



Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Monobind Inc.

**100 North Pointe Drive
Lake Forest, CA 92630
USA**

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

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

**Additional sites covered under this multi-site certification are listed on the
Annex (File No. MD19.4585)**

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.4585
Certification Granted: May 18, 2010
Effective Date: September 25, 2019
Expiry Date: September 24, 2022





NSAI

Annex to Certificate Number: MD19.4585

Scope of Registration:

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

Activity

Location

Headquarters, Administration,
Design, Manufacturing,
Distribution

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA
File No.: MD19.4585

Manufacturing, Distribution

Monobind Inc.
103 North Pointe Drive
Lake Forest, CA 92630
USA
File No.: MD19.4585/A

**Verified by:
Operations Manager**



NSAI

Quality System Approval Certificate

In Vitro Diagnostic Medical Devices Directive 98/79/EC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(In Vitro Diagnostics Medical Devices) Regulations (S.I. No. 304 of 2001)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Monobind Inc.

**100 North Pointe Drive
Lake Forest
CA 92630
USA**

For the Product Family

**Total and Free Prostate Specific Antigen (PSA and Free PSA) IVD,
kit, chemiluminescent immunoassay (CLIA) and enzyme
immunoassay (ELISA) and control.**

GMDN Code: 54664, 54669

*On the basis of examination under the requirements of Annex IV, Section 3 of Directive 98/79/EC,
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product is hereby authorized.*

Registration Number:	304.1006
Original Approval:	28 October 2011
Last Amended on:	25 August 2021
Remains valid until:	12 July 2023

Signed:

(Signature of Dr. Caroline Dore Geraghty)
Approved by
Dr Caroline Dore Geraghty
Director, Medical Devices

(Signature of Dr. Elaine Darcy)
Approved by
Dr Elaine Darcy
European Medical Device Operations
Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI**

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.



DECLARATION OF CONFORMITY

Product Family TOTAL AND FREE PROSTATE SPECIFIC ANTIGEN (PSA and FPSA)

Specific Product Details						
Product Description	Item # ELISA	Item # CLIA	EDMS Code	GMDN ELISA Code	GMDN CLIA Code	Risk Class
Total PSA Test System	2125-300A 2125-300B	2175-300A 2175-300B	12.03.01.32.00	54664	54665	High/ List B
Total PSA Extra Sensitive Test System	8725-300A 8725-300B	8775-300A 8775-300B	12.03.01.32.00	54664	54665	High/ List B
Free PSA Test System	2325-300A 2325-300B	2375-300A 2375-300B	12.03.01.33.00	54668	54669	High/ List B
Cancer VAST Test System	8425-300B 8425-300D 8425-300E	8475-300B 8475-300D 8475-300E	12.03.01.32.00	54664	54665	High/ List B
Multi Ligand Control	ML-300B	ML-300B	12.03.01.32.00	38207	38207	High/ List B

Manufacturer

Name Monobind Inc.
Address 100 North Pointe, Lake Forest, CA 92630
Country United States

Representative

Name CEpartner4U BV,
Address Esdoornlaan 13, 3951DB Maarn
Country The Netherlands
Telephone +31 (0)6 – 516.536.26

Notified Body

Name NSAI
Body ID Number 0050
CE Cert # 304.1006
Registration # NL-CA002-2011-23306

Means of Conformity

Monobind Inc. declares that the product listed is in conformity with the Annex IV, IVD Type List B essential requirements and provisions of Council Directive: 98/79/EC

And is in conformance with the following standards:

EN 13612:2002	EN 15223-1:2016	EN ISO 14971:2019
EN ISO 18113:2011	EN 13641:2002	EN ISO 23640:2015
Under the principles of	EN ISO 13485:2016	

Signature

Place and effective date

Monobind Inc.

January 30, 2021 revision 04

Signature

Name

Tony Shatola

Title

QA Director

DECLARATION OF CONFORMITY

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

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

and

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

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

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

Immunoassay products;

AccuBind® ELISA,

AccuLite® CLIA,

QSure® Control,

Instruments

see appendix

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

<u>Document No.</u>	<u>Title</u>
98/79/EC	<i>In vitro</i> Diagnostic Medical Devices Directive

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

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

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

Lake Forest, USA; 2021-09-20



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

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

Appendix

Date: 2021-09-20

List of devices.

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

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

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

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

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru- ment	EDMS code	Risk Class	First date of CE-marking
	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triiodothyronine (tT3) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E			12.04.01.01.00	Low	2005-11-11
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E			12.04.01.01.00	Low	2010-06-29

Miscellaneous Controls							
Anti-H. Pylori Control (IgA, IgG, IgM) – Positive & Negative			HPC-300		12.50.01.16.00	Low	2013-09-16
Anti-Tg & Anti-TPO Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level			MC-300		12.50.01.16.00	Low	2010-06-29
TBG Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Tg Control – Tri-Level			TG-300		12.50.01.16.00	Low	2010-06-29
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level			TMC-300		12.50.01.16.00	Low	2013-09-16

Miscellaneous Instruments							
Autoplex® ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex® G2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Autoplex® G3 ELISA & CLIA Analyzer				IN006-3	21.02.10.01	Low	2017-07-05
NeoEldex® ELISA Analyzer				IN009	21.02.10.01	Low	2011-09-26
Impulse® 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
NeoLumax® CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26
LuMatic® CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
PrisMatic® ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
PlateWash - Immunoassay Washer				IN002	21.02.10.01	Low	2010-06-29
TITIN® ELISA & CLIA Analyzer				IN015-EC	21.02.10.01	Low	2017-07-05
TITIN® ELISA Analyzer				IN015-E	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA & CLIA Analyzer				IN016-EC	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA Analyzer				IN016-E	21.02.10.01	Low	2017-07-05



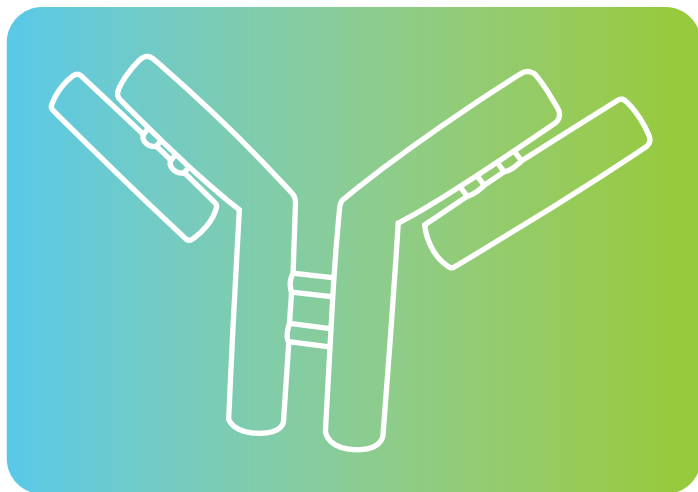
Attachment to Certificate 304.1006 dated 28 October 2011

This Certificate covers 9 model(s)

Model Reference	Detail
PSA/ 2125-300	Total PSA by ELISA Method
PSA/ 2175-300	Total PSA by CLIA Method
PSA XS/ 8725-300	Total PSA by ELISA Method
PSA XS/ 8775-300	Total PSA by CLIA Method
Free PSA/ 2325-300	Free PSA by ELISA Method
Free PSA/ 2375-300	Free PSA by CLIA Method
Cancer Marker VAST/ 8425-300	Total PSA by ELISA Method (in combo calibrator)
Cancer Marker VAST/ 8475-300	Total PSA by CLIA Method (in combo calibrator)
Quality Control/ ML-300A and B	Quality Control Containing Total PSA and Free PSA

Product Catalog | 2019-2020

Immunoassays, Controls & Equipment



VAST 
Versatile Analyte Selection Technology

AccuBind 
ELISA Microwells

AccuLite 
CLIA Microwells



Message from Monobind's president:



Dr. Frederick R. Jerome, CEO

Since its inception in 1978, Monobind, an ISO 13485 certified company, has pioneered in providing diagnostic tools to healthcare professionals at affordable prices. The expertise acquired through years of hard work has allowed Monobind significant immunoassay market penetration. With a distributor network spanning established and emerging worldwide markets in 110+ countries, Monobind looks forward to an even brighter future. As a global brand and leading manufacturer, our company is a major player in the field of diagnostic immunoassay systems.

Monobind's success can be attributed to the high quality and user friendliness of our product line. Customer care and quality consciousness are the hallmarks of Monobind. Close connections with universities and reference labs allow Monobind to provide the technical support to launch new projects in reduced time frames. Our experience in producing quality raw materials, for our own use and for other diagnostic manufacturers, delivers a sustainable competitive advantage built from cost-efficiency. Monobind's history

reveals a commitment to R&D and an impressive record of innovation in basic diagnostic techniques. Our products have helped transform the diagnostic practices from science to art by enabling improved, reliable patient care at an affordable cost.

In recent years, Monobind has integrated its systems to harmonize communications and work between R&D, QC, Manufacturing and Administration. We make continual improvements and have put substantial investment into our website to allow customers to access their account 24 x 7. Customers can go online to place orders, check order status, and view their account history and statements. Monobind's focus and dedication, as well as the market's growing demand for our product line make our many innovations possible.

This includes our totally unique, VAST® immunoassay product line which uses combination calibrators to support detection of multiple analytes in just one kit. VAST® is available in ELISA and CLIA for Anemia, Cancer, Diabetes, Fertility, Prenatal and Thyroid Panels with more to come in the future..

Monobind works with leading automated and semi-automated instrument makers to customize equipment for our AccuBind® ELISA and AccuLite CLIA® products. Monobind offers analyzers for both products, including NeoEldex®, PrisMatic®, Impulse®, NeoLumax®, Autoplex®, TITIN® as well as Plate Wash. With TITN, we introduce a larger format automated analyzer with two-reaction plates for ELISA and CLIA assays. Additionally, we provide 100s of applications for existing instrumentation from such companies as Awareness Technology, Gold Standard Diagnostics and Dynex. We thank our partners for their collaboration and support, which has allowed our positioning to meet the needs of small-to-large volume testing in clinical labs.

Finally, I wish to thank our customers and distributors for their support and dedication. Their efforts have resulted in Monobind brand recognition in the highly competitive, global immunoassay market. This would not be possible without Monobind's team of skilled professionals who provide the fundamental base for our market success. With our rigorous pursuit of excellence and new product development, Monobind is building a robust future in the biomedical field. We hope to share this vision with you.

Dr. Frederick R. Jerome
CEO





FDA Registered – ISO 13485 Certified –



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"Monobind Inc. manufactures 125+ enzyme-based immunoassay kits. We create these completely in-house from R&D and product design, to reagent and automated production." Dr. Rick Jerome, CEO

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VAST

ELISA & CLIA Kits

A diagnostic first – VAST combination calibrators – deliver the greatest flexibility in assay performance. Labs can measure one (of up to four) analytes per well in a universal plate. Kits available in 192 packs size (as well as 96 for diabetes and prenatal).

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Monobind Immunoassay Benefits

» Product Stability

Our **thermal stability** allows for short-term (<3 days) transit in temperatures of up to 37°C, which is critical for tropical climates and worldwide distribution. The product's shelf life is at least one year from shipment, given that it's stored at 2-8°C after receipt. To ensure stability against a number of adverse conditions, Monobind performs sophisticated **stress testing** on all finished product lots and will not release goods until minimum thresholds are met.

» Ease of Use

Designed as simple and innovative, Monobind's diagnostic assays enable users to quickly reach reliable results. We utilize **color coding/packaging** to differentiate our products and steps, **liquid reagents** to omit reconstitution, **uniform-testing** procedures and common reagents with many products, and incorporate other leading-edge technologies such as multi-purpose **streptavidin plates** to deliver user and automation-friendly, quality assays.

