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

Digitally signed by Oleg Cosciug-Tudor
Date: 2021.12.04 10:26:11 EET
Reason: MoldSign Signature
Location: Moldova

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

Monobind Inc.
The World Resource for Diagnostic Products

www.monobind.com

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Orange County, California, January 11, 2021

IM Global Biomarketing Group - Moldova SRL,
Tighina str.65,office 607
MD-2001,Chisinau, Republic of Moldova

Commercialization Agreement

To Whom It May Concern:

We, Monobind Inc., an ISO 13485 certified company specializing in the research, development and manufacturing of in vitro diagnostic products for clinical and research application, located at 100 North Pointe Drive, Lake Forest, California 92630 USA;

Hereby authorizes and entitles IM Global Biomarketing Group from Moldova legally registered at Tighina str.65,office 607 MD-2001,Chisinau to effect clinical trials and evaluation of goods, registration of the goods at Health Ministry of Moldova, receive certificate of registration and conclude an agreement on consulting and examination of the documents needed for the registration in Moldova.

This is also to confirm that IM Global Biomarketing Group is the exclusive distributor our AccuBind® ELISA and AccuLite® CLIA products and accessories in Moldova. IM Global Biomarketing Group is authorized to promote and supply our products, to contract for their delivery and take part in tenders with our products.

This authorization is valid until January 1, 2022.

On behalf of the Monobind Inc.

Alicia Jerome Volkov
Marketing Director
Monobind Inc.

Monobind Inc.
Lake Forest, CA 92630, USA

AccuBind
ELISA Microwells

Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System

Product Codes: 12525-300

1.0 INTRODUCTION

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

2.0 SUMMARY AND EXPLANATION OF THE TEST

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

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

Tests for immunoglobulin G (IgG) antibodies are of particular interest since they are produced in high amounts and indicate previous or recovering infection of pathogens. High levels of IgG are also known to mark immunity to a pathogen.[6] Additionally, IgG antibodies can be a good marker for efficacy of treatment of COVID-19 and successful immunization against SARS-CoV-2. However, IgG antibodies to SARS-CoV-2 do not usually appear in detectable levels until 10-20 days after symptom onset.[7-8] Therefore it is recommended that patient samples be repeated on a weekly basis to monitor the increase and stabilization of anti-SARS-CoV-2 S1-RBD IgG antibodies.

The Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG AccuBind® ELISA test kit is a qualitative test designed to produce highly sensitive and specific results with a simple and brief protocol. The test utilizes a recombinant receptor binding domain (RBD) from the spike region of SARS-CoV-2 coated on microwells to capture native antibodies in the sample. In the first step, prediluted samples are added directly to the wells. After the first incubation, excess sample material is washed out and an anti-human IgG (anti-hIgG) antibody labeled with an enzyme is added to the wells. After the second incubation, excess material is washed out again and substrate is added to produce a measurable color through the reaction with the enzyme and hydrogen peroxide.

3.0 PRINCIPLE

Sequential Sandwich ELISA Method (TYPE 10):

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

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

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

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

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

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

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

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

4.0 REAGENTS

Materials provided:

A. Anti-SARS-CoV-2 S1-RBD IgG Controls – 1ml/vial - Icons PC, NC, CC
Three (3) vials of ready-to-use references for anti-SARS-CoV-2 at positive, negative, and cut-off levels of IgG. Store at 2-8°C. A preservative has been added.

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

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

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

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

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

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

H. Product Instructions.

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

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

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

4.1 Required But Not Provided:

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

5.0 PRECAUTIONS

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

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

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

6.0 SPECIMEN COLLECTION AND PREPARATION

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

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

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

7.0 QUALITY CONTROL

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

8.0 REAGENT PREPARATION

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

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

9.0 TEST PROCEDURE

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

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

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

10.0 INTERPRETATION OF RESULTS

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

1. Record the absorbance of all samples obtained from the printout of the microplate reader as outlined in Example 1.
2. Multiply the average absorbance of the Cut-Off Control by the Cut-Off Factor to obtain the Cut-Off Value.
2. Divide the average absorbance of each sample by the Cut-Off Value and multiply by 10 to obtain the relative value unit (RV).
3. If RV <9, the sample is negative for Anti-SARS-CoV-2 S1-RBD IgG and if RV >10, the sample is positive for Anti-SARS-CoV-2 S1-RBD IgG
4. Samples with RV that fall within the range of 9-10 are considered borderline and should be retested with a new blood draw within 4-7 days for reevaluation.

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

EXAMPLE 1
(Cut Off Factor = 1.0)

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

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

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

11.0 Q.C. PARAMETERS

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

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

12.0 RISK ANALYSIS

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

12.1 Assay Performance

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the Cut-Off control.
5. The addition of substrate solution initiates a kinetic reaction, which is terminated by the addition of the stop solution. Therefore, the substrate and stop solution should be added in the same sequence to eliminate any time-deviation during reaction.
6. Plate readers measure vertically. Do not touch the bottom of the wells.
7. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
8. Use components from the same lot. No intermixing of reagents from different batches.
9. Very high concentration of anti-SARS-CoV-2 in patient specimens can contaminate samples immediately following these extreme levels. Bad duplicates are indicative of cross contamination. Repeat any sample, which follows any patient specimen with over 3.0 units of absorbance.
10. The Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG AccuBind® ELISA Test System is a qualitative assay and does not necessarily give an indication of quantities of IgG antibodies.
11. Samples, which are contaminated microbiologically, should not be used.
12. Any patient samples used in manufacturing have been heat inactivated prior to handling. However, treat all samples, including the control samples, as potentially hazardous or infectious.
13. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from Monobind's IFU may yield inaccurate results.
14. All applicable national standards, regulations and laws, including, but not limited to, good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
15. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.
16. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.

12.2 Interpretation

1. ***Measurements and interpretation of results must be performed by a skilled individual or trained professional.***
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
4. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
5. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.
6. The clinical significance of the result should be used in evaluating the possible presence of SARS-CoV-2 infection or COVID-19. However, **clinical inferences should not be solely based on this test** but rather as an adjunct to the clinical manifestations of the patient and other relevant tests such as Histology, nasophyrangeal swab, etc. A positive result does not indicate active COVID-19 infection and does not distinguish between infection or contagiousness of COVID-19. Similarly, a negative result does not eliminate the absence COVID-19 infection but rather a very low titer of antibody that may be related to the early stages of disease.
7. A positive result on the Anti-SARS-CoV-2 S1-RBD IgG AccuBind® ELISA test system does not necessarily predict immunity to the SARS-CoV-2. There has not yet been a conclusive study to indicate that the presence of IgG antibodies confirms immunity to the SARS-CoV-2 virus.
8. There have not been sufficient studies to determine the longevity of Anti-SARS-CoV-2 S1-RBD IgG in human patients. Therefore, it is possible that a positive IgG may decrease to a negative result over the course of several months or years on some patients.
9. If the Anti-SARS-CoV-2 S1-RBD IgG AccuBind® ELISA Test System is used to monitor antibody response in vaccinated patients, samples should be taken two weeks after the full course of vaccine doses have been administered. It is not uncommon to observe a negative result on a sample with only one dose of a vaccine regimen that requires two or more doses.

13.0 EXPECTED RANGES OF VALUES

A study of apparently healthy population (>150) from prior to December 2019 was undertaken to determine expected values for the Anti-SARS-CoV-2 Accubind® ELISA test system. Based on the data, the following cut-off point was established.

