STATEMENT

We, **Rapid Labs Limited** having a registered office at Unit 2 & 2A, Hall Farm Business Centre, Church Road, Little Bentley, Colchester, Essex CO7 8SD, United Kingdom assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: March 5th, 2025

Signature: Tracy Wu Rapid Labs Rapid Labs Limited

Digitally signed by Dolgopol Iulian
Date: 2026.01.13 11:40:19 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Unit 2 & 2A, Hall Farm Business Centre,
Church Road, Little Bentley, Colchester,
Essex CO7 8SD, United Kingdom

Certificate of Registration

This certificate has been awarded to

Rapid Labs Limited

Unit 2 & 2A Hall Farm, Business Centre, Church Road, Little Bentley, Colchester, Essex, CO7 8SD, United Kingdom

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Please refer to the Appendix

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by Mukesh Singhal - On behalf of the Schemes Manager

Appendix to Certificate

Design, Development, Manufacture and Supply of In-Vitro Diagnostic Products for the Blood Grouping products, Detection of Hormones, Drug of Abuse, Infectious Disease, Tumour Markers and Cardiac Markers, and the related POCT Analyzer. Supply of Glass Vials and Bottles

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

Mukesh Singhal - On behalf of the Schemes Manager

CE

Rapid Labs

Declaration of Conformity

for Syphilis reagents & kits

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

In accordance with Article 9(1) and by reference to Annex III, Rapid Labs Ltd has assessed the conformity for the following listed devices to the essential requirements of Directive 98/79/EC of the European Parliament and of the Council of the European Union on *in vitro* diagnostic medical devices.

General Product Name:	Syphilis reagents & kits
Manufacturer:	Rapid Labs Ltd. Unit 2 & 2a Hall Farm, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
Variants:	n/a
Intended Use:	The kits and reagents uses serum or plasma samples in the detection of *T.Pallidum* antibodies.
Intended User:	Professional use
IVD Directive Category:	General
Notified Body:	n/a
CE Certificate Reference:	n/a
IVD Directive Assessment Route:	Annex III
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Rowland King **Position** Managing Director

Signed **Date** 04/02/2022

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

CE

Rapid Labs

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 13612:2002	Performance evaluation of in-vitro medical devices
EN 13641:2002	Elimination or reduction of risk infection related to in-vitro diagnostics
EN ISO 15223-1:2016	Medical devices - Symbols
EN ISO 23640:2015	Evaluation of stability

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
RL-VDRL250	VDRL Carbon Antigen Kit with no accessories	51819
D-RPR100 D-RPR250 D-RPR500	RPR Test Kit	51819
RL-TPHA100 RL-TPHA200 RL-TPHA500	TPHA Test Kit (haemagglutination)	51800
RL-TPHA-PC-1	TPHA positive control	51800
RL-TPHA-NC-1	TPHA Negative control	51800
RL-RPR5ML	VDRL (RPR) Carbon Reagent	51821
RL-RPRP1ML	RPR Positive Control	32449
RL-RPRN1ML	RPR Negative Control	32449

Version History

Version	Compiled by	Date	Description
2.0	Emily Swager	04/02/2022	Update to director

TPHA - 100, 200 & 500 Tests

IVD CE +2°C +8°C REF

RAPID BIOTEC™

Cat. No.	Product Description
RL-TPHA100	TPHA 100 Test Kit
RL-TPHA200	TPHA 200 Test Kit
RL-TPHA500	TPHA 500 Test Kit

INTRODUCTION AND INTENDED USE

Intended for the qualitative detection of Treponema pallidum IgG and IgM antibodies to syphilis in human serum or EDTA plasma and to determine the titre level of the samples. The intended use population is patients with a suspected syphilis infection or at elevated risk of syphilis infection who attend STI clinics or other healthcare settings. This assay is not intended for automated use. This assay is not intended for blood screening or as a confirmatory assay on donor samples.

PRINCIPLE OF THE TEST

Syphilis is caused by the spirochaete *Treponema pallidum,* and is usually acquired by sexual contact, although the disease may be transmitted by transfusion of infected blood. Intrauterine infection also occurs. The infection is a chronic condition that typically progresses through distinct primary, secondary, tertiary, and quaternary stages of infection. These stages produce diverse clinical symptoms, typically producing initial sores known as chancres, then syphilitic rash followed by long periods of dormancy. Untreated infection may eventually result in cardiovascular problems and neurosyphilis.

The organism cannot be routinely cultured in artificial media, and diagnosis of the infection usually depends on the demonstration of antibodies in the blood, which appear soon after initial infection.

TPHA uses preserved avian erythrocytes coated with extracted antigens of *T.pallidum* (Nichols strain). Specific antibodies present in a sample of plasma or serum bind to these antigens when the sample is incubated with the erythrocytes. This causes the erythrocytes to agglutinate, then settle to form a characteristic pattern in the test well. Non-specific reactions are eliminated by the use of absorbents.

Additional required materials:

Micro-pipettes capable of delivering; 10, 25, 75 & 190µl

REAGENT PREPARATION

Bring all reagents and samples to room temperature before use.
Kit controls must be run with each assay
Ensure Test and Control Cells are thoroughly re-suspended.

STORAGE AND SHELF LIFE AFTER OPENING

Test cells and Control Cells must be stored upright position at 2-8°C. Do not freeze
After opening, Test cells, Control cells, Sample diluent and controls are stable for up to 3 months when stored upright at 2-8°C
Do not use after expiration date.

KIT CONTENTS

Name	Description	100 tests	200 tests	500 tests
Test Cells	Avian erythrocytes coated with antigens of *T. pallidum*	7.6 mL	2 x 7.6 mL or 1 x 15.2mL	2 x 20 mL or 1 x 40 mL
Control Cells	Avian erythrocytes	7.6 mL	2 x 7.6 mL or 1 x 15.2mL	2 x 20 mL or 1 x 40 mL
Sample Diluent	Saline solution containing absorbents	20 mL	2 x 20mL or 1 x 40mL	2 x 50mL
Positive Control	Human antiserum Titre 1/1280	1 mL	1 mL	1 mL
Negative Control	Normal Rabbit Serum	1 mL	1 mL	1 mL