» Cost

Unique among the industry, Monobind **manufactures all essential ingredients** in-house to ensure consistent quality while lowering its cost of goods. A completely **advanced automation system** further reduces cost by increasing production efficiency.

» Quality

By using **state-of-the-art packaging** such as thermal ID on every product piece and innovative color-coded labeling, we produce an attractive, easy to use assay that's second to none. Our **leading edge assay design** backed by substantial, ongoing R&D efforts represents our fundamental commitment to delivering best-in-class products.

» ELISA & CLIA Comparison

Item	AccuBind® ELISA Microwells	AccuLite® CLIA Microwells
Incubation Time	Typical assay times 60 + 15 120 + 15	Typical assay times 45 + 5 60 + 5
Sensitivity	Detection of analyte concentration for TSH 0.025 µIU/ml	Detection of analyte concentration for TSH 0.01 µIU/ml
Dynamic Range	Maximum OD of readers limited to 2.5 - 3.0	Up to 10x greater signal detection than ELISA
Procedure	Consistent steps that fit MB Assays Types (1-8) Classification	Consistent steps that fit MB Assays Types (1-8) Classification
Marketability	Proven technology	State-of-the-art technology may command higher price and reimbursement from government programs
Safety	No radioactive or toxic waste	No radioactive or toxic waste
Shelf Life	Up to 18 Months (12 Guaranteed)	Up to 18 Months (12 Guaranteed)
Reading	450 nm with 620 nm	RLUs

ALLERGY & ANEMIA

IgE	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	IgE (Cat #)	2525-300A (96 wells)	2575-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 5, 25, 50, 150, 400 IU/ml 2nd (IRP 75/502)	0, 5, 25, 50, 150, 400 IU/ml 2nd (IRP 75/502)
	Sample	25 µl	25 µl
	Sensitivity	0.125 IU/ml	0.023 IU/ml
	Total Assay Time	75 min	65 min

Ferritin	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	Ferritin (Cat #)	2825-300A (96 wells)	2875-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 10, 50, 150, 400, 800 ng/ml (3rd IS 94/572)	0, 10, 50, 150, 400, 800 ng/ml (3rd IS 94/572)
	Sample	25 µl	25 µl
	Sensitivity	0.17 ng/ml	0.011 ng/ml
	Total Assay Time	75 min	65 min

Folate	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	Folate (Cat #)	7525-300A (96 wells)	7575-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 1, 2.5, 5, 10, 25 ng/ml	0, 1, 2.5, 5, 10, 25 ng/ml
	Sample	50 µl	50 µl
	Sensitivity	0.52 ng/ml	0.234 ng/ml
	Total Assay Time	65 min	50 min

sTfR	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	Soluble Transferrin Receptor (Cat #)	8625-300A (96 wells)	8675-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 3, 10, 20, 40, 80 nmol/L	0, 3, 10, 20, 40, 80 nmol/L
	Sample	10 µl	10 µl
	Sensitivity	0.055 nmol/ml	0.046 nmol/L
	Total Assay Time	90 min	65 min

Vit B12	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	Vitamin B12 (Cat #)	7625-300A (96 wells)	7675-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Competitive	Competitive
	Calibrators	0, 100, 200, 400, 1000, 2000 pg/ml	0, 100, 200, 400, 1000, 2000 pg/ml
	Sample	50 µl	50 µl
	Sensitivity	70.13 pg/ml	37.92 pg/ml
	Total Assay Time	95 min	80 min

AUTOIMMUNE THYROID



Anti-Tg	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item			
	Anti-Tg (Cat #)	1025-300A (96 wells)		1075-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay		Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 50, 125, 500, 1000, 2000 - IU/ml (IRP 65/93)		0, 50, 125, 500, 1000, 2000 IU/ml (IRP 65/93)
	Sample	50 µl (1:100 Dilution)		50 µl (1:100 Dilution)
	Sensitivity	1.94 IU/ml		1.95 IU/ml
Anti-TPO	Total Assay Time	105 min		65 min
	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item			
	Anti-TPO (Cat #)	1125-300A (96 wells)		1175-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay		Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 25, 50, 100, 250, 500 IU/ml - (IS 66/387)		0, 25, 50, 100, 250, 500 IU/ml (IS 66/387)
	Sample	25 µl (1:100 Dilution)		25 µl (1:100 Dilution)
	Sensitivity	0.92 IU/ml		1.0 IU/ml
	Total Assay Time	105 min		65 min

BONE METABOLISM

Calcitonin	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item			
	Calcitonin (Cat #)	9325-300A (96 wells)		9375-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Sandwich Assay, Antibody-Coated Plate		Sandwich Assay, Antibody-Coated Plate
	Calibrators	0, 10, 40, 150, 400, 1000 pg/ml		0, 10, 40, 150, 400, 1000 pg/ml
	Sample	50 µl		50 µl
	Sensitivity	4.4871 pg/ml		4.4871 pg/ml
PTH Intact	Total Assay Time	80 min		50 min
	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item			
	PTH (Cat #)	9025-300A (96 wells)		9075-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Sandwich Assay, Antibody-Coated Plate		Sandwich Assay, Antibody-Coated Plate
	Calibrators	0, 15, 75, 150, 500, 1000 pg/ml		0, 15, 75, 150, 500, 1000 pg/ml
	Sample	50 µl		50 µl
	Sensitivity	LoB/ LoD 1.39/ 1.50 pg/ml		LoB/ LoD 1.39/ 1.50 pg/ml
	Total Assay Time	80 min		50 min
	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item			
	PTH (Cat #)	10025-300A (96 wells)		10075-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Sandwich Assay, Antibody-Coated Plate		Sandwich Assay, Antibody-Coated Plate
	Calibrators	0, 15, 75, 150, 500, 1000 pg/ml		0, 15, 75, 150, 500, 1000 pg/ml
	Sample	50 µl		50 µl
	Sensitivity	LoB/ LoD 1.49/ 1.93 pg/ml		LoB/ LoD 1.49/ 1.93 pg/ml
PTH Whole & Intact	Total Assay Time	80-95 min (depending on Gen 2/3)		50-65 min (depending Gen2/3)
	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item			
	Vit D Direct (Cat #)	9425-300A (96 wells) 9425-300B (192 wells)		9475-300A (96 wells) 9475-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Competitive Assay, Antibody-Coated Plate		Competitive Assay, Antibody-Coated Plate
Vitamin D Direct	Calibrators	0, 5, 10, 25, 46, 85, 150 ng/ml		0, 5, 10, 25, 46, 85, 150 ng/ml
	Sample	25 µl		25 µl
	Sensitivity	1.14 ng/ml		0.517 ng/ml
	Total Assay Time	80 min		60 min

CANCER MARKERS

AFP	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	AFP (Cat #)	1925-300A (96 wells) 1925-300B (192 wells)	1975-300A (96 wells) 1975-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0 , 5, 25, 50, 250, 500 ng/ml (IRP 72/225) 25 µl 0.44 ng/ml 75 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0 , 5, 25, 50, 250, 500 ng/ml (IRP 72/225) 25 µl 0.134 ng/ml 50 min

CA15-3	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	CA 15-3 (Cat#)	5625-300A (96 wells) 5625-300B (192 wells)	5675-300A (96 wells) 5675-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay 0 , 10, 40, 100, 200, 400 U/ml 25 µl 0.2 U/ml 140 min	Enzyme Immunoassay, Chemiluminescence Competitive Assay 0 , 10, 40, 100, 200, 400 U/ml 25 µl 0.2 U/ml 95 min

CA 19-9	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	CA-19-9 (Cat #)	3925-300A (96 wells) 3925-300B (192 wells)	3975-300A (96 wells) 3975-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 10, 50, 100, 250, 500 U/ml 25 µl 1.0 U/ml 135 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 10, 50, 100, 250, 500 U/ml 25 µl 0.04 U/ml 80 min

CA 125	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	CA-125 (Cat #)	3025-300A (96 wells) 3025-300B (192 wells)	3075-300A (96 wells) 3075-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 15, 50, 100, 200, 400 U/ml 25 µl 1.0 U/ml 75 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 15, 50, 100, 200, 400 U/ml 25 µl 0.11 U/ml 50 min

CEA	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	CEA (Cat #)	1825-300A (96 wells) 1825-300B (192 wells)	1875-300A (96 wells) 1875-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0 , 5, 10, 25, 50, 250 ng/ml (IRP 73/601) 25 µl 1.0 ng/ml 75 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0 , 5, 10, 25, 50, 250 ng/ml (IRP 73/601) 25 µl 0.5 ng/ml 50 min



CEA Next Gen	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	CEA Next Gen (Cat #)	4625-300A (96 wells) 4625-300B (192 wells)	4675-300A (96 wells) 4675-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 5, 10, 25, 100, 250 ng/ml (IRP 73/601)	0, 5, 10, 25, 100, 250 ng/ml (IRP 73/601)
	Sample	25 µl	25 µl
	Sensitivity	1.0 ng/ml	0.063 ng/ml
	Total Assay Time	75 min	50 min

fβhCG	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	Free β-hCG (Cat #)	2025-300A (96 wells)	2075-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 5, 10, 25, 100, 250 ng/ml (IRP 75/551)	0, 5, 10, 25, 100, 250 ng/ml (IRP 75/551)
	Sample	25 µl	25 µl
	Sensitivity	0.026 ng/ml	0.00314 ng/ml
	Total Assay Time	60 min	50 min

PSA	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	PSA (Cat #)	2125-300A (96 wells) 2125-300B (192 wells)	2175-300A (96 wells) 2175-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 5, 10, 25, 50, 100 ng/ml 1st (IS 96/670)	0, 5, 10, 25, 50, 100 ng/ml (IS 96/670)
	Sample	25 µl	25 µl
	Sensitivity	0.013 ng/ml	0.006 ng/ml
	Total Assay Time	45 min	35 min

PSA Extra Sensitive	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	PSA XS (Cat #)	8725-300A (96 wells) 8725-300B (192 wells)	8775-300A (96 wells) 8775-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 1, 2.5, 5, 10, 25 ng/ml (IS 96/670)	0, 1, 2.5, 5, 10, 25 ng/ml (IS 96/670)
	Sample	25 µl	25 µl
	Sensitivity	4.72 pg/ml	1.1 pg/ml
	Total Assay Time	45 min	35 min

fPSA	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	fPSA (Cat #)	2325-300A (96 wells) 2325-300B (192 wells)	2375-300A (96 wells) 2375-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 0.5, 1, 2.5, 5, 10 ng/ml (1st IS 96/668)	0, 0.5, 1, 2.5, 5, 10 ng/ml (1st IS 96/668)
	Sample	50 µl	50 µl
	Sensitivity	0.008 ng/ml	0.015 ng/ml
	Total Assay Time	75 min	50 min

CARDIAC MARKERS

CKMB	Item	 ELISA Microwells	 CLIA Microwells
	CK-MB (Cat #)	2925-300A (96 wells) 2925-300B (192 wells)	2975-300A (96 wells) 2975-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0 , 5, 25, 100, 200, 400 ng/ml 25 µl 0.182 ng/ml 30 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0 , 5, 25, 100, 200, 400 ng/ml 25 µl 0.5 ng/ml 20 min

Digoxin	Item	 ELISA Microwells	 CLIA Microwells
	Digoxin (Cat #)	925-300A (96 wells)	975-300A (96 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay 0, 0.25, 0.5, 1, 2, 4 ng/ml 25 µl 0.072 ng/ml 45 min	Enzyme Immunoassay, Chemiluminescence Competitive Assay 0, 0.25, 0.5, 1, 2, 4 ng/ml 25 µl 0.169 ng/ml 35 min

