ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ФСР 2009/05681

от **15 сентября 2009 года** Срок действия: **не ограничен.**

Настоящее удостоверение выдано

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

и подтверждает, что изделие медицинского назначения
(изделие медицинской техники)

Дозаторы пипеточные, одно- и многоканальные, "Блэк"
по ТУ 9443-008-33189998-2009

Digitally signed by Ceaicovschi Tudor
Date: 2020.11.11 16:28:48 EET
Reason: MoldSign Signature
Location: Moldova

производства

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

класс потенциального риска **2а** ОКП **94 4370**

соответствующее комплекту регистрационной документации

КРД № 33014 от 09.07.2009

приказом Росздравнадзора **от 15 сентября 2009 года № 7252-Пр/09**

разрешено к производству, продаже и применению на территории Российской Федерации

Руководитель Федеральной службы
по надзору в сфере здравоохранения
и социального развития **Н.В. Юргель**

006376

Бланк изготовлен ЗАО «ОПЦИОН» (лицензия № 05-05-09/003 ФНС РФ, уровень В), договор РД № 08/63, тел. (495) 648 6068, 608 7617, г. Москва, 2008 г.

Дозаторы пипеточные
Ленпипет Блэк

Стиль и надежность в Вашей лаборатории

Part of Thermo Fisher Scientific

Thermo
SCIENTIFIC

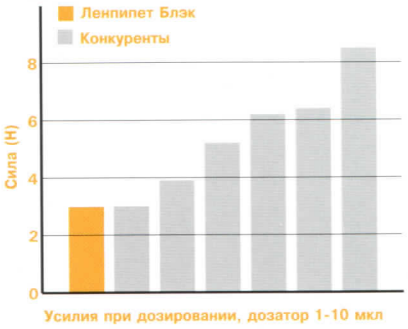
Дозаторы пипеточные Ленпипет Блэк

Усовершенствованный механизм установки объема дозировнания (AVG)

Поскольку точность и воспроизводимость - самые важные свойства любого дозатора, Ленпипет Блэк обладает специально разработанным механизмом регулировки объема, выполненным в виде автономного модуля. Поскольку механизм регулировки объема отделен от корпуса дозатора, он обладает существенно большей точностью, воспроизводимостью и прочностью. Кроме того, чтобы исключить возможное влияние тепла руки на точность измерений, механизм регулировки объема дозирования изолирован от корпуса дозатора.

Большой дисплей

Ленпипет Блэк имеет большой, легко читаемый дисплей, позволяющий легко и четко задавать объем. Кроме того, новый механизм установки объема позволяет легко устанавливать объем до сотых долей мкл, который виден на фоне. Точность обеспечивается также благодаря прецизионной регулировке объема, где каждый шаг при установке объема сопровождается щелчком. Это позволяет регулировать объем с шагом от 0,01 мкл до 20 мкл в зависимости от модели дозатора. Возле дисплея предусмотрено удобное место для идентификационных ярлычков пользователя. Такие ярлычки нужны, чтобы не перепутать дозаторы и чтобы они не затерялись в лаборатории.



Легкость дозирования

Как и у всех дозаторов Ленпипет, усилия, необходимые при дозировании, минимизированы. Конструкция Ленпипет Блэк позволяет пользователю нажимать кнопку дозирования очень легко, что обеспечивает легкость, ровность и стабильность дозирования. Это, в свою очередь, позволяет получать лучшие результаты дозирования в течение более длительных периодов работы. Кроме того, запатентованный механизм "супервыталкивания" жидкости позволяет точно дозировать даже микрообъемы. Такой механизм есть в дозаторах объемом 50 мкл и меньше.

Новая конструкция операционнной кнопки

Ленпипет Блэк имеет новую конструкцию операционной кнопки с вращающейся верхней частью, позволяющую исключительно легко устанавливать объем. Дополнительное преимущество заключается в том, что вращающаяся верхняя часть кнопки движется независимо от механизма регулировки объема, что предотвращает случайное изменение объема. Как и нижняя часть операционной кнопки, она выполнена из мягкого пластика, обеспечивающего отличный захват при регулировке объема без приложения усилий.

Полная автоклавируемость

Высокое качество результатов зависит от абсолютной стерильности. Чтобы обеспечить ее и предотвратить перекрестное загрязнение, Ленпипет Блэк может стерилизоваться в автоклаве при 121°C. Стерилизовать дозатор можно целиком в сборе или отдельными деталями в стерилизационном мешке. Дозатор выполнен из материалов, обладающих высокой стойкостью к реактивам, УФ свету и влаге.

Легкость обслуживания и калибровки в лаборатории

Ленпипет Блэк очень легко обслуживать: просто разберите дозатор, сняв сбрасыватель наконечника рукой, а затем с помощью удобного инструмента для обслуживания удалите конус наконечника. Тот же практичный инструмент используется для регулирования калибровки пипетки с помощью калибровочной гайки, расположенной наверху рукоятки дозатора.

Сочетание комфорта и автоклавируемости

Удобство и эргономичность

Ленпипет Блэк имеет широкий упор для пальца, который позволяет держать дозатор под идеальным для дозирования углом и дает руке расслабиться между циклами дозирования. В результате длительные циклы дозирования становятся более комфортными и менее утомительными, снижается риск развития травмы, возникающей из-за постоянной нагрузки (repetitive strain injury, RSI). Кнопка сбрасывателя наконечника закруглена и имеет эргономичную конструкцию, обеспечивающую наиболее комфортное положение большого пальца при сбрасывании.

Разнообразие типов и ассортимента объемов дозирования

Чтобы удовлетворить потребности каждой лаборатории, дозаторы Ленпипет Блэк выпускаются в одноканальных и многоканальных вариантах. Одноканальные дозаторы могут быть переменного или фиксированного объема.
По желанию заказчика поставляются штативы как для одноканальных, так и для многоканальных дозаторов.
Каждый дозатор Ленпипет Блэк имеет удобную цветовую кодировку на операционной кнопке и корпусе рукоятки, а также на многоканальных модулях, чтобы легче было находить нужный наконечник Finntip.

Многоканальные дозаторы Ленпипет Блэк

Многоканальные дозаторы Ленпипет Блэк выпускаются 8-канальными с различными диапазонами объема. Как и в одноканальных моделях Ленпипет Блэк, механизм усовершенствованной регулировки объема обеспечивает высокий уровень точности и воспроизводимости. Кроме того, в моделях малого объема функция супервыталкивания жидкости обеспечивает точное дозирование даже самых малых объемов.

Одноканальные дозаторы пипеточные Ленпипет Блэк постоянного объема

Кат. №	Объем мкл	Точность мкл	%	Воспр-мость s.d.*мкл	CV%*	Наконечник
4652002	1	±0,040	±4,00	0,040	4,00	Flex 10,10, 50
4652012	5	±0,070	±1,40	0,070	1,40	Flex 10,10, 50
4652022	10	±0,090	±0,90	0,080	0,80	Flex 200, 250 Унив., 200 Удл.
4652132	20	±0,14	±0,70	0,10	0,50	Flex 200, 250 Унив., 200 Удл.
4652032	25	±0,15	±0,60	0,13	0,50	Flex 200, 250 Унив., 200 Удл.
4652042	50	±0,30	±0,60	0,20	0,40	Flex 200, 250 Унив., 200 Удл.
4652052	100	±0,40	±0,40	0,30	0,30	Flex 200, 250 Унив., 200 Удл.
4652142	200	±0,80	±0,40	0,60	0,30	Flex 1000,1000,1000 Удл.
4652062	250	±1,0	±0,40	0,8	0,30	Flex 1000,1000,1000 Удл.
4652072	500	±1,5	±0,30	1,5	0,30	Flex 1000,1000,1000 Удл.
4652082	1000	±3,0	±0,30	3,0	0,30	Flex 1000,1000, 1000 Удл.

Одноканальные дозаторы пипеточные Ленпипет Блэк переменного объема

Кат. №	Диапазон	Шаг	Объем мкл	Точность мкл	%	Воспр-мость s.d.*мкл	CV%*	Цветов. код	Наконечник
4642022	0,5-5 мкл	0,01 мкл	5 0,5	±0,075 ±0,030	±1,50 ±6,00	0,050 0,025	1,00 5,00	Розовый	Flex 10, 10, 50
4642032	1-10 мкл	0,02 мкл	10 1	±0,100 ±0,025	±1,00 ±2,50	0,050 0,020	0,50 2,00	Розовый	Flex 10, 10, 50
4642042	1-10 мкл	0,02 мкл	10 1	±0,100 ±0,035	±1,00 ±3,50	0,080 0,030	0,80 3,00	Желтый	Flex 200, 250 Унив.
4642052	2-20 мкл	0,02 мкл	20 2	±0,20 ±0,06	±1,00 ±3,00	0,08 0,05	0,40 2,50	Бирюзовый	50
4642062	2-20 мкл	0,02 мкл	20 2	±0,20 ±0,06	±1,00 ±3,00	0,08 0,05	0,40 2,50	Желтый	Flex 200, 250 Унив.
4642132	5-50 мкл	0,1 мкл	50 5	±0,30 ±0,15	±0,60 ±3,00	0,15 0,125	0,30 2,50	Желтый	Flex 200, 250 Унив., 300, 200 Удл.
4642072	10-100 мкл	0,2 мкл	100 10	±0,80 ±0,25	±0,80 ±2,50	0,20 0,10	0,20 1,00	Желтый	Flex 200, 250 Унив., 300, 200 Удл.
4642082	20-200 мкл	0,2 мкл	200 20	±1,2 ±0,36	±0,60 ±1,80	0,4 0,14	0,20 0,70	Желтый	Flex 200, 250 Унив., 300, 200 Удл.
4642092	100-1000 мкл	1 мкл	1000 100	±6,0 ±1,0	±0,60 ±1,00	2,0 0,6	0,20 0,60	Синий	Flex 1000, 1000, 1000 Удл.
4642102	0,5-5 мл	0,01 мл	5000 500	±25,0 ±5,0	±0,50 ±1,00	10,0 4,0	0,20 0,80	Зеленый	5 мл
4642112	1-10 мл	0,02 мл	10 000 1000	±50,0 ±10,0	±0,50 ±1,00	20,0 8,0	0,20 0,80	Красный	10 мл

