{-}2)} - Ag_{(rNCP)}$ = Immune Complex (Variable Quantity)
k_a = Rate Constant of Association
k_{-a} = Rate Constant of Disassociation

After the incubation time, the well is washed to separate the unbound components by aspiration and/or decantation. The enzyme linked species-specific antibody (anti-h-IgG,) is then added to the microwells. This conjugate binds to the immune complex that formed.

$$IC_{(h\text{-}IgG,)} + {}^{ENZ}Ab_{(X\text{-}h\text{-}IgG)} \Rightarrow {}^{ENZ}Ab_{(X\text{-}h\text{-}IgG)} - IC_{(h\text{-}IgG)}$$

$IC_{(h\text{-}IgG)}$ = Immobilized Immune complex (Variable Quantity)

${}^{ENZ}Ab_{(X\text{-}h\text{-}IgG)}$ = Enzyme-antibody Conjugate (Constant Quantity)
${}^{ENZ}Ab_{(X\text{-}h\text{-}IgG)}$ - I.C. $_{(h\text{-}IgG)}$ = Ag-Ab Complex (Variable)

The anti-h-IgG enzyme conjugate that binds to the immune complex in a second incubation is separated from unreacted material by a wash step. The enzyme activity in this fraction is directly proportional to the antibody concentration in the specimen. By utilizing a serum reference equivalent to the positive-negative cut-off value, the absorbance value can be compared to the cut-off to determine a positive or negative result.

4.0 REAGENTS

Materials provided:

A. Anti-SARS-CoV-2 IgG Controls – 1ml/vial - Icons PC, NC, CC
Three (3) vials of ready-to-use references for anti-SARS-CoV-2 at positive, negative, and cut-off levels of IgG. Store at 2-8°C. A preservative has been added.

B. Anti-hIgG Enzyme Reagent – 12 ml/vial - Icon
One (1) vial of anti-human IgG-horseradish peroxides (HRP) conjugate in a buffering matrix. A preservative has been added. Store at 2-8°C.

C. SARS-CoV-2 Antigen Coated Plate – 96 wells - Icon
One 96-well microplate coated with recombinant nucleocapsid protein from SARS-CoV-2 and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

D. Serum Diluent Concentrate – 20ml
One (1) vial of concentrated serum diluent containing buffer salts and a dye. Store at 2-8°C.

E. Wash Solution Concentrate – 20ml - Icon
One (1) vial containing a surfactant in buffered saline. A preservative has been added. Store at 2-8°C

F. Substrate – 12ml/vial - Icon
One (1) vial containing tetramethylbenzidine (TMB) and hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C.

G. Stop Solution – 8ml/vial – Icon
One (1) vial contains a strong acid (0.5 M H_2SO_4). Store at 2-8°C.

H. Product Instructions.

Note 1: Do not use reagents beyond the kit expiration date.

Note 2: Avoid extended exposure to heat and light. **Opened reagents are stable for sixty (60) days when stored at 2-8°C. Kit and component stability are identified on the label.**

Note 3: Above reagents are for a single 96-well microplate.

4.1 Required But Not Provided:

1. Fixed volume or variable volume pipette capable of delivering volumes ranging from 10 to 1000 µl with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.050 ml, 0.100 ml, and 0.350 ml volumes with a precision of better than 1.5%.
3. Microplate washers or a squeeze bottle (optional).
4. Microplate Reader with 450nm and 620nm wavelength absorbance capability.
5. Absorbent Paper for blotting the microplate wells.
6. Plastic wrap or microplate cover for incubation steps.
7. Vacuum aspirator (optional) for wash steps.
8. Timer.
9. Quality control materials.

5.0 PRECAUTIONS

For In Vitro Diagnostic Use
Not for Internal or External Use in Humans or Animals

Any components containing human serum from COVID-19 patients have been heat inactivated prior to handling and manufacturing. All products that contain human serum have been found to be non-reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV Antibodies by FDA licensed reagents. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

Safe Disposal of kit components must be according to local regulatory and statutory requirement.

6.0 SPECIMEN COLLECTION AND PREPARATION

The specimens shall be blood; serum or plasma in type and the usual precautions in the collection of venipuncture samples should be observed. The blood should be collected in a plain redtop venipuncture tube without additives or anti-coagulants (for serum) or evacuated tube(s) containing EDTA or heparin (for plasma). Allow the blood to clot for serum samples. Centrifuge the specimen to separate the serum or plasma from the cells.

Please note that there has been no evidence of COVID-19 transmission through blood handling, but technicians should always exercise caution and treat all patient samples as potentially hazardous.[9]

Samples may be refrigerated at 2-8°C for a maximum period of seven (7) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20°C for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing. When assayed in duplicate, 0.200ml of the diluted specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the normal, borderline and elevated range for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. The individual laboratory should set acceptable assay performance limits. In addition, maximum absorbance should be consistent with past experience. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

8.0 REAGENT PREPARATION

1. **Serum Diluent**
   Dilute contents of Serum Diluent Concentrate to 200ml (1:10 Dilution) in a suitable container with distilled or deionized water. Store at 2-8°C.
2. **Wash Buffer**
   Dilute contents of wash solution concentrate to 1000 ml with distilled or deionized water in a suitable storage container. Store at 2-30°C for up to 60 days.
3. **Patient Sample Dilution (1/100)**
   For example, dispense 0.010ml (10µl) of each patient specimen into 0.990 ml (990 µl) of serum diluent or 0.0101 ml (10.1 µl) into 1 ml (1000 µl). Cover and vortex or mix thoroughly by inversion. Store at 2-8°C for up to forty-eight (48) hours.