HS-CRP	Item	 ELISA Microwells	 CLIA Microwells
	HS-CRP (Cat #)	3125-300A (96 wells)	3175-300A (96 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 0.5, 2.0, 5, 15, 30 µg/ml (CRM-470) 25 µl 0.014 µg/ml 30 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 0.5, 2.0, 5, 15, 30 µg/ml (CRM-470) 25 µl 0.007 µg/ml 20 min

Myoglobin	Item	 ELISA Microwells	 CLIA Microwells
	Myoglobin (Cat #)	3225-300A (96 wells) 3225-300B (192 wells)	3275-300A (96 wells) 3275-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 10, 25, 50, 150, 400 ng/ml 25 µl 0.178 ng/ml 30 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 10, 25, 50, 150, 400 ng/ml 25 µl 0.03 ng/ml 20 min

cTnl	Item	 ELISA Microwells	 CLIA Microwells
	cTnl (Cat #)	3825-300A (96 wells) 3825-300B (192 wells)	3875-300A (96 wells) 3875-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Sandwich Assay, Antibody-Coated Plate 0, 0.4, 1.25, 2.5, 7.5, 20 ng/ml 25 µl LoB/ LoD 0.0639/ 0.0759 ng/ml 30 min	Enzyme Immunoassay, Chemiluminescence Sandwich Assay, Antibody-Coated Plate 0, 0.4, 1.25, 2.5, 7.5, 20 ng/ml 25 µl LoB 0.0304/ LoD 0.0853 ng/ml 20 min



ACTH	AccuBind [®] ELISA Microwells		AccuLite [®] CLIA Microwells	
	Item			
	Insulin (Cat #)	10625-300A (96 wells)	10675-300A (96 wells)	
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence	
	Principle	Sandwich Assay, Antibody-Coated Plate	Sandwich Assay, Antibody-Coated Plate	
	Calibrators	0, 20, 100, 250, 750, 2000 pg/ml	0, 20, 100, 250, 750, 2000 pg/ml	
	Sample	50 µl	50 µl	
	Sensitivity	LoB/ LoD 0.054/ 0.095 pg/ml	LoB/ LoD 0.054/ 0.095 pg/ml	
Aldosterone	Total Assay Time	80 min	50 min	
	AccuBind [®] ELISA Microwells		AccuLite [®] CLIA Microwells	
	Item			
	Insulin (Cat #)	10125-300A (96 wells)	10175-300A (96 wells)	
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence	
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay	
	Calibrators	0, 25, 125, 250, 500, 1500 pg/ml	0, 25, 125, 250, 500, 1500 pg/ml	
	Sample	25 µl	25 µl	
	Sensitivity	LoB/ LoD 14.39/ 22.18 pg/ml	LoB/ LoD 15.36/ 19.65 pg/ml	
	Total Assay Time	80 min	65 min	

DIABETES

C-Peptide	AccuBind [®] ELISA Microwells		AccuLite [®] CLIA Microwells	
	Item			
	C-Peptide(Cat #)	2725-300A (96 wells) 2725-300B (192 wells)	2775-300A (96 wells) 2775-300B (192 wells)	
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence	
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay	
	Calibrators	0, 0.2, 1, 2, 5, 10 ng/ml 1st (IRP 84/510)	0, 0.2, 1, 2, 5, 10 ng/ml 1ST (IRR 84/510)	
	Sample	50 µl	50 µl	
	Sensitivity	0.020 ng/ml	0.012 ng/ml	
Insulin	Total Assay Time	135 min	65 min	
	AccuBind [®] ELISA Microwells		AccuLite [®] CLIA Microwells	
	Item			
	Insulin (Cat #)	2425-300A (96 wells)	2475-300A (96 wells)	
	Rapid Insulin*	2425-300B (192 wells) 5825-300A* (96 wells)	2475-300B (192 wells)	
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence	
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay	
	Calibrators	0, 5, 25, 50, 100, 300 µIU/ml 1st (IRP 66/304)	0, 5, 25, 50, 100, 300 µIU/ml 1st (IRP 66/304)	
	Sample	50 µl	50 µl	
	Sensitivity	0.182 µIU/ml 0.75 µIU/ml*	0.114 µIU/ml	
	Total Assay Time	135 min 75 min*	65 min	

FERTILITY

AMH	AccuBind [®] ELISA Microwells		AccuLite [®] CLIA Microwells	
	Item			
	hCG (Cat #)	9725-300A (96 wells)	9775-300A (96 wells)	
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence	
	Principle	Competitive Assay, Antibody-Coated Plate	Competitive Assay, Antibody-Coated Plate	
	Calibrators	0, 0.2, 0.5, 1.0, 5, 15 ng/ml	0, 0.2, 0.5, 1.0, 5, 15 ng/ml	
	Sample	50 µl	50 µl	
	Sensitivity	LoB/ LoD 0.024/ 0.045 ng/ml	LoB/ LoD 0.0069/ 0.035 ng/ml	
	Total Assay Time	80 min	65 min	

FERTILITY cont.

hCG	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	hCG (Cat #)	825-300A (96 wells) 825-300B (192 wells)	875-300A (96 wells) 875-300B (192 wells)
hCG Extended Range	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 5, 25, 50, 100, 250 mIU/ml (3rd IS 75/537) 25 µl 0.102 mIU/ml 75 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 5, 25, 50, 100, 250 mIU/ml (3rd IS 75/537) 25 µl 0.016 mIU/ml 50 min
	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
hCG Extended Range	hCG XR (Cat #)	8825-300A (96 wells) 8825-300B (192 wells)	8875-300A (96 wells) 8875-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 5, 25, 100, 250, 1,000 mIU/ml (3rd IS 75/537) 25 µl 0.332 mIU/ml 35 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 5, 25, 100, 250, 1,000 mIU/ml (3rd IS 75/537) 25 µl 0.182 mIU/ml 25 min
Rapid hCG	Item	AccuBind [®] ELISA Microwells	
	RhCG (Cat #)	3325-300A (96 wells) 3325-300B (192 wells)	
Rapid hCG	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 25, 50, 100, 250 mIU/ml (3rd IS 75/537) 25 µl 2.5 mIU/ml 15 min	
	Item	AccuBind [®] ELISA Microwells	
FSH	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	FSH (Cat #)	425-300A (96 wells) 425-300B (192 wells)	475-300A (96 wells) 475-300B (192 wells)
FSH	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 5, 10, 25, 50, 100 mIU/ml (2nd IRP 78/549) 50 µl 0.134 mIU/ml 75 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 5, 10, 25, 50, 100 mIU/ml (2nd IRP 78/549) 50 µl 0.084 mIU/ml 50 min
	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
LH	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	LH (Cat #)	625-300A (96 wells) 625-300B (192 wells)	675-300A (96 wells) 675-300B (192 wells)
LH	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 5, 25, 50, 100, 200 mIU/ml (2nd IS 80/552) 50 µl 0.054 mIU/ml 75 min	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 5, 25, 50, 100, 200 mIU/ml (2nd IS 80/552) 50 µl 0.010 mIU/ml 50 min
	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells





PAPP-A	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	PAPP-A (Cat #)	12625-300A (96 wells)	12675-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 0.64, 1.6, 3.2, 9.6, 32 µg/ml	0, 0.64, 1.6, 3.2, 9.6, 32 µg/ml
	Sample	10 µl	10 µl
	Sensitivity	0.125 µg/ml	0.125 µg/ml
	Total Assay Time	110 min	80 min

PRL	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	PRL (Cat #)	725-300A (96 wells) 725-300B (192 wells)	775-300A (96 wells) 775-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 5, 10, 25, 50, 100 ng/ml (3rd IS 84/500)	0, 5, 10, 25, 50, 100 ng/ml (3rd IS 84/500)
	Sample	25 µl	25 µl
	Sensitivity	0.150 ng/ml	0.11 ng/ml
	Total Assay Time	75 min	50 min

PRLs	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	PRLs (Cat #)	4425-300A	4475-300A
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 10, 25, 50, 100, 250 ng/ml (3rd IS 84/50)	0, 10, 25, 50, 100, 250 ng/ml (3rd IS 84/50)
	Sample	25 µl	25 µl
	Sensitivity	0.8 ng/ml	0.8 ng/ml
	Total Assay Time	75 min	65 min

GROWTH DEFICIENCY

hGH	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	hGH(Cat #)	1725-300A (96 wells) 1725-300B (192 wells)	1775-300A (96 wells) 1775-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 2, 10, 25, 50, 150 µIU/ml (2nd IS 98/574)	0, 2, 10, 25, 50, 150 µIU/ml (2nd IS 98/574)
	Sample	50 µl	50 µl
	Sensitivity	0.104 µIU/ml	0.118 µIU/ml
	Total Assay Time	75 min	50 min

INFECTIOUS DISEASES

X-h Pylori IgA	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
	Anti-H. Pylori IgA	1625-300A (96 wells)	1675-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 10, 25, 50, 100 U/ml * (Lot Specific)	0, 10, 25, 50, 100 U/ml * (Lot Specific)
	Sample	50 µl (1:100 Dilution)	50 µl (1:100 Dilution)
	Sensitivity	0.304 U/ml	0.2100 U/ml
	Total Assay Time	105 min	80 min

INFECTIOUS DISEASES cont.

X-h Pylori IgG	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item	1425-300A (96 wells)	1475-300A (96 wells)	
X-h Pylori IgM	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence	
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay	
	Calibrators	0, 10, 25, 50, 100 U/ml * (Lot Specific)	0, 10, 25, 50, 100 U/ml * (Lot Specific)	
	Sample	25 µl (1:100 Dilution)	25 µl (1:100 Dilution)	
	Sensitivity	0.1424 U/ml	0.0956 U/ml	
	Total Assay Time	105 min	80 min	
Procalcitonin	AccuBind ELISA Microwells		AccuLite CLIA Microwells	
	Item	9225-300A (96 wells)	9275-300A (96 wells)	
N-TBG	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence	
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay	
	Calibrators	0, 0.5, 1.0, 2.5, 10, 25 ng/ml	0, 0.5, 1.0, 2.5, 10, 25 ng/ml	
	Sample	50 µl	50 µl	
	Sensitivity	LoB/ LoD 0.024/ 0.05 ng/ml	LoB/ LoD 0.024/ 0.05 ng/ml	
	Total Assay Time	45 min	35 min	

NEONATAL THYROID

N-TSH	AccuBind ELISA Microwells			
	Item	8925-300A (96 wells)	8925-300B (192 wells)	
N-T4	Method	Enzyme Immunoassay, Colorimetric		
	Principle	Competitive Assay		
	Calibrators	0-750 nmol/L (Lot Specific) Dried blood spots on S&S 903 paper		
	Sample	1/8" Dot		
	Sensitivity	28.6 nmol/L		
	Total Assay Time	2.25 hrs		
N-T4	AccuBind ELISA Microwells			
	Item	3425-300A (96 wells) 3425-300D (480 wells) 3425-300F (1920 wells)	3425-300B (192 wells) 3425-300E (960 wells)	
N-T4	Method	Enzyme Immunoassay, Colorimetric		
	Principle	Streptavidin Biotin Based Sandwich Assay		
	Calibrators	0 - 250 uIU/ml (Lot Specific) (2nd IRP 80/558) Dried blood spots on S&S 903 paper		
	Sample	1/8" dot		
	Sensitivity	1.0 uIU/ml		
	Total Assay Time	3 hrs		