Presence of SARS-CoV-2 antibodies Confirmed

IgG > 10 RV

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precision of the Anti-SARS-CoV-2 (COVID-19) S1-RBD AccuBind® ELISA Test System were determined by analyses on three different levels of pool control sera. The number, mean value, standard deviation (σ) and coefficient of variation for each of these control sera are presented below.

TABLE 1
Within Assay Precision (Values in RV)

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

TABLE 2*
Between Assay Precision (Values in RV)

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

*As measured in eight experiments in duplicate.

14.2 Sensitivity

The sensitivity of the Anti-SARS-CoV-2 S1-RBD IgG AccuBind® ELISA Test System was determined by testing samples from 60 patients who had previously tested positive for SARS-CoV-2 via RT-PCR. The patient samples were sourced from three different blood banks. 59 out of the 60 patients tested positive indicating that the sensitivity of the test is at least 98.3% Positive Percent Agreement (PPA).

14.3 Accuracy

The Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG AccuBind® ELISA test system was used to test samples drawn at subsequent time intervals from 60 patients who tested PCR and IgG positive for SARS-CoV-2. The data is shown in Table 3 below.

TABLE 3

		Candidate Test Results		
Days from Symptom Onset	Number of Subjects Tested	IgG Positive Results	IgG PPA	95% CI
0-7 days	10	10	100%	72.2%-100%
8-14 days	24	24	100%	86.2%-100%
≥15 days	12	12	100%	75.8%-100%
Unknown	14	13	92.9%	68.5%-98.7%
Total Subjects	60	N/A	N/A	N/A

Overall IgG PPA: (98.3% 59/60); [95% CI (91.1% - 99.7%)]

14.4 Specificity

>150 different patient samples drawn prior to December 2019 were assayed to determine the prevalence of false positives. No false positive samples were detected indicating the Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG AccuBind® ELISA Test System has a 100% Specificity.

16.0 REFERENCES

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9. https://www.nybc.org/donate-blood/covid-19-and-blood-donation-copy/

Effective Date: 2021-APR-16 Rev 0 **DCO: NA**
MP12525 **Product Code: 12525-300**

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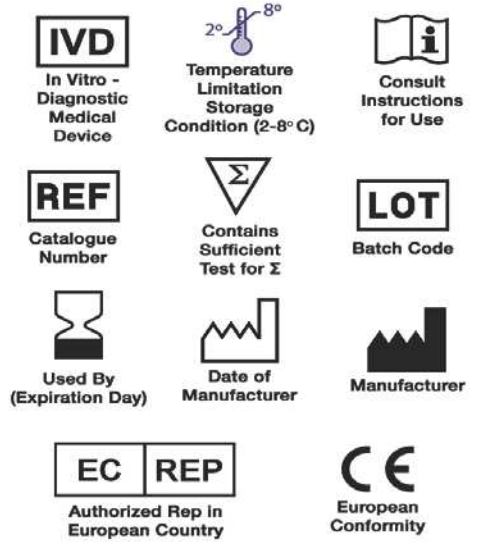
Please visit our website to learn more about our products and services.

Glossary of Symbols
(EN 980/ISO 15223)



General information

Manufacturer name and address:	**Monobind, Inc.** **100 North Pointe** **Lake Forest, CA 92630**

Product(s) (*category/group/type*):	***In Vitro Diagnostic Use Only product assessment of ANTI-SARS-COV-2 S1 RBD IgG in human circulation using colorimetric or chemiluminescence.***

Risk analysis carried out by (*names and job titles and qualifications*):

Dr. Frederick Jerome – President (Product characteristics, Tables, and possible Hazards) – Administration
Dr. Frederick Jerome – Director of Research and Development (Product characteristics, Tables, and possible Hazards) – R&D
Rom Morales – Operations Director (Possible Hazards – 3E, 3F, 3G) – Manufacturing
Anthony Shatola – Authorized Quality Representative – Quality Systems and Regulatory

Standard(s): EN ISO 14971:2019

Employees responsible for reviewing and updating the risk analysis:

Signature	Name	Title	Date
	Frederick R. Jerome	President/Director R&D	2020/12/24
	Rom Morales	Operations Director	2020/12/24
	Anthony Shatola	Quality Representative	2020/12/24
	Dr. Girish	Clinical Input/Reviewer	2020/12/24

Annex I **Intended use and identification of characteristics related to the safety of the medical device following EN ISO 14971:2019, Annex C**

Ann. C	Qualitative and Quantitative product characteristics (see standard)	Answer	Document
2.1	What is the intended use and how is the medical device to be used?	The quantitative determination of 12525 in Human Serum by a microplate enzyme immunoassay, colorimetric or chemiluminescence	IFU rev0-sec1.0
2.2	Is the medical device intended to be implanted?	NO	N/A
2.3	Is the medical device intended to contact the patient or other persons?	NO	N/A
2.4	What materials and/or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Purified antibodies and buffer formulations	DO rev0-secReagents IFU rev0-sec4.0
2.5	Is energy delivered to or extracted from the patient?	NO	N/A
2.6	Are substances delivered to or extracted from the patient?	NO	N/A
2.7	Are biological materials processed by the medical devices for subsequent re-use, transfusion or transplantation?	NO	N/A
2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO	N/A
2.9	Is the medical device intended to be routinely cleaned or disinfected by the user?	NO	N/A
2.10	Is the medical device intended to modify the patient's environment?	NO	N/A
2.11	Are measurements taken?	YES – By trained professionals	IFU rev0-sec12.2(1)
2.12	Is the medical device interpretative?	YES – By trained professionals and with a host of other relevant data from historical, physical and clinical sources	IFU rev0-sec12.2(1)
2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	YES – Instruments for reading results	IFU rev0-sec4.0
2.14	Are there unwanted outputs of energy or substances?	NO	N/A
2.15	Is the medical device susceptible to environmental influences?	YES – Extended exposure to heat and light	IFU rev0-sec4.0 (Note2)
2.16	Does the device influence the environment?	NO	N/A
2.17	Are there essential consumables or accessories with the medical device?	YES	IFU rev0-sec4.0
2.18	Is maintenance and/or calibration necessary?	YES	IFU rev0-sec12.1(12)
2.19	Does the medical device contain software?	NO	N/A
2.20	Does the medical device have a restricted shelf-life?	YES	IFU rev0-sec4.0 Product label StabilityStudy MB080 rev3
2.21	Are there any delayed or long-term effects?	NO	N/A
2.22	To what mechanical forces will the medical device be subjected?	None	N/A
2.23	What determines the lifetime of the medical device?	Stability of open reagents.	Stability Study IFU rev0-sec4.0