WARNINGS AND PRECAUTIONS

- Rapid Biotec's TPHA is for in vitro diagnostic use only. For professional use only
- Test cells, Control cells, Sample Diluent and Controls contain sodium azide (< 0.1% w/v) as a preservative, which can accumulate in lead or copper pipes to form potentially explosive azides. To prevent azide build-up, flush with large volumes of water after disposing of solutions containing azide into the drains.
- Caution: Controls contain material of human or animal origin. All human origin material in the TPHA has been tested and found negative or nonreactive for HBsAG, HIV 1 Ag [or HIV PCR(NAT)], HIV 1/2 antibody, HCV antibody, and HCV PCR (NAT) as required at the time of collection using FDA licensed test kits. No known test methods can offer total assurance that products derived from human origin will not transmit HIV, hepatitis, or other potentially infectious agents. Therefore, the Controls and all specimens should be handled as potentially infectious.
- Reagents contain material of animal origin. Any bovine albumin used in the manufacture of this product is sourced from donor animals that have been inspected and certified by Veterinary Service inspectors to be disease free.
- Do not freeze Test cells, Control cells, Sample Diluent and Controls.
- Test cells and Control cells must be thoroughly re-suspended prior to use. Failure to do so could result in an inadequate dilution and erroneous results.
- Test cell and Control cell erythrocytes should be covered by suspension medium during storage, where this has not been the case then erythrocytes should be re-suspended. Failure to do so could result in clumping in the test well.
- Test cells, Control cells and Sample Diluent from the same lot may be pooled using good laboratory practices.
- Reagents showing visible signs of microbial growth or gross turbidity may indicate degradation and should be discarded according to local rules.
- The effects of microbial contamination in specimens cannot be predicted.
- Do not use Test cells, Control cells, Sample Diluent, or Controls after the expiration date.
- Do not interchange caps between the Positive and Negative Control vials. Controls are differentiated by colour coded caps and the vial label. If caps are inadvertently switched, the Control tubes should be discarded.
- Samples exhibiting gross lipemia, haemolysis or icterus may be compromised and may require alternative testing.
- Deviations from the TPHA Instructions for Use can lead to erroneous results.
- Dispose of leftover reagents in a safe manner, in accordance with local regulations.

SAMPLE COLLECTION, HANDLING AND STORAGE

TPHA may be used for testing with either human serum or EDTA plasma specimens for up to 7 days after collection. Specimens should be free of particulate matter to prevent interference with the assay result. If erythrocytes or other visible components are present in the specimen, remove by centrifugation to prevent interference with the test results. Store EDTA plasma and serum specimens at 2-8°C up to 7 days. EDTA plasma and serum specimens can be frozen at less than -20°C for up to one month, thawed and mixed thoroughly prior to testing. Specimens may be frozen and thawed up to 5 times.

Allow all specimens to equilibrate to room temperature before use.

ASSAY PROCEDURE

Each sample requires 3 wells plus 2 additional wells for Positive and Negative Controls.

1. Sample Dilution (to 1 in 20)

Add 190µL of sample diluent to the first well.
Add 10µL of sample to the same well.
Mix thoroughly.
Note: Kit controls are pre-diluted (i.e., diluted 1 in 20)

2. Test

Add 25µL of Positive Control and Negative Control to designated test wells.
Transfer 25µL of diluted sample from step 1 to a test well.
Transfer 25µL of diluted sample from step 1 to a control well.
Re-suspend the Test and Control Cells thoroughly.
Add 75µL of Test Cells to Positive Control and Negative Control wells.
For diluted samples add 75µL of Test Cells to test wells, and 75µL Control Cells to control wells.
(Final sample or Control dilution is 1 in 80)

Mix wells thoroughly.
Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes.
Read the agglutination patterns. Patterns are stable if undisturbed.

Sample titration assay procedure (optional)

9 wells are needed for each sample from 1 in 80 to 1 in 10240 dilution.
2 additional wells for Positive and Negative Controls (if run at 1 in 80 only)
1 additional well is needed if Controls Cells are run

1. Sample Dilution (to 1 in 20)

Add 190µL of sample diluent to the first well.
Add 10µL of sample to the same well.
Mix thoroughly.
Note: Kit controls are pre-diluted (i.e. diluted 1 in 20)

2. Titration

Leave the second and third wells empty, add 25µL of diluent to well 4 to well 10 in the sequence.
Transfer 25µL from step 1 to the second and third wells.
Transfer 25µL from step 1 to the fourth well and mix, then serially dilute along the well sequence, discard the excess 25µL from the final well.
Note: Care must be taken to avoid carryover of sample between serial dilution steps
Kit Positive Control can be titrated if required

3. Test

Re-suspend the Test Cells and Control Cells thoroughly
Add 75µL of Control Cells to well 2
Add 75µL of Test Cells to wells 3 to 10.
(Final sample dilution for Test Cells is 1 in 80 – 1 in 10,240)

Mix wells thoroughly.
Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes.
Read the agglutination patterns. Patterns are stable if undisturbed.
The titre of the sample is the reciprocal of the final positive sample dilution.

CONTROL PROCEDURE

The Positive and Negative Controls must be run with each assay. If required, the Kit Positive can be titrated, and the expected end point is 1/640 – 1/2560. Additional QC testing may be performed by the operator by the inclusion of other characterised specimens or reference material.

The Positive Control should produce a positive result and the Negative Control should produce a negative result with the test. If the appropriate results are not obtained with the controls, the assay is considered invalid and all samples within that assay should be retested.

TPHA Controls are pre-diluted. They should be added directly to the reaction well without being diluted in TPHA Sample Diluent. Test Cells are added directly to the Controls.

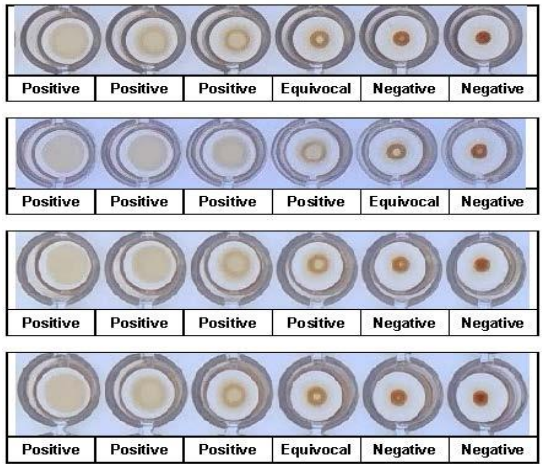
TPHA - 100, 200 & 500 Tests

IVD CE +2°C +8°C REF

RAPID BIOTEC™

INTERPRETATION OF RESULTS

A sample where the Test Cell well is non-reactive should be considered as **negative for *T.pallidum* antibodies**.
Reactivity less than equivocal is considered negative.
A sample where the Test Cell well is reactive or equivocal indicates antibodies to *T.pallidum* resulting from a syphilis infection. The sample should be repeated in duplicate. Where either repeat duplicate result is reactive or equivocal the sample should be considered as **positive *for T.pallidum* antibodies**. Where both duplicate repeat results are non-reactive then the samples are determined as non-reactive.
Where a sample is reactive in both Test and Control Cells, if the agglutination is greater in the Test Cells then the sample is considered positive and should be repeated as above.
When running the sample titration procedure, a titre of ≥ 1/80 is considered reactive and the sample should be repeated in duplicate.
Reactive results may indicate active, past, or successfully treated syphilis infections.
Examples of result interpretation are shown in the figure below.