N-170HP

Item	AccuBind [®] ELISA Microwells	
N170HP (Cat #)	5525-300A (96 wells)	5525-300B (192 wells)
Method	Enzyme Immunoassay, Colorimetric	
Principle	Competitive Assay	
Calibrators	0-105 ng/ml (Lot Specific) Dried blood spots on S&S 903 Paper	
Sample	1/8" dot	
Sensitivity	0.56 ng/ml	
Total Assay Time	2.25 Hours	

STEROIDS

ANST

Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
Cortisol (Cat #)	12425-300A (96 wells)	12475-300A (96 wells)
Method	Enzyme Immunoassay, Colorimetric	
Principle	Competitive Assay, Antibody-Coated Plate	
Calibrators	0, 0.1, 0.3, 1, 3, 10 ng/ml	
Sample	25 µl	
Sensitivity	LoB 0.025 ng/ml	
Total Assay Time	80 min	

Cortisol

Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
Cortisol (Cat #)	3625-300A (96 wells)	3675-300A (96 wells)
Method	Enzyme Immunoassay, Colorimetric	
Principle	Streptavidin Biotin Based Competitive Assay	
Calibrators	0, 1, 4, 10, 20, 50 µg/dl	
Sample	25 µl	
Sensitivity	0.366 µg/dl	
Total Assay Time	75 min	

DHEA

Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
DHEA (Cat #)	7425-300A (96 wells)	7475-300A (96 wells)
Method	Enzyme Immunoassay, Colorimetric	
Principle	Competitive Assay	
Calibrators	0, 0.5, 2, 5, 10, 30 ng/ml	
Sample	25 µl	
Sensitivity	0.10 ng/ml	
Total Assay Time	80 min	

DHEA-S

Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
DHEA-S (Cat #)	5125-300A (96 wells)	5175-300A (96 wells)
Method	Enzyme Immunoassay, Colorimetric	
Principle	Competitive Assay	
Calibrators	0, 0.2, 1, 2, 4, 8 µg/ml	
Sample	10 µl	
Sensitivity	0.042 µg/ml	
Total Assay Time	45 min	

E1

Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
E1 (Cat #)	10325-300A (96 wells)	10375-300A (96 wells)
Method	Enzyme Immunoassay, Colorimetric	
Principle	Competitive Assay	
Calibrators	0, 15, 30, 100, 300, 1000 pg/ml	
Sample	25 µl	
Sensitivity	LoB/ LoD 6.03/ 10.68 pg/ml	
Total Assay Time	65 min	

STEROIDS cont.

E2	Item	AccuBind® ELISA Microwells	AccuLite® CLIA Microwells
	E2 (Cat #)	4925-300A (96 wells)	4975-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Competitive Assay	Competitive Assay
	Calibrators	0, 20, 100, 250, 500, 1500 & 3000 pg/ml	0, 20, 100, 250, 500, 1500 & 3000 pg/ml
	Sample	25 µl	25 µl
	Sensitivity	8.2 pg/ml	4.162 pg/ml
	Total Assay Time	140 min	95 min
uE3	Item	AccuBind® ELISA Microwells	AccuLite® CLIA Microwells
	uE3 (Cat #)	5025-300A (96 wells)	5075-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Competitive Assay	Competitive Assay
	Calibrators	0, 0.4, 2.0, 5, 15 & 30 ng/ml	0, 0.4, 2.0, 5, 15 & 30 ng/ml
	Sample	25 µl	25 µl
	Sensitivity	0.115 ng/ml	0.237 ng/ml
	Total Assay Time	75 min	50 min
Progesterone	Item	AccuBind® ELISA Microwells	AccuLite® CLIA Microwells
	Progesterone (Cat #)	4825-300A (96 wells)	4875-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Competitive Assay	Competitive Assay
	Calibrators	0, 0.3, 2, 5, 15, 30 and 60 ng/ml	0, 0.3, 2, 5, 15, 30 and 60 ng/ml
	Sample	25 µl	25 µl
	Sensitivity	0.105 ng/ml	0.208 ng/ml
	Total Assay Time	80 min	65 min
17OHP	Item	AccuBind® ELISA Microwells	AccuLite® CLIA Microwells
	17OHP (Cat #)	5225-300A (96 wells)	5275-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Competitive Assay	Competitive Assay
	Calibrators	0, 0.1, 0.5, 1.0, 2.5, 10 ng/ml	0, 0.1, 0.5, 1.0, 2.5, 10 ng/ml
	Sample	25 µl	25 µl
	Sensitivity	0.077 ng/ml	0.040 ng/ml
	Total Assay Time	80 min.	50 min
17OHP-SI	Item	AccuBind® ELISA Microwells	AccuLite® CLIA Microwells
	17OHP-SI (Cat #)	9925-300A (96 wells)	9975-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Competitive	Competitive
	Calibrators	0, 0.1, 0.5, 1.0, 5, 10, 20 ng/ml	0, 0.1, 0.5, 1.0, 5, 10, 20 ng/ml
	Sample	25 µl	25 µl
	Sensitivity	0.03 ng/ml	0.03 ng/ml
	Total Assay Time	80 min.	50 min
SHBG	Item	AccuBind® ELISA Microwells	AccuLite® CLIA Microwells
	SHBG (Cat #)	9125-300A (96 wells)	9175-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay	Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 10, 25, 50, 100, 250 nmol/L (2nd IS 08/266)	0, 10, 25, 50, 100, 250 nmol/L (2nd IS 08/266)
	Sample	25 µl	25 µl
	Sensitivity	0.0122 nmol/L	0.0132 nmol/L
	Total Assay Time	45 min	35 min

Testosterone	AccuBind[®] ELISA Microwells		AccuLite[®] CLIA Microwells	
	Item			
	Testosterone (Cat #)	3725-300A (96 wells)		3775-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Competitive Assay		Streptavidin Biotin Based Competitive Assay
	Calibrators	0, 0.1, 0.5, 1, 2.5, 5, 12 ng/ml		0, 0.1, 0.5, 1, 2.5, 5, 12 ng/ml
	Sample	10 µl		10 µl
	Sensitivity	0.0576 ng/ml		0.0371 ng/ml
	Total Assay Time	75 min		50 min

Free Testosterone	AccuBind[®] ELISA Microwells		AccuLite[®] CLIA Microwells	
	Item			
	Free Testosterone (Cat #)	5325-300A (96 wells)		5375-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Competitive Assay		Streptavidin Biotin Based Competitive Assay
	Calibrators	0, 0.2, 1, 2.5, 7.5, 20, 60 pg/ml		0, 0.2, 1, 2.5, 7.5, 20, 60 pg/ml
	Sample	20 µl		20 µl
	Sensitivity	LoB/ LoD 0.0295/ 0.0519 pg/ml		0.120 pg/ml
	Total Assay Time	75 min		50 min

THYROID

TBG	AccuBind[®] ELISA Microwells		AccuLite[®] CLIA Microwells	
	Item			
	TBG (Cat #)	3525-300A (96 wells) 3525-300B (192 wells)		3575-300A (96 wells) 3575-300B (192 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay		Streptavidin Biotin Based Sandwich Assay
	Calibrators	1, 4, 8, 16, 32, 64 µg/ml (IS 88/638)		1, 4, 8, 16, 32, 64 µg/ml (IS 88/638)
	Sample	10 µl		10 µl
	Sensitivity	1.0 µg/ml		1.0 µg /ml
	Total Assay Time	45 min		35 min

Tg	AccuBind[®] ELISA Microwells		AccuLite[®] CLIA Microwells	
	Item			
	Tg (Cat #)	2225-300A (96 wells)		2275-300A (96 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay		Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 2.0, 10, 40, 100, 250 ng/ml		0, 2.0, 10, 40, 100, 250 ng/ml
	Sample	50 µl		50 µl
	Sensitivity	0.44 ng/ml		0.031 ng/ml
	Total Assay Time	Long Procedure 255 min/ Short 135 min		Long Procedure 245 min/ Short 125 min

TSH	AccuBind[®] ELISA Microwells		AccuLite[®] CLIA Microwells	
	Item			
	TSH (Cat #)	325-300A (96 wells) 325-300B (192 wells) 325-300D (480 wells) 325-300E (960 wells)		375-300A (96 wells) 375-300B (192 wells) 375-300D (480 wells) 375-300E (960 wells)
	Method	Enzyme Immunoassay, Colorimetric		Enzyme Immunoassay, Chemiluminescence
	Principle	Streptavidin Biotin Based Sandwich Assay		Streptavidin Biotin Based Sandwich Assay
	Calibrators	0, 0.5, 2.5, 5.0, 10, 20, 40 µIU/ml-2nd (IRP 80/558)		0, 0.5, 2.5, 5.0, 10, 20, 40 µIU/ml (2nd IRP 80/558)
	Sample	50 µl		50 µl
	Sensitivity	0.078 µIU/ml 0.027 µIU/ml		0.0062 µIU/ml
	Total Assay Time	75 min 135 min		50 min

THYROID cont.

Rapid TSH	AccuBind[®] ELISA Microwells AccuLite[®] CLIA Microwells	
	Item	
	Rapid TSH (Cat #)	6025-300A (96 wells) 6025-300B (192 wells) 6075-300A (96 wells) 6075-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay 0, 0.5, 2.5, 10, 30, 100 µIU/ml-2nd (IRP 80/558) 25 µl 30 Min incubation: 0.10 µIU/ml 45 min Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay 0, 0.5, 2.5, 10, 30, 100 µIU/ml-2nd (IRP 80/558) 25 µl 0.03 µIU/ml 35 min
T3	AccuBind[®] ELISA Microwells AccuLite[®] CLIA Microwells	
	Item	
	T3 (Cat #)	125-300A (96 wells) 125-300B (192 wells) 125-300D (480 wells) 125-300E (960 wells) 175-300A (96 wells) 175-300B (192 wells) 175-300D (480 wells) 175-300E (960 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay 0, 0.5, 1.0, 2.5, 5.0, 7.5 ng/ml 50 µl 0.04 ng/ml 75 min Enzyme Immunoassay, Chemiluminescence Competitive Assay 0, 0.5, 1.0, 2.5, 5.0, 7.5 ng/ml 50 µl 0.126 ng/ml 50 min
T3 Rapid	AccuBind[®] ELISA Microwells	
	Item	
	T3 Rapid (Cat #)	11225-300A (96 wells) 11225-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay, Antibody-Coated Plate 0 , 0.5, 1.0, 2.5, 5.0, 7.5 ng/ml 50 µl 0.068 ng/ml 45 min (from 75 min)
T3 SBS	AccuBind[®] ELISA Microwells AccuLite[®] CLIA Microwells	
	Item	
	T3 (Cat #) SBS	8125-300A (96 wells) 8125-300B (192 wells) 8175-300A (96 wells) 8175-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay (Streptavidin Based) 0, 0.5, 1.0, 2.5, 5.0, 7.5 ng/ml 50 µl 0.4 ng/ml 75 min Enzyme Immunoassay, Chemiluminescence Competitive Assay (Streptavidin Based) 0, 0.5, 1.0, 2.5, 5.0, 7.5 ng/ml 50 µl 0.04 ng/ml 50 min
T3U	AccuBind[®] ELISA Microwells AccuLite[®] CLIA Microwells	
	Item	
	T3-Uptake (Cat #)	525-300A (96 wells) 525-300B (192 wells) 575-300A (96 wells) 575-300B (192 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay 18, 25, 35, 47 %U* (Lot Specific) 25 µl N/A 75 min Enzyme Immunoassay, Chemiluminescence Competitive Assay 18, 25, 35, 47 %U* (Lot Specific) 25 µl N/A 50 min