Многоканальные дозаторы пипеточные Ленпипет Блэк переменного объема

Кат. №	Кол-во каналов	Диапазон	Шаг	Объем мкл	Точность мкл	Воспр-мость %	s.d.*мкл	Цветов. код CV%*	Наконечник
4662002	8	1,0-10 мкл	0,02 мкл	10 1	±0,240 ±0,080	±2,40 ±8,00	0,160 0,070	1,60 7,00	Розовый	Flex 10, 10, 50
4662012	8	5-50 мкл	0,1 мкл	50 5	±0,75 ±0,25	±1,50 ±5,00	0,35 0,10	0,70 2,00	Желтый	Flex 200, 250 Унив., 200 Удл.
4662022	8	10-100 мкл	0,2 мкл	100 10	±1,30 ±0,25	±1,30 ±2,50	0,50 0,20	0,50 2,00	Желтый	Flex 200, 250 Унив., 200 Удл.
4662032	8	30-300 мкл	1 мкл	300 30	±3,0 ±0,6	±1,00 ±2,00	0,9 0,6	0,30 2,00	Оранжевый	Flex 300, 300

Санкт-Петербург
Тел.: (812) 703 4215
Факс: (812) 703 4216
196240, г. Санкт-Петербург
ул. Кубинская, 73А, корп. 1
E-mail: info.lcp.spb@thermofisher.com

Москва
Тел.: (495) 739 7641
Факс: (495) 739 7642
141400, Московская область, г. Химки
ул. Ленинградская, 39, Бизнес Парк Химки,
офисное здание 2, офис ОВ02_03_В2
E-mail: info.btd.moscow@thermofisher.com

http://www.thermo.com.ru

Thermo SCIENTIFIC

EC CERTIFICATE

Lorne Laboratories Ltd

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

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and manufacture of in vitro diagnostic reagents for identification of blood groups

Device Classification:
Annex II, List A and B

Device Descriptions:
Please refer to Attachment 1

Model:
Please refer to Attachment 1

File Number	A12241	Cycle Start Date	23 May 2017
Certificate No.	354.170425	Effective Date	23 May 2017
		Expiry Date	22 May 2022

Authorised by

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11640248 , following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing model numbers.

Notified Body

0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Lorne Laboratories Ltd

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

Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Device Description	Model	Classification
Anti-A Monoclonal	600005/600010/600000	Annex II List A
Anti-B Monoclonal	610005/610010/610000	Annex II List A
Anti-A,B Monoclonal	620005/620010/620000	Annex II List A
Anti-C Monoclonal	690005	Annex II List A
Anti-E Monoclonal	691005	Annex II List A
Anti-c Monoclonal	692005	Annex II List A
Anti-e Monoclonal	693005	Annex II List A
Anti-K Monoclonal	760005/760010	Annex II List A
Anti-D Clone 2 Monoclonal	710010/710000	Annex II List A
Anti-D Clone 1 Monoclonal	730010/730000	Annex II List A
Anti-D Duoclone Monoclonal	740010/740000	Annex II List A
Anti-Jka Polyclonal	323002/323000	Annex II List B
Anti-Jkb Polyclonal	324002/324000	Annex II List B
Anti-Fyb Polyclonal	317002/317000	Annex II List B
AHG Elite Clear	415010/415100/415000	Annex II List B
AHG Elite Green	435010/435100/435000	Annex II List B
Anti-Fya Monoclonal	774000/774002	Annex II List B
Anti-C+D+E Monoclonal	700005/700010/700000	Annex II List A
Anti-Human IgG Clear	401010/401000	Annex II List B
Anti-Human IgG Green	402010/402000	Annex II List B
Monoclonal Rh Control	640010	Annex II List A
Monoclonal D Negative Control	650010	Annex II List A

File Number A12241
Certificate No. 354.170425

Cycle Start Date 23 May 2017
Effective Date 23 May 2017
Expiry Date 22 May 2022

Authorised by

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body

0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

Сертификат

mdc medical device certification GmbH
удостоверяет, что на предприятии

ВЕКТОР БЕСТ

АО «Вектор-Бест»
630559, Новосибирская область, р.п. Кольцово,
Научно-производственная зона, корпус 36, к. 211,
Российская Федерация

с производственными площадками согласно приложению к Сертификату

применительно к областям

проектирование и разработка, производство и реализация медицинских изделий in-vitro диагностики (ПЦР, ИФА, биохимия)

была введена и применяется

СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ

Проведенная проверка системы управления качеством показала, что данная система соответствует требованиям стандарта:

EN ISO 13485

Изделия медицинские – Системы менеджмента качества – Регулирующие системные требования

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Дата выдачи	2020-07-04
Срок действия до	2023-07-03
Регистрационный №	D1213100019
Отчет №	P20-00568-173687
Штутгарт, Германия	2020-06-02

Руководитель сертификационного органа

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Приложение к Сертификату

№ D1213100019 от 2020-06-02 Стр. 1 из 1

Месторасположение	**Область действия**
АО «Вектор-Бест», ул. Арбузова, 1/1, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство и реализация медицинских изделий in vitro диагностики
АО «Вектор-Бест», 630559, Новосибирская область, р.п. Кольцово, Научно-производственная зона, корпус 36, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики
АО «Вектор-Бест», ул. Пасечная, 3, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики

Руководитель сертификационного органа

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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 Tel.: +31 (0)6 516 536 26;
or as: CEpartner4U, 3951DB; 13. NL tel: +31 (0)6 – 516.536.26)

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

Immunoassay products; **ELISA**, **CLIA**, **Control,** **Instruments** (see appendix)

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

Document No.	Title	Edition / Date of issue
L 331; 98/79/EC	In-Vitro-Diagnostic Directive	1998-10-27

5) Additional information *(conformity procedure, Notified Body, CE certificate, etc.)*:

Conformity assessment procedure for CE marking: IVD Directive, Annex III

Lake Forest, USA;2011-09-27 ---------- A Shatola ----------

Tony Shatola; QA Director, Monobind Inc.

(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of manufacturer)*

Maarn, NL; 2011-09-27 ----------

Olga Teirlinck; Consultant, CEpartner4U BV

(Place & date of issue (yyyy-mm-dd)) *(name; function and signature of authorized representative)*

Appendix

Date: 2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
Thyroid								
T3 – Triidothyronine	125-300	175-300			12.04.01.05.00	Low		2005-11-11
fT3 – Free Triidothyronine	1325-300	1375-300			12.04.01.01.00	Low		2005-11-11
T4 – Thyroxine	225-300	275-300			12.04.01.07.00	Low		2005-11-11
fT4 – Free Thyroxine	1225-300	1275-300			12.04.01.02.00	Low		2005-11-11
TSH – Thyrotropin	325-300	375-300			12.04.01.11.00	Low		2005-11-11
Rapid TSH – Rapid Thyrotropin	6025-300	6075-300			12.04.01.11.00	Low		2010-06-29
T3U – Triidothyronine Uptake	525-300	575-300			12.04.01.06.00	Low		2005-11-11
TBG – Thyroxine-Binding Globulin	3525-300	3575-300			12.04.01.09.00	Low		2005-11-11
Tg – Thyroglobulin	2225-300	2275-300			12.04.01.08.00	Low		2005-11-11
T3, T4 & TSH – Triidothyronine, Thyroxine & Thyrotropin Combo (VAST)	8025-300	8075-300			12.04.01.01.00	Low		2005-11-11
T3 – Triidothyronine (SBS)	8125-300	8175-300			12.04.01.01.00	Low		2010-06-29
T4- Thyroxine (SBS)	8225-300	8275-300			12.04.01.01.00	Low		2010-06-29
fT3, fT4 & TSH – Free Triidothyronine, Free Thyroxine & Thyrotropin Combo (VAST)	7025-300	7075-300			12.04.01.01.00	Low		2010-06-29
Neonatal Thyroid & Genetics								
NTSH – Neonatal Thyrotropin	3425-300	3475-300			12.04.01.90.00	Low		2005-11-11
NT4 – Neonatal Thyroxine	2625-300	2675-300			12.04.01.12.00	Low		2005-11-11
N 17OHP – Neonatal 17 OH Progesterone	5525-300				12.05.01.07	Low		2008-02-01
Biotinidase	8825-300				12 07 02 90 00	Low		2011-09-26
AutoImmune Thyroid								
Anti-Tg – Anti-Thyroglobulin Antigen	1025-300	1075-300			12.10.03.04.00	Low		2005-11-11
Anti-TPO – Anti-Thyroperoxidase Antigen	1125-300	1175-300			12.10.03.01.00	Low		2005-11-11
Fertility & Prenatal								
LH – Lutropin	625-300	675-300			12.05.01.05.00	Low		2005-11-11
FSH – Follitropin	425-300	475-300			12.05.01.04.00	Low		2005-11-11
PRL – Prolactin	725-300	775-300			12.05.01.08.00	Low		2005-11-11
PRL – Prolactin Sequential	6025-300	6075-300			12.05.01.08.00	Low		2005-11-11
hCG – Human Chorionic Gonadotropin	825-300	875-300			12.05.02.05.00	Low		2005-11-11
Rapid hCG – Rapid Human Chorionic Gonadotropin	3325-300				12.05.02.05.00	Low		2005-11-11
FSH, LH, hCG, sPRL Combo (VAST)	8325-300	8375-300			12.05.01.90.00	Low		2006-08-24
AFP, hCG, uE3 Combo (VAST)	8525-300	8575-300			12.05.01.90.00	Low		2010-06-29
Steroid								
Cortisol	3625-300	3675-300			12.06.02.04.00	Low		2005-11-11
DHEA-S – Dehydroepiandrosterone sulfate	5125-300	5175-300			12.05.01.02.00	Low		2010-06-29
DHEA - Dehydroepiandrosterone	7425-300	7475-300			12.05.01.02.00	Low		2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
E2 – Estradiol	4925-300	4975-300			12.05.01.03.00	Low		2010-06-29
uE3 – Estriol, Unconjugated	5025-300	5075-300			12.05.02.02.00	Low		2010-06-29
Progesterone	4825-300	4875-300			12.05.01.06.00	Low		2010-06-29
Testosterone	3725-300	3775-300			12.05.01.10.00	Low		2007-11-01
Free Testosterone	5325-300	5375-300			12.05.01.10.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone	5225-300	5275-300			12.05.01.07.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone Ext. Range	9925-300	9975-300			12.05.01.07.00	Low		2010-10-18
Vitamin D3 – 25-Hydroxyvitamin D3	7725-300	7775-300			12.06.03.10.00	Low		2011-09-26
Growth & Bone Metabolism								
hGH - Human Growth Hormone	1725-300	1775-300			12.06.04.02.00	Low		2005-11-11
PTH - Parathyroid Hormone	7825-300	7875-300			12.06.03.13.00	Low		2011-09-26
Diabetes								
Insulin	2425-300	2475-300			12.06.01.03.00	Low		2005-11-11
Insulin Rapid	5825-300				12.06.01.03.00	Low		2010-06-29
C-peptide	2725-300	2775-300			12.06.01.01.00	Low		2005-11-11
Insulin & C-peptide Combo (VAST)	7325-300	7375-300			12.06.01.03.00	Low		2005-11-11
Cardiac Markers								
CKMB – Circulating Creatine Kinase (MB)	2925-300	2975-300			12.13.01.02.00	Low		2005-11-11
CTnI – Troponin I	3825-300	3875-300			12.13.01.07.00	Low		2005-11-11
DIG – Digoxin	925-300	975-300			12.08.01.01.00	Low		2005-11-11
HS-CRP – High Sensitivity C-Reactive Protein	3125-300	3175-300			12.13.01.90.00	Low		2005-11-11
Myoglobin	3225-300	3275-300			12.13.01.05.00	Low		2005-11-11
Infectious Diseases								
IgG – Anti/H. Pylori	1425-300	1475-300			15.01.04.03.00	Low		2005-11-11
IgM – Anti/H. Pylori	1525-300	1575-300			15.01.04.03.00	Low		2005-11-11
IgA – Anti/H. Pylori	1625-300	1675-300			15.01.04.03.00	Low		2005-11-11
Cancer Markers								
AFP – Alpha-Fetoprotein	1925-300	1975-300			12.03.90.01.00	Low		2005-11-11
CA 125 Ovarian Cancer Antigen	3025-300	3075-300			12.03.01.06.00	Low		2005-11-11
CA 15-3 Breast Cancer Antigen	5625-300	5675-300			12.03.01.02.00	Low		2010-06-29
CA 19-9 - Pancreatic Cancer Antigen	3925-300	3975-300			12.03.01.03.00	Low		2005-11-11
CEA – Carcinoembryonic Antigen	1825-300	1875-300			12.03.01.31.00	Low		2005-11-11
CEA - Carcinoembryonic Antigen Next Generation	4625-300	4675-300			12.03.01.31.00	Low		2010-06-29
fβhCG – Free Beta Human Chorionic Gonadotropin	2025-300	2075-300			12.03.01.90.00	Low		2005-11-11
Allergy & Anemia								
Ferritin	2825-300	2875-300			12.07.01.02.00	Low		2005-11-11
Folate	7525-300	7575-300			12.07.01.03.00	Low		2010-06-29
IgE – Immunoglobulin E	2525-300	2575-300			12.02.01.02.00	Low		2005-11-11
sTfR - Transferrin Soluble Receptor	8625-300	8675-300			12.07.01.06.00	Low		2010-06-29
Vitamin B12	7625-300	7675-300			12.07.02.04.00	Low		2011-09-26