Test cells	Control cells	Repeat	Absorption	Interpretation
+ (strong)	+ (weak)	Y	N	TP positive
+ (equal to CC)	+ (equal to TC)	Y	Y	TP positive
+ (weak)	+ (strong)	Y	Y	TP positive
+	-	Y	N	TP positive
-	-	N	N	TP negative
-	+	Y	N	TP negative

Absorption of Non-specific Reactions (only to be performed where a sample has greater or equal agglutination in the Control cells than the Test Cells)
1. Add 10µL of sample to 190µL of re-suspended Control Cells, mix thoroughly and leave for 30 minutes.
2. Centrifuge to deposit the cells at a minimum of 1500g for 3 minutes.
3. Add 25µL of supernatant from step 2 to each of 2 wells.
4. Ensure Test and Control Cells are re-suspended.
Add 75µL of Test Cells to the first well.
Add 75µL of Control Cells to the second well.
5. Mix wells thoroughly and Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes
6.Read and interpret patterns as above.
During absorption of Non-Specific reactions, the supernatant is added directly to the reaction well without dilution in Sample Diluent. Performing this step incorrectly may result in false negative results.

PERFORMANCE CHARATERISTICS

Limit of detection

TPHA has an expected limit of detection of ≤0.1 IU/mL against the WHO 1st IS for human syphilitic plasma IgG NIBSC code:05/122.

Reproducibility

Assay reproducibility was assessed using a characterised, mixed titre panel comprising 25 syphilis positive and 5 syphilis negative samples. The panel was tested using multiple lots of TPHA on 5 testing days over a 7 day period, in duplicate, with two separate runs on each testing day.
Reproducibility Study – rate of agreement

Samples	Agreement N=	Total N=	Rate of Agreement	95% CI
Syphilis positive	250	250	100.00%	98.54 – 100%
Syphilis negative	50	50	100.00%	92.89 – 100%
Overall	300	300	100.00%	98.78 – 100%

Cross reactivity and interference

140 syphilis negative samples containing antibodies to infectious diseases (Rubella, Toxoplasma, Borrelia, EBV, HCV, HBV, HAV, HIV, HTLV, Herpes, Chlamydia), ANA antibodies, Rheumatoid Factor antibodies and samples from pregnant (multiparous) subjects were tested in TPHA. All samples gave the expected negative result.
151 syphilis positive samples containing these antibodies and samples from pregnant (multiparous) subjects were tested in TPHA. All samples gave the expected positive result.

Prozone

Prozone effects may be seen at very high antibody levels for haemagglutination assays. In studies for TPHA, no negative results were obtained at high levels of TP antibodies up to 100 IU/mL.

Diagnostic sensitivity

A panel of 205 commercially sourced, well characterised TP positive samples (157 serum and 48 EDTA plasma) were tested using the TPHA in comparison with PK TPHA 500. The true clinical status for the commercially obtained syphilis positive samples was presumed to be that defined by the vendor assay results.
Initial testing for TPHA v PK TPHA 500

Sample	Agreement measure	Agreement N=	Total N=	ROA	95% CI
Serum	PPA	157	157	100.0%	97.68-100.0%
EDTA plasma	PPA	48	48	100.0%	92.60-100.0%
Combined	PPA	205	205	100.0%	98.22-100.0%

Statistical summary against clinical status

Sample	Agreement measure	Agreement N=	Total N=	ROA	95% CI
All samples	Sensitivity	205	205	100.0%	98.22-100.0%

Diagnostic specificity

A panel of 1248 known TP negative EDTA plasma samples were tested using the TPHA in comparison with PK TPHA 500. Initial reactive samples were retested in duplicate with the relevant method.
Initial testing for TPHA v PK TPHA 500

Sample	Agreement measure	Agreement N=	Total N=	ROA (%)	95% CI (%)
EDTA plasma	NPA	1236	1238	99.84	99.42-99.98

Repeat testing for TPHA v PK TPHA 500

Sample	Agreement measure	Agreement N=	Total N=	ROA	95% CI
EDTA plasma	Specificity	1247	1248	99.92	99.55-100.0

Statistical summary by sample type against clinical status — after repeat testing

Sample	Agreement measure	Agreement N=	Total N=	ROA	95% CI
EDTA plasma	NPA	1245	1246	99.92	99.55-100.0

LIMITATIONS

TPHA may be used for serum and EDTA plasma samples. No interfering substances have been identified however TPHA can cross react with other treponemal infections such as *T.pertenue* and *T.carateum* so positive results should be confirmed by another method.
In early primary syphilis, occasionally, specific antibodies may not be detected.

REFERENCES

1.Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65.
2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
3. Rathlev T. - Haemagglutination test utilizing pathogenic Treponema pallidum for the serodiagnosis of syphilis. Br J Vener Dis 1967 ; 43 : 181-5
4. Tomizawa T. Kasamatsu S. Yamaya S. - Usefulness of the haemagglutination test using Treponema pallidum antigen (TPHA) for the serodiagnosis of syphilis. Jap J Med Sci Biol 1969 ; 22 : 341-50.
5. Sequeira P,J,L. Eldridge A,E. - Treponemal Haemagglutination test. Br J Vener Dis 1973 ; 49 : 242-8.
6. Larsen S.A., Hambie E.A., et coll., Specificity, sensitivity, and reproducibility among the fluorescent treponemal antibody absorption test, the microhemagglutination assay for Treponema pallidum antibodies, and the hemagglutination treponemal test for syphilis. J. Clin. Microbiol., 1981 ; 14 : 441 – 445.
7. Wasley G.D. & Wong H.H.Y. Syphilis Serology Principles and Practice. Oxford Medical Publications 104 – 105

Consult instructions for use	REF Catalogue number
+2°C +8°C Store between 2-8ºC	Manufacturer
IVD In-vitro diagnostic use	Date of manufacture
Use by	LOT Batch code or lot number

Manufactured By:
Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex
CO7 8SD United Kingdom

Doc Ref: TPHA Kit RB 1 - 06/2024

RAPID BIOTEC™ CE IVD

RPR Test Kit

– 100, 250 & 500 Tests

Cat. No.	Product Description
D-RPR500	RPR 500 Test Kit
D-RPR250	RPR 250 Test Kit
D-RPR100	RPR 100 Test Kit

INTENDED USE

Intended for the qualitative detection of reagin antibodies in human serum and EDTA plasma as an aid in the diagnosis of syphilis. The intended use population is patients with a suspected syphilis infection or at elevated risk of syphilis infection who attend STI clinics or other healthcare settings. This assay is not intended for automated use. This assay is not intended for blood screening or as a confirmatory assay on donor samples.