FT3	AccuBind® ELISA Microwells		AccuLite® CLIA Microwells	
	Item			
	FT3 (Cat #)	1325-300A (96 wells) 1325-300B (192 wells) 1325-300D (480 wells) 1325-300E (960 wells)		1375-300A (96 wells) 1375-300B (192 wells) 1375-300D (480 wells) 1375-300E (960 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay 0, 1.0, 3.0, 5.0, 8.0, 16.0 pg/ml* (Lot Specific) 50 µl 0.835 pg/ml 75 min		Enzyme Immunoassay, Chemiluminescence Competitive Assay 0, 1.0, 3.0, 5.0, 8.0, 16.0 pg/ml* (Lot Specific) 50 µl 0.742 pg/ml 50 min
T4	AccuBind® ELISA Microwells		AccuLite® CLIA Microwells	
	Item			
	T4 (Cat #)	225-300A (96 wells) 225-300B (192 wells) 225-300D (480 wells) 225-300E (960 wells)		275-300A (96 wells) 275-300B (192 wells) 275-300D (480 wells) 275-300E (960 wells)
	Method Principle Calibrators Sample Sensitivity Time	Enzyme Immunoassay, Colorimetric Competitive Assay 0, 2.0, 5.0, 10.0, 15.0, 25.0 µg/dl 25 µl 0.128 µg/dl 75 min		Enzyme Immunoassay, Chemiluminescence Competitive Assay 0, 2.0, 5.0, 10.0, 15.0, 25.0 µg/dl 25 µl 0.318 µg/dl 50 min
T4 Rapid	AccuBind® ELISA Microwells			
	Item			
	T4 Rapid (Cat #)	11125-300A (96 wells) 11125-300B (192 wells)		
	Method Principle Calibrators Sample Sensitivity Time	Enzyme Immunoassay, Colorimetric Competitive Assay, Antibody-Coated Plate 0, 2.0, 5.0, 10.0, 15.0, 25.0 µg/dl 20 µl 0.128 ug/dl 45 min (from 75 min)		
T4 SBS	AccuBind® ELISA Microwells		AccuLite® CLIA Microwells	
	Item			
	T4 (Cat #) SBS	8225-300A (96 wells) 8225-300B (192 wells) 8225-300D (480 wells) 8225-300E (960 wells)		8275-300A (96 wells) 8275-300B (192 wells) 8275-300D (480 wells) 8275-300E (960 wells)
	Method Principle Calibrators Sample Sensitivity Time	Enzyme Immunoassay, Colorimetric Competitive Assay (Streptavidin Based) 0, 2.0, 5.0, 10.0, 15.0, 25.0 µg/dl 25 µl 0.4 µg/dl 75 min		Enzyme Immunoassay, Chemiluminescence Competitive Assay (Streptavidin Based) 0, 2.0, 5.0, 10.0, 15.0, 25.0 µg/dl 50 µl 0.2 µg/dl 50 min
FT4	AccuBind® ELISA Microwells		AccuLite® CLIA Microwells	
	Item			
	FT4 (Cat #)	1225-300A (96 wells) 1225-300B (192 wells) 1225-300D (480 wells) 1225-300E (960 wells)		1275-300A (96 wells) 1275-300B (192 wells) 1275-300D (480 wells) 1275-300E (960 wells)
	Method Principle Calibrators Sample Sensitivity Total Assay Time	Enzyme Immunoassay, Colorimetric Competitive Assay 0, 0.4, 1.25, 2.10, 5.0, 7.40 ng/dl* (Lot Specific) 50 µl 0.314 ng/dl 75 min		Enzyme Immunoassay, Chemiluminescence Competitive Assay 0, 0.4, 1, 1.85, 3.50, 7.20 ng/dl* (Lot Specific) 50 µl 0.28 ng/dl 50 min

VAST

Versatile Analyte Selection Technology

Monobind created VAST for smaller labs and combined up to four analytes in one kit to support smaller testing volumes. Labs choose which analyte they want to run in each well. It is the only product of its kind on the market today!



ANEMIA PANEL

Folate, Vit B12	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
		7825-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix	7875-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix
Method Principle		Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay
Calibrators		Folate: 0, 1, 2.5, 5, 10, 25 ng/ml Vit B12: 0, 125, 250, 500, 1000, 2500 pg/ml	Folate: 0, 1, 2.5, 5, 10, 25 ng/ml Vit B12: 0, 125, 250, 500, 1000, 2500 pg/ml
Sample Sensitivity		Folate, Vit B12: 50 µl Folate: 0.52 ng/ml Vit B12: 70.13 pg/ml	Folate, Vit B12: 50 µl Folate: 0.23 ng/ml Vit B12: 42.12 pg/ml
Total Assay Time		Folate: 65 min Vit B12: 95 min	Folate: 50 min Vit B12: 80 min

CANCER PANEL

AFP,CEA,PSA	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
		8425-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix	8475-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix
Method Principle		Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay
Calibrators		AFP: 0, 5, 25, 100, 250, 500ng/ml (IRP 72/225) CEA: 0, 5, 10, 25, 100, 250ng/ml (IRP 73/601) PSA: 0, 2, 5, 10, 25, 50ng/ml (IS 96/670)	AFP: 0, 5, 25, 100, 250, 500ng/ml (IRP 72/225) CEA: 0, 5, 10, 25, 100, 250ng/ml (IRP 73/601) PSA: 0, 2, 5, 10, 25, 50ng/ml (IS 96/670)
Sample Sensitivity		AFP, CEA, PSA: 25µl AFP: 0.454 ng/ml CEA: 0.078 ng/ml PSA: 0.041 ng/ml	AFP, CEA, PSA: 25ul AFP: 0.168 ng/ml CEA: 0.018 ng/ml PSA: 0.004 ng/ml
Total Assay Time		75 min	50 min

DIABETES PANEL

C-peptide, Insulin	Item	AccuBind [®] ELISA Microwells	AccuLite [®] CLIA Microwells
		7325-300A (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix	7375-300A (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix
Method Principle		Enzyme Immunoassay, Colorimetric Streptavidin Biotin Based Sandwich Assay	Enzyme Immunoassay, Chemiluminescence Streptavidin Biotin Based Sandwich Assay
Calibrators		Insulin: 0, 5, 25, 50, 100, 300 µIU/ml C-peptide: 0, 0.2, 1, 2, 5, 10 ng/ml	Insulin: 0, 5, 25, 50, 100, 300 µIU/ml C-peptide: 0, 0.2, 1, 2, 5, 10 ng/ml
Sample Sensitivity		Insulin, C-peptide: 50 µl Insulin: 0.182 µIU/ml and C-peptide: 0.020 ng/ml	Insulin, C-peptide: 50 µl Insulin: 0.114 µIU/ml and C-peptide: 0.012 ng/ml
Total Assay Time		135 min	65 min

FERTILITY PANEL



hCG, FSH, LH, PRLs	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	LH, FSH, PRLs, hCG (Cat #)	8325-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix	8375-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix
	Method Principle	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Calibrators	Streptavidin Biotin Based Sandwich Assay hCG: 0, 25, 100, 250, 500, 1000 mIU/ml (3rd IS 75/537) FSH: 0, 5, 10, 25, 50, 100 mIU/ml (2nd IRP 78/549) LH: 0, 5, 25, 50, 100, 200 mIU/ml (1st IRP 68/40) PRLs: 0, 10, 25, 50, 100, 250 ng/ml (3rd IS 84/500)	Streptavidin Biotin Based Sandwich Assay hCG: 0, 25, 100, 250, 500, 1000 mIU/ml (3rd IS 75/537) FSH: 0, 5, 10, 25, 50, 100 mIU/ml (2nd IRP 78/549) LH: 0, 5, 25, 50, 100, 200 mIU/ml (1st IRP 68/40) PRLs: 0, 10, 25, 50, 100, 250 ng/ml (3rd IS 84/500)
	Sample	hCG & PRLs: 25 µl FSH & LH: 50 µl	hCG & PRLs: 25 µl FSH & LH: 50 µl
	Sensitivity	hCG: 3 mIU/ml FSH: 0.4 mIU/ml LH: 0.5 mIU/ml PRLs: 1.6 ng/ml	hCG: 5 mIU/ml FSH: 0.2 mIU/ml LH: 0.2 mIU/ml PRLs: 0.8 ng/ml
	Total Assay Time	hCG: 3.5 min FSH, LH, PRLs: 75 min	hCG: 25 min FSH, LH: 50 min, PRLs: 65 min

PRENATAL PANEL

AFP, hCG, uE3	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	AFP, hCG, uE3 (Cat #)	8525-300A (96 wells) 8525-300B (192 wells) (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix	8575-300A (96 wells) 8575-300B (192 wells) (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix
	Method Principle	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Calibrators	Streptavidin Biotin Based Sandwich Assay AFP: 0, 10, 25, 75, 150, 400 ng/ml hCG: 0, 10, 25, 50, 100, 250 mIU/ml uE3: 0, 0.5, 1.0, 2.5, 10, 20 ng/ml	Streptavidin Biotin Based Sandwich Assay AFP: 0, 10, 25, 75, 150, 400 ng/ml hCG: 0, 10, 25, 50, 100, 250 mIU/ml uE3: 0, 0.5, 1.0, 2.5, 10, 20 ng/ml
	Sample	AFP, hCG, uE3: 25 µl	AFP, hCG, uE3: 25 µl
	Sensitivity	AFP: 1.0 ng/ml, hCG: 0.8 mIU/ml uE3: 0.115 ng/ml	AFP: 1.0 ng/ml, hCG: 0.8 mIU/ml uE3: 0.115 ng/ml
	Total Assay Time	75 min	50 min

THYROID PANEL

T3, T4, TSH	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	T3, T4, TSH (Cat #)	8025-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix	8075-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix
	Method Principle	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Calibrators	Streptavidin Biotin Based Sandwich Assay T3: 0, .5, 1, 2.5, 5, 7.5 ng/ml T4: 0, 2, 5, 10, 15, 25 µg/dl TSH: 0, 0.5, 2.5, 10, 20, 40 µIU/ml	Streptavidin Biotin Based Sandwich Assay T3: 0, .5, 1, 2.5, 5, 7.5 ng/ml T4: 0, 2, 5, 10, 15, 25 µg/dl TSH: 0, 0.5, 2.5, 10, 20, 40 µIU/ml
	Sample	T3, TSH: 50 µl T4: 25 µl T3: 0.04 ng/ml T4: 0.4 µg/dl	T3, TSH: 50 µl T4: 25 µl T3: 0.02 ng/ml T4: 0.2 µg/dl
	Sensitivity	TSH: 0.078 µIU/ml (1 hour incubation)	TSH: 0.05 µIU/ml
	Total Assay Time	75 min	50 min

FT3, FT4, TSH	Item	AccuBind ELISA Microwells	AccuLite CLIA Microwells
	FT3, FT4, TSH (Cat#)	7025-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix	7075-300B (192 wells, universal-analyte plate) Combi-Cal® single-serum-analyte matrix
	Method Principle	Enzyme Immunoassay, Colorimetric	Enzyme Immunoassay, Chemiluminescence
	Calibrators	Streptavidin Biotin Based Sandwich Assay FT3: 0, 1.3, 3.0, 8, 12, 22 pg/ml FT4: 0, 0.5, 1.2, 2.4, 4.2, 7.6 ng/dl TSH: 0, 0.5, 2.5, 10, 20, 40 µIU/ml	Streptavidin Biotin Based Sandwich Assay FT3: 0, 1.3, 3.0, 8, 12, 22 pg/ml FT4: 0, 0.5, 1.2, 2.4, 4.2, 7.6 ng/dl TSH: 0, 0.5, 2.5, 10, 20, 40 µIU/ml
	Sample	FT3: 50 µl, TSH & FT4: 25 µl	FT3: 50 µl, TSH & FT4: 25 µl
	Sensitivity	FT3: 0.04 pg/ml, FT4: 0.04 ng/dl TSH: 0.065 µIU/ml (1 hour incubation)	FT3: 0.04 pg/ml, FT4: 0.03 ng/dl TSH: 0.065 µIU/ml (1 hour incubation)
	Total Assay Time	75 min	65 min