Miscellaneous Controls								
Anti-Tg & Anti-TPO – Positive & Negative - Anti-Thyroglobulin, Anti-Thyroperoxidase			AIT-101		12.50.01.16.00	Low		2010-06-29
High Level Fertility Control – Single Level – Progesterone, Estradiol, Human Chorionic Gonadotropin			FC-300		12.50.01.16.00	Low		2010-06-29
Maternal Control – Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Feta Protein, Estriol			MC-300		12.50.01.16.00	Low		2010-06-29
Thyroglobulin Control – Tri Level			TG-300		12.50.01.16.00	Low		2010-06-29
H. Pylori IgG Control – Positive & Negative			HPy-IgG-300		12.50.01.16.00	Low		2010-06-29
Miscellaneous Instruments								
IC hardware + dedicated accessories + software – Autoplex ELISA Analyzer & CLIA Processor				IN006	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax Chemiluminescence Strip Reader				IN001	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Neo-Lumax Chemiluminescence Strip Reader				IN010	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Impulse 2 Chemiluminescence Strip Reader				IN005	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Impulse 3 Chemiluminescence Strip Reader				IN007	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax96 Chemiluminescence Plate Reader				IN004	21.02.10.01	Low		2007-03-01
IC hardware + dedicated accessories + software – LuMatic Chemiluminescence Plate Reader				IN008	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Eldex 3.8 ELISA Strip Reader				IN003	21.02.10.01	Low		2007-09-10
IC hardware + dedicated accessories + software – Neo-Eldex ELISA Strip Reader				IN009	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Mircoplate Washer				IN002	21.02.10.01	Low		2010-06-29

Zertifikat

mdc medical device certification GmbH
bescheinigt hiermit, dass das Unternehmen

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Deutschland

im Geltungsbereich

Entwicklung, Herstellung und Vertrieb von
In-vitro-Diagnostika der Produktgruppen: Blutgruppenserologie,
Bakteriologische Testreagenzien und Nährmedien sowie
Produktion von Rohstoffen für die Herstellung von In-vitro-Diagnostika

ein

Qualitätsmanagementsystem

eingeführt hat und anwendet.

Ein Audit von mdc hat den Nachweis erbracht, dass dieses Qualitätsmanagementsystem die Forderungen der folgenden Norm erfüllt:

DIN EN ISO 13485

Medizinprodukte – Qualitätsmanagementsysteme –
Anforderungen für regulatorische Zwecke

DIN EN ISO 13485:2016 + AC:2016 - EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Gültig ab	2018-10-23
Gültig bis	2021-10-22
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Leiter Zertifizierungsstelle

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Monobind Inc.
Lake Forest, CA 92630, USA

AccuBind
ELISA Microwells

Total Triiodothyronine (tT3) Test System
Product Code: 125-300

1.0 INTRODUCTION

Intended Use: The Quantitative Determination of Total Triiodothyronine Concentration in Human Serum or Plasma by a Microplate Enzyme Immunoassay

2.0 SUMMARY AND EXPLANATION OF THE TEST

Measurement of serum triiodothyronine concentration is generally regarded as a valuable tool in the diagnosis of thyroid dysfunction. This importance has provided the impetus for the significant improvement in assay methodology that has occurred in the last two decades. The advent of monospecific antiserum and the discovery of blocking agents to the T3 binding serum proteins have enabled the development of procedurally simple radioimmunoassays (1,2).
This microplate enzyme immunoassay methodology provides the technician with optimum sensitivity while requiring few technical manipulations. In this method, serum reference, patient specimen, or control is first added to a microplate well. Enzyme-T3 conjugate is added, and then the reactants are mixed. A competition reaction results between the enzyme conjugate and the native triiodothyronine for a limited number of antibody combining sites immobilized on the well.
After the completion of the required incubation period, the antibody bound T3-enzyme conjugate is separated from the unbound T3-enzyme conjugate by aspiration or decantation. The activity of the enzyme present on the surface of the well is quantitated by reaction with a suitable substrate to produce color. The employment of several serum references of known triiodothyronine concentration permits construction of a graph of activity and concentration. From comparison to the dose response curve, an unknown specimen's activity can be correlated with T3 concentration.

3.0 PRINCIPLE

Competitive Enzyme Immunoassay (TYPE 5):
The essential reagents required for a solid phase enzyme immunoassay include immobilized antibody, enzyme-antigen conjugate and native antigen.
Upon mixing immobilized antibody, enzyme-antigen conjugate and a serum containing the native antigen, a competition reaction results between the native antigen and the enzyme-antigen conjugate for a limited number of insolubulized binding sites.

The interaction is illustrated by the following equation:

$$Enz_{Ag} + Ag + Ab_{C.W.} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} AgAb_{C.W.} + Enz_{AgAb_{C.W.}}$$

$Ab_{C.W.}$ = Monospecific Immobilized Antibody (Constant Quantity)
Ag = Native Antigen (Variable Quantity)
Enz_{Ag} = Enzyme-antigen Conjugate (Constant Quantity)
$AgAb_{C.W.}$ = Antigen-Antibody Complex
$Enz_{Ag\ Ab_{C.W.}}$ = Enzyme-antigen Conjugate -Antibody Complex
k_a = Rate Constant of Association
k_{-a} = Rate Constant of Disassociation
$K = k_a / k_{-a}$ = Equilibrium Constant

After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity in the antibody-bound fraction is inversely proportional to the native antigen concentration. By utilizing several different serum references of known antigen con-centration, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

4.0 REAGENTS

Materials Provided:

A. Human Serum References – 1ml/vial - Icons A-F
Six (6) vials of serum reference for triiodothyronine at concentrations of 0 (**A**), 0.5 (**B**), 1.0 (**C**), 2.5 (**D**), 5.0(**E**) and 7.5(**F**) ng/ml. Store at 2-8°C. A preservative has been added. **For SI units: ng/ml x 1.536 = nmol/L**

B. T3 Enzyme Reagent – 1.5ml/vial - Icon (E)
One (1) vial of T3-horseradish peroxidase (HRP) conjugate in an albumin-stabilizing matrix. A preservative has been added. Store at 2-8°C

C. T3/T4 Conjugate Buffer – 13ml - Icon (B)
One (1) bottle reagent containing buffer, red dye, preservative, and binding protein inhibitors. Store at 2-8°C.

D. T3 Antibody Coated Plate – 96 wells - Icon
One 96-well microplate coated with Sheep anti-T3 serum and packaged in an aluminum bag with a drying agent. 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 A – 7 ml/vial - Icon S^A
One (1) bottle containing tetramethylbenzidine (TMB) in buffer. Store at 2-8°C.

G. Substrate B – 7 ml/vial - Icon S^B
One (1) bottle containing hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C.

H. Stop Solution – 8ml/vial - Icon (STOP)
One (1) bottle of stop solution containing a strong acid (1N HCL). Store at 2-30°C.

I. Product Instructions.

Note 1: Do not use reagents beyond the kit expiration date.
Note 2: Opened reagents are stable for sixty (60) days when stored at 2-8°C. **Opened reagents are stable for sixty (60) days when stored at 2-8ºC. Kit and component stability are identified on the label.**
Note 3: Above reagents are for a single 96-well microplate.

4.1 Materials Required But Not Provided:
1 Pipettes capable of delivering 50µl volumes with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100ml and 0.350ml volumes with a precision of better than 1.5%.
3. Adjustable volume (20-200µl) and (200-1000µl) dispenser(s) for conjugate and substrate preparation.
4. Microplate washers or a squeeze bottle (optional).
5. Microplate Reader with 450nm and 620nm wavelength absorbance capability.
6. Test tubes for preparation of enzyme conjugate and substrate A plus B.
7. Absorbent Paper for blotting the microplate wells.
8. Plastic wrap or microplate cover for incubation steps.
9. Vacuum aspirator (optional) for wash steps.
10. Timer.
11. Quality control materials.

5.0 PRECAUTIONS

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

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 required tests. 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. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. 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. Allow the blood to clot for serum samples. Centrifuge the specimen to separate the serum or plasma from the cells.