Note : Do not use reagents that are contaminated or have bacteria growth.

9.0 TEST PROCEDURE

Before proceeding with the assay, bring all reagents, serum references and controls to room temperature (20-27°C).
*****Test Procedure should be performed by a skilled individual or trained professional*****

1. Format the microplates' wells for each control sample and patient specimen to be assayed in duplicate. Dilute the patient or any external control samples 1/100 (see Reagent Preparation **Section 8.0)** **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.**
2. Pipette 0.100 ml (100µl) of the appropriate control or diluted patient specimen into the assigned well for IgG determination.
   DO NOT SHAKE THE PLATE AFTER SAMPLE ADDITION
3. Cover and incubate 30 minutes at room temperature.
4. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.
5. Add 350µl of wash buffer (see Reagent Preparation Section 8.0), decant (blot) or aspirate. Repeat two (2) additional times for a total of three (3) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat two (2) additional times.**
6. Add 0.100 ml (100µl) of Anti-hIgG Enzyme Reagent to all wells. **Always add reagents in the same order to minimize reaction time differences between wells.**
   DO NOT SHAKE THE PLATE AFTER ENZYME ADDITION
7. Cover and incubate for thirty (30) minutes at room temperature.
8. Wash the wells three (3) times with 350 µl wash buffer by repeating steps (4 & 5) as explained above.
9. Add 0.100 ml (100µl) of Substrate Reagent to all wells. **Always add reagents in the same order to minimize reaction time differences between wells. Do not use the Substrate Reagent if it looks blue.**
   DO NOT SHAKE THE PLATE AFTER SUBSTRATE ADDITION
10. Incubate at room temperature for fifteen (15) minutes.
11. Add 0.050ml (50µl) of stop solution to each well and swirl the microplate gently for 15-20 seconds to mix. **Always add reagents in the same order to minimize reaction time differences between wells.**
12. Read the absorbance in each well at 450nm (using a reference wavelength of 620-630nm to minimize well imperfections) in a microplate reader. **The results should be read within fifteen (15) minutes of adding the stop solution.**

Note: The relationship of absorbance to cut-off value is not necessarily linear so samples need not be diluted further if the absorbance is higher than the plate reader's capability (usually 3.0). However, these samples should be interpreted as strongly positive.

10.0 INTERPRETATION OF RESULTS

A Cut-Off Control (CC) and kit specific Cut-Off Factor is used to ascertain the positivity or negativity of samples. Follow the following procedure to interpret the sample results.

1. Record the absorbance of all samples obtained from the printout of the microplate reader as outlined in Example 1.
2. Multiply the average absorbance of the Cut-Off Control by the Cut-Off Factor to obtain the Cut-Off Value.
2. Divide the average absorbance of each sample by the Cut-Off Value and multiply by 10 to obtain the relative value unit (RV).
3. If RV <9, the sample is negative for Anti-SARS-CoV-2 IgG and if RV >10, the sample is positive for Anti-SARS-CoV-2 IgG
4. Samples with RV that fall within the range of 9-10 are considered borderline and should be retested with a new blood draw within 4-7 days for reevaluation.

Note: Computer data reduction software designed for ELISA assay may also be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

EXAMPLE 1
(Cut Off Factor = 1.0)

COV = MeanCC x COF
COV = Cut-Off Value
MeanCC = Mean Absorbance of Cut-Off Control
COF = Cut-Off Factor (See Certificate of Analysis)
COV = 0.667 x 1.0 = 0.667

Sample I.D.	Abs	Mean Abs	RV	Pos/Neg
Negative	0.178	0.173	÷0.667 x 10 = 2.6	Negative
	0.167			
Cut-Off	0.668	0.667	÷0.667 x 10 = 10	Cut-Off
	0.667			
Positive	2.805	2.845	÷0.667 x 10 = 42.6	Positive
	2.884			
Patient 1	0.177	0.176	***÷0.667 x 10 = 2.6***	***Negative***
	0.175			
Patient 2	1.534	1.603	***÷0.667 x 10 = 24.0***	***Positive***
	1.671			
Patient 3	0.621	0.628	***÷0.667 x 10 = 9.4***	***Borderline***
	0.635			

*The data presented in Example 1 is for illustration only and **should not** be used in lieu of a Cut-Off Control run and Cut-Off Factor with each assay. **In this example, since the Cut-Off Factor = 1.0, the average absorbance of the Cut-Off Control = Cut-Off Value**

11.0 Q.C. PARAMETERS

In order for the assay results to be considered valid the following criteria should be met:

1. Maximum Absorbance (Positive control) > 1.8
2. Positive control RV > 15
3. Negative control RV < 6

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product is available on request from Monobind Inc.