CONTROLS

Multi-Ligand	Item	Multiligand Tri-Level Universal Control, Dried
	(Cat #)	ML-300B
	Analytes	Tri-level assayed control to validate range of immunoassays AFP, CEA, Cortisol, C-Peptide, DHEA, DHEA-S, DIG, Estradiol, Estriol, Ferritin, Folate, FSH, hCG, hGH, IgE, Insulin, LH, PRL, Progesterone, PSA, FPSA, SHBG, TBG, Testosterone, Free Testosterone, T3, FT3, T3U, T4, FT4, TSH, Vit B12, Vit D, 17OHP
	Sensitive & Specific	Human Serum Based
	Packaging	3 levels x 2 each at 3 ml fill = 18 ml
	Shelf Life	3 years unopened & 30 day open at 2-8°C
Universal Control		Use with RIA, EIA, ELISA, CLIA, FIA & FPIA
Assayed Values		Mean analysis for Monobind AccuBind ELISA & AccuLite CLIA



Maternal	Item	Maternal Tri-Level Control, Dried
	(Cat #)	MC-300
	Description	Tri-level control for hCG, Free β hCG, AFP, and uE3 for pregnancy monitoring
	Sensitive & Specific	Human Serum Based
	Packaging	3 levels x 2 each at 5 ml fill = 30 ml
	Shelf Life	3 years unopened & 30 day open at 2-8°C
	Universal Control	Use with RIA, EIA, ELISA, CLIA, FIA & FPIA
	Assayed Values	Mean analysis for Monobind AccuBind ELISA & AccuLite CLIA

Anti-Tg & Anti-TPO	Item	Anti-Tg & Anti-TPO Control - Positive & Negative, Liquid
	(Cat #)	AIT-101
	Description	Liquid, positive & negative control to validate TgAb/ TPOAb assays used in diagnosis of autoimmune thyroid conditions
	Sensitive & Specific	Human Serum Based
	Packaging	2 levels x 3 each at 1 ml fill = 6 ml
	Shelf Life	5 years unopened & 30 day open at 2-8°C
	Universal Control	Use with RIA, EIA, ELISA, CLIA, FIA & FPIA
	Assayed Values	Mean analysis for Monobind AccuBind ELISA & AccuLite CLIA

TBG	Item	TBG Tri-Level Control, Liquid
	(Cat #)	TBG-300
	Description	Liquid, tri-level control to validate TBG assays used in diagnosis of thyroid conditions
	Sensitive & Specific	Human Serum Based
	Packaging	3 levels x 2 each at 1 ml fill = 6 ml
	Shelf Life	5 years unopened & 30 day open at 2-8°C
	Universal Control	Use with RIA, EIA, ELISA, CLIA, FIA & FPIA
	Assayed Values	Mean analysis for Monobind AccuBind ELISA & AccuLite CLIA

Tg	Item	Tg Tri-Level Control, Liquid
	(Cat #)	TG-300
	Description	Liquid, tri-level control to validate Tg assay used in monitoring of thyroid functionality in post-operative thyroidectomy patients
	Sensitive & Specific	Human Serum Based
	Packaging	3 levels x 2 each at 3 ml fill = 18 ml
	Shelf Life	3 years unopened & 30 day open at 2-8°C
	Universal Control	Use with RIA, EIA, ELISA, CLIA, FIA & FPIA
	Assayed Values	Mean analysis for Monobind AccuBind ELISA & AccuLite CLIA



Anti-H. Pylori	Anti-H. Pylori Control – Positive & Negative, Dried	
	(Cat #)	HPC-300
	Description	Lyophilized, positive and negative control to Validate H. Pylori (IgA, IgG, IgM) assays
	Sensitive & Specific	Human Serum Based
	Packaging	2 levels x 3 each at 1 ml fill = 6ml
	Shelf Life	3 years unopened & 30 day open at 2-8°C
	Universal Control	Use with RIA, EIA, ELISA, CLIA, FIA & FPIA
	Assayed Values	Mean analysis for Monobind AccuBind ELISA & AccuLite CLIA

Tumor Marker	Tumor Marker Tri-Level Control, Liquid	
	(Cat #)	TMC-300
	Description	Liquid, tri-level control to validate cancer antigen (CA 125, CA 15-3, CA 19-9) assays.
	Sensitive & Specific	Human Serum Based
	Packaging	3 levels x 2 each at 2 ml fill = 12 ml
	Shelf Life	3 years unopened & 30 day open at 2-8°C
	Universal Control	Use with RIA, EIA, ELISA, CLIA, FIA & FPIA (Assayed Values for AccuBind & AccuLite)
	Assayed Values	Mean analysis for Monobind AccuBind ELISA & AccuLite CLIA

Custom Control	Custom Matrix Controls	
	(Cat #)	CustControl
	Description	Control manufacturing to exact requirements. Matrices developed on project basis and have included homocystine, CRP and general immunology.
	Sensitive & Specific	Human or Animal Serum
	Packaging	Per Customer Requirements
	Universal Control	Use with RIA, EIA, ELISA, CLIA, FIA & FPIA

» Contact us with your project.

DILUANTS

“0” Calibrator Matrix	Item	440MM	625MM	144MM	8525145MM	731MM
	Use	0 Calibrator for multi-ligands (see website for analyte list)	0 Calibrator for Steroid (All) & Thyroid (T3, T4, TSH) Assays	Dilutant for Anti-Tg, Anti-TPO, Anti-H-Pylori Assays	Dilutant for High Value Pregnancy Patients & Assays	0 Calibrator for FSH, Ferritin, Folate & Vit B12
	Volume	20 ml	20 ml	20 ml	40 ml	20 ml

Plate Wash

Fully Automated Plate Washer



> Fast, Precise, Reliable, and Programmable

- Washes flat, round, and V-bottom plates and strips.
- No user adjustments required. Automatic calibration, alignment, and last row detection.
- Wash cycles set for Monobind assays.
- 6 ready-to-run wash programs.
- Large, non-volatile memory stores at least 50 user-specified wash protocols.
- Precision operation with constant monitoring of vacuum and pressure. Pump cycles only when necessary for quiet operation.
- Programmable automatic rinse cycle.
- Ready to run: bottles, aerosol shield, 8-way manifold included.
- 12 and 16 position wash heads available.
- NRTL and CE certified.





Ready-to-use ELISA instrument programmed with Monobind assays and proprietary formula designed, optimized and certified by Monobind for two-point analysis.

> Features

- Standalone ELISA reader with integrated computer and printer
- Easy and intuitive touch-screen operation with stylus
- Dynamic reading to 4.5 OD or above (from 3.0 maximum with Eldex 3.8)
- Carrier with (new) automated movement handles 3 strips with 1 to 12 wells/ strip
- Ability to program and read different analytes in strip 1 through 3 or to read all 3strips with the same analyte automatically
- Full 96 well-plate read in 3 to 4 shifts (2 minutes per load/ shift)
- Test storage increased from 100 to 120 tests
- Ten digit alphanumeric sample ID now available for patient tracking
- Password protection system enables open or closed instrument use
- Administrator tool provides summary of wells read per each stored test to assist distributors with laboratory-use monitoring
- USB port easily imports new software or exports readings, including graphs to a PC for archiving
- 110/220 power options, light weight, small footprint
- Optics include 4 filters (405, 450, 492 and 630)
- Quality instrument, US-built, CE mark and ISO standards, NRTL certified

> NeoEldex is completely integrated with our immunoassays

- Programmed with Monobind’s 50+ AccuBind® ELISA tests, parameters and data analytics for optimal results
- Exceptionally easy: Simply select test using touch screen then insert wells
- Exclusive 2PT Calibration enables labs to cut cost-per-test by using two calibrators (instead of six or seven) on same lot kits within 30-days of running full curve
- Run with Monobind multi-ligand controls to ensure total quality, recommended for 2PT calibration



Broad Spectrum of 30+ Analytes



Available in 55+ analytes

prisMaticTM

ELISA Microplate Reader



> Compact Convenience

'Plug and play' instrument with compact design offers convenience in ELISA testing. With its streamlined lines and metal enclosure, PrisMatic fits on any lab bench and provides excellent optics and performance, reading a 96-well plate in about 8 seconds using its 8-channel reader.

> A Winning Combination

With PrisMatic and AccuBind, Monobind delivers a powerful ELISA platform with a 50+ test menu of assays preloaded in the instrument's manger software.

> Tiny Footprint, PC Powered Analytics

PrisMatic uses the power and efficiency of your PC to deliver sophisticated data analysis, curve fitting, reporting and data storage.

Simply connect via USB and load PrisMatic's software containing the device manager and AccuBind test data. Then select desired assay(s) and start running AccuBind ELISAs right away.

> Test with Ease and Confidence

PrisMatic is a user-friendly instrument certified by Monobind to ensure the optimal performance of AccuBind reagents giving you the very best in ELISA testing. Built-in references further monitor calibration to maintain peak function.

All the flexibility a clinical lab needs: Users may add new ELISA protocols specifying a variety of calculation modes, including point-to-point, linear regressions, and dose response modes and protocol types such as immunometric, competitive, cutoff and raw data.

> Key Features

- Drag-and-drop test selection to easily format plate
- Program and read any number of assays per plate
- Stored curve and two point calibration options
- Storage of unlimited protocols (only limit is PC memory)
- Full support of kit lot numbers
- Storage of assay results, allowing off-line reevaluation
- Curve plotting and editing
- Open Instrument for use with other ELISA-assays
- Password protected for limited or closed system use
- Test counter to monitor instrument use



> Specifications

Measurement Range	-0.20 to 4.5 or above optical density
Photometric Accuracy	+/- 1%
Stability	Drift of no more than 0.005A in 8 hrs
Light Source	Remote halogen lamp with saver features
Wave Lengths	405, 450, 492, 630 plus optional filters available
PC operating system	USB Port, Win 2000, Win NT, Win XP, Win Vista, Win 7
Power supply	115V or 230V AC, 50 -60Hz
Weight, Dimensions	4.5 kg, 18.5 x 18.5 x 42 cm
Quality	US-built, NRTL listed, CE Mark and ISO Standards



New Design. Touch Screen. Multiple Analyte Reading & More.