Samples may be refrigerated at 2-8°C for a maximum period of five (5) 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, 0.100ml of the specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assay external controls at levels in the hypothyroid, euthyroid and hyperthyroid 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. Working Reagent A - T3-enzyme Conjugate Solution
Dilute the T3-enzyme conjugate 1:11 with T3/T4 conjugate buffer in a suitable container. For example, dilute 160µl of conjugate with 1.6ml of buffer for 16 wells (A slight excess of solution is made). This reagent should be used within twenty-four hours for maximum performance of the assay. Store at 2-8°C.
General Formula:
Amount of Buffer required = Number of wells * 0.1
Quantity of T3-Enzyme necessary = # of wells * 0.01
i.e. = 16 x 0.1 = 1.6ml for Total T3/T4 Conjugate Buffer
16 x 0.01 = 0.16ml (160µl) for T3 enzyme conjugate

2. Wash Buffer
Dilute contents of wash concentrate to 1000ml with distilled or deionized water in a suitable storage container. Store diluted buffer at 2-30°C for up to 60 days.

3. Working Substrate Solution
Pour the contents of the amber vial labeled Solution 'A' into the clear vial labeled Solution 'B'. Place the yellow cap on the clear vial for easy identification. Mix and label accordingly. Store at 2 - 8°C.

Note1 : Do not use the working substrate if it looks blue.
Note 2: 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 serum reference, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8ºC.**
2. Pipette 0.050 ml (50µl) of the appropriate serum reference, control or specimen into the assigned well.
3. Add 0.100 ml (100µl) of Working Reagent A, T3 Enzyme Reagent to all wells (see Reagent Preparation Section).
4. Swirl the microplate gently for 20-30 seconds to mix and cover.
5. Incubate 60 minutes at room temperature.
6. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.
7. Add 350µl of wash buffer (see Reagent Preparation Section), decant (tap and 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.**
8. Add 0.100 ml (100µl) of working substrate solution to all wells (see Reagent Preparation Section). **Always add reagents in the same order to minimize reaction time differences between wells.**

DO NOT SHAKE THE PLATE AFTER SUBSTRATE ADDITION

9. Incubate at room temperature for fifteen (15) minutes.
10. Add 0.050ml (50µl) of stop solution to each well and gently mix for 15-20 seconds. **Always add reagents in the same order to minimize reaction time differences between wells.**
11. 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 thirty (30) minutes of adding the stop solution.**

Note: For re-assaying specimens with concentrations greater than 7.5ng/ml, pipette 25µl of the specimen and 25µl of the 0 serum reference into the sample well (this maintains a uniform protein concentration). Multiply the readout value by 2 to obtain the triiodothyronine concentration.

10.0 CALCULATION OF RESULTS

A dose response curve is used to ascertain the concentration of triiodothyronine in unknown specimens.
1. Record the absorbance obtained from the printout of the microplate reader as outlined in Example 1.
2. Plot the absorbance for each duplicate serum reference versus the corresponding T3 concentration in ng/ml on linear graph paper (do not average the duplicates of the serum references before plotting).
3. Draw the best-fit curve through the plotted points.
4. To determine the concentration of T3 for an unknown, locate the average absorbance of the duplicates for each unknown on the vertical axis (y-axis) of the graph, find the intersecting point on the curve, and read the concentration (in ng/ml) from the horizontal axis (X-axis) of the graph (the duplicates of the unknown may be averaged as indicated). In the following example, the average absorbance (1.130) intersects the dose response curve at 1.95ng/ml T3 concentration (See Figure 1).

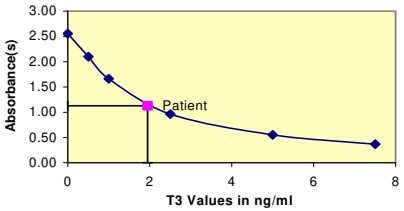
Note: Computer data reduction software designed for ELISA assays may be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

EXAMPLE 1

Sample I.D.	Well Number	Abs (A)	Mean Abs (B)	Value (ng/ml)
Cal A	A1	2.604	2.556	0
	B1	2.507		
Cal B	C1	2.073	2.101	0.5
	D1	2.128		
Cal C	E1	1.678	1.662	1.0
	F1	1.646		
Cal D	G1	0.964	0.966	2.5
	H1	0.969		
Cal E	A2	0.550	0.551	5.0
	B2	0.551		
Cal F	C2	0.372	0.370	7.5
	D2	0.369		
Ctrl 1	E2	1.701	1.726	***0.92***
	F2	1.638		
Ctrl 2	G2	0.755	0.734	***3.58***
	H2	0.791		
Patient	A3	1.145	1.130	***1.95***
	B3	1.115		

*The data presented in Example 1 and Figure 1 are for illustration only and **should not** be used in lieu of a dose response curve prepared with each assay.

Figure 1



11.0 Q.C. PARAMETERS

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

1. The absorbance (OD) of calibrator 0 ng/ml should be ≥ 1.3.
2. Four out of six quality control pools should be within the established ranges.

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 dose response curve.
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. Patient specimens with T3 concentrations above 7.5 ng/mL may be diluted ½ with '0' serum reference. The sample's concentration is obtained by multiplying the result by the dilution factor, 2.
10. 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.
11. 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.
12. 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.
13. 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. Total serum triiodothyronine concentration is dependent upon a multiplicity of factors: thyroid gland function and its regulation, thyroxine binding globulin (TBG) concentration, and the binding of triiodothyronine to TBG (3, 4). **Thus, total triiodothyronine concentration alone is not sufficient to assess clinical status.**
7. A decrease in total triiodothyronine values is found with protein-wasting diseases, certain liver diseases and administration of testosterone, diphenylhydantoin or salicylates. A table of interfering drugs and conditions, which affect total triiodothyronine values, has been compiled by the Journal of the American Association of Clinical Chemists[3].

13.0 EXPECTED RANGES OF VALUES

A study of euthyroid adult population was undertaken to determine expected values for the T3 AccuBind™ ELISA Test System. The mean (R) values standard deviations (σ) and expected ranges (±2 σ) are presented in Table 1. The total number of samples was 105.

TABLE I
Expected Values for the T3 ELISA Test System (in ng/ml)

Mean (X)	**1.184**
Standard Deviation (σ)	0.334
Expected Ranges (±2 σ)	0.52 – 1.85

It is important to keep in mind that establishment of a range of values which can be expected to be found by a given method for a population of "normal"-persons is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precisions of the tT3 AccuBind™ ELISA test system were determined by analyses on three different levels of pool control sera. The number (N), mean value (X), standard deviation (σ) and coefficient of variation (C.V.) for each of these control sera are presented in Table 2 and Table 3.

TABLE 2
Within Assay Precision (Values in ng/ml)

Sample	N	X	σ	C.V.
Low	16	0.78	0.06	7.9%
Normal	16	1.92	0.10	5.4%
High	16	3.55	0.14	3.9 %

TABLE 3
Between Assay Precision (Values in ng/ml)

Sample	N	X	σ	C.V.
Low	10	0.76	0.07	8.9%
Normal	10	1.85	0.13	6.7%
High	10	3.43	0.16	4.5%

*As measured in ten experiments in duplicate over a ten day period.

14.2 Sensitivity

The tT3 AccuBind™ ELISA test system has a sensitivity of 0.04 ng/ml. The sensitivity was ascertained by determining the variability of the 0 ng/ml serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose.

14.3 Accuracy

The tT3 AccuBind™ ELISA method was compared with a reference radioimmunoassay method. Biological specimens from hypothyroid, euthyroid and hyperthyroid populations were used (The values ranged from 0.15ng/ml – 8.0ng/ml). The total number of such specimens was 120. The least square regression equation (y= mx+b) and the correlation coefficient were computed for the tT3 AccuBind™ ELISA method in comparison with the reference method. The data obtained is displayed in Table 4.

TABLE 4

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
This Method	1.62	y = 3.8 + 0.947(x)	0.987
Reference	1.68		

Only slight amounts of bias between this method and the reference method are indicated by the closeness of the mean values. The least square regression equation and correlation coefficient indicates excellent method agreement.

14.4 Specificity

The cross-reactivity of the triiodothyronine antibody to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of triiodothyronine needed to displace the same amount of conjugate.

Substance	Cross Reactivity	Concentration
l-Triiodothyronine	1.0000	-
l-Thyroxine	< 0.0002	10µg/ml
Iodothyrosine	< 0.0001	10µg/ml
Diiodothyrosine	< 0.0001	10µg/ml
Diiodothyronine	< 0.0001	10µg/ml
Phenylbutazone	< 0.0001	10µg/ml
Sodium Salicylate	< 0.0001	10µg/ml

15.0 REFERENCES

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Revision: 3 **Date: 061112** **DCO: 0640**
Cat #: ***125-300***

Size		96(A)	192(B)	480(D)	960(E)
Reagent (fill)	A)	1ml set	1ml set	2ml set	2ml set x2
	B)	1 (1.5ml)	2 (1.5ml)	1 (8ml)	2 (8ml)
	C)	1 (13ml)	2 (13ml)	1(60ml)	2 (60ml)
	D)	1 plate	2 plates	5 plates	10 plates
	E)	1 (20ml)	1 (20ml)	1 (60ml)	2 (60ml)
	F)	1 (7ml)	2 (7ml)	1 (30ml)	2 (30ml)
	G)	1 (7ml)	2 (7ml)	1 (30ml)	2 (30ml)
	H)	1 (8ml)	2 (8ml)	1 (30ml)	2 (30ml)

For Orders and Inquiries, please contact

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

Tel: +1 949.951.2665 Email: info@monobind.com
Fax: +1 949.951.3539 Web: www.monobind.com

Please visit our website to learn more about our other interesting products and services.

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EC REP **CEpartner4U,** Esdoornlaan 13, 3951DB Maarn, The Netherlands www.cepartner4u.eu

Monobind Inc.
Lake Forest, CA 92630, USA

AccuBind
ELISA Microwells

Total Thyroxine (tT4) Test System
Product Code: 225-300

1.0 INTRODUCTION

Intended Use: The Quantitative Determination of Total Thyroxine Concentration in Human Serum or Plasma by a Microplate Enzyme Immunoassay

2.0 SUMMARY AND EXPLANATION OF THE TEST

Measurement of serum thyroxine concentration is generally regarded as an important *in-vitro* diagnostic test for assessing thyroid function. This importance has provided the impetus for the significant improvement in assay methodology that has occurred in the last three decades. This procedural evolution can be traced from the empirical protein bound iodine (PBI) test (1) to the theoretically sophisticated radioimmunoassay (2).

This microplate enzyme immunoassay methodology provides the technician with optimum sensitivity while requiring few technical manipulations. In this method, serum reference, patient specimen, or control is first added to a microplate well. Enzyme-T4 conjugate is added, and then the reactants are mixed. A competition reaction results between the enzyme conjugate and the native thyroxine for a limited number of antibody combining sites immobilized on the well.