Ann. C	Qualitative and Quantitative product characteristics (see standard)	Answer	Document
			(Note2)
2.24	Is the medical device intended for single use?	NO	N/A
2.25	Is safe decommissioning or disposal of the medical device necessary?	YES	IFU rev0-sec5.0 MSDS rev0
2.26	Does installation or use of the medical device require special training or special skills?	YES	IFU rev0-sec12.2(1)
2.27	How will information for safe use be provided?	Information will be given directly to the end user.	IFU rev0 SOP-MB304 rev11
2.28	Will new manufacturing processes need to be established or introduced?	NO	N/A
2.29	Is successful application of the medical device critically dependent on human factors such as user interface?	YES – Trained laboratory professionals need to work with the device.	IFU rev0-sec12.2(1)
2.29.1	Can the user interface design features contribute to use error?	NO	N/A
2.29.2	Is the medical device used in an environment where distractions can cause use error?	NO	N/A
2.29.3	Does the medical device have connecting parts or accessories?	NO	N/A
2.29.4	Does the medical device have a control interface?	NO	N/A
2.29.5	Does the medical device display information?	NO	N/A
2.29.6	Is the medical device controlled by a menu?	NO	N/A
2.29.7	Will the medical device be used by persons with special needs?	NO – Trained laboratory professionals need to work with the device.	IFU rev0-sec12.2(1)
2.29.8	Can the user interface be used to initiate user actions?	NO	N/A
2.30	Does the medical device use an alarm system?	NO	N/A
2.31	In what way(s) might the medical device be deliberately misused?	Neglect of manufacturer's recommended maintenance.	IFU rev0-sec9.0 sec12.1(10)
2.32	Does the medical device hold data critical to patient care?	NO	N/A
2.33	Is the medical device intended to be mobile or portable?	NO	N/A
2.34	Does the use of the medical device depend on essential performance?	NO	N/A

Annex II Tables following EN ISO 14971:2019

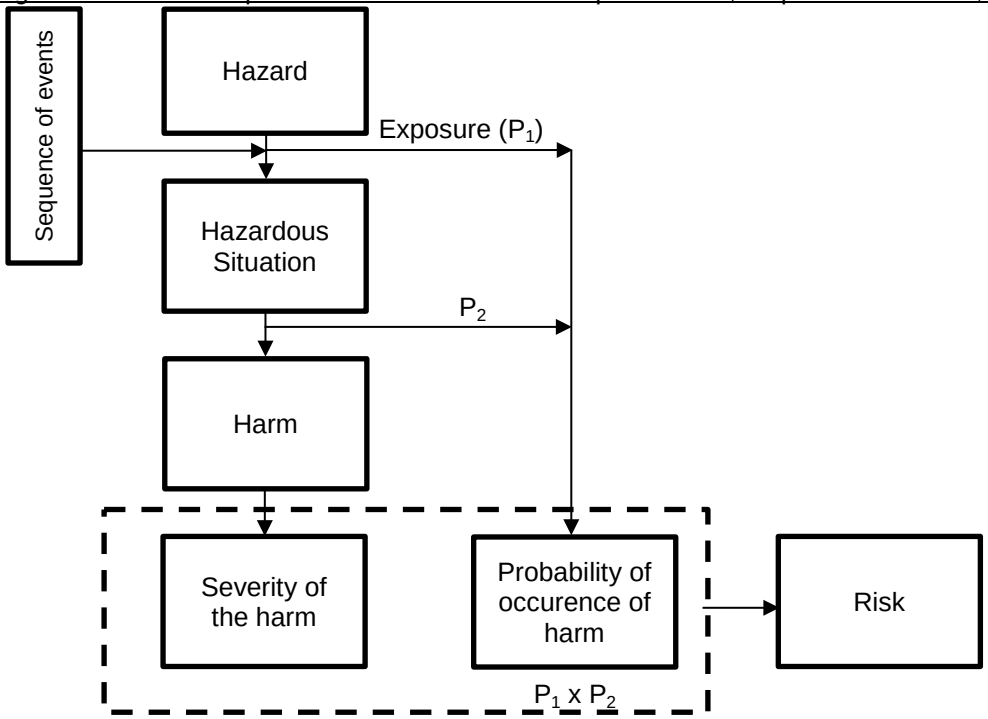
2a.1 Probability estimation (probability of harm per use / probability of harm per device / probability of harm per hour of use / etc.), ISO standard: table D.4 (Does a hazard occur in the absence of a failure, in a failure mode, or only in a multiple-fault condition?):

Probability	Range
(5) Frequent	$\geq 10^{-3}$
(4) Probable	$< 10^{-3}$ and $\geq 10^{-4}$
(3) Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
(2) Remote	$< 10^{-5}$ and $\geq 10^{-6}$
(1) Improbable	$< 10^{-6}$

NOTE:
Risk data and frequency are established based on device history and complaint file. Over (2×10^6) vials/year are dispensed and over 400,000 kits/year manufactured.

Probability of occurrence of harm is calculated using a $P_1 \times P_2 = P_{TOTAL}$ Estimation, where P_1 is the probability of a hazardous situation occurring and P_2 is the probability of a hazardous situation leading to harm. This is depicted below in Figure 1.

Figure 1 – Pictorial representation of the relationship of hazard, sequence of events, hazardous situation and harm



P_1 and P_2 are assigned numerical values based on the table above (2a.1), which, when multiplied together, estimate the approximate value of P_{TOTAL}.

2b. Severity levels, ISO standard: table D.3 / H2.5.4.6:

	Severity	Description
(I)	Negligible	Temporary discomfort
(II)	Minor	Temporary impairment not requiring medical intervention, minor physical injury, reversible deterioration of the state of health
(III)	Serious	Injury requiring medical intervention to prevent serious harm
(IV)	Critical	Permanent damage to a body function/structure, permanent impairment, Irreversible deterioration of the state of health, reduction in life expectancy, life-threatening injury
(V)	Catastrophic	Death

Severity levels of the Harm are not reduced from pre-mitigation to post-mitigation. Only probability may be reduced by limiting the degree of bias, imprecision, or interference of the assay.

Risk is calculating according to the table below (2c) wherein the severity of consequence and total probability are compared to generate a level of Risk.

2c. Risk level table (guidance) (using table 2a and 2b):

	Severity of consequence				
Probability (P_{TOTAL})	(I) Negligible	(II) Minor	(III) Serious	(IV) Critical	(V) Catastrophic
(5) Frequent	**1**	**1**	**1**	**1**	**1**
(4) Probable	**1**	**1**	**1**	**1**	**1**
(3) Occasional	2	2	**1**	**1**	**1**
(2) Remote	3	2	2	**1**	**1**
(1) Improbable	3	3	2	2	2

2d. Acceptability table (guidance):

1	(I)	Unacceptable:	**risk reduction is required**
2	(U)	ALARP:	**As-low-as-reasonably-practicable; further investigation required (benefits/costs)**
3	(N)	Insignificant:	Risk reduction not required; risk reduced as low as possible. Medical benefits outweigh the risk.

IVD-specific characteristics:

H.2.1	Identification of intended uses	Answer	Document
H.2.1.1	User:	Operator	IFU rev0-sec1.0 DO rev0
H.2.1.2	Intended use	The quantitative determination of ANTI-SARS-COV-2 S1 RBD IgG concentration in Human Serum by a microplate enzyme immunoassay, colorimetric	IFU rev0-sec1.0
H.2.1.3	Indications for use.	Immunoassay for the in vitro quantitative determination of ANTI-SARS-COV-2 S1 RBD IgG in human serum.	IFU rev0-sec1,2

Annex IV Risk reduction steps

Steps to reduce intolerable, undesirable or unacceptable risks are: none, or ….
(or, when risk reduction is required: *as follows by means of (in the priority order listed):*

- *direct safety means: re-design;*
- *protective measures in the manufacturing process;*
- *information for safety:*
  - *descriptive safety means: period or frequency of use, lifetime, restricting application, environment*
  - *redefining intended use*
  - *user instructions: manual, education)*

Risk Control:

	Hazard	2. Risk control measure (CAPA) or risk / benefit	3. Risk control implementation	4. Probability See table 2a)	5. Severity See table 2b)	6. Risk level See table 2c)	7. Acceptability See table 2d)	Document
	Manufacturing process – Changes to manufacturing processes; materials/materials compatibility information; manufacturing process; subcontractors.	CAPA	Quality Management System	2	I	3	N	MB723 rev7 MB029 rev4
	Transport and storage – Inadequate packaging; contamination or deterioration; inappropriate environmental conditions.	CAPA	Quality Management System	2	I	3	N	MB723 rev7 MB029 rev4

Annex V New hazards

Risk reduction procedure has introduced no new hazards (or, *new hazards as follows:*)

Annex VI Evaluation of all identified hazards.

