General Information of the product, its variants and manufacture.

Manufacturer contact details:

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

Telephone: +44 (0)0208 123 204 or + 44 (0)1206 250484
Website: www.rapidlabs.co.uk

Identification of Device

Rapid Labs sells products for *in vitro* diagnostic screening and confirmation of syphilis. Rapid Labs VDRL and RPR products are non-treponemal antibody tests whereas TPHA kits are treponemal antibody tests. Syphilis EIA tests are used for total antibody detection. In this range the following product variants are available:

Device/Product name	Catalogue Number (REF)	Variant(s)
RPR Kit	D-RPR100	100 test kit
	D-RPR250	200 test kit
	D-RPR500	500 test kit
	D-RPR500A	500 test kit with no accessories
	D-RPRCARDS100	RPR test cards – 10 well
VDRL Antigen + Controls	RL-VDRL250	VDRL carbon antigen 5mL + controls with no accessories
	RL-RPR5ML	RPR carbon antigen
	RL-RPRP1ML	RPR carbon antigen positive control
	RL-RPRN1ML	RPR carbon antigen negative control
TPHA test kit	RL-TPHA100	100 test kit
	RL-TPHA200	200 test kit
	RL-TPHA500	500 test kit
RPR Carbon Reagent	RL-RPR5ML	5mL
	RL-RPR10ML	10mL
	RL-RPR1L	1000mL
RPR Positive Control	RL-RPRP1ML	1mL
	RL-RPRP100	100mL
RPR Negative Control	RL-RPRN1ML	1mL
	RL-RPRN100	100mL
Syphilis EIA	DA-SYT96	96
	DA-SYT192	192
	DA-SYT480	480

These syphilitic Rapid Labs devices can be classified by European Diagnostic Manufacturers' Association (EDMA) and Global Medical Device Nomenclature (GMDN) systems. See table below.

Product	EDMA Classification	GMDN Classification
RPR kits and VDRL reagent	15 01 90 90	32450
Syphilitic Control Sera	15 50 01 01	32449
TPHA Kits	15 01 03 03	37290

Manufacturer's Quality System/Certifying Body

Classification within Directive 98/79/EC on *in vitro* diagnostic medical devices: These products are self-certified by the manufacturer as meeting the essential requirements of the Directive, in accordance with Article 9(1) and Annex III.

Classification within Annex I of the Common Procurement Vocabulary (CPV) of Regulation (EC) No 2195/2002 is 24421140-4 (Diagnostic Reagents).

The quality management system of Rapid Labs Ltd has been assessed and registered (Certificate number 55321/A/0001/UK/En) since 9th November 2012 as meeting the requirements of ISO 9001:2008 & 13485:2012 within the scope of the manufacture and sale of diagnostic kits and reagents by: URS

None of these products variants are covered by Annex II within Directive 98/79/EC. These products are therefore self-certified following the EC declaration of conformity procedure, in accordance with Annex III.

All products in this range are for professional *in vitro* diagnostic use only. The intended purpose application, method of use and materials provided are also described in the Instructions for Use (IFU).

Some of the reagents in the syphilis test kits contain components of animal origin. TPHA control and test cells contain chicken erythrocytes. These chicken erythrocytes are collected and manufactured by the supplier. They are collected from areas within Norfolk and Suffolk in the United Kingdom where there is no avian flu nor has there been any avian flu in the last 10 years. The effectiveness of the suppliers treatment has been confirmed by DEFRA. Rabbit serum is used within the controls for some of the syphilitic tests, this serum is of European origin, there are no restrictions on transport nor is it deemed to be of any risk.

As these products are general IVD medical device (i.e. not in Annex II List A or B and not intended for self-test) then you need to follow Annex III of Directive 98/79/EC, this annex does not require a manufacturer to have a specific quality system.

Certified by:
United Registrar of Systems Ltd.
Derby Manor
Derby Road
Bournemouth
BH1 3QB

The Rapid Labs quality management system conforms to EN ISO 9001:2008 (Quality Management Systems – Requirements) and to EN ISO 13485:2012 (Medical devices – Quality management systems – Requirements for regulatory purposes).