PRINCIPLE OF THE TEST

RPR utilises carbon particles coated with cardiolipin antigen to detect reagin antibodies present in serum or plasma of syphilitic persons. RPR measures IgM & IgG antibodies to lipoidal material released from damaged host cells as well as possibly cardiolipin released from treponemes. If antibodies are present, they combine with lipid particles of the antigen, causing them to aggregate. The carbon particles appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non aggregated pattern which may form buttons in the centre of the test area.

KIT CONTENTS

Kit size (no. of tests)	100	250	500
RPR Carbon Antigen	2ml	5ml	10ml
Positive Control	1ml	1ml	1ml
Negative Control	1ml	1ml	1ml
Stirrers	100	250	500
Test Slides	10	25	50
Dispensing Bottle	1	1	1
Dispensing tip	1	1	1
Pack insert (IFU)	1	1	1

MATERIALS REQUIRED, BUT NOT PROVIDED

Micropipettes capable of dispensing 50µl.
Rotator set at 90-110 r.p.m.

REAGENT PREPARATION

Bring all reagents and samples to room temperature before use.

STORAGE AND SHELF LIFE AFTER FIRST OPENING

Antigen and controls should be stored at 2–8°C. Do not freeze.
After opening Antigen and Controls are stable for up to 3 months when stored at 2–8°C.
Do not use after the expiration date.

WARNING & PRECAUTIONS

- RPR is for in vitro diagnostic use only. For professional use only.
- Antigen and Controls contain sodium azide (< 0.1% w/v) as a preservative, which can accumulate in lead or copper pipes to form potentially explosive azides. To prevent azide build-up, flush with large volumes of water after disposing of solutions containing azide into the drains.
- Refer to RPR Safety Data Sheet for detailed information on reagent chemicals.
- This device contains material of animal origin. All bovine material is origin certified from approved sources.
- Do not freeze Antigen and Controls.
- Reagents from the same lot may be pooled using good laboratory practices.
- Reagents showing visible signs of microbial growth or gross turbidity may indicate degradation and should be discarded according to local rules.
- The effects of microbial contamination in specimens cannot be predicted.
- Do not use reagents after the expiration date.
- Do not interchange caps between the Positive and Negative Control vials. Controls are differentiated by colour coded caps and the vial label. If caps are inadvertently switched, the Control tubes should be discarded.
- The reaction areas on the Test Cards should not be touched as this may invalidate results.
- Samples exhibiting gross lipemia, hemolysis or icterus may be compromised and may require alternative testing.
- Deviations from the RPR Instructions for Use can lead to erroneous results.
- Dispose of leftover reagents in a safe manner, in accordance with local regulations

SAMPLE COLLECTION, HANDLING & STORAGE

RPR may be used for testing with either human serum or EDTA plasma specimens for up to 7 days after collection. Specimens should be free of particulate matter to prevent interference with the assay result. If erythrocytes or other visible components are present in the specimen, remove by centrifugation to prevent interference with the test results. Store EDTA plasma and serum specimens at 2-8°C up to 7 days. EDTA plasma and serum specimens can be frozen at less than -20°C for up to one month, thawed and mixed thoroughly prior to testing. Specimens may be frozen and thawed up to 5 times. Allow all specimens to equilibrate to room temperature before use.

DIRECTIONS FOR USE

1) Place 50µl of sample into a circle marked on the test card.
2) Spread the sample evenly over the test circle area.(Note: The distance between the test circle area on the slide shall not be less than 0.5cm) The flat end of the pipsters can be used to spread the sample over the test circle.
3) Shake the vial of RPR antigen to ensure even mixing.
4) Attach the dropping needle to the plastic dropping bottle and take up the RPR antigen by suction.
5) Invert the dropper bottle containing antigen and gently squeeze to expel air from the needle.
6) Holding the dropper bottle vertically over the test sample dispense a single drop,17.5 µl, of antigen.
7) Place test card on a card rotator and rotate at 100 RPM for 8 minutes.
8) Read and interpret results visually in good light. See interpretation.
9) It is recommended that the kit positive and negative controls are run with each batch of test samples.
10) Return unused antigen from dropper bottle to glass vial.
11) Clean out dropper bottle and needle with distilled water and allow to dry before re-using.

Sample titration assay procedure

1) Make doubling dilutions from Undiluted to 1:16 in normal saline.
2) Place 50µl of each dilution in to a separate circle on the test card.
3) Spread each dilution evenly over the test circle. 4) Continue as from Assay procedure section (3). The titre of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

CONTROL PROCEDURE

The Positive and Negative Controls must be run with each assay. Additional QC testing may be performed by the operator by the inclusion of other characterised specimens or reference material. The Positive Control should produce a positive result and the Negative Control should produce a negative result with the test. If the appropriate results are not obtained with the controls, the assay is considered invalid and all samples within that assay should be

retested.

INTERPRETATION OF RESULTS

Strong reactive: Large clumps of carbon particles with a clear background

Reactive: Large clumps of carbon particles somewhat more disperse than strong reactive pattern

Weak Reactive: Small clumps of carbon particles with light Grey background

Trace reactive: Slight clumping of carbon particles typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the test circle.

Non-reactive: Typically a smooth grey pattern or a button of non-aggregated carbon particles in the centre of the test circle.

PERFORMANCE CHARACTERISTICS

Reproducibility

A panel of syphilis-negative samples and syphilis-positive samples of varying reactivity were tested twice per day for 5 days over a 7 day period using 3 reagent lots.

Samples	Agreement N=	Total N=	Rate of Agreement	95%CI
Syphills positive	250	250	100.00%	98.54-100%
Syphills negative	50	50	100.00%	92.89-100%
Over all	300	300	100.00%	98.78-100%

Cross reactivity and interference

At least 9 syphilis positive samples and 9 syphilis negative samples from patients with a variety of potentially interfering diseases and conditions were tested using 3 different lots of RPR reagents in order to determine whether these diseases or conditions cause positive or negative analytical interference. Cross reactivity and interference of Rubella, Toxoplasma, Borrelia, EBV, HCV, HBV, HAV, HIV, HTLV, Herpes, Chlamydia), ANA antibodies, Rheumatoid Factor antibodies and samples from pregnant (multiparous) subjects were tested. All samples tested (151 syphilis positives and 140 syphilis negatives) showed concordance with the clinical status of the sample.