12.1 Assay Performance

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the Cut-Off control.
5. The addition of substrate solution initiates a kinetic reaction, which is terminated by the addition of the stop solution. Therefore, the substrate and stop solution should be added in the same sequence to eliminate any time-deviation during reaction.
6. Plate readers measure vertically. Do not touch the bottom of the wells.
7. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
8. Use components from the same lot. No intermixing of reagents from different batches.
9. Very high concentration of anti-SARS-CoV-2 in patient specimens can contaminate samples immediately following these extreme levels. Bad duplicates are indicative of cross contamination. Repeat any sample, which follows any patient specimen with over 3.0 units of absorbance.
10. The Anti-SARS-CoV-2 (COVID-19) IgG AccuBind® ELISA Test System is a qualitative assay and does not necessarily give an indication of quantities of IgG antibodies.
11. Samples, which are contaminated microbiologically, should not be used.
12. Any patient samples used in manufacturing have been heat inactivated prior to handling. However, treat all samples, including the control samples, as potentially hazardous or infectious.
13. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from Monobind's IFU may yield inaccurate results.
14. All applicable national standards, regulations and laws, including, but not limited to, good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
15. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.
16. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.

12.2 Interpretation

1. ***Measurements and interpretation of results must be performed by a skilled individual or trained professional.***
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
4. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
5. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.
6. The clinical significance of the result should be used in evaluating the possible presence of SARS-CoV-2 infection or COVID-19. However, **clinical inferences should not be solely based on this test** but rather as an adjunct to the clinical manifestations of the patient and other relevant tests such as Histology, nasophyrangeal swab, etc. A positive result does not indicate COVID-19 and does not distinguish between infection or contagiousness of COVID-19. Similarly, a negative result does not eliminate the absence COVID-19 infection but rather a very low titer of antibody that may be related to the early stages of disease.

13.0 EXPECTED RANGES OF VALUES

A study of apparently healthy population (n=154) from prior to December 2019 was undertaken to determine expected values for the Anti-SARS-CoV-2 Accubind® ELISA test system. Based on the data, the following cut-off point was established.

Presence of SARS-CoV-2 antibodies Confirmed

IgG > 10 RV

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precision of the Anti-SARS-CoV-2 (COVID-19) AccuBind® ELISA Test System were determined by analyses on three different levels of pool control sera. The number, mean value, standard deviation (σ) and coefficient of variation for each of these control sera are presented below.

TABLE 1
Within Assay Precision (Values in RV)

Sample	N	X	σ	C.V.
Negative	20	3.3	0.13	3.95%
Borderline	20	9.5	0.29	2.64%
Positive	20	19.3	0.32	1.65%

TABLE 2*
Between Assay Precision (Values in RV)

Sample	N	X	σ	C.V.
Negative	16	1.6	0.14	8.75%
Borderline	16	9.1	0.35	3.50%
Positive	16	29.8	1.45	4.85%

*As measured in eight experiments in duplicate.

14.2 Sensitivity

The sensitivity of the Anti-SARS-CoV-2 IgG AccuBind® ELISA Test System was determined by testing samples from 30 patients who had previously tested positive for SARS-CoV-2 via RT-PCR. The patient samples were sourced from three different blood banks. 29 out of the 30 patients tested positive indicating that the sensitivity of the test is at least 96.6% True Positive Rate.

14.3 Accuracy

The Anti-SARS-CoV-2 (COVID-19) IgG AccuBind® ELISA test system was used to test samples drawn at subsequent time intervals from 90 patients who tested PCR and IgG positive for SARS-CoV-2. The data is shown in Table 3 below.
*Time Interval listed is in days after first hospital visit and is not indicative of date of symptom onset.

TABLE 3

		Candidate Test Results		
Days from Hospitalization	Number of Subjects Tested	Total Antibody Positive results	Total Antibody PPA	95% CI
0-7 days	72	71	98.6%	92.5%-99.8%
8-14 days	11	10	90.9%	62.3%-98.4%
15-30 days	4	4	100%	51%-100%
≥31 days	3	3	100%	43.9%-100%
Total Subjects	90	N/A	N/A	N/A

14.4 Specificity

>150 different patient samples drawn prior to December 2019 were assayed to determine the prevalence of false positives. No false positive samples were detected indicating the Anti-SARS-CoV-2 (COVID-19) IgG AccuBind® ELISA Test System has a 100% Specificity.

16.0 REFERENCES

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Glossary of Symbols
(EN 980/ISO 15223)

IVD — In Vitro - Diagnostic Medical Device

2°-8° — Temperature Limitation Storage Condition (2-8° C)

Consult Instructions for Use

REF — Catalogue Number

Σ — Contains Sufficient Test for Σ

LOT — Batch Code

Used By (Expiration Day)

Date of Manufacturer

Manufacturer

EC REP — Authorized Rep in European Country

CE — European Conformity