The structure of the quality management system documentation is as follows:

Level 1	Quality Manual	An overview of the scope, organisation and processes of the quality management system and the structure of its documentation.
Level 2	**NOT CURRENTLY USED**	
Level 3	Generic SOPs	Detailed descriptions of standard operating procedures for meeting the basic requirements of the ISO 9001 & ISO 13485 standards generally applicable to the control and management of product supply
Level 4	Work Instruction SOPs	Detailed descriptions of standard operating procedures for managing and controlling specific product realisation phases and the supply of specific product types
Level 5	Product Technical Files	Specifications for and the application of the quality plan to specific products
Level 6	Records	Durable and traceable evidence of the operation of the quality management system

All quality management system documentation at levels 4, 5 and 6 specific to the supply of syphilis products is held in the relevant parts of this medical device file.

General documentation at levels 1, 2 and 3 applicable to the supply of syphilis products is held in the relevant Rapid Labs quality management system master files.

Conformity assessment procedure (Directive 98/79/EC)

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

Rapid Labs diagnostic products for syphilis screening and confirmation comply with the *In Vitro* Diagnostic Medical Devices Regulations (SI 2003 No 618). These regulations are the means through which European Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices is implemented in the United Kingdom (UK).

Description of Device(s)

In the Rapid Labs syphilitic product range there are two types of rapid tests available. Both types of kits are used to test for syphilis. TPHA tests are a passive particle agglutination assay for the qualitative and semi quantitative detection of IgG and IgM antibodies to *Treponema pallidum.* The test uses serum or plasma samples in the detection of *T.pallidum* antibodies. Using the instructions for use a positive/negative agglutination result can be obtained for a qualitative test. The IFU also contains a titre method that will give a semi-quantitative result. The image shows the components for a 100 test TPHA kit, for larger kit sizes, the positive and negative controls are the same however the diluent, control and test cells are in larger volumes but in the same type of container.

RPR tests are used in the non-treponemal flocculation test for qualitative and semi-quantitative determination of regain antibodies in serum or plasma. This kit can be used for qualitative slide agglutination or a semi-quantitative result can be obtained by using a titre. Both methods will give a negative/positive result and are described in the IFU. The image shows the components for a 500-test kit. Smaller kit sizes are provided with the same components of a smaller quantity with the exception of the controls.

Both TPHA and RPR test kits contain positive and negative controls without these the test results must be considered invalid. A positive control should test positive and the negative control should test negative to validate any result obtained from testing. The image shows an example of TPHA positive and negative controls, the controls will look identical to that of RPR positive and negative controls with different Ref and Lot numbers. The controls are supplied in two different coloured lidded vials with matching coloured labels to aide users.

Performance Characteristics of the Products

All syphilis test kits and their components have under gone different validation processes to evaluate their performance.

Product	Sensitivity (%)	Specificity (%)	Analytical Sensitivity	Accuracy and Precision (%)
RPR Assay	100	100	No data available	0
TPHA Assay	100	100	0.05 IU/mL against WHO IS	0
Syphilis EIA	100	100	0.0015 IU/mL against NIBSC 05/132 IS	No data available

Rapid Labs

IVD Directive Essential Requirements Checklist

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
General Requirements			
Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes	Annex III	Ref – BS EN 14971:2012 Medical Devices Risk Analysis Internal Risk Analysis Reports based on above
The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: ▪ identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, ▪ eliminate risks as far as reasonably practicable through inherently safe design and manufacture, ▪ reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, ▪ inform users of any residual risks.	Yes	Annex III	Using sodium azide at <0.1% Risk analysis reports IFU – warnings and precautions section