All identified hazards are evaluated and reviewed in this risk analysis report.

Annex VII Risk Analysis conclusion.

All hazards are negligible, acceptable or tolerable

Annex VIII Review Risk Analysis / Verify risk control effectiveness

Future information and problems will be evaluated and corrected, and the risk analysis will be revised.

Completed By:

AShatola	Anthony Shatola	Quality Representative	2020/12/24
Signature	**Name**	**Title**	**Date**

Approved By:

	Frederick R. Jerome	President/Director R&D	2020/12/24
Signature	**Name**	**Title**	**Date**

Revised By:

AShatola	Anthony Shatola	Quality Representative	2020/12/24
Signature	**Name**	**Title**	**Date**

Approved By:

	Frederick R. Jerome	President/Director R&D	2020/12/24
Signature	**Name**	**Title**	**Date**

Risk ID	Hazard	Cause of the Hazard	Hazardous Situation	Harm	S	Pre-Mitigation				Method of Control	Risk Control Measure	Verification, Validation Traceability	S	Post-Mitigation					Notes
						P1	P2	PTotal	Risk					P1	P2	PTotal	Risk	Acceptability?	
Energy Hazards																			
	Electromagnetic Energy																		
A1	Line Voltage	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A2	Leakage current	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A3	- Enclosure leakage current	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A4	- Earth leakage current	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A5	- Patient leakage current	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A6	Electric fields	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A7	Magnetic fields	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Radiation energy																		
A8	Ionizing radiation	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A9	Non-ionizing radiation	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Thermal energy																		
A10	High temperature	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A11	Low temperature	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Mechanical energy																		
A12	Gravity	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A13	- Falling	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A14	- Suspended masses	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A15	Vibration	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A16	Stored energy	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A17	Moving parts	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A18	Torsion, shear and tensile force	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A19	Moving and positioning of patient	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A20	Acoustic energy	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A21	- Ultrasonic energy	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A22	- Infrasound energy	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A23	- Sound	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
A24	High pressure fluid injection	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
Biological and Chemical Hazards																			
	Biological																		
B1	Bacteria	Contamination of product	Incorrect result	Delayed diagnosis	I	2	2	2	3	Design Safety Info	Preservatives added IFU specifies to discard reagents that have bacteria growth	DO rev0 secReagents IFU rev0 sec8	I	2	1	2	3	N	
B2	Viruses	Contamination of product	Incorrect result	Delayed diagnosis	I	2	1	2	3	Design	Raw materials screen prior to use Preservatives added IFU cautions to treat all products as potentially hazardous	CofA of Raw Materials IFU rev0 sec5	I	2	1	2	3	N	
B3	Other agents (e.g. prions)	Contamination of product	Incorrect result	Delayed diagnosis	I	2	2	2	3	Protective	Raw materials screen prior to use Preservatives added IFU cautions to treat all products as potentially hazardous	DO rev0 secReagents IFU rev0 sec8	I	2	1	2	3	N	
B4	Re- or cross-infection	Contamination of product	Incorrect result	Delayed diagnosis	I	2	2	2	3	Protective	Preservatives added IFU specifies to discard reagents that are contaminated	DO rev0 secReagents IFU rev0 sec8	I	2	1	2	3	N	
	Chemical																		
B5	Exposure of airway, tissues, environment or property, e.g. to foreign materials:	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
B6	- Acids or alkalis	Stop solution comes in contact with user and causes irritation to user	Test delayed	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Level lowered as low as possible Identify Stop Solution with different color cap and label Add warning to SDS	DO rev0 secReagents SDS rev0	I	1	2	2	3	N	
B7	- Residues	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
B8	- Contaminates	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
B9	- Additives or processing aids	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
B10	- Cleaning, disinfecting or testing agents	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
B11	- Degradation products	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
B12	- Medical gasses	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
B13	- Anesthetic products	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Biocompatibility																		
B14	Toxicity of chemical constituents, e.g.:																		
B15	Allergenicity / irritancy	Stop solution comes in contact with user and causes irritation to user	Test delayed	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Level lowered as low as possible Identify Stop Solution with different color cap and label Add warning to SDS	DO rev0 secReagents SDS rev0	I	1	2	2	3	N	
B16	pyrogenicity	Stop solution comes in contact with user and causes irritation to user	Test delayed	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Level lowered as low as possible Identify Stop Solution with different color cap and label Add warning to SDS	DO rev0 secReagents SDS rev0	I	1	2	2	3	N	
Operational Hazards																			
	Function																		
C1	Incorrect or inappropriate output or functionality	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	

Risk ID	Hazard	Cause of the Hazard	Hazardous Situation	Harm	S	Pre-Mitigation				Method of Control	Risk Control Measure	Verification, Validation Traceability	S	Post-Mitigation					Notes
						P1	P2	PTotal	Risk					P1	P2	PTotal	Risk	Acceptability?	
C2	Incorrect measurement	Test fails and results are read as accurate or test succeeds but results are misread	Incorrect results	Misdiagnosis	II	2	2	2	2	Design Protective Safety Info	Test must be run with control and parameters should be met; include instructions on proper measurement Results to be used with other clinical observations IFU identifies only to be used by qualified personnel	IFU rev0-sec10,12.1	II	I	1	1	3	N	
C3	Erroneous data transfer	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
C4	Loss or deterioration of function	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Use error																		
C5	Attentional failure	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
C6	Memory failure	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
C7	Rule-based failure	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
C8	Knowledge-based failure	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Safety Info	Test run outside of parameters will not generate curve and results cannot be read; include instructions on running assay with all kits IFU identifies only to be used by qualified personnel	IFU rev0-sec9,12.1,14	I	1	1	1	3	N	
C9	Routine violation	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
Information Hazards																			
	Labelling																		
D1	Incomplete instructions for use	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	2	2	2	3	Design Safety Info	IFU reviewed prior to release by QC and QA Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec9.0	I	1	1	1	3	N	
D2	Inadequate description of performance characteristics	Will use test outside of specification	Limited interpretation of results	Delayed diagnosis	I	1	1	1	3	Design Safety Info	IFU reviewed prior to release by QC and QA - must complete release checklist Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	MF004 - Product Implementation and Document Checklist rev2, IFU rev0-sec14.0	I	1	1	1	3	N	
D3	Inadequate specification of intended use	Will use test outside of intended use	No result will be obtained	Delayed diagnosis	I	1	2	2	3	Design Safety Info	IFU reviewed prior to release by QC and QA; new customers complete application which asks purpose of use Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec1.0	I	1	1	1	3	N	
D4	Inadequate disclosure of limitations	Will use test outside of specification	Limited interpretation of results	Delayed diagnosis	I	1	1	1	3	Design Safety Info	IFU reviewed prior to release by QC and QA - must complete release checklist Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	MF004 - Product Implementation and Document Checklist rev2, IFU rev0-sec14.0	I	1	1	1	3	N	
	Operating instructions																		
D5	Inadequate specification of accessories to be used with the medical device	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Safety Info	IFU reviewed prior to release by QC and QA; list all supplied all required, but not supplied, equipment Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec4	I	1	1	1	3	N	
D6	Inadequate specification of pre-use checks	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Safety Info	IFU reviewed prior to release by QC and QA Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec7,9,12	I	1	1	1	3	N	
D7	Over-complicated operating instructions	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	2	2	2	3	Design Safety Info	IFU reviewed prior to release by QC and QA Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec2,3,8,9	I	1	2	2	3	N	
	Warnings																		
D8	Of side effects	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
D9	Of hazards likely with re-use of single –use medical devices	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
D10	Specification of service and maintenance	Test run with uncalibrated pipettes or equipment	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Safety Info	IFU reviewed prior to release by QC and QA Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel with calibrated equipment	IFU rev0-sec12.1	I	1	1	1	3	N	
Initiating Events and Circumstances																			
	Incomplete requirements																		
	Inadequate specification of:																		
E1	· Design parameters	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E2	· Operating parameters	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E3	· Performance requirements	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E4	· In-service requirements (e.g. maintenance, reprocessing)	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E5	· End of life	Test will be run with expired reagents; performance characteristics may be diminished	Limited interpretation of results	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Reagents labeled with expiration date on vial and CofA; IFU identifies stablity of opened reagents and where to locate expiration date IFU identifies performance characteristics to be met for valid results IFU identifies only to be used by qualified personnel with fresh reagents	DO rev0 secSpecifications-Performance Sample Labels revX IFU rev0-sec4,12.1	I	2	1	2	3	N	
	Manufacturing Processes	Insufficient control of:																	