Monobind now offers a second generation of its revolutionary entry-level instrument that puts chemiluminescence within reach of any lab

> Carrier handles 3 strips of 1 to 12 wells per strip

- Full 96-well plate read in 3 to 4 shifts (2 minutes per load/ shift)
- Program and read different analytes on each strip or same analyte on all three strips automatically
- Monobind's robust CLIA reagents produce a stable light signal for 10-minutes after test completion allowing ample time for measurement

> Instrument utilizes photo-multiplier tube (PMT) as detection device

- Superior to electronic diode allows full benefit of CLIA: increased sensitivity and detection range
- Fully stand alone instrument with an internal thermal printer – computer may be used to download assay data

> NeoLumax Specifications

- Sensitivity of 1 x 10-20 M/L
- Essentially no crosstalk
- Power options 110-120/220-240 VAC, 50-60 Hz, 50 Watts, switchable
- USB port allow for import of new software and export of readings, including graphs
- Compact unit with dimensions of 24.7 x 34 x 13 cm and weight of 2.5 kg
- Quality instrument, US-built, CE mark and ISO standards, NRTL certified

> NeoLumax is completely integrated with our immunoassays

- Preprogrammed with all Monobind's 45+ CLIA tests, parameters and optimal settings to allow plug-and-play
- Exceptionally easy: Simply select test using intuitive touch-screen then insert wells
- Exclusive 2PT Calibration enables labs to cut cost-per-test by using only two calibrators (instead of six) on same lot kits within 20-days of running full curve
- Run with Monobind multi-ligand controls to ensure total quality, recommended for 2PT
- NeoLumax is an open system to allow maximum value for labs and offers a password system for optional closed system control

> Additional Features

- Test storage increased from 100 to 120 tests
- Ten digit alphanumeric sample ID now available for patient tracking
- Administrator tool provides summary of wells read per each stored test to assist distributors with laboratory-use monitoring



Broad Spectrum
of 30+ Analytes



Available in 55+ Analytes

> Today's Most Affordable Analyzer

Making another leap towards bringing CLIA to labs everywhere, Monobind presents LuMatic™, the world's lowest-priced plate chemiluminescence analyzer – a machine optimized for Monobind's AccuLite® reagent line and an excellent plug-in for Monobind's Autoplex™ Automated ELISA and CLIA Analyzer.

> A Winning Combination

Now you can have all the benefits of CLIA technology: sensitivity, speed and dynamic range, in an affordable package. With LuMatic and AccuLite, Monobind gives you the only open-system CLIA platform with a 45+ test menu.

> Tiny Footprint, PC Powered Analytics

LuMatic uses the power and efficiency of your PC to deliver sophisticated data analysis, curve fitting, reporting and data storage. It is based on the same software Monobind's Autoplex Analyzer, and may be used together with a single interface.

Simply connect via USB and load LuMatic's software containing the device manager and AccuLite test data. Then select desired assay(s) and start running AccuLite CLIA right away.

> Test with Ease and Confidence

LuMatic is a user-friendly instrument certified by Monobind to ensure the optimal performance of AccuLite reagents giving you the very best in CLIA testing. Built-in references further maintain peak function with continuous instrument calibration. All the flexibility a clinical lab needs: Users may add new CLIA protocols specifying a variety of calculation modes, including point-to-point, linear and log regressions, and log logit modes and protocol types such as immunometric, competitive, cutoff and raw data.

> Specifications

Detection	Glow chemiluminescence by Photomultiplier Tube (PMT)
Sensitivity/ Limit	HRP 1 x 10 ⁻¹⁸ moles, ALP 1x10 ⁻²¹ moles
Linear Dynamic Range	106 RLU
PC operating system	Win 2000, Win NT, Win XP, Win Vista
Power supply	110-250V AC
Weight, Dimensions	5 kg, 19 x 20.3 x 42 cm
Regulations	NRTL listed, CE



> Key Features

- Drag-and-drop test selection to easily format plate
- Multiple analytes per plate (up to 12)
- Two point calibration using stored curve
- Storage of unlimited protocols (only limit is PC memory)
- Full support of kit lot numbers
- Storage of assay results, allowing off-line reevaluation
- Curve plotting and editing
- Open Instrument for use with other CLIA-assays

> 2-Point Calibration, Big Value

The robustness of AccuLite allows for two-point calibration enabling labs to run more patient samples per plate, reducing reagent use and overall test cost. LuMatic and AccuLite offer a convenient and affordable package designed to bring high quality immunoassays to markets worldwide.



Impulse 3 CLIA Plate Reader

> Monobind is a Leader in CLIA

As a pioneer in open-system chemiluminescence assays, Monobind developed its AccuLite® product line in 2003 capturing the benefits of CLIA technology: sensitivity, speed and dynamic range. In 2005, it launched Impulse, the first open-system luminometer designed for clinical labs providing a critical component in the adoption of CLIA technology worldwide.

Today, AccuLite represents the largest portfolio of open-system CLIA assays with 45+ analytes which Monobind complements with many instrument options, including Impulse3 a hallmark of excellence and precision.



> Highly Sensitive

The Impulse3 and AccuLite System is distinguished by its exceptionally high sensitivity, thereby allowing clinically significant detection limits with low reagent concentrations. A wide selection of high-quality standardization procedures ensures optimum accuracy and precision in the measurement of assays.

> Simple, Intuitive Menus

The instrument connects to a PC via a USB plug and comes with Impulse3 software which contains all AccuLite test definitions. After installation, users simply select desired assay(s) and begin measurement with routines tested and certified by Monobind. The user-friendly interface and integrated reagent package deliver clinical users an unparalleled confidence.

> 2-Point Calibration

The robustness of AccuLite allows for two-point calibration enabling labs to run more patient samples per plate, reducing reagent use and cost. Impulse3 and AccuLite offer a convenient and affordable package designed to bring high quality immunoassays to markets worldwide.

> Designed for Clinical Labs

An unlimited number of protocols may be stored. Protocol types are immunometric (ILMA), Competitive (LIA), CutOff and Raw Data. Additionally,

- Automatic Performance Test with optional test plate
- Two point calibrations using stored curve or master curve
- Flexible definition of wells to be measured
- Sequence selection for column or row strip assays
- Multiple assays per plate (up to eight)
- Full support of kit lot numbers
- Storage of assay results, allowing off-line reevaluation
- Shaking, 3 modes, variable amplitude and speed
- Sophisticated curve-fitting, logit-log or log-log transformation with optimized auto or manual smoothing
- Curve fitting, provides full standardization
- Storage of standard curves
- Open Instrument for use with other CLIA-assays

AutoPlex®

ELISA & CLIA Workstation

Get the convenient, flexible & precise solution for ELISA & CLIA automation

> Monobind offers an automated platform for managing & running assays.

> Features

- Internal optical ELISA reader, CLIA read in separately sold device through integrated software
- Exceptional performance with Monobind immunoassays
- Simultaneous processing of 1 to 12 analytes with automated work-schedule
- Within assay precision ($<4\%$ CV) based on five samples run in duplicate
- Reproducibility of dose response variable ($<3\%$ CV) based on adjacent duplicate samples
- Dose response drift ($<5\%$ CV) based on three positions in microplate
- Excellent correlation (.99 R) and nearly perfect slope with manual method
- Fast processing rates in single plate design
- On average 50 samples performed per hour with Monobind immunoassay
- Dilutions, possible, dispensing single or multiple reagents
- Two syringe pumps for accuracy, stainless steel probes
- Min and max dispensing volumes 2 μ L and 1.95 mL
- Maximum number of specimens 96, up to 44 reagents with standard reagent rack of 27
- Custom reagent rack for Monobind AccuBind and AccuLite kits with easy to read icons



Autoplex shown with optional LuMatic CLIA reader, ask us about package rates.



> Autoplex™ is completely integrated with Monobind's immunoassays

- Programmed with all of Monobind's 55+ tests to allow plug-and-play
- Simply choose CLIA or ELISA mode to access test parameters
- Internal CLIA reader in development
- PC controlled using intuitive Windows® based program
- Versatile, open system
- NRTL Listed, CE Marked

AutoPlex[®] 2nd GENERATION

ELISA & CLIA Workstation

Get the convenient, flexible & precise solution for ELISA & CLIA automation



> Features

- Internal optical ELISA and combination luminescence CLIA reader
- Exceptional performance with Monobind immunoassays
- Simultaneous processing of 1 to 12 analytes with automated work-schedule
- Within assay precision ($<4\%$ CV) based on five samples run in duplicate
- Reproducibility of dose response variable ($<3\%$ CV) based on adjacent duplicate samples
- Dose response drift ($<5\%$ CV) based on three positions in microplate
- Excellent correlation (.99 R) and nearly perfect slope with manual method
- Fast processing rates in single plate design
- On average 50 samples performed per hour with Monobind immunoassay
- Dilutions, possible, dispensing single or multiple reagents
- Two syringe pumps for accuracy, stainless steel probes
- Min and max dispensing volumes 2 μ l and 1.95 mL
- Maximum number of specimens 96, up to 44 reagents with standard reagent rack of 27
- Custom reagent rack for Monobind AccuBind and AccuLite kits with easy to read icons



> Autoplex is completely integrated with Monobind's immunoassays

- Programmed with all of Monobind's 55+ tests to allow plug-and-play
- Simply choose CLIA or ELISA mode to access test parameters
- PC controlled using intuitive Windows® based program
- Versatile, open system
- NRTL Listed, CE Marked

> Also available in ELISA only model



Titration Instrument Automation for ELISA & CLIA



Monobind offers a powerful & compact walk-away platform
manufactured by Gold Standard Diagnostics

- Internal LED spectrophotometer for ELISA and (optional) combination-luminescence reader for CLIA
- Dual (2) microplate design offers streamlined processing, reading and reporting of results
- Open architecture, fully customizable reporting and test designer allows assay configuration (down to minute detail) with intuitive software (Multilanguage support, Windows-7 based and installed in the included laptop)
- Best-of-breed features: intelligent rack, built-in patient-barcode scanner, and on-board camera for remote troubleshooting
- High-volume sample capacity with 192 patient positions on convenient sliding sample-tray
- Programmable for 16 custom reagent positions
- Simultaneous processing of 1 to 8 analytes in a single batch
- Compact footprint of 2' x 2', fits on 60cm deep standard lab bench and weighs just 65 pounds

Instrument & Software Specifications

- Pre-dilution of samples on one plate, incubator with $\leq 40^{\circ}\text{C}$ (for non-Monobind assays) and two external wash bottles
- Single probe, dual needle with dispense volume up to 500 μl
- Photometer Wavelengths 405, 450, 550, 570 and 620 nm standard (other lengths available)
- Orbital shaker for both plates, with no-spill design, amplitude of 1mm, speeds up to 900RPM and times from 0-2 hours
- Report designer with numerous data reduction options; point-to-point, linear regression, cubic spline, 4PL, 5PL, Lin-Lin, Lin-Log, Log-Log representation
- Power supply 120-265V, 50-60Hz
- Lab System Integration (LSI) with Bi-directional, RS232, USB, TCP/IP options NRTL Listed, CE Marked

Monobind assay integration

- Exceptional performance with Monobind immunoassays and optimized test files
- Within assay precision ($\leq 5\%$ CV) based on five samples run in duplicate
- Excellent correlation and nearly perfect slope with manual method
- Software flexibility post-run in worklist assists users with data analysis and maximizes lab efficiency

Training & Support

- Included virtual or CA-provided training and learning resources by Gold Standard Diagnostics (on-site, fee based on request)
- Front-line operational support by Monobind



TITIN-s™

Titration Instrument Automation for ELISA & CLIA



Monobind offers a powerful & compact walk-away platform manufactured
by Gold Standard Diagnostics in Single Plate Design

- Internal LED spectrophotometer for ELISA and (optional) combination-luminescence reader for CLIA
- Single microplate design offers streamlined processing, reading and reporting of results
- Open architecture, fully customizable reporting and test designer allows assay configuration (down to minute detail) with intuitive software (Multilanguage support, Windows-7 based and installed in the included laptop)
- High-volume sample capacity with 96 patient positions on convenient sliding sample-tray with option for 12, 13 and 16 mm diameter tubes (or custom)
- Programmable for 9 custom reagent positions
- Simultaneous processing of 1 to 8 analytes in a single batch
- Low consumable costs, no disposable tips
- Compact footprint of 2' x 2', fits on 53cm deep standard lab bench and weighs just 60 pounds
- Cost effective and efficient

Instrument & Software Specifications

- Pre-dilution plate for samples (in addition to reaction-plate), incubator with $\leq 40^{\circ}\text{C}$ (for non-Monobind assays) and two external wash bottles
- Single probe, dual needle with dispense volume up to $300\mu\text{l}$
- Photometer wavelengths 405, 450, 490, 550 and 630 nm standard (other lengths available)
- Linear shaker, with no-spill design, amplitude of 1mm, speeds up to 900RPM and times from 0-2 hours
- Report designer with numerous data reduction options; point-to-point, linear regression, cubic spline, 4PL, 5PL, Lin-Lin, Lin-Log, Log-Log representation
- Power supply 120-265V, 50-60Hz
- Lab System Integration (LSI) with Bi-directional, RS232, USB, TCP/IP options
- NRTL Listed, CE Marked

Monobind assay integration

- Exceptional performance with Monobind immunoassays and optimized test files for AccuBind® ELISA and AccuLite® CLIA (55+ analytes)
- Within assay precisions $<5\%$ on five plus sample duplication
- Excellent correlation and nearly perfect slope with manual method
- Software flexibility post-run in worklist assists users with data analysis and maximizes lab efficiency

Training & Support

- Included virtual or CA-provided training and learning resources by Gold Standard Diagnostics (on-site, fee-based on request)
- Front-line operational support by Monobind

Clinical Laboratories

Please place your orders through the Monobind Distributor in your region. If you do not know your regional distributor, you may contact Monobind for a referral.

