04955196001V4.0

RPR Control Set

SEKISUI

REF **04955196** 190

2 x 1 mL positive control

2 x 1 mL negative control

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 136 for the positive control and 135 for the negative control.

Please note: For technical reasons it is necessary to specify dummy units (mg/dL) on Roche/Hitachi analyzers. The values can be converted to the correct units via the host computer.

Intended use

The RPR Control Set is used for quality control of the Sekisui Medical "Mediace RPR" and "Mediace RPR Gen.2" immunoturbidimetric assays (Cat. Nos. 04955153190 and 07404174190).

Summary

The RPR Control Set contains 2 x 2 controls in the positive and negative ranges based on human serum.

The controls are used for monitoring accuracy and precision.

Reagents – working solutions

Reactive components:

Human serum and bovine serum albumin (BSA) with chemical additives and material of biological origin as specified. The origin of the biological additive is as follows:

Analyte	Origin
Syphilitic anti-lipid antibodies	human

Non-reactive components:

BSA, stabilizers and preservatives

The concentrations of the control components are lot-specific. The exact target values are given on the labels of each vial and in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control barcode sheets for Roche/Hitachi MODULAR analyzers.

For the **cobas c** analyzers the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Target values and ranges

The target values were determined using the Sekisui Mediace RPR immunoturbidimetric method. Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

A clinically insignificant difference may be seen between the value(s) listed on the value sheet and the value(s) obtained from the instrument readable data. This is caused by:

- the rounding of value(s) during conversion from the unit in the instrument readable data to the unit that is being used.
- the calculation of the ranges by the analyzer using the percentage values for the ranges encoded in the barcodes.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Controls contain < 0.1 % sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azide buildup. Flush with copious amounts of water when discarding material.
Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.
The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[1,2]

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for the Roche/Hitachi MODULAR and **cobas c** analyzers to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

Storage and stability[3]

Storage:

Store at 2-8 °C.

Do not freeze.

Criterion for the stability data stated:
Recovery within ± 20 % of initial value.

Stability:

Unopened:	up to the stated expiration date at 2-8 °C
After opening:	24 hours at 15-25 °C
	4 weeks at 2-8 °C, provided that dispensing of the control occurs without microbial contamination, e.g. by pouring out.

Store controls tightly capped when not in use.

Materials provided

- See “Reagents – working solutions” section
- Barcoded labels