Risk ID	Hazard	Cause of the Hazard	Hazardous Situation	Harm	S	Pre-Mitigation				Method of Control	Risk Control Measure	Verification, Validation Traceability	S	Post-Mitigation					Notes
						P1	P2	PTotal	Risk					P1	P2	PTotal	Risk	Acceptability?	
E6	changes to manufacturing processes	Test run incorrectly due to unexpected changes	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Any changes to manufacturing process must be approved by production, QA and management QC does not release product that does not pass *established* parameters Advisory notices sent out when changes to product occur	MB119 rev5 Device Change Order MB094 rev5 Procedure and Specification for Final Product Release MB007 rev3 Product Recall and Advisory Notice	I	1	1	1	3	N	
E7	materials/materials compatibility information	Test run with incorrect reagents or sample type	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read; intended use identifies sample type Reagents identified on label in name and with icons and have different colored caps for identification IFU identifies only to be used by qualified personnel with materials of the same lot	DO rev0secSpecifications-Packaging Sample Labels revX IFU rev0-sec4,12.1	I	1	1	1	3	N	
E8	manufacturing processes	Test run incorrectly due to unexpected changes	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Any changes to manufacturing process must be approved by production, QA and management QC does not release product that does not pass *established* parameters Advisory notices sent out when changes to product occur	MB119 rev5 Device Change Order MB094 rev5 Procedure and Specification for Final Product Release MB007 rev3 Product Recall and Advisory Notice	I	1	1	1	3	N	
E9	subcontractors	Test run incorrectly due to unexpected changes	Test may not generate curve	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Any changes to manufacturing process must be approved by production, QA and management QC does not release product that does not pass *established* parameters Advisory notices sent out when changes to product occur	MB119 rev5 Device Change Order MB094 rev5 Procedure and Specification for Final Product Release MB007 rev3 Product Recall and Advisory Notice	I	1	1	1	3	N	
	Transport and storage																		
E10	Inadequate packaging	Test kit damaged; test run with insufficient reagent; performance characteristics may be diminished	Limited interpretation of results	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Packaging procedure gives instructions on proper packaging process & is double-checked by additional technicians; test run outside of parameters will not generate curve and results cannot be read IFU identifies reagents to be used and volume - if insufficient or missing, should not be used IFU identifies only to be used by qualified personnel	MB304 rev11 Kit Packaging Protocol & Flowchart	I	1	1	1	3	N	
E11	Contamination or deterioration	Test run with contaminated or deteriorated reagents	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Safety Info	Preservatives added to reagents to prevent contamination; test run outside of parameters will not generate curve and results cannot be read; color will generate if contamination of substrate reagent occurs (identified on IFU) IFU identifies only to be used by qualified personnel and to reject kit if run with contaminated reagents	MB080 rev3 Stability for Monobind Products	I	1	1	1	3	N	
E12	Inappropriate environmental conditions	Product deteriorates due to improper storage	Test may not generate curve	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read Storage conditions identified on box and vials (2-8°C) IFU identifies only to be used by qualified personnel with fresh reagents	MB080 rev3 Stability for Monobind Products	I	1	1	1	3	N	
	Environmental factors																		
E13	Physical (e.g. heat, pressure, time)	Product deteriorates due to improper storage	Test may not generate curve	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read Storage conditions identified on box and vials (2-8°C) IFU identifies only to be used by qualified personnel with fresh reagents	MB080 rev3 Stability for Monobind Products IFU rev0-sec4	I	1	1	2	3	N	
E14	Chemical (e.g. corrosions, degradation, contamination)	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E15	Electromagnetic fields (e.g. susceptibility to electromagnetic disturbance)	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E16	Inadequate supply of power	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E17	Inadequate supply of coolant	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Cleaning, disinfection and sterilization																		
E18	Lack of, or inadequate specification for, validated procedures for cleaning, disinfection and sterilization	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E19	Inadequate conduct of cleaning, disinfection and sterilization	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Disposal and scrapping																		
E20	No or inadequate information provided	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	IFU reviewed prior to release by QC and QA Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec12	I	1	1	1	3	N	
E21	Use error	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec12	I	1	1	1	3	N	
	Formulation																		