After the completion of the required incubation period, the antibody bound enzyme-thyroxine conjugate is separated from the unbound enzyme-thyroxine conjugate by aspiration or decantation. The activity of the enzyme present on the surface of the well is quantitated by reaction with a suitable substrate to produce color.

The employment of several serum references of known thyroxine concentration permits construction of a graph of activity and concentration. From comparison to the dose response curve, an unknown specimen's activity can be correlated with thyroxine concentration.

3.0 PRINCIPLE

Competitive Enzyme Immunoassay (TYPE 5)
The essential reagents required for a solid phase enzyme immunoassay include immobilized antibody, enzyme-antigen conjugate and native antigen.

Upon mixing immobilized antibody, enzyme-antigen conjugate and a serum containing the native antigen, a competition reaction results between the native antigen and the enzyme-antigen conjugate for a limited number of insolubulized binding sites. The interaction is illustrated by the equation in the following below.

$$Enz_{Ag} + Ag + Ab_{C.W.} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} AgAb_{C.W.} + {}^{Enz}AgAb_{C.W.}$$

$Ab_{C.W}$ = Monospecific Immobilized Antibody (Constant Quantity)

Ag = Native Antigen (Variable Quantity)
^{Enz}Ag = Enzyme-antigen Conjugate (Constant Quantity)
$AgAb_{C.W.}$ = Antigen-Antibody Complex
$^{Enz}Ag\ Ab_{C.W.}$ = Enzyme-antigen Conjugate -Antibody Complex
k_a = Rate Constant of Association
k_{-a} = Rate Constant of Disassociation
$K = k_a / k_{-a}$ = Equilibrium Constant

After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity in the antibody-bound fraction is inversely proportional to the native antigen concentration. By utilizing several different serum references of known antigen concentration, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

4.0 REAGENTS

A. Human Serum References – 1ml/vial - Icons A-F
Six (6) vials of serum reference for thyroxine at concentrations of 0 (**A**), 2.0 (**B**), 5.0 (**C**), 10.0 (**D**), 15.0 (**E**) and 25.0 (**F**) µg/dl. Store at 2-8°C. A preservative has been added. **For SI units: µg/dl x 12.9 = nmol/L**

B. T4-Enzyme Reagent – 1.5ml/vial - Icon Ⓔ
One (1) vial of thyroxine-horseradish peroxidase (HRP) conjugate in a bovine albumin-stabilizing matrix. A preservative has been added. Store at 2-8°C.

C. T3/T4 Conjugate Buffer – 13 ml - Icon Ⓑ
One (1) bottle reagent containing buffer, red dye, preservative, and binding protein inhibitors. Store at 2-8°C.

D. T4 Antibody Coated Plate – 96 wells - Icon
One 96-well microplate coated with sheep anti-thyroxine serum and packaged in an aluminum bag with a drying agent. 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 A – 7ml/vial - Icon S^A
One (1) bottle containing tetramethylbenzidine (TMB) in buffer. Store at 2-8°C.

G. Substrate B – 7ml/vial - Icon S^B
One (1) bottle containing hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C.

H. Stop Solution – 8ml/vial - Icon STOP
One (1) bottle containing a strong acid (1.0N HCl). Store at 2-8°C.

I. Product Insert.

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. Pipette capable of delivering 25µl & 50µl volumes with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100ml and 0.350ml volumes with a precision of better than 1.5%.
3. Adjustable volume (20-200µl) and (200-1000µl) dispenser(s) for conjugate and substrate preparation
4. Microplate washer or a squeeze bottle (optional).
5. Microplate Reader with 450nm and 620nm wavelength absorbance capability.
6. Test tubes for preparation of enzyme conjugate.
7. Absorbent Paper for blotting the microplate wells.
8. Plastic wrap or microplate cover for incubation steps.
9. Vacuum aspirator (optional) for wash steps.
10. Timer.
11. Quality control materials.

5.0 PRECAUTIONS

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

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 required tests. 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 PEPARATION

The specimens shall be blood; serum or plasma in type and the usual precautions in the collection of venipuncture samples should be observed. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. 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. Allow the blood to clot for serum samples. Centrifuge the specimen to separate the serum or plasma from the cells.

Samples may be refrigerated at 2-8°C for a maximum period of five (5) 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, 0.050ml of the specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the hypothyroid, euthyroid and hyperthyroid 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. **Working Reagent A = T4-Enzyme Conjugate Solution**
   Dilute the T4-enzyme conjugate 1:11 with Total T3/T4 conjugate buffer in a suitable container. For example, dilute 160µl of conjugate with 1.6ml of buffer for 16 wells (A slight excess of solution is made). This reagent should be used within twenty-four hours for maximum performance of the assay. Store at 2-8°C.
   General Formula:
   Amount of Buffer required = Number of wells ∗ 0.1
   Quantity of T4 Enzyme necessary = # of wells ∗ 0.01
   i.e. = 16 x 0.1 = 1.6ml for Total T3/T4 conjugate buffer
   16 x 0.01 = 0.16ml (160µl) for T4 enzyme conjugate
2. **Wash Buffer**
   Dilute contents of wash concentrate to 1000ml with distilled or deionized water in a suitable storage container. Store diluted buffer at 2-30°C for up to 60 days.
3. **Working Substrate Solution**
   Pour the contents of the amber vial labeled Solution 'A' into the clear vial labeled Solution 'B'. Place the yellow cap on the clear vial for easy identification. Mix and label accordingly. Store at 2 - 8°C.

Note1 : Do not use the working substrate if it looks blue.
Note 2: 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 microplate's wells for each serum reference, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.**
2. Pipette 0.025 ml (25µl) of the appropriate serum reference, control or specimen into the assigned well.
3. Add 0.100 ml (100µl) of Working Reagent A, T4 Enzyme Reagent to all wells (see Reagent Preparation Section).
4. Swirl the microplate gently for 20-30 seconds to mix and cover.
5. Incubate 60 minutes at room temperature.
6. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.
7. Add 350µl of wash buffer (see Reagent Preparation Section), decant (tap and 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.**
8. Add 0.100 ml (100µl) of working substrate solution to all wells (see Reagent Preparation Section). **Always add reagents in the same order to minimize reaction time differences between wells.**

DO NOT SHAKE THE PLATE AFTER SUBSTRATE ADDITION

9. Incubate at room temperature for fifteen (15) minutes.
10. Add 0.050ml (50µl) of stop solution to each well and gently mix for 15-20 seconds. **Always add reagents in the same order to minimize reaction time differences between wells.**
11. 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 thirty (30) minutes of adding the stop solution.**

Note: For reassaying specimens with concentrations greater than 25 µg/dl, pipet 12.5µl of the specimen and 12.5µl of the 0 serum reference into the sample well (this maintains a uniform protein concentration). Multiply the readout value by 2 to obtain the thyroxine concentration.

10.0 CALCULATION OF RESULTS

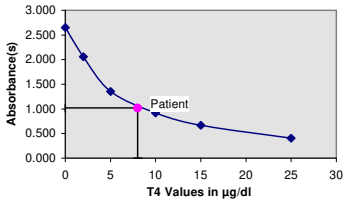
A dose response curve is used to ascertain the concentration of thyroxine in unknown specimens.
1. Record the absorbance obtained from the printout of the microplate reader as outlined in Example 1.
2. Plot the absorbance for each duplicate serum reference versus the corresponding T4 concentration in µg/dl on linear graph paper (do not average the duplicates of the serum references before plotting).
3. Connect the points with a best-fit curve.
4. To determine the concentration of T4 for an unknown, locate the average absorbance of the duplicates for each unknown on the vertical axis of the graph, find the intersecting point on the curve, and read the concentration (in µg/dl) from the horizontal axis of the graph (the duplicates of the unknown may be averaged as indicated). In the following example, the average absorbance (1.022) intersects the standard curve at (8 µg/dl) T4 concentration (See Figure 1).

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

Sample I.D.	Well Number	Abs (A)	Mean Abs (B)	Value (µg/dl)
Cal A	A1	2.648	2.650	0
	B1	2.652		
Cal B	C1	2.090	2.060	2
	D1	2.031		
Cal C	E1	1.344	1.355	5
	F1	1.366		
Cal D	G1	0.897	0.918	10
	H1	0.939		
Cal E	A2	0.676	0.668	15
	B2	0.659		
Cal F	C2	0.408	0.406	25
	D2	0.404		
Ctrl 1	E2	1.425	1.435	**4.6**
	F2	1.383		
Ctrl 2	G2	0.611	0.613	**16.3**
	H2	0.608		
Patient	A3	0.984	1.022	**8.0**
	B3	1.060		

EXAMPLE 1

Figure 1



The data presented in Example 1 and Figure 1 are for illustration only and **should not** be used in lieu of a standard curve prepared with each assay.

11.0 Q.C. PARAMETERS

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

1. The absorbance (OD) of calibrator 0 µg/dl should be ≥ 1.3.
2. Four out of six quality control pools should be within the established ranges.

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 dose response curve.
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. Patient specimens with T4 concentrations greater than 35 µg/dl may be diluted ½ with the '0' serum reference into the sample well; pipet 12.5µl of the specimen and 12.5µl of the '0' serum reference in the sample well to maintain a uniform protein concentration. The sample's concentration is obtained by multiplying the result by the dilution factor, 2.
10. 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.
11. 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.
12. 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.
13. 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.
2. Total serum thyroxine concentration is dependent upon a multiplicity of factors: thyroid gland function and its regulation, thyroxine binding globulin (TBG) concentration, and the binding of thyroxine to TBG (3, 4). **Thus, total thyroxine concentration alone is not sufficient to assess clinical status.**
3. Total serum thyroxine values may be elevated under conditions such as pregnancy or administration of oral contraceptives. A T3 uptake test may be performed to estimate the relative TBG concentration in order to determine if the elevated T4 is caused by TBG variation.
4. A decrease in total thyroxine values is found with protein-wasting diseases, certain liver diseases and administration of testosterone, diphenylhydantoin or salicylates. A table of interfering drugs and conditions, which affect total thyroxine values, has been compiled by the Journal of the American Association of Clinical Chemists.

"NOT INTENDED FOR NEWBORN SCREENING"

13.0 EXPECTED RANGES OF VALUES

A study of euthyroid adult population was undertaken to determine expected values for the tT4 AccuBind™ ELISA Test System. The mean (X) values, standard deviations (**σ**) and expected ranges (±2 **σ**) are presented in Table 1.

TABLE 1
Expected Values for the T4 ELISA Test System (in µg/dl)

	Male	Female *
Number of Specimens	42	58
Mean (X)	7.6	8.2
Std.Dev (σ)	1.6	1.7
Expected Ranges (±2 σ)	4.4 – 10.8	4.8 – 11.6

*Normal patients with high TBG levels were **not** excluded except if pregnant.