Diagnostic sensitivity

The diagnostic sensitivity for RPR was calculated for 168 samples (37 EDTA plasma and 131 sera) which had been confirmed as RPR positive by two other CE marked assays for non-treponemal antibodies

Sample	Agreement measure	Agreement N=	Total N=	ROA (%)	95%CI (%)
EDTA Plasma	Sensitivity	37	37	100%	90.51-100.00
Sera	Sensitivity	131	131	100%	97.22-100.00
All Samples	Sensitivity	168	168	100%	97.83-100.00

Diagnostic specificity

The false positive rate of RPR was compared with another CE-marked assay for non-treponemal antibodies associated with syphilis infection using known syphilis-negative samples.

		RPR	
		R	NR
CE Marked RPR	R	0	0
	NR	0	1246

R: Reactive

NR: Non-Reactive

NPA agreement for RPR and alternative RPR product

Sample	Agreement measure	Agreement N=	Total N=	ROA (%)	95%CI (%)
EDTA Plasma	NPA	1246	1246	100%	99.70-100.0%

LIMITATIONS

Pinta, yaws, bejel and other treponemal diseases may produce reactive results with non-treponemal tests.

RPR is intended for use as an aid to diagnosis. Results should be interpreted in combination with other serological test results and clinical evaluation.

POST MARKET SURVEILLANCE

Should this IVD be implicated in any serious incident a report shall be made to the manufacturer and competent authority of the Member State in which the user and/or the patient is established.

SUMMARY OF SAFETY AND PERFORMANCE

SSP can be obtained from the EUDAMED website

Index of Symbols

	Consult instructions for use	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	LOT	Batch code
2°C 8°C	Store between 2-8°C		Use-by date
	Manufacturer		Date of manufacture
Σ	Contains sufficient for <*n*> test	EU REP	European Authorized Representative

EU REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 20/11/2025

Declaration of Conformity

for Blood grouping reagents

Digitally signed by Tricolici Lidia
Date: 2025.08.20 14:35:59 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Blood grouping reagents
Manufacturer:	Rapid Labs Ltd. Unit 2 & 2a Hall Farm Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
Variants:	n/a
Intended Use:	To qualitatively determine the presence or absence of the specific antigens on the red cells of blood donors or patients requiring a blood transfusion .
Intended User:	Professional use
IVD Directive Category:	Annex II List A
Notified Body:	Polskie Centrum Badarí i Certyfikacji S.A, 23A Klobucka Street, 02-699 Warsaw, Poland, Notified Body Number 1434.
CE Certificate Reference:	1434-IVDD-031/2022 and 1434-IVDD-032/2022
IVD Directive Assessment Route:	Annex II List A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Rowland King **Position** Managing Director

Signed **Date** 23rd May 2023

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN 13612:2002	Performance evaluation of in-vitro medical devices
EN 13641:2002	Elimination or reduction of risk infection related to in-vitro diagnostics
EN ISO 15223-1:2016	Medical devices - Symbols
EN ISO 23640:2015	Evaluation of stability

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
BG-A10	Anti-A Monoclonal CE marked	52532
BG-B10	Anti-B Monoclonal CE marked	52538
BG-AB10	Anti-A, B Monoclonal CE marked	46442
BG-D10	Anti-D Monoclonal (IgG + IgM) CE Marked	52647
BG-ABOD10	ABOD Blood grouping Kit CE Marked	43508

Version History

Version	Compiled by	Date	Description
5.0	Emily Swager	08/11/2023	Addition of ABOD blood grouping kit

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

RAPID BIOTEC™

CATALOGUE NUMBER
Anti-A: BG-A10, BG-A10X10
Anti-B: BG-B10, BG-B10X10
Anti-A,B: BG-AB10, BG-AB10X10

INTENDED USE
The intended use of Rapid Biotec ABO blood grouping reagents is to be used in a qualitative method to identify the presence or absence of A or B antigens on the surface of red blood cells in donors or patients who require a blood transfusion.

These reagents are suitable for use by the slide, tube and Bio-Rad ID card and are designed for use by operators trained in serological techniques.

INTRODUCTION
The ABO Blood Group System
In 1900, Landsteiner discovered that the serum of some individuals would agglutinate the red cells of others and that this phenomenon could be used to classify individuals into different blood group phenotypes. Four common phenotypes are recognised – O, A, B and AB. Subgroups of the A and B antigens have since been identified. The ABO phenotype of an individual is usually determined by the agglutination reactions of the individual's red cells with Anti-A, Anti-B and Anti-A,B antisera (forward grouping). In testing blood samples from adults, confirmation of the ABO blood group can be provided by the reactions of the individual's serum with standard A and B red cell suspensions (reverse grouping).

PRINCIPLE
When used by the recommended techniques these reagents will cause agglutination (clumping) of red cells carrying the specific antigen (positive test).
Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).
These reagents have been optimised for use by the recommended techniques without further dilution or additions. These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS
Blood grouping reagents contain monoclonal murine IgM antibodies in a buffer solution. The solution is a phosphate buffer containing sodium chloride, EDTA and bovine material. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-A	Blue	Patent blue	BIRMA-1
Anti-B	Yellow	Tartrazine	LB-2
Anti-A,B	Colourless	None	ES-15/ES-4

Materials needed but not provided:
- Microscope slide/Plastic slides
- Plastic stirrers
- Timer
- Isotonic saline/LISS
- Compatible serum/plasma
- Test tubes
- Centrifuge (1000 rcf)
- Bio-Rad ID Cards (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID-diluent 2

PRECAUTIONS
- The cell lines used to produce these reagents are of murine origin and have been tested and found to be negative for Mouse Antibody Production (MAP) viruses. Care must be taken in the use and disposal of each container and its contents.
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE
For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS
- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.
- Each 10ml vial contains approx number of tests:

Methods	Drop size	No. of tests
Slide & Tube	45µl	<218
	50µl	<200

STORAGE AND STABILITY
Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION AND PREPARATION
- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.
- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE
SLIDE METHOD:
1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum or in isotonic saline.
2. Add one drop (45-50µl) of either Anti-A, Anti-B or Anti-A,B reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination

TUBE METHOD (recommended for A_x):
1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of either Anti-A, Anti-B or Anti- A,B reagent to an appropriately labelled test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

RAPID BIOTEC™

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-ABO reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