Risk ID	Hazard	Cause of the Hazard	Hazardous Situation	Harm	S	Pre-Mitigation				Method of Control	Risk Control Measure	Verification, Validation Traceability	S	Post-Mitigation					Notes
						P1	P2	PTotal	Risk					P1	P2	PTotal	Risk	Acceptability?	
E22	Biodegration	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E23	Biocompatibility	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E24	No information or inadequate specification provided	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E25	Inadequate warning of hazards associated with incorrect formulations	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E26	Use error	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Human factors	Potential for use errors triggered by design flaws, such as:																	
E27	Confusing or missing instructions for use	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	IFU reviewed prior to release by QC and QA Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec2,3,8,9	I	1	1	1	3	N	
E28	Complex or confusing control system	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E29	Ambiguous or unclear device state	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E30	Ambiguous or unclear presentation of settings, measurements or other information	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E31	Misrepresentation of results	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E32	Insufficient visibility, audibility or tactility	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E33	Poor mapping of controls to actions, or of displayed information to actual state	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E34	Controversial modes or mapping as compared to existing equipment	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E35	Use by unskilled/untrained personnel	Test run incorrectly	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	New Customer application asks for details of end user - only released to qualified personnel Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel	IFU rev0-sec12.2	I	1	1	1	3	N	
E36	Insufficient warning of side effects	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E37	Inadequate warning of hazards associated with re-use of single-use medical devices	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E38	Incorrect measurement and other metrological aspects	Test fails and results are read as accurate or test succeeds but results are misread	Incorrect results	Misdiagnosis	II	1	2	2	2	Protective Safety Info	Test must be run with control and parameters should be met; include instructions on measurement calculations Results to be used with other clinical observations IFU identifies only to be used by qualified personnel	IFU rev0-sec10, 12	II	1	1	1	3	N	
E39	Incompatibility with consumables/accessories/other medical devices	Test run with incompatible consumables (ex. Pipette tips) or readers or expired materials	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU specifies required but not provided equipment including correct reader andpipettes IFU identifies only to be used by qualified personnel; IFU identifies kit should be used with calibrated equipment	IFU rev0-sec12	I	1	1	1	3	N	
E40	Slips, laps and mistakes	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Failure modes																		
E41	Unexpected loss of electrical/mechanical integrity	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E42	Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of ageing, wear and repeated use	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
E43	Fatigue failure	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
IVD-Specific Characteristics																			
H.2.2	Identification of possible use errors																		
H.2.2.1	Use errors																		
	Procedure shortcuts	Test procedure not followed correctly - steps skipped or altered	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU provided with all tests and warns that deviation from IFU may yield inaccurate results IFU identifies only to be used by qualified personnel	IFU rev0-sec9,12	I	1	1	1	3	N	
	Optimization attempts and improvizations	Test procedure not followed correctly - steps altered	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU provided with all tests and warns that deviation from IFU may yield inaccurate results IFU identifies only to be used by qualified personnel	IFU rev0-sec9,12	I	1	1	1	3	N	
	Omissions of actions intended by the manufacturer	Test procedure not followed correctly	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU provided with all tests and warns that deviation from IFU may yield inaccurate results IFU identifies only to be used by qualified personnel	IFU rev0-sec9,12	I	1	1	1	3	N	
H.2.2.2	Possible use errors by laboratory personnel:																		

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						P1	P2	PTotal	Risk					P1	P2	PTotal	Risk	Acceptability?	
	Use of an IVD medical device with an inappropriate calibrator, reagent, instrument or sample matrix	test procedure performed using incorrect calibrators. incorrect sample type, or read on the incorrect instrument	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Proper Identification on Components	Test run outside of parameters will not generate curve and results cannot be read Components listed on IFU and CofA; IFU states there shall be no intermixing of reagents IFU identifies only to be used by qualified personnel	IFU rev0-sec4, 12	I	1	2	2	3	N	
	attempt to optimize an examination procedure in order to improve its performance characteristics	Test procedure not followed correctly - steps altered	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU provided with all tests and warns that deviation from IFU may yield inaccurate results IFU identifies only to be used by qualified personnel	IFU rev0-sec9,12	I	1	1	1	3	N	
	abbreviation of an examination procedure (taking "shortcuts")	Test procedure not followed correctly - steps skipped or altered	Test may not generate curve	Delayed diagnosis	I	1	1	1	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU provided with all tests and warns that deviation from IFU may yield inaccurate results IFU identifies only to be used by qualified personnel	IFU rev0-sec9,12	I	1	1	1	3	N	
	neglect of instrument maintenance	Test run with uncalibrated pipettes or equipment	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	1	1	1	3	Design Safety Info	IFU reviewed prior to release by QC and QA Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel with calibrated equipment	IFU rev0-sec12	I	1	1	1	3	N	
	disabling or failing to enable safety features	Test procedure performed on equipment that is out of calibration; without controls; without regard to temperature and time restrictions	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU warns that deviation from IFU may yield inaccurate results and identifies all safety features to be utilized IFU identifies only to be used by qualified personnel	IFU rev0-sec12	I	1	2	2	3	N	
	operation in adverse environmental conditions	Product deteriorates due to improper storage	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read Storage conditions identified on box and vials (2-8°C) IFU identifies only to be used by qualified personnel with fresh reagents	IFU rev0-sec4, 9	I	1	2	2	3	N	
	assay drift	Too much time passes between pipetting of samples	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	2	2	2	3	Design Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel and to limit pipetting of samples to within ten (10) minutes	IFU rev0-sec12	I	1	2	2	3	N	
	time-deviation during reaction	Reagents added in different sequence during test procedure	Test may not generate curve	Delayed diagnosis	I	2	2	2	3	Design Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel and reagents added in same sequence during procedure to eliminate time-deviation during reaction	IFU rev0-sec9,12	I	1	2	2	3	N	
	Incorrect pipetting	reagents added to test system incorrectly (i.e. touching the bottom of the wells)	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Safety Info	Test run outside of parameters will not generate curve and results cannot be read IFU identifies only to be used by qualified personnel and to avoid touching the bottom of the wells, as plate readers measure vertically	IFU rev0-sec12	I	1	1	1	3	N	
	Out of range samples	high level samples are not diluted	Limited interpretation of results	Delayed diagnosis	I	1	2	2	3	Design Safety Info	Test run outside of parameters will not generate curve and results cannot be read; values of calibrators listed on IFU and vials IFU identifies only to be used by qualified personnel and that high level samples should be diluted and appropriate dilution factor used to calculate results	IFU rev0-sec9,12	I	1	1	1	3	N	
H.2.2.3	Possible use errors by healthcare providers:																		
	Incorrect Usage	use of IVD examination results for a new clinical application that is not claimed by the manufacturer	Limited interpretation of results	Delayed diagnosis	I	1	2	2	2	Design Protective Safety Info	Test must be run with control and parameters should be met; Controls will fail if test is run incorrectly and results should not be used Results to be used with other clinical observations - results should be used in conjunction with other test results IFU identifies only to be used by qualified personnel	IFU rev0-sec2,12	I	1	1	1	3	N	
H.2.3	Identification of characteristics related to safety																		
H.2.3.2	Performance characteristics of quantitative examination procedures	Test procedure is inconsistent with results; cannot test sensitive subjects; is subject to interference	Test will produce incorrect results (false high, low, or inconclusive)	Misdiagnosis	II	2	2	2	2	Design Protective Safety Info	Degree of bias was limited, precision improved as great as possible, sensitivity measured and confirmed at low levels, and specificity tested to ensure minimal interference QC tests product prior to release to ensure meets predetermined qualifications All performance characteristics identified in IFU IFU identifies only to be used by qualified personnel	MB053 rev1 CofA IFU rev0-sec12	II	1	1	1	3	N	
H.2.3.4	Dependability characteristics	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
H.2.3.5	Ancillary patient information	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
H.2.4	Identification of known and foreseeable hazards																		
H.2.4.1	Hazards to the patient																		
	Incorrect results	Test is run incorrectly and incorrect results generate	Test will produce incorrect results (false high, low, or inconclusive)	Misdiagnosis	II	1	1	1	3	Design Protective Safety Info	Test must be run with control and parameters should be met; Controls will fail if test is run incorrectly and results should not be used Results to be used with other clinical observations - results should be used in conjunction with other test results IFU identifies only to be used by qualified personnel	MB053 rev1 CofA IFU rev0-sec12	II	1	1	1	3	N	
	Delayed results	Delay in results given to clinician	Delay in results given to patient	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Test run outside of procedure and parameters will not generate curve and results cannot be read IFU provided with all tests and warns that deviation from IFU may yield inaccurate results IFU identifies only to be used by qualified personnel	IFU rev0-sec12.0	I	1	2	2	3	N	