It is important to keep in mind that establishment of a range of values which can be expected to be found by a given method for a population of "normal"-persons is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precisions of the tT4 AccuBind™ ELISA test system were determined by analyses on three different levels of pool control sera. The number (N), mean values (X), standard deviation (σ) and coefficient of variation (C.V.) for each of these control sera are presented in Table 2 and Table 3.

TABLE 2
Within Assay Precision (Values in µg/dl)

Sample	N	X	σ	C.V.%
Low	20	6.87	0.16	2.3
Normal	20	9.95	0.16	1.6
High	20	13.13	0.17	1.3

TABLE 3
Between Assay Precision (Values in µg/dl)

Sample	N	X	σ	C.V.%
Low	20	5.76	0.37	6.3
Normal	20	9.41	0.57	6.1
High	20	16.18	1.21	7.5

*As measured in ten experiments in duplicate over a ten day period.

14.2 Sensitivity

The tT4 AccuBind™ ELISA test system has a sensitivity of 3.2ng/well. This is equivalent to a sample containing a concentration of 0.128 µg/dl. The sensitivity was ascertained by determining the variability of the 0 µg/dl serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose.

14.3 Accuracy

The tT4 AccuBind™ ELISA method was compared with a coated tube radioimmunoassay method. Biological specimens from hypothyroid, euthyroid and hyperthyroid populations were used (The values ranged from 0.8µg/dl – 25µg/dl). The total number of such specimens was 131. The least square regression equation and the correlation coefficient were computed for the tT4 AccuBind™ ELISA method in comparison with the reference method. The data obtained is displayed in Table 4.

TABLE 4

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
This Method	8.07	y = 0.39+0.952(x)	0.934
Reference	8.06		

Only slight amounts of bias between this method and the reference method are indicated by the closeness of the mean values. The least square regression equation and correlation coefficient indicates excellent method agreement.

14.4 Specificity

The cross-reactivity of the thyroxine antibody to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of thyroxine needed to displace the same amount of conjugate.

Substance	Cross Reactivity	Concentration
l–Thyroxine	1.0000	-
d-Thyroxine	0.9800	10µg/dl
d-Triiodothyronine	0.0150	100µg/dl
l–Triiodothyronine	0.0300	100µg/dl
Iodothyrosine	0.0001	100µg/ml
Diiodothyrosine	0.0001	100µg/ml
Diiodothyronine	0.0001	100µg/ml

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Revision: 3 **Date: 061112** **DCO: 0640**
Cat #: *225-300*

Size		96(A)	192(B)	480(D)	960(E)
Reagent (fill)	A)	1ml set	1ml set	2ml set	2ml set x2
	B)	1 (1.5ml)	2 (1.5ml)	1 (8ml)	2 (8ml)
	C)	1 (13ml)	2 (13ml)	1(60ml)	2 (60ml)
	D)	1 plate	2 plates	5 plates	10 plates
	E)	1 (20ml)	1 (20ml)	1 (60ml)	2 (60ml)
	F)	1 (7ml)	2 (7ml)	1 (30ml)	2 (30ml)
	G)	1 (7ml)	2 (7ml)	1 (30ml)	2 (30ml)
	H)	1 (8ml)	2 (8ml)	1 (30ml)	2 (30ml)

For Orders and Inquiries, please contact

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

Tel: +1 949.951.2665 Email: info@monobind.com
Fax: +1 949.951.3539 Web: www.monobind.com

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MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация, 196240

была признана соответствующей стандарту:
ISO 9001:2015

Настоящий сертификат действителен для следующей области:
ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.

Место и дата:
Москва, 21 июня 2018

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DNV GL – Business Assurance
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S. Grubine

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Представитель руководства

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Monobind Inc.
Lake Forest, CA 92630, USA

AccuBind
ELISA Microwells

Thyrotropin (TSH) Test System

Product Code: 325-300

1.0 INTRODUCTION

Intended Use: The Quantitative Determination of Thyrotropin Concentration in Human Serum by a Microplate Immunoenzymometric assay

2.0 SUMMARY AND EXPLANATION OF THE TEST

Measurement of the serum concentration of thyrotropin (TSH), a glycoprotein with a molecular weight of 28,000 Daltons and secreted from the anterior pituitary, is generally regarded as the most sensitive indicator available for the diagnosis of primary and secondary (pituitary) hypothyroidism (1, 2). The structure of human TSH is similar to that of the pituitary and placental gonadotropins, consisting of an 89-amino acid α-subunit which is similar or identical between these hormones and a 115-amino acid β-subunit, which apparently confers hormonal specificity. The production of the 2 subunits is separately regulated with apparent excess production of the α-subunit. The TSH molecule has a linear structure consisting of the protein core with carbohydrate side chains; the latter accounts for 16% of the molecular weight.

TSH measurements are equally useful in differentiating secondary and tertiary (hypothalamic) hypothyroidism from the primary thyroid disease. TSH release from the pituitary is regulated by thyrotropin releasing factor (TRH), which is secreted by the hypothalamus, and by direct action of T4 and triiodothyronine (T3), the thyroid hormones, at the pituitary. Increase levels of T3 and T4 reduces the response of the pituitary to the stimulatory effects of TRH. In secondary and tertiary hypothyroidism, concentrations of T4 are usually low and TSH levels are generally low or normal. Either pituitary TSH deficiency (secondary hypothyroidism) or insufficiency of stimulation of the pituitary by TRH (tertiary hypothyroidism) causes this. The TRH stimulation test differentiates these conditions. In secondary hypothyroidism, TSH response to TRH is blunted while a normal or delayed response is obtained in tertiary hypothyroidism.

Further, the advent of immunoenzymometric assays has provided the laboratory with sufficient sensitivity to enable the differentiating of hyperthyroidism from euthyroid population and extending the usefulness of TSH measurements. This method is a second-generation assay, which provides the means for discrimination in the hyperthyroid-euthyroid range. The functional sensitivity (<20% between assay CV) of the one-hour procedure is 0.195 µIU/ml while the two-hour procedure has a functional sensitivity of 0.095µIU/ml (3).

In this method, TSH calibrator, patient specimen or control is first added to a streptavidin coated well. Biotinylated monoclonal and enzyme labeled antibodies are added and the reactants mixed. Reaction between the various TSH antibodies and native TSH forms a sandwich complex that binds with the streptavidin coated to the well.

After the completion of the required incubation period, the antibody bound enzyme-thyrotropin conjugate is separated from the unbound enzyme-thyrotropin conjugate by aspiration or decantation. The activity of the enzyme present on the surface of the well is quantitated by reaction with a suitable substrate to produce color.

The employment of several serum references of known thyrotropin levels permits construction of a dose response curve of activity and concentration. From comparison to the dose response curve, an unknown specimen's activity can be correlated with thyrotropin concentration.

3.0 PRINCIPLE

Immunoenzymometric assay (TYPE 3):

The essential reagents required for an immunoenzymometric assay include high affinity and specificity antibodies (enzyme conjugated and immobilized), with different and distinct epitope recognition, **in excess,** and native antigen. In this procedure, the immobilization takes place during the assay at the surface of a microplate well through the interaction of streptavidin coated on the well and exogenously added biotinylated monoclonal anti-TSH antibody.

Upon mixing monoclonal biotinylated antibody, the enzyme-labeled antibody and a serum containing the native antigen, reaction results between the native antigen and the antibodies, without competition or steric hindrance, to form a soluble sandwich complex. The interaction is illustrated by the following equation:

$$Enz_{Ab\,(p)} + Ag_{TSH} + {}^{Btn}Ab_{(m)} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} Enz_{Ab(p)}\text{-}Ag_{TSH}\text{-}{}^{Btn}Ab_{(m)}$$

$^{Btn}Ab_{(m)}$ = Biotinylated Monoclonal Antibody (Excess Quantity)

Ag_{TSH} = Native Antigen (Variable Quantity)

$Enz_{Ab\,(p)}$ =Enzyme -Polyclonal Antibody (Excess Quantity)

$Enz_{Ab\,(p)}\text{-}Ag_{TSH}\text{-}{}^{Btn}Ab_{(m)}$ = Antigen-Antibodies Sandwich Complex

k_a = Rate Constant of Association

k_{-a} = Rate Constant of Dissociation

Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin and biotinylated antibody. This interaction is illustrated below:

$Enz_{Ab\,(p)}\text{-}Ag_{TSH}\text{-}{}^{Btn}Ab_{(m)}$ +$Streptavidin_{CW} \Rightarrow$ immobilized complex

$Streptavidin_{C.W.}$ = Streptavidin immobolized on well

Immobilized complex = sandwich complex bound to the well surface

After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity in the antibody-bound fraction is directly proportional to the native antigen concentration. By utilizing several different serum references of known antigen values, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

4.0 REAGENTS

Materials Provided:

A. Thyrotropin Calibrators – 1ml/vial - Icons A-G
Seven (7) vials of references for TSH Antigen at levels of 0(**A**), 0.5(**B**), 2.5(**C**), 5.0(**D**), 10(**E**), 20(**F**) and 40(**G**) µIU/ml. Store at 2-8°C. A preservative has been added.
Note: The calibrators, human serum based, were calibrated using a reference preparation, which was assayed against the WHO 2nd IRP 80/558.

B. TSH Enzyme Reagent – 13ml/vial - Icon
One (1) vial containing enzyme labeled affinity purified polyclonal goat antibody, biotinylated monoclonal mouse IgG in buffer, dye, and preservative. Store at 2-8°C.

C. Streptavidin Coated Plate – 96 wells - Icon
One 96-well microplate coated with streptavidin and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

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

E. Substrate A – 7ml/vial - Icon S^A
One (1) bottle containing tetramethylbenzidine (TMB) in buffer. Store at 2-8°C.

F. Substrate B – 7ml/vial - Icon S^B
One (1) bottle containing hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C.

G. Stop Solution – 8ml/vial - Icon STOP
One (1) bottle containing a strong acid (1N HCl). 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. Pipette(s) capable of delivering 50µl and 100µl volumes with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100ml and 0.350ml volumes with a precision of better than 1.5% (optional).
3. Microplate washer 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. Storage container for storage of wash buffer.
10. Distilled or deionized water.
11. Quality Control Materials.

5.0 PRECAUTIONS

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

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 required tests. 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.

Safe disposal of kit componenets must be according to local regulatory and statutory requirement.

6.0 SPECIMEN COLLECTION AND PREPARATION

The specimens shall be blood, serum in type, and the usual precautions in the collection of venipuncture samples should be observed. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. The blood should be collected in a plain redtop venipuncture tube without additives or gel barrier. Allow the blood to clot. Centrifuge the specimen to separate the serum from the cells.