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
The characteristics and performances referred to should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	Yes	Annex III	TPHA stability report RPR stability report Syphilis stability report
The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	Yes	Annex III	TPHA stability report/transport study RPR stability report/transport study Syphilis stability report/transport study
The benefits must be determined to outweigh any undesirable side effects for the performances intended.			
Design and Manufacturing Requirements			
Chemical, physical and biological properties			
The devices should be designed and manufactured in such a way as to ensure the characteristics and performance meet requirements. Particular attention should be paid to: ▪ the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, ▪ the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device, ▪ the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.	Yes	Annex III	Validation/Verification reports Syphilis calibration report Manufactured to ISO 9001:2008/ISO 13485:2012 compliant with QMS
The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.	Yes	Annex III	TPHA stability report/transport study RPR stability report/transport study Syphilis stability report/transport study

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	Yes	Annex III	Interference studies
The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.	Yes	Annex III	Design files History of existing packaging
Infection and microbial contamination			
The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: ▪ allow easy handling, and, where necessary: ▪ reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use, ▪ prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.	Yes	Annex III	Design files History of existing packaging
Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.	Yes	Annex III	Material Safety Data sheets Material specifications – reduce risk by selection Biological material obtained from approved traceable sources All human origin material for use in product is donor tested negative for Hep B & C, HIV 1 & 2

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	Yes	Annex III	No sterility claims
Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.	Yes	Annex III	No sterility claims
Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.	Yes	Annex III	No sterility claims
Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	Yes	Annex III	No sterility claims
Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.	Yes	Annex III	High quality clean/sealed containers Materials specification – reduce risk by selection Filter to 0.2µm liquid reagents
The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.	Yes	Annex III	No sterility claims No claims on product cleanliness
Manufacturing and environmental properties			
If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.	Yes	Annex III	Validation reports – to be produced as required

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: ▪ the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; ▪ risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; ▪ the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; ▪ the risks of accidental penetration of substances into the device; ▪ the risk of incorrect identification of specimens; ▪ the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; ▪ risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	Yes	Annex III	Cardboard packaging, easy to handle and open containers Plastic packaging, easy to handle and open containers Clear storage instructions
Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	Yes	Annex III	N/A – water based materials, stored at atmospheric pressure
Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	Yes	Annex III	Syphilis risk analysis RPR risk analysis TPHA risk analysis Warnings in IFU. No CHIP labelled reagents. Residual risk from biological material and clinical samples
Devices with a diagnostic or measuring function			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.	Yes	Annex III	Qualitative assay Sensitivity & Specificity have 95% confidence limits shown
Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device. **Note:** While SG1 generally supports convergence on the global use of internationally standardised measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement units.	Yes	Annex III	1st IS for human syphilitic plasma IgG and IgM NIBSC code: 05/132
Protection against radiation			
General			
Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Yes	Annex III	No radiation source
Intended radiation			
Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.	Yes	Annex III	No radiation source
Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Yes	Annex III	No radiation source
Unintended radiation			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.	Yes	Annex III	No radiation source
Instructions for use			
The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Yes	Annex III	No radiation source
Ionizing radiation			
Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.	Yes	Annex III	No radiation source
Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.	Yes	Annex III	No radiation source
Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.	Yes	Annex III	No radiation source
Requirements for medical devices connected to or equipped with an energy source			
Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.	Yes	Annex III	No power required

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.	Yes	Annex III	No power required
Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.	Yes	Annex III	No power required
Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health	Yes	Annex III	No power required
Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.	Yes	Annex III	No power required
Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	Yes	Annex III	No power required
Protection against electrical risks Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.	Yes	Annex III	No power required
Protection against the risks posed to the patient for devices for self-testing or self-administration			
Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.	Yes	Annex III	Not self-test

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.	Yes	Annex III	Not self-test
Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the manufacturer.	Yes	Annex III	Not self-test
Information supplied by the manufacturer			
Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood. **Note:** Further information is provided in *SG1/N009 Labelling for Medical Devices* and in SG1/N043 *Labelling for Medical Devices (revised).*	Yes	Annex III	Approval of labels & IFU Conform to BS EN ISO 18113-2:2011 Information Supplied by the Manufacturer with *in vitro* diagnostic reagents for professional use