Distributors

Existing distributors: please order online by logging into our web site using your account information, or send us a formal purchase order including the item catalog number, description, quantity required, the item rate, extended and total value.

New distributors: we welcome the opportunity to do business with you. To better understand and meet your diagnostic needs, please contact us with your product interest and distribution region. You may also visit us online and complete the New Customer Inquiry Form located in the Support Area of our web site.



Monobind Contact Information

www.monobind.com

Email:

Sales: sales@monobind.com

Orders: orders@monobind.com

Customer Service: customerservice@monobind.com

Technical Support: techsupport@monobind.com

Phone: 949.951.2665

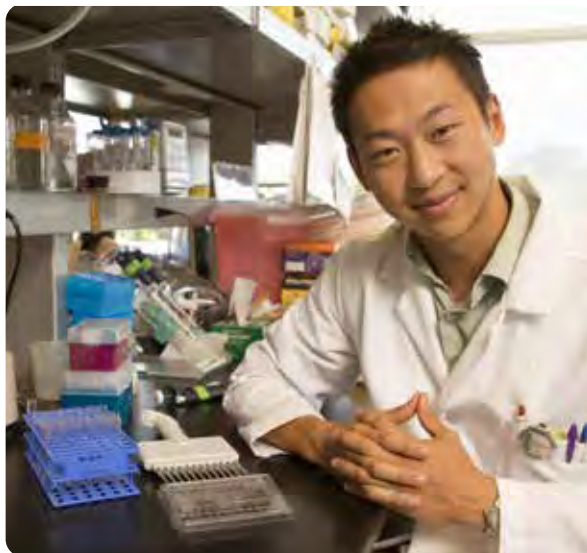
Fax: 949.951.3539

Hours of Operation: 8:30AM – 5PM Pacific Standard Time

Mail:

100 North Pointe Drive

Lake Forest, California 92630



Monobind, Inc. is a leader in diagnostic development and innovation. Founded in 1978, the company has manufactured more than 200 million immunoassays, ranking it among the industry's largest in-vitro diagnostic producers.

As a global provider, Monobind reaches more than 110+ countries with its assays, diagnostic tools, and biological raw materials. Customers such as biomedical researchers, laboratories, manufacturers, and distributors trust Monobind for quality, reliable, and cost-effective products.

With its pioneering experience and recognized R&D authority, Monobind is able to deliver products that set standards of excellence in diagnostic healthcare. We look forward to working with you!



Monobind Inc.

	AO Vector-Best EC Declaration of conformity EIA-1-17	Rev. 01 Page 1 of 3
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EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 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)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2012 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2012+AC:2012 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2013 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

AO Vector-Best

Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49

European authorized representative:

Bioron GmbH

Address: Rheinhorststr. 18, D-67071 Ludwigshafen, Germany, tel.: +49 (0) 621 5720 915, fax: +49 (0) 621 5720 916

Date: 2017/10/16



Murat Khusainov
General Director AO Vector-Best

Valid until: 2022/07/03

	AO Vector-Best	Rev. 01
	EC Declaration of conformity EIA-1-17	Page 2 of 3

No.	Product name	Identification data	REF
1.	Vectohep A-IgG	Enzyme immunoassay kit for the qualitative and quantitative determination of IgG to hepatitis A virus	D-0362
2.	VectoMeasles-IgG	Enzyme immunoassay kit for the quantitative and qualitative determination of IgG to measles virus in blood serum (plasma)	D-1356
3.	VectoMeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma)	D-1358
4.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen	D-1652
5.	Adenovirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen	D-1654
6.	VectoEBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to nuclear antigen of Epstein-Barr virus in blood serum (plasma)	D-2170
7.	VectoEBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to early antigens of Epstein-Barr virus in blood serum (plasma)	D-2172
8.	VectoEBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma)	D-2176
9.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma)	D-2602
10.	VectoMumps-IgM	Enzyme immunoassay kit for the detection of IgM to mumps virus in blood serum (plasma)	D-2604
11.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Toxocara antigens in blood serum (plasma)	D-2752
12.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Trichinella antigens in blood serum (plasma)	D-3152
13.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis	D-3202
14.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis	D-3204
15.	Yersinia-IgM-EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis	D-3206
16.	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Echinococcus granulosus antigens in blood serum (plasma)	D-3356
17.	Ascaris-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Ascaris lumbricoides antigens in blood serum (plasma)	D-3452
18.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgA to tissue transglutaminase in blood serum (plasma)	D-3758
19.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgG to tissue transglutaminase in blood serum (plasma)	D-3760
20.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 1 concentration in blood serum	D-3762
21.	Pepsinogen 2-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 2 concentration in blood serum	D-3764

	AO Vector-Best	Rev. 01
	EC Declaration of conformity EIA-1-17	Page 3 of 3

22.	VectoHanta-IgG	Enzyme immunoassay kit for the detection of IgG to Hantavirus in blood serum (plasma)	D-4902
23.	VectoHanta-IgM	Enzyme immunoassay kit for the detection of IgM to Hantavirus in blood serum (plasma)	D-4904
24.	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile Virus in blood serum (plasma)	D-5150
25.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile Virus in blood serum (plasma)	D-5152
26.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of avidity index of IgG to West Nile Virus in blood serum (plasma)	D-5154



CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC
PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 11/12/2003
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
2003 12 0392 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de /In favour of:

Fabricante/Manufacturer:

Nombre/Name: DIA. Pro Diagnostic Bioprobes S.r.l.

Dirección/Address: Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem **Dirección/Address:** Idem

Para el producto/For the product:

Categoría/Category: Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

Grupo genérico/Generic group: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

Tipo/Type: Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

Elaborado en/In the facilities:

Dia. Pro Diagnostic Bioprobes S.r.l.

Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de
medicamentos y
productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: B86E8DZ586

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

on0318@aemps.es

Página 1 de 2

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89



CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
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2003 12 0392 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:

Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.

Dirección/Address: Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem **Dirección/Address:** Idem

Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

Clasificación/Classification: Lista A, Anexo II / List A, Annex II

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis C, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]

HCV Ab ELISA cualitativo / ELISA qualitative

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests - for Dia.Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de
medicamentos y
productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: B86E8DZ586

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

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Página 2 de 2

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Fax: (+34) 91.822.52.89



Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE E DELL'ORDINAMENTO DEL SERVIZIO
SANITARIO NAZIONALE
DIREZIONE GENERALE DEI DISPOSITIVI MEDICI, DEL SERVIZIO FARMACEUTICO
E DELLA SICUREZZA DELLE CURE
UFFICIO IV ex DGFDM – DIAGNOSTICI IN VITRO

L.5.l.e.2/IV/2011/37

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;

VISTO il D.lgs. n. 332/2000 recante attuazione della direttiva 98/79/CE;

VISTA l'istanza del 29/09/2011 presentata dalla ditta Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159;

CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 24 Maggio 2004;

VISTI gli atti d'ufficio;

HAVING REGARD to 98/79/EC directive concerning the in vitro diagnostic medical-devices;

HAVING REGARD to legislative Decree (D.lgs.) n. 332/2000 reporting the accomplishment of 98/79/EC Directive;

HAVING REGARD to the request dated 29/09/2011 submitted by the company Dia.Pro Diagnostic Bioprobes Srl with legal site in Via Columella, 31 – 20128 Milano – C.F. and P.Iva 11924660159;

WHEREAS this company paid the fees required by Ministerial Decree (D.M.) May 24, 2004;

HAVING REGARD to the official deeds;

SI ATTESTA IT IS ATTESTED

che la ditta, Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, ha prodotto e marcato CE, come dispositivo medico- diagnostico in vitro, secondo le procedure previste dalla direttiva 98/79/CE, il prodotto:

that the Company Dia.Pro Diagnostic Bioprobes Srl located in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, manufactured and affixed CE marking as in vitro diagnostic medical device, according to the Directive 98/79/EC, the following product:

DP-9 DIA.BLOOD INSTRUMENT

Il suddetto prodotto, in base all'art. 4 della direttiva 98/79/CE, è di libera circolazione e può essere messo in commercio in Italia e in tutto il territorio dell'Unione Europea.



Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione nei paesi extra UE.

The above mentioned product, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union. This certificate is issued on the interested company's request according to the law and to export to non-European countries

IC/CM



Сертификат

mdc medical device certification GmbH

удостоверяет, что на предприятии

ВЕКТОР



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



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



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>


Руководитель сертификационного органа

Certificate

mdc medical device certification GmbH
certifies that

VECTOR



**AO Vector-Best
Research and Production Area
Building 36, Office 211, Koltsovo
630559 Novosibirsk region
Russian Federation**

**with the locations listed in the attachment
for the scope**

**Design and development, production and distribution of
medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)**
has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

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

Valid from	2020-07-04
Valid until	2023-07-03
Registration no.	D1213100019
Report no.	P20-00568-173687
Stuttgart	2020-06-02


Head of Certification Body



Attachment of the certificate

No. D1213100019

date 2020-06-02

Page 1 of 1

Location	Scope
AO Vector-Best Arbuzova str. 1/1, 630117 Novosibirsk Russian Federation	design and development, production and distribution of medical devices for in vitro diagnostics
AO Vector-Best Research and Production area, building 36, Koltsovo, 630559 Novosibirsk region Russian Federation	design and development, production of medical devices for in vitro diagnostics
AO Vector-Best Pasechnaya str, 3, 630117 Novosibirsk Russian Federation	design and development, production of medical devices for in vitro diagnostics



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>


Head of Certification Body

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 G).

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 Khussainov
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.	RecombBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombBest 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-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	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. Ascend-IgG-EIA-BEST	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25. Lambda antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lambda antibodies	D-3552
26. Lambda-IgM-EIA-BEST	ELISA kit for determination of IgM to Lambda antibodies	D-3554
27. Lambda antigen-EIA-BEST	ELISA kit for determination of Lambda 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. PAP-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-4356
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. Vedocriean - CHF - IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39. Vedocriean - 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 pro-hormone of brain natriuretic peptide	A-9102
59. Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106