LIMITATIONS

- The results of red cell grouping should be confirmed by reverse grouping the individual's serum with known A1 and B red cells.
- No recipient should be given AB blood unless the cells of the recipient are clearly positive with Anti-A and Anti- B and the recipient's serum shown to give negative reactions with A1 and B cells (unless the recipient has been shown to be a subgroup of AB with Anti-A1 in the serum).
- Rapid Biotec Anti-A,B does not detect A3 antigens neither does it detect "Acquired B cells"
- Rapid Biotec Anti-B does not react with "Acquired B cells"
- Anti-A blood grouping reagent is not validated to detect all examples of A_x cells. False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.
- ABO antigens are not fully developed at birth therefore weaker reactions may occur with cord or neonatal samples.
- Using the reagent to detect weak B subgroups may give rise to false negative or weaker reactions when using slide, microtitre plates or gel cards.
- Stored blood may give weaker reactions than fresh blood.
- False positive or false negative results may also occur due to:
  - •Contamination of test materials
  - •Improper storage, cell concentration, incubation time or temperature
  - •Improper or excessive centrifugation
  - •Deviation from the recommended techniques
  - •Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARATERISTICS

- Reagents will work best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping tested by the recommended techniques against a panel of antigen-positive red cells.
- Anti-A,B can detect A_x antigens however, only through tube technique; see recommended technique in this IFU.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC):
  Anti- A = 03/188
  Anti- B = 03/164
- Rapid Biotec ABO reagents do not detect crypt antigens such as T, Tn or Cad.
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- BG-A, BG-B and BG-A,B have been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-A, Anti-B and Anti-A,B is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Moore, S. *et al.* Vox Sang 47: 427-434 (1984). A Mouse Monoclonal Antibody with Anti-A,(B) Specificity which Agglutinates Ax Cells.
2. McDonald, D.F. and Thompson, J.M. Vox Sang 1991;61:53-58. A New Monoclonal Anti-A Antibody BIRMA-1.
3. Issitt, P.D. and Anstee, D.J. Applied Blood Group Serology, 4th Edition, Montgomery Scientific Publications, 1998.
4. Race, R.R. and Sanger, R. Blood Groups in Man 6th Edition Oxford Blackwell Scientific Publishers 1975.
5. Guidelines for the Blood Transfusion Services in the United Kingdom. Current edition.

Index of symbols	
Consult instructions for use	REF Catalogue number
Store between 2-8^{0}C	Manufacturer
IVD For in vitro diagnostic use only	Lot number
Use by	Date of manufacturer

Manufactured By:
Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex
CO7 8SD United Kingdom

Doc Ref: CE ABO RB - 04/2024

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

RAPID BIOTEC™

CATALOGUE NUMBER
Anti-A: BG-A10, BG-A10X10
Anti-B: BG-B10, BG-B10X10
Anti-A,B: BG-AB10, BG-AB10X10

INTENDED USE
The intended use of Rapid Biotec ABO blood grouping reagents is to be used in a qualitative method to identify the presence or absence of A or B antigens on the surface of red blood cells in donors or patients who require a blood transfusion.

These reagents are suitable for use by the slide, tube and Bio-Rad ID card and are designed for use by operators trained in serological techniques.

INTRODUCTION
The ABO Blood Group System
In 1900, Landsteiner discovered that the serum of some individuals would agglutinate the red cells of others and that this phenomenon could be used to classify individuals into different blood group phenotypes. Four common phenotypes are recognised – O, A, B and AB. Subgroups of the A and B antigens have since been identified. The ABO phenotype of an individual is usually determined by the agglutination reactions of the individual's red cells with Anti-A, Anti-B and Anti-A,B antisera (forward grouping). In testing blood samples from adults, confirmation of the ABO blood group can be provided by the reactions of the individual's serum with standard A and B red cell suspensions (reverse grouping).

PRINCIPLE
When used by the recommended techniques these reagents will cause agglutination (clumping) of red cells carrying the specific antigen (positive test).
Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).
These reagents have been optimised for use by the recommended techniques without further dilution or additions. These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS
Blood grouping reagents contain monoclonal murine IgM antibodies in a buffer solution. The solution is a phosphate buffer containing sodium chloride, EDTA and bovine material. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-A	Blue	Patent blue	BIRMA-1
Anti-B	Yellow	Tartrazine	LB-2
Anti-A,B	Colourless	None	ES-15/ES-4

Materials needed but not provided:
- Microscope slide/Plastic slides
- Plastic stirrers
- Timer
- Isotonic saline/LISS
- Compatible serum/plasma
- Test tubes
- Centrifuge (1000 rcf)
- Bio-Rad ID Cards (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID-diluent 2

PRECAUTIONS
- The cell lines used to produce these reagents are of murine origin and have been tested and found to be negative for Mouse Antibody Production (MAP) viruses. Care must be taken in the use and disposal of each container and its contents.
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE
For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS
- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.
- Each 10ml vial contains approx number of tests:

Methods	Drop size	No. of tests
Slide & Tube	45µl	<218
	50µl	<200

STORAGE AND STABILITY
Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION AND PREPARATION
- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.
- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE
SLIDE METHOD:
1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum or in isotonic saline.
2. Add one drop (45-50µl) of either Anti-A, Anti-B or Anti-A,B reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination

TUBE METHOD (recommended for A_x):
1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of either Anti-A, Anti-B or Anti- A,B reagent to an appropriately labelled test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

RAPID BIOTEC™

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-ABO reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

LIMITATIONS

- The results of red cell grouping should be confirmed by reverse grouping the individual's serum with known A1 and B red cells.
- No recipient should be given AB blood unless the cells of the recipient are clearly positive with Anti-A and Anti- B and the recipient's serum shown to give negative reactions with A1 and B cells (unless the recipient has been shown to be a subgroup of AB with Anti-A1 in the serum).
- Rapid Biotec Anti-A,B does not detect A3 antigens neither does it detect "Acquired B cells"
- Rapid Biotec Anti-B does not react with "Acquired B cells"
- Anti-A blood grouping reagent is not validated to detect all examples of A_x cells. False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.
- ABO antigens are not fully developed at birth therefore weaker reactions may occur with cord or neonatal samples.
- Using the reagent to detect weak B subgroups may give rise to false negative or weaker reactions when using slide, microtitre plates or gel cards.
- Stored blood may give weaker reactions than fresh blood.
- False positive or false negative results may also occur due to:
  - •Contamination of test materials
  - •Improper storage, cell concentration, incubation time or temperature
  - •Improper or excessive centrifugation
  - •Deviation from the recommended techniques
  - •Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARATERISTICS

- Reagents will work best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping tested by the recommended techniques against a panel of antigen-positive red cells.
- Anti-A,B can detect A_x antigens however, only through tube technique; see recommended technique in this IFU.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC):
  Anti- A = 03/188
  Anti- B = 03/164
- Rapid Biotec ABO reagents do not detect crypt antigens such as T, Tn or Cad.
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- BG-A, BG-B and BG-A,B have been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-A, Anti-B and Anti-A,B is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Moore, S. *et al.* Vox Sang 47: 427-434 (1984). A Mouse Monoclonal Antibody with Anti-A,(B) Specificity which Agglutinates Ax Cells.
2. McDonald, D.F. and Thompson, J.M. Vox Sang 1991;61:53-58. A New Monoclonal Anti-A Antibody BIRMA-1.
3. Issitt, P.D. and Anstee, D.J. Applied Blood Group Serology, 4th Edition, Montgomery Scientific Publications, 1998.
4. Race, R.R. and Sanger, R. Blood Groups in Man 6th Edition Oxford Blackwell Scientific Publishers 1975.
5. Guidelines for the Blood Transfusion Services in the United Kingdom. Current edition.