Samples may be refrigerated at 2-8°C for a maximum period of five (5) 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, 0.100 ml of the specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the low, normal, 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. Other parameters that should be monitored include the 80, 50 and 20% intercepts of the dose response curve for run-to-run reproducibility. 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. **Wash Buffer**
   Dilute contents of wash concentrate to 1000ml with distilled or de-ionized water in a suitable storage container. Store at 2-30°C for up to 60 days.
2. **Working Substrate Solution**
   Pour the contents of the amber vial labeled Solution 'A' into the clear vial labeled Solution 'B'. Place the yellow cap on the clear vial for easy identification. Mix and label accordingly. Store at 2 - 8°C.

Note1 : Do not use the working substrate if it looks blue.
Note 2: 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 serum reference, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.**
2. Pipette 0.050 ml (50µl) of the appropriate serum reference, control or specimen into the assigned well.
3. Add 0.100 ml (100µl) of the TSH Enzyme Reagent to each well. **It is very important to dispense all reagents close to the bottom of the coated well.**
4. Swirl the microplate gently for 20-30 seconds to mix and cover.
5. Incubate 60 minutes at room temperature. **
6. Discard the contents of the microplate by decantation or aspiration. If decanting, tap and blot the plate dry with absorbent paper.
7. Add 350µl of wash buffer (see Reagent Preparation Section) decant (tap and 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.**
8. Add 0.100 ml (100µl) of working substrate solution to all wells (see Reagent Preparation Section). **Always add reagents in the same order to minimize reaction time differences between wells.**
   DO NOT SHAKE THE PLATE AFTER SUBSTRATE ADDITION
9. Incubate at room temperature for fifteen (15) minutes.
10. Add 0.050ml (50µl) of stop solution to each well and mix gently for 15-20 seconds. **Always add reagents in the same order to minimize reaction time differences between wells.**
11. 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 thirty (30) minutes of adding the stop solution.**

** For better low-end sensitivity (< 0.5µIU/ml), incubate 120 minutes at room temperature. The 40µIU/ml calibrator should be excluded since absorbance over 3.0 units will be experienced. Follow the remaining steps.

Note: Dilute samples reading over 40 µIU/ml by 1:5 and 1:10 with TSH '0' Calibrator. Multiply the results by the dilution factor to obtain accurate results.

10.0 CALCULATION OF RESULTS

A dose response curve is used to ascertain the concentration of thyrotropin in unknown specimens.

1. Record the absorbance obtained from the printout of the microplate reader as outlined in Example 1
2. Plot the absorbance for each duplicate serum reference versus the corresponding TSH concentration in µIU/ml on linear graph paper (do not average the duplicates of the serum references before plotting).
3. Draw the best-fit curve through the plotted points.
4. To determine the concentration of TSH for an unknown, locate the average absorbance of the duplicates for each unknown on the vertical axis of the graph, find the intersecting point on the curve, and read the concentration (in µIU/ml) from the horizontal axis of the graph (the duplicates of the unknown may be averaged as indicated). In the following example, the average absorbance (0.775) intersects the dose response curve at (7.66 µIU/ml) TSH concentration (See Figure 1).

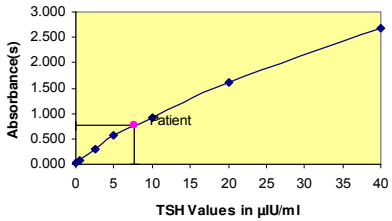
Note: Computer data reduction software designed for ELISA assay may also be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

EXAMPLE 1

Sample I.D.	Well Number	Abs	Mean Abs	Value (µIU/ml)
Cal A	A1	0.018	0.019	0
	B1	0.021		
Cal B	C1	0.076	0.079	0.5
	D1	0.082		
Cal C	E1	0.302	0.298	2.5
	F1	0.293		
Cal D	G1	0.556	0.567	5.0
	H1	0.577		
Cal E	A2	0.926	0.921	10
	B2	0.916		
Cal F	C2	1.610	1.619	20
	D2	1.629		
Cal G	E2	2.694	2671	40
	F2	2.647		
Control	G2	0.800	0.775	**7.66**
	H2	0.751		
Patient	A3	1. 391	1.383	**16.65**
	B3	1.375		

*The data presented in Example 1 and Figure 1 are for illustration only and **should not** be used in lieu of a dose response curve prepared with each assay.

Figure 1



11.0 Q.C. PARAMETERS

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

1. The absorbance of calibrator 'G' (40 µIU/ml) should be ≥ 1.3.
2. Four out of six quality control pools should be within the established ranges.

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 dose response curve.
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. 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.
10. Patient specimens with TSH concentrations over 40µIU/ml may be diluted (1:5 or 1:10) with the '0' calibrator and re-assayed. The sample's concentration is obtained by multiplying the result by the dilution factor.
11. 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.
12. 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.
13. 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. ***Measurement 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. Serum TSH concentration is dependent upon a multiplicity of factors: hypothalamus gland function, thyroid gland function, and the responsiveness of pituitary to TRH. **Thus, thyrotropin concentration alone is not sufficient to assess clinical status.**
7. Serum TSH values may be elevated by pharmacological intervention. Domperiodone, amiodazon, iodide, phenobarbital, and phenytoin have been reported to increase TSH levels.
8. A decrease in thyrotropin values has been reported with the administration of propranolol, methimazol, dopamine and d-thyroxine (4).
9. Genetic variations or degradation of intact TSH into subunits may affect the binding characteristics of the antibodies and influence the final result. Such samples normally exhibit different results among various assay systems due to the reactivity of the antibodies involved.

"NOT INTENDED FOR NEWBORN SCREENING"

13.0 EXPECTED RANGES OF VALUES

A study of euthyroid adult population was undertaken to determine expected values for the TSH AccuBind™ ELISA Test System. The number and determined range are given in Table 1. A nonparametric method (95% Percentile Estimate) was used.

TABLE I
Expected Values for the TSH ELISA Test System (in µIU/ml)

Number	139	2.5 Percentile–70% Conf Int	
Low Normal	0.39	Low Range	0.28 – 0.53
High Normal	6.16	High Range	5.60 – 6.82

It is important to keep in mind that establishment of a range of values which can be expected to be found by a given method for a population of "normal"-persons is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precisions of the TSH AccuBind™ test system were determined by analyses on three different levels of pool control sera. The number (N), mean (X) value, standard deviation **(σ)** and coefficient of variation (C.V.) for each of these control sera are presented in Table 2 and Table 3.

TABLE 2
Within Assay Precision (Values in µIU/ml)

Sample	N	X	σ	C.V.
Pool 1	24	0.37	0.03	8.1%
Pool 2	24	6.75	0.43	6.4%
Pool 3	24	29.30	1.94	6.6%

TABLE 3
Between Assay Precision* (Values in µIU/ml)

Sample	N	X	σ	C.V.
Pool 1	10	0.43	0.04	9.3%
Pool 2	10	6.80	0.54	7.9%
Pool 3	10	28.40	1.67	5.9%

*As measured in ten experiments in duplicate over seven days.

14.2 Sensitivity

The sensitivity (detection limit) was ascertained by determining the variability of the 0 µIU/ml serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose:

For I hr incubation = 0.078 µIU/ml
For 2 hr incubation = 0.027 µIU/ml

14.3 Accuracy

The TSH AccuBind™ ELISA test system was compared with a reference immunochemiluminescence assay. Biological specimens from hypothyroid, euthyroid and hyperthyroid populations were used (The values ranged from 0.01µIU/ml – 61µIU/ml). The total number of such specimens was 241. The least square regression equation and the correlation coefficient were computed for the TSH AccuBind™ ELISA method in comparison with the reference method. The data obtained is displayed in Table 4.

TABLE 4

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
This Method	4.54	y = 0.47 + 0.968 (x)	0.995
Reference	4.21		

Only slight amounts of bias between the TSH AccuBind™ ELISA method and the reference method are indicated by the closeness of the mean values. The least square regression equation and correlation coefficient indicates excellent method agreement.

14.4 Specificity

The cross-reactivity of the TSH AccuBind™ ELISA test system to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of thyrotropin needed to produce the same absorbance.

Substance	Cross Reactivity	Concentration
Thyrotropin (hTSH)	1.0000	-
Follitropin (hFSH)	< 0.0001	1000ng/ml
Lutropin Hormone (hLH)	< 0.0001	1000ng/ml
Chorionic Gonadotropin(hCG)	< 0.0001	1000ng/ml

14.5 Correlation between 1 hr and 2 hr incubation

The one- (1) hr and two (2) hr (optional) incubation procedures were compared. Thirty (30) biological specimens (ranging from 0.1 – 18.5 µIU/ml) were used The least square regression equation and the correlation coefficient were computed for the 2 hr procedure (y) in comparison with the 1 hr method (x). Excellent agreement is evidenced by the correlation coefficient, slope and intercept: Y = 0.986 (x) + 0.119 Regression Correlation =0.998

15.0 REFERENCES

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Revision: 3 **Date: 061112** **DCO: 0640**
Cat #: *325-300*

Size		96(A)	192(B)	480(D)	960(E)
Reagent (fill)	A)	1ml set	1ml set	2ml set	2ml set x2
	B)	1 (13ml)	2 (13ml)	1(60ml)	2 (60ml)
	C)	1 plate	2 plates	5 plates	10 plates
	D)	1 (20ml)	1 (20ml)	1 (60ml)	2 (60ml)
	E)	1 (7ml)	2 (7ml)	1 (30ml)	2 (30ml)
	F)	1 (7ml)	2 (7ml)	1 (30ml)	2 (30ml)
	G)	1 (8ml)	2 (8ml)	1 (30ml)	2 (30ml)

For Orders and Inquiries, please contact

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630 USA
Tel: +1 949.951.2665 Email: info@monobind.com
Fax: +1 949.951.3539 Web: www.monobind.com

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TÜV SÜD Italia

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Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
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I-64026 ROSETO DEGLI ABRUZZI (TE)

SEDE OPERATIVA:
OPERATIONAL SITE:

CONTRADA PIANE VOMANO – TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine (IAF 12, 29)

Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità /*Validity*

Dal / From: **2019-02-11**

Al / To: **2022-02-10**

Data emissione / *Issuing Date*

2019-02-11

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

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Urine Analysis with Test Strips

The use of urine test strips is acknowledged as modern screening method in medical practice. With these non-invasive tests important information on the health status of the patient is rapidly obtained. The urine sample is easily drawn and can immediately be investigated with a test strip. Thus one obtains within minutes a result, whichfacilitates the decision for further diagnostic and therapeutic action.

Only on pathological results for certain parameters, a subsequent, e.g. microscopic, examination of the urine is necessary. If the test strip result is without pathological finding and the patient is not clinically conspicuous, further time- and cost-intensive investigations, can often be avoided. This saves considerable costs for the healthcare system and spares the patient unnecessary examinations.

