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

Digitally signed by Dolgopol Iulian
Date: 2026.04.24 14:26:28 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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'.

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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 2-8ºC. Do not freeze
After opening, Test cells, Control cells, Sample diluent and controls are stable for up to 3 months when stored upright at 2-8ºC
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 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.

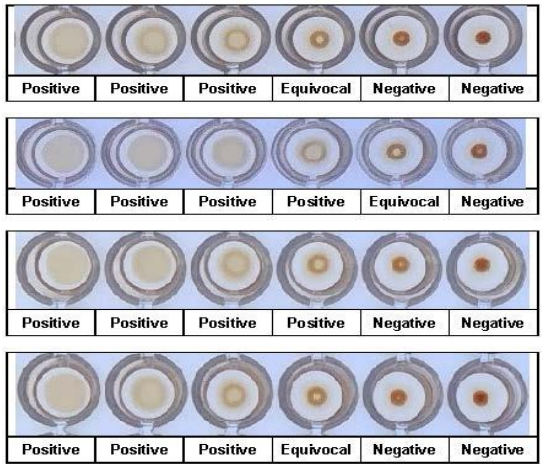
TPHA - 100, 200 & 500 Tests

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

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2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
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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.
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Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex CO7 8SD
United Kingdom

Index of symbols

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

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

Revision 1 01/04/2024

SAFETY DATA SHEET

TPHA Kit

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: TPHA Kit or controls.

Product code: RL-TPHA100, RL-TPHA200, RL-TPHA500, RL-TPHA-PC-1, RL-TPHA-NC-1

Animal components: Chicken Erythrocytes

Rabbit Serum

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: This product is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS.

1.3. Details of the supplier of the safety data sheet

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

www.rapidlabs.co.uk

Tel: +44 (0)0208 123 2014 or +44 (0)1206 250 484

Fax: n/a

Email: info@rapidlabs.co.uk

1.4. Emergency telephone number

Emergency tel: +44 (0)0208 123 2014

(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.

2.2. Label elements

Label elements: The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

Precautionary statements: P102: Keep out of reach of children.

P234: Keep only in original container.

2.3. Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: Sodium azide 0.098g/L is classified according to EEC directive 88/379 (the Chemicals act and Hazardous Goods Regulations) as non-hazardous.

Contains: Contains no hazardous substances in reportable quantities under the CLP.

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, seek medical advice/attention.

Ingestion: Do not induce vomiting. Wash mouth with water and give plenty of water to drink immediately. Obtain medical attention if necessary and show label on container.

Inhalation: Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable Extinguishing Media: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam

5.2. Special hazards arising from the substance or mixture

Exposure hazards: In case of fire, the following can be released: Hazardous fumes and vapours

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear full protective suit and self- contained breathing apparatus (SCBA) when extinguishing fires

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 for protective measures when handling the spillage.

Turn leaking containers leak-side up to prevent the escape of liquid.

6.2. Environmental precautions

Environmental precautions: Avoid release to the environment

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Collect material and dispose of as waste according to Section 13

6.4. Reference to other sections

Reference to other sections: Refer to section 8 and 13 of SDS

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements:
Avoid contact with the eyes, skin and mucous membranes
Keep out of reach of children
Specimens should be handled as potentially infectious materials
Refer to Directive 2000/54/EC for information on handling biohazardous materials
Wash hands before breaks and after work
Clean work areas with hypochlorite or other disinfecting agent

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in original container at 2-8°C

Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): Use as per instructions for use

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: The product does not contain any relevant quantities of material with critical values that have to be monitored at the workplace

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Not relevant for this material

Respiratory protection: Respiratory protection not required.

Hand protection: Protective gloves

Eye protection: Safety glasses

Skin protection: Laboratory coat

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Liquid

Colour: Test cells – clear liquid with tan particles
Sample diluent – yellow
Controls – clear to straw

Odour: Odourless

Odour Threshold: Not applicable

pH (Value): 6.4-8.5

Melting Point (°C) / Freezing Point (°C): Not determined

Boiling Point / Boiling Range (°C): Not determined

Flash Point (°C): Not applicable

Evaporation rate (BA = 1): Not applicable

Flammability (solid, gas): Not determined

Explosive limit ranges: Not applicable

Vapour Pressure (mm Hg): Not applicable

Vapour Density (Air=1): Not applicable

Density (g/mL): Not determined

Solubility (Water): Not applicable

Solubility (Other): Not applicable

Partition Coefficient (n-Octanol/water): Not determined

Auto Ignition Temperature (°C): Not applicable

Decomposition Temperature (°C): Not determined

Viscosity (mPa.s): Not determined

Explosive properties: Not explosive

Oxidising properties: Not oxidising

9.2 Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: None known

10.2. Chemical stability

Chemical stability: The product is stable in accordance with the recommended storage conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: None known

10.4. Conditions to avoid

Conditions to avoid: No known specific conditions to avoid

10.5. Incompatible materials

Materials to avoid: Sodium azide may cause explosive salts if built up in copper piping. Flush with water.

10.6. Hazardous decomposition products

Section 11: Toxicological information

11.1. Information on toxicological effects

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: No significant harmful effects anticipated
Eye contact: No significant harmful effects anticipated
Ingestion: No significant harmful effects anticipated
Inhalation: No symptoms

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: The product does not contain significant quantities of ingredients that are environmentally toxic

12.2. Persistence and degradability

Persistence and degradability: The product is unlikely to persist in the environment

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: The product is predicted to have high mobility in soil

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: Not applicable

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations:

Product: Used devices should be disposed of as potentially biohazardous material in compliance with anti -pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Packaging: Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled.

Contact your local service providers for further information

Section 14: Transport information

14.1. UN number

UN number: N/A

14.2. UN proper shipping name

Shipping name: This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.3. Transport hazard class(es)

Not classified as dangerous for transport

14.4. Packing group

Not applicable

14.5. Environmental hazards

Environmentally hazardous: No **Marine pollutant:** No

14.6. Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Specific regulations: Not applicable.

15.2. Chemical Safety Assessment

Not applicable

SAFETY DATA SHEET

TPHA Kit

Section 16: Other information

Other information

Legal disclaimer: To the best of our knowledge, the information contained herein is accurate. However, Rapid Labs does not assume any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user.

All materials may present unknown hazards and should be used with caution. Although certain hazards described herein, we cannot guarantee that these are the only hazards that exist

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.