Risk ID	Hazard	Cause of the Hazard	Hazardous Situation	Harm	S	Pre-Mitigation				Method of Control	Risk Control Measure	Verification, Validation Traceability	S	Post-Mitigation					Notes
						P1	P2	PTotal	Risk					P1	P2	PTotal	Risk	Acceptability?	
	Incorrect information accompanying the result	Incorrect information given to clinician	Delay in results given to patient	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Performance Characteristics demonstrate a strong test system so test results will indicate a discrepancy with other clinical observations Results to be used with other clinical observations - mismatched data indicate further studies necessary IFU identifies only to be used by qualified personnel	IFU rev0-sec12, 13	I	1	1	1	3	N	
H.2.4.2	Relationship to performance characteristics										IFU identifies only to be used by qualified personnel								
	Failure to meet specifications for performance characteristics related to safety	Will use test outside of specification	Limited interpretation of results	Delayed diagnosis	I	2	2	2	3	Design Protective Safety Info	Performance Characteristics demonstrate a strong test system so test results will indicate a discrepancy with other clinical observations Results to be used with other clinical observations - mismatched data indicate further studies necessary IFU identifies only to be used by qualified personnel	IFU rev0-sec11,14	I	1	2	2	3	N	
H.2.4.3	Identifying hazards in fault conditions																		
	Within-batch inhomogeneity	Different parts of test system generates different values	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	2	1	2	3	Design Protective Safety Info	Test run outside of parameters will not generate curve and results cannot be read; trend analysis is performed to ensure within-batch homogeneity QC does not release product that does not pass established parameters IFU states if controls do not pass, to reject test	MB017 rev5 Performance of Trend Analysis IFU rev0-sec7,12	I	2	1	2	3	N	
	Batch-to-batch inconsistency	Repeated testings have different results	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Batch to batches consistency is tested and monitored; test run outside of parameters will not generate curve and results cannot be read QC does not release product that does not pass established parameters IFU states if controls do not pass, to reject test	MB017 rev5 Performance of Trend Analysis IFU rev0-sec7,13	I	1	2	2	3	N	
	Non-traceable calibrator value	Calibrator does not have consistent or accurate values	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Calibrators are assigned according to traceable WHO standards; test run outside of parameters will not generate curve and results cannot be read QC does not release product that does not pass established parameters IFU states if controls do not pass, to reject test	MB501 Rev0 Traceability to International Standard IFU rev0-sec7,12	I	1	2	2	3	N	
	Non-commutable calibrator	Test run with incorrect reagents	False positives	Misdiagnosis	II	1	2	2	3	Design Protective Safety Info	Trend analysis with batches is tested to ensure consistency; test run outside of parameters will not generate curve and results cannot be read QC does not release product that does not pass established parameters IFU states if controls do not pass, to reject test	IFU rev0-sec7,12	II	1	2	2	3	N	
	Non-specificity (e.g., interfering factors)	Values interfere with test results	Interference	Delayed diagnosis	I	2	1	2	3	Design Safety Info	Interfering factors tested prior to product release, minimized when possible, and listed on IFU test run outside of parameters will not generate curve and results cannot be read	IFU rev0-sec7,12	I	2	1	2	3	N	
	Sample or reagent carryover	Contamination of product	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Trend analysis with batches is tested to ensure consistency; test run outside of parameters will not generate curve and results cannot be read QC does not release product that does not pass established parameters IFU states if controls do not pass, to reject test	IFU rev0-sec7,12	I	1	2	2	3	N	
	Measurement imprecision (instrument-related)	Repeated testings have different results	Performance characteristics may be diminished; Limited interpretation of results	Delayed diagnosis	I	2	1	2	3	Design Protective Safety Info	Precision is tested and test system made as precise as possible; test run outside of parameters will not generate curve and results cannot be read QC does not release product that does not pass established parameters IFU states if controls do not pass, to reject test	IFU rev0-sec7,12, 13	I	2	1	2	3	N	
	Stability failures (storage, transportation, in-use)	Test stored incorrectly and deteriorates	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Storage of product specified on product label and IFU; test run outside of parameters will not generate curve and results cannot be read; stability studies are performed prior to product release and tested on a lot to lot basis QC does not release product that does not pass established parameters	MB080 Stability for Monobind Products rev03 IFU rev0-sec7,12	I	1	2	2	3	N	
	Unstable reagent	Test run with reagents that have deteriorated	Test may not generate curve	Delayed diagnosis	I	2	1	2	3	Design Protective Safety Info	Storage of product specified on product label and IFU; test run outside of parameters will not generate curve and results cannot be read; stability studies are performed prior to product release and tested on a lot to lot basis QC does not release product that does not pass established parameters	MB080 Stability for Monobind Products rev03 IFU rev0-sec7,12	I	2	1	2	3	N	
	Hardware/software failure	None	None	None	None	None	None	None	None	N/A	N/A	N/A	None	None	None	None	None	No Risk	
	Packaging failure	Test run with reagents that have deteriorated	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Design Protective Safety Info	Storage of product specified on product label and IFU; test run outside of parameters will not generate curve and results cannot be read; stability studies are performed prior to product release and tested on a lot to lot basis QC does not release product that does not pass established parameters	MB304 rev11 Kit Packaging Protocol and Flowchart IFU rev0-sec7,12	I	1	2	2	3	N	
H.2.4.4	Identifying hazards in normal use																		
	imperfect discrimination between positive and negative samples:	qualitative examination procedures typically exhibit inherent false negative and false positive rates, caused in part by uncertainties associated with determination of a suitable cut-off value	Test will produce incorrect results (false high, low, or inconclusive)	Misdiagnosis	II	1	2	2	2	Design Protective Safety Info	Test must be run with control and parameters should be met; Controls will fail if test is run incorrectly and results should not be used Results to be used with other clinical observations - results should be used in conjunction with other test results IFU identifies only to be used by qualified personnel	IFU rev0-sec6,7,10,12,14	II	1	2	2	3	N	