Index of symbols			
	Consult instructions for use	REF	Catalogue number
	Store between 2-8^{0}C		Manufacturer
IVD	For in vitro diagnostic use only	LOT	Lot number
	Use by		Date of manufacturer

Manufactured By:
Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex
CO7 8SD United Kingdom

Doc Ref: CE ABO RB - 04/2024

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 Hall Farm
Church Road
Little Bentley, Colchester
Essex. CO7 8SD. U.K.

CERTIFICATE OF ANALYSIS

Product Description : Anti-A Monoclonal

Cat. No. : BG-A10

Size : 10mL

Lot Number : A0425-28RB

Manufacture Date : 2025-04-28

Expiry Date : 2027-10-28

Preservative : <0.1% w/v Sodium Azide

Sterility : Product filtered through a sterile 0.2µm filter

Storage : REFRIGERATE AT 2 - 8°C

Micro Testing : Source materials used to produce this lot were tested at source and found to be non-reactive for anti- HIV 1+2, anti-HCV and HBsAg

Dye : 0.005% Patent Blue

Potency

Cells	Tube Test
A_1	1 in 1024
A_2B	1 in 1024

Avidity : **A_1 Cells** – 2 seconds

: **A_2B Cells** – 2 seconds

Slide Specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 5	B Cells	Negative
A_2B Cells	Grade 5	O Cells	Negative

Tube Test Specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 5	B Cells	Negative
A_2B Cells	Grade 5	O Cells	Negative

The above lot number of the material is certified to comply with the specifications for which it was designed.

For & on behalf of Rapid Labs

Date 29-04-2025

Alison Gosling
Site Director

Rapid Labs
Rapid Labs Limited
Unit 2 • Hall Farm • Church Road • Little Bentley
Colchester • Essex • CO7 8SD • UK
Registered No. 06519288

Rapid Labs Ltd
Unit 2 Hall Farm
Church Road
Little Bentley, Colchester
Essex. CO7 8SD. U.K.

CERTIFICATE OF ANALYSIS

Product Description : Anti-B Monoclonal

Cat. No. : BG-B10

Size : 10mL

Lot Number : B0425-28RB

Manufacture Date : 2025-04-28

Expiry Date : 2027-10-28

Preservative : <0.1% w/v Sodium Azide

Sterility : Product filtered through a sterile 0.2µm filter

Storage : REFRIGERATE AT 2 - 8°C

Micro Testing : Source materials used to produce this lot were tested at source and found to be non-reactive for anti- HIV 1+2, anti-HCV and HBsAg

Dye : 0.015% Tartrazine yellow

Potency

Cells	Tube Test
B	1 in 512
A_1B	1 in 512

Avidity : **B Cells** – 3 seconds

: **A_1B Cells** – 3 seconds

Slide Specificity

Positive Phenotypes		Negative Phenotypes	
B Cells	Grade 5	O Cells	Negative
A_1B Cells	Grade 5	A_1 Cells	Negative

Tube Test Specificity

Positive Phenotypes		Negative Phenotypes	
B Cells	Grade 5	O Cells	Negative
A_1B Cells	Grade 5	A_1 Cells	Negative

The above lot number of the material is certified to comply with the specifications for which it was designed.

For & on behalf of Rapid Labs

Date 29-04-2025

Alison Gosling
Site Director

Rapid Labs
Rapid Labs Limited
Unit 2 • Hall Farm • Church Road • Little Bentley
Colchester • Essex • CO7 8SD • UK
Registered No. 06519288

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)

CE
1434

Rapid Labs

CATALOGUE NUMBER
BG-D10
BG-D10X10

INTENDED USE
Rapid Labs Anti-D (IgG & IgM) is a blood grouping reagent which is intended to be used to qualitatively determine the presence or absence of the RhD antigen on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

INTRODUCTION
The Rh Blood Group System
RhD (D or RH1), originally identified in 1939, was the first clinically important blood group to be found following the discovery of ABO 39 years earlier. A phenotypic relationship between D and an antigen on human red cells detected by antibodies made in rabbits immunized with rhesus monkey red cells, led to D being inappropriately named the Rhesus antigen. A vestige of that term remains in Rh, the name of the blood group system that contains D.
Approximately 15% of Caucasians lack the RhD antigen and are easily stimulated by an RhD positive pregnancy or blood transfusion to produce anti-D. This may cause haemolytic disease of the fetus and newborn or severe haemolytic transfusion reactions.
The frequency of the D+ phenotype is about 85% in Caucasians, around 95% in sub-Saharan Africa, and greater than 99·5% in eastern Asia (Daniels, 2013).

WEAK AND PARTIAL D
Anti-D (-RH1) of the Rh blood group system is clinically important as it causes haemolytic transfusion reactions and haemolytic disease of the foetus and new-born. Although most people are either D+ or D-, there is a plethora of D variants, often categorized as either weak D or partial D. These two types are inadequately defined and the dichotomy is potentially misleading. D^{VI} is the D variant most commonly associated with anti-D production and UK guidelines recommend that patients are tested with anti-D reagents that do not react with D^{VI}.
Rapid Labs Anti-D (IgG & IgM) reagent will detect most examples of weak D by direct agglutination; see the recommended technique stated in this IFU.
Rapid Labs Anti-D (IgG & IgM) reagent will detect partial D category D^{VI} by indirect agglutination; see the recommended technique stated in this IFU.