Urine test strips from MACHEREY-NAGEL are especially user-friendly. Due to the high resistance towards interferences by ascorbic acid, a second testing for sensitive parameters such as blood or glucose is unnecessary in most cases. The optimised, flexible shape of the test strips also allows the examination of very small amounts of urine. This is an indispensable advantage, especially in the field of pediatrics.

	Blood	Urobilinogen	Bilirubin	Protein	Nitrite	Ketone	Ascorbic Acid	Glucose	pH	Specific Gravity	Leukocytes	Kreatinin	Glutaraldehyde	Oxidisers	Microalbumines
Glucose[1)]								X							
Glucose / Keton[1)]						X		X							
Protein 2[1)]				X					X						
Ketones[1)]						X									
Microalbumines												X			X
Nitrite[1)]					X										
Urbi		X	X												
Combi 2[1)]				X				X							
Combi 3A®				X			X	X	X						
Combi 5[6/7)]	X			X			X	X	X						
Combi 5N®[6/7)]	X			X	X		X	X	X						

Combi 5S[6/7]	X			X		X		X	X						
Combi 6[6/7]	X	X		X	X			X				X			
Combi 6A[6]	X		X	X		X	X	X	X						
Combi 7[6/7]	X			X	X	X	X	X	X						
Combi 8L[6/7]	X			X	X		X	X	X	X	X				
Combi 9®[6/7]	X	X	X	X	X	X	X	X	X						
Combi 10®[6/7]	X	X	X	X	X	X	X	X	X	X					
Combi 10®L[6]	X	X	X	X	X	X	X	X	X		X				
Combi 10®SGL[6/7]	X	X	X	X	X	X		X	X	X	X				
URYXXON®Stick10[3/4/6/7]	X	X	X	X	X	X		X	X	X	X				
Test strip for veterinary applications															
Combi 10®VET[5/6/7]	X	X	X	X	X	X		X	X	X	X				
Test strip for detection of urine adulteration															
Medi-Test Adulteration Stick[5]					X				X	X		X	X	X	

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2-4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products:	Other devices (all devices except Annex II and self-testing devices)
Conformity assessment procedure:	Annex III (not including section 6).
Manufacturer:	ZAO "Vector-Best" Address: AHC, Koltsovo, Novosibirsk Region, 630559, Russia, Tel. +7 (383) 363 20 60, Fax: +7 (383) 363 35 55
European authorized representative:	Bioron GmbH, Rheinhorststr. 18, D-67071 Ludwigshafen, Germany. tel.: +49 (0) 621 5720 915, fax: +49 (0) 621 5720 916

Date: 2013/04/12

Murat Khusainov
General Director ZAO «Vector-Best»

No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep TTV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectoHSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectoHSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectoHHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectoHHV-6 - IgG	ELISA kit for determination of IgG to human herpes virus type 6	D-2166
17.	Ureaplasma urealyticum – IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum – IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis – IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

		antigens	
24.	Ascarid-IgG-EIA-BEST	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lamblia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lamblia antibodies	D-3552
26.	Lamblia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lamblia antibodies	D-3554
27.	Lamblia-antigen-EIA-BEST	ELISA kit for determination of Lamblia antigen	D-3556
28.	Helicobacter pylori-CagA-antigen-EIA-BEST	ELISA kit for determination of total antibodies to CagA Helicobacter pylori	D-3752
29.	TSH-EIA-BEST	ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST	ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST	ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST	ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST	ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST	ELISA kit for determination of IgA to Mycoplasma hominis	D-4358
36.	Mycoplasma pneumoniae-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST	ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectocrimean – CHF – IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectocrimean – CHF – IgM	ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST	ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST	ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST	ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST	ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST	ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST	ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST	ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST	ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST	ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST	ELISA kit for determination of concentration of Interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST	ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST	ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST	ELISA kit for determination of concentration of Interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST	ELISA kit for determination of concentration of Interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST	ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST	ELISA kit for determination of concentration of N-terminal prohormone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106
61.	HBsAg-EIA-BEST kit 2	ELISA kit for the detection of HBs-antigen.	D-0543
62.	HBsAg-EIA-BEST kit 3	ELISA kit for the detection of HBs-antigen.	D-0544
63.	VectoHBcAg-antibodies	ELISA kit for the detection of total antibodies against hepatitis B core-antigen	D-0566
64.	HepaBest anti-HBc-IgG	Enzyme immunoassay kit for the detection of IgG against hepatitis B core-antigen	D-0574
65.	Best anti-HCV (set 3)	Enzyme immunoassay kit for the detection of IgG and IgM against hepatitis C virus.	D-0773
66.	Best anti-HCV (set 2)	Enzyme immunoassay kit for the detection of IgG and IgM against hepatitis C virus.	D-0772
67.	Vectohep D-IgM	Enzyme immunoassay kit for the detection of IgM against hepatitis D virus	D-0952
68.	Chlamydia tr. IgG-EIA-BEST	ELISA kit for determination of IgG to Chlamidia trachomatis	D-1964
69.	Chlamydia tr. IgM-EIA-BEST	ELISA kit for determination of IgM to Chlamidia trachomatis	D-1966
70.	Chlamydia tr. IgA-EIA-BEST	ELISA kit for determination of IgA to Chlamidia trachomatis	D-1968
71.	CMV-IgG-EIA-BEST	ELISA kit for the qualitative and quantitative determination of IgG against Cytomegalovirus	D-1556
72.	VectoCMV-IgM	ELISA kit for the detection of IgM against Cytomegalovirus	D-1552

ООО "Медиклон"

МЕДИКЛОН
127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон анти А во флаконах по 10 мл с красными крышками

Серия: 005708 **Единица:** 100 мл.

Изготовлен: 10.08.2020 **Количество единиц:** 1

Годен до: 10.08.2022 **Объем серии:** 10000 мл.

Паспорт: А005708 от 10.08.2020

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1. Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2. Цоликлон анти-В	Прозрачная жидкость синего цвета	
1.3. Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства:		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1:64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1:64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая
ОТК ООО "Медиклон" К.В. Ющенко

ООО "Медиклон"
МЕДИКЛОН
127276 Москва, Ботаническая ул, 35 , т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А 1 и Анти-А сл)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон анти А1

Серия: 309609 **Единица:** 100 мл.

Изготовлен: 14.09.2020 **Количество единиц:** 1

Годен до: 14.09.2022 . **Объем серии:** 10000 мл.

Паспорт: А1309609 от 14.09.2020

Наименование показателя	Характеристика нормы	Результаты испытаний
1. Внешний вид :		
1.1 Цоликлон анти-А1	Прозрачная жидкость бежевого цвета	Соответствует
1.2 Цоликлон анти-Ас1	Прозрачная жидкость малинового цвета	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А1 не должен давать агглютинацию с эритроцитами групп А2(II) , B(III) , A2B(IV) и O(I)	Соответствует
	Цоликлон анти-Ас1 не должен давать агглютинации с эритроцитами групп B(III) и O(I)	
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов группы А(II) с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
2.3 Титр	Титр Цоликлона А1 в прямой реакции агглютинации на плоскости с эритроцитами А1 на плоскости 1:64	Соответствует
	Титр Цоликлона Ас1 в прямой реакции агглютинации на плоскости с эритроцитами А1 на плоскости 1:64 . А2(II) – 1:32	
3. Добавки	ЭДТА, БСА, Глицин	

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» ОТК М.С.Орлова

ООО "Медиклон"

МЕДИКЛОН
127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон анти АВ

Серия: 204008 **Единица:** 100 мл.

Изготовлен: 24.08.2020 **Количество единиц:** 1

Годен до: 24.08.2022 **Объем серии:** 10000 мл.

Паспорт: АВ204008 от 24.08.2020

Наименование показателя	Норма по ТУ	Результаты испытаний
Внешний вид Цоликлон анти-А Цоликлон анти-В Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
Серологическая специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
Агглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1:64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1:64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая
лабораторией ООО «Медиклон» К.В. Ющенко

ООО "Медиклон"

МЕДИКЛОН
127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон анти В во флаконах по 10 мл с синими крышками

Серия: 005608 **Единица:** 100 мл.

Изготовлен: 10.08.2020 **Количество единиц:** 1

Годен до: 10.08.2022 **Объем серии:** 10000 мл.

Паспорт: В005608 от 10.08.2020

Наименование показателя	Норма по ТУ	Результаты испытаний
Внешний вид 1. Цоликлон анти-А 2. Цоликлон анти-В 3. Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
Серологические свойства: 1. Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1:64 Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:32 - 1:64 Соответствует 1:64 Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» К.В. Ющенко

ООО "Медиклон"

МЕДИКЛОН
121276 Москва, Ботаническая ул., 35, т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-D Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон анти D супер во флаконах по 10 мл с зелеными крышками

Серия: 200508

Изготовлен: 03.08.2020

Годен до: 03.08.2022

Паспорт: Дс200508 от 03.08.2020

Единица: 100 мл.

Количество единиц: 1

Объем серии: 10000 мл.

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(–) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами	Соответствует 30 сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроци-тами в микроплате не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Начальник ОТК ООО «Медиклон»

Медиклон ОТК

Ющенко К.В.

ООО "Медиклон"

МЕДИКЛОН

127486 Москва, Ботаническая ул., 35 , т./ф (495) 231-2272 (499) 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-Kell Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон анти Kell супер

Серия: 109906

Изготовлен: 29.06.2020

Годен до: 29.06.2022.

Паспорт: К109906 от 29.06.2020

Единица: 100 мл.

Количество единиц: 1

Объем серии: 10000 мл.

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1.Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты К(-)	Соответствует
2.2 Гематагглютинирующая способность	Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микропланте не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

Федеральное агентство по техническому регулированию и метрологии

НОПСС

Система добровольной сертификации "НОПСС". РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

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СЕРТИФИКАТ СООТВЕТСТВИЯ

выдан

Общество с ограниченной ответственностью «МиниМед»

ИНН 3234007127 / ОГРН 1023202138332

241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

Подтверждает что система менеджмента качества соответствует требованиям ГОСТ ISO 9001-2015 (ISO 9001:2015)

При осуществлении работ согласно приложению №1 к настоящему сертификату

Сертификат выдан на основании решения экспертной комиссии

от 24.09.2018

Срок действия до 24 сентября 2021

Номер в едином реестре системы С1256

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «НОПСС» РОСС RU.31827.04ЖСН1

Руководитель органа по сертификации: **Подпись** _____ **Платонов Б.А.**

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Федеральное агентство по техническому регулированию и метрологии

НОПСС

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ПРИЛОЖЕНИЕ №1

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НОПСС

Руководитель органа по сертификации: Подпись _____ Платонов Б.А.

НОПСС СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