Risk ID	Hazard	Cause of the Hazard	Hazardous Situation	Harm	S	Pre-Mitigation				Method of Control	Risk Control Measure	Verification, Validation Traceability	S	Post-Mitigation					Notes
						P1	P2	PTotal	Risk					P1	P2	PTotal	Risk	Acceptability?	
	uncertainty of measurement	technology can limit the precision of quantitative IVD medical devices; if performance criteria only require 95 % of the results to meet a specified limit based on medical utility, then up to 5 % of the individual results are allowed to fall outside the limit	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Protective Safety Info	Test must be run with control and parameters should be met; Controls will fail if test is run incorrectly and results should not be used Results to be used with other clinical observations - results should be used in conjunction with other test results IFU identifies only to be used by qualified personnel and that results generated by computer controlled data reduction requires calibrators to fall within 10% of assigned concentration	IFU rev0-sec10,12	I	1	2	2	3	N	
	unexpected influence of other constituents (interfering factors) in the sample matrix:	new drugs, biochemical metabolites, heterophilic antibodies and sample preparation materials can affect the performance characteristics of an IVD examination procedure	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Protective Safety Info	Results to be used with other clinical observations - results should be used in conjunction with other test results IFU identifies only to be used by qualified personnel and notifies that certain antibodies will interfere with results.	IFU rev0-sec6,7,10,12,14	I	1	2	2	3	N	
	natural heterogeneity of the analyte:	antibodies and other proteins in blood samples are mixtures of different isoforms; published performance characteristics of an IVD examination procedure might not apply to all components of the mixture	Test may not generate curve	Delayed diagnosis	I	1	2	2	3	Protective Safety Info	Results to be used with other clinical observations - results should be used in conjunction with other test results IFU identifies only to be used by qualified personnel and notifies that certain antibodies will interfere with results.	IFU rev0-sec6,7,10,12,14	I	1	2	2	3	N	
H.2.4.5	Identifying hazardous situations																		
	False negative results	a physician receives false negative results when screening analyte levels	False Negative Results	Misdiagnosis	II	1	2	2	2	Design Protective Safety Info	Test must be run with control and parameters should be met Results to be used with other clinical observations IFU identifies only to be used by qualified personnel in conjunction with other clinical observations	IFU rev0-sec12	II	1	1	1	3	N	
	Interference	a physician makes a diagnosis of disease based on examination results that were affected by interference	Test will produce incorrect results (false high, low, or inconclusive)	Misdiagnosis	II	1	2	2	2	Design Protective Safety Info	Interference has been reduced as low as possible and identified on IFU; Test must be run with control and parameters should be me Results to be used with other clinical observations IFU identifies only to be used by qualified personnel	IFU rev0-sec14	II	1	1	1	3		
H.2.5	Estimation of risk to patients	Estimating probability of occurrence:																	
	Incorrect result	- Probability that the IVD medical device will produce an incorrect result;	Incorrect diagnosis	Misdiagnosis	II	1	2	2	3	Design Protective Safety Info	Test must be run with control and parameters should be met Results to be used with other clinical observations IFU identifies only to be used by qualified personnel in conjunction with other clinical observations	IFU rev0-sec12.2	II	1	1	1	3	N	
	Failure to detect incorrect result	- the probability that the laboratory will fail to detect the result as incorrect and will report the incorrect result;	Incorrect diagnosis	Misdiagnosis	II	1	2	2	3	Design Protective Safety Info	Test must be run with control and parameters should be met Results to be used with other clinical observations IFU identifies only to be used by qualified personnel in conjunction with other clinical observations	IFU rev0-sec12.2	II	1	1	1	3	N	
	incorrect result leads to action / inaction	- the probability that the physician will fail to recognise the result as incorrect and will be led to take (or not take) action;	Incorrect diagnosis	Misdiagnosis	II	1	2	2	3	Design Protective Safety Info	Test must be run with control and parameters should be met Results to be used with other clinical observations and test results IFU identifies only to be used by qualified personnel in conjunction with other clinical observations	IFU rev0-sec12.2	II	1	1	1	3	N	
	action/ inaction	- the probability that the patient will be harmed by the physician's action or inaction.	Incorrect diagnosis	Misdiagnosis	II	1	1	1	3	Design Protective Safety Info	Test must be run with control and parameters should be met Results to be used with other clinical observations IFU identifies only to be used by qualified personnel in conjunction with other clinical observations	IFU rev0-sec12.2	II	1	1	1	3	N	

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

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Lake Forest, CA 92630

LICENSE NUMBER: 43042
EXPIRATION DATE: 11/16/2023

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the provisions of Division 104, Chapter 6, Article 6 of the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

DECLARATION OF CONFORMITY

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

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

and

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

Address**: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS Tel.: +31 (0)6 516 536 26;
or as: CEpartner4U, 3951DB; 13. NL tel: +31 (0)6 – 516.536.26)

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

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

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

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

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

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

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

Tony Shatola; QA Director, Monobind Inc.

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

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

Olga Teirlinck; Consultant, CEpartner4U BV

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

Appendix

Date: 2011-09-26

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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 3868-7-2011

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor Address**
See Attached List (Two Pages)	Manufacturer: Monobind, Inc. 100 North Pointe Drive Lake Forest, CA 92630. Distributor: Monobind, Inc. 100 North Pointe Drive Lake Forest, CA 92630.

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the products(s) listed above.

Ann M. Ferriter
Acting Director
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 10 day of Aug month 2011 year.

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013

Certificate to Foreign Government – Attachment (Page 1 of 2)

NAME OF PRODUCT(S)

Total T3 TEST SYSTEM
Total T4 TEST SYSTEM
Free T4 TEST SYSTEM
Free T3 TEST SYSTEM
TSH TEST SYSTEM
T3 Uptake TEST SYSTEM
TBG TEST SYSTEM
Tg TEST SYSTEM
N-T4 TEST SYSTEM
N-TSH TEST SYSTEM
N-17-OHP TEST SYSTEM
Anti-Tg TEST SYSTEM
Anti-TPO TEST SYSTEM
LH TEST SYSTEM
FSH TEST SYSTEM
PRL TEST SYSTEM
HCG TEST SYSTEM
Cortisol TEST SYSTEM
Testosterone TEST SYSTEM
Free Testosterone TEST SYSTEM
Progesterone TEST SYSTEM
17-OH Progesterone TEST SYSTEM
Estradiol TEST SYSTEM
Estriol TEST SYSTEM
DHEA-S TEST SYSTEM
DHEA TEST SYSTEM
HGH TEST SYSTEM
Insulin TEST SYSTEM
C-Peptide TEST SYSTEM
IgE TEST SYSTEM
Ferritin TEST SYSTEM
Transferrin Soluble Receptor TEST SYSTEM
Vit B12 TEST SYSTEM
Folate TEST SYSTEM
Creatine Kinase TEST SYSTEM
Digoxin TEST SYSTEM
hsCRP TEST SYSTEM
Myoglobin TEST SYSTEM
cTnI TEST SYSTEM
H. Pylori Ab TEST SYSTEM
HbSAg TEST SYSTEM

NAME OF MANUFACTURER/DISTRIBUTOR, ADDRESS

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

Certificate to Foreign Government – Attachment (Page 2 of 2)

NAME OF PRODUCT(S)

Rubella TEST SYSTEM
Toxoplasma TEST SYSTEM
AFP TEST SYSTEM
CEA TEST SYSTEM
tPSA TEST SYSTEM
fPSA TEST SYSTEM
CA-125 TEST SYSTEM
CA-19-9 TEST SYSTEM
CA-15-3 TEST SYSTEM
Free Beta hCG TEST SYSTEM
Mulit-Ligand Quality Control Material
Cardiac Panel Quality Control Material
Tumor Marker Quality Control Material
Thyroid Panel Quality Control Material
Fertility Quality Control Material

TEST SYSTEMS available in ELISA (AccuBind®), CLIA (AccuLite®) and VAST® formats.
Quality Control Material available in (QSure®) Assayed and Unassayed formats.

Lumax® CLIA Analyzer
NeoLumax™ CLIA Analyzer
LuMatic™ CLIA Analyzer
Lumax-96™ CLIA Analyzer
Impulse 2™ CLIA Analyzer
Impulse3™ CLIA Analyzer
Eldex 3.8® ELISA Analyzer
NeoEldex™ ELISA Analyzer
Autoplex™ ELISA & CLIA Analyzer
Immunoassay Plate Washer

"END OF PRODUCT LIST"

NAME OF MANUFACTURER/DISTRIBUTOR, ADDRESS

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

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