PRINCIPLE
When used by the recommended techniques these reagents will cause direct agglutination (clumping) of red cells carrying the specific antigen (positive test) and indirect agglutination of red cells that are classified as D^{VI} in the antiglobulin phase recommended technique.
Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).
These reagents have been optimised for use by the recommended techniques without further dilution or additions.
These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS
Blood grouping reagents contain monoclonal human IgM and IgG antibodies in a buffer solution. The solution containing macromolecular chemical potentiators. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-D (IgG &IgM)	Straw/clear	None	MS-26 & RUM-1

Materials needed but not provided:

Slide technique
- Microscope slide/plastic slides
- Isotonic saline, PBS or compatible plasma/serum
- Plastic stirrers
- Timer

Tube technique
- Test tubes 75 x 12mm (glass)
- Isotonic saline
- 37^0C incubator (if needed)
- Timer
- Centrifuge (1000 rcf)

Indirect antiglobulin technique
- Anti-Human globulin reagent
- IgG sensitised red cells (Coombs control cells)

Bio-Rad ID Card technique
- Column agglutination technique Bio-Rad ID Card (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID diluent 2

PRECAUTIONS
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- All blood products should be treated as potential infectious. The human donor or cell line used to produce this reagent has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV. No known tests can guarantee that any products derived from human blood is free from infectious agents. Care must be taken in the use and disposal of each container and its contents.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- Do not use reagent past the expiration date.
- Protective clothing must be worn when handling reagent, such as, disposable gloves and lab coat.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
- No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE
For more information of disposal of reagent and decontamination plus handling spillages, please contact Rapid Labs for a material safety data sheet.

ADVICE TO USERS
- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- The use of the reagent and the interpretation of results must be carried out by properly trained and competent professionals.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Weak and D^{VI} antigens are poorly detected by Bio-Rad ID card and slide techniques. It is recommended that weak D variants should be tested by tube test and D^{VI} should be tested by indirect antiglobulin technique.
- The antiglobulin tube technique can only be considered valid if all negative tests react positively with IgG sensitised red cells.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8^0C.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.

STORAGE AND STABILITY
Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.
This reagent has undergone transportation stability studies at 37^0C and 2-8^0C as described in BS EN ISO 23640:2015.

SPECIMEN COLLECTION AND PREPARATION
- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)

CE 1434

Rapid Labs®

- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE

SLIDE METHOD:

1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum, isotonic saline or PBS.
2. Add one drop (45-50µl) of Anti-D (IgG & IgM) reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination.

TUBE METHOD: (recommended for weak D):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Labs Anti-D (IgG & IgM) reagent.
4. Centrifuge cassette(s) in a Bio-Rad gel card centrifuge.
5. Read macroscopically for agglutination.

INDIRECT ANTIGLOBULIN TECHNIQUE (recommended for D^{VI}):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix well and incubate at 37^0C for 15 minutes.
5. Wash the cells once with isotonic saline, thoroughly decanting saline.
6. Add 2 drops (80-100µl) of Anti-Human Globulin reagent, mix and centrifuge at 1000 rcf for 20 seconds.
7. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
8. Confirm validity of negative results with IgG sensitised red cells

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

LIMITATIONS

- ABO antigens are not fully developed at birth and so weaker reactions may therefore occur with cord or neonatal specimens
- Stored blood may give weaker reactions than fresh blood.
- False positive or false negative results may also occur due to:
  - Contamination of test materials
  - Improper storage, cell concentration, incubation time or temperature
  - Improper or excessive centrifugation
  - Deviation from the recommended techniques
  - Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARATERISTICS

- Reagents will work optimised best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Labs monoclonal blood grouping reagent is tested by the recommended techniques against a panel of antigen-positive red cells.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC): Anti-D = 99/836
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- Rapid Labs Anti-D (IgG & IgM) has been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Labs Anti-D (IgG & IgM) is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Kholer, G. and Milstein, C. Continuous culture of fused cells secreting antibody of predefined specificity. Nature. 256 : 495-497 (1975).
2. Race RR, Sanger R. Blood Groups in Man 6th Edition, Oxford, Blackwell Scientific Publishers Chapter 2 (1975).
3. Issitt PD. Applied Blood Group Serology, 3rd Edition, Montgomery Scientific, Miami, Chapter 10 (1985).
4. Mollison PL. Blood Transfusion in Clinical Medicine, 8thEdition, Oxford, Blackwell Scientific Publications, Chapter 7 (1987).
5. Tippett P. Sub-divisions of the Rh (D) antigen. Medical. Laboratory Science; 45: 88-93 (1988).
6. Thompson KM, Hughes-Jones NC. Production and characteristics of monoclonal anti-Rh. Bailliere's Clinical Haematology; (1990).
7. Jones J, Scott ML, Voak D. Monoclonal anti-D specificity and Rh D structure: criteria for selection of monoclonal anti-D reagents for routine typing of patients and donors. Transfusion Medicine 5: 171-184 (1995).
8. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
9. Daniels, G. Variants of RhD – Current Testing and Clinical Consequences, British Journal of Haematology; 161: 461-470 (2013).

Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only
REF	Catalogue Number	LOT	Lot Number
+2°C +8°C	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2a
Hall Farm Business Centre
Church Road
Little Bentley
Colchester, Essex, CO7 8SD United Kingdom

Email: info@rapidlabs.co.uk

Website www.rapidlabs.co.uk

revision 9 30/11/2021

Rapid Labs Ltd
Unit 2 Hall Farm
Church Road
Little Bentley, Colchester
Essex. CO7 8SD. U.K.

CERTIFICATE OF ANALYSIS

Product Description : Anti-D IgG & IgM Monoclonal

Cat. No. : BG-D10

Size : 10mL

Lot Number : D0425-30RB

Manufacture Date : 2025-04-30

Expiry Date : 2027-10-30

Preservative : <0.1% w/v Sodium Azide

Sterility : Product filtered through a sterile 0.2µm filter

Storage : REFRIGERATE AT 2 - 8°C

Micro Testing : Source materials used to produce this lot were tested at source and found to be non-reactive for anti- HIV 1+2, anti-HCV and HBsAg

Dye None

Potency

	Tube Test
OR1r Cells	1 in 512
OR2r Cells	1 in 256

Avidity : **OR1r Cells** – 5 seconds
: **OR2r Cells** – 5 seconds

Slide Specificity

Positive Phenotypes		Negative Phenotypes	
OR1r cells	Grade 4	rr cells	negative
OR2r cells	Grade 3	r'r cells	Negative
		r"r cells	Negative

Tube Test Specificity

Positive Phenotypes		Negative Phenotypes	
OR1r cells	Grade 5	rr cells	negative
OR2r cells	Grade 5	r'r cells	Negative
Weak D (D_u)	Grade 3	r"r cells	Negative

The above lot number of the material is certified to comply with the specifications for which it was designed.

For & on behalf of Rapid Labs

Date 01-05-2025

Rapid Labs
Rapid Labs Limited
Unit 2 • Hall Farm • Church Road • Little Bentley
Colchester • Essex • CO7 8SD • UK
Registered No. 06519288

Alison Gosling
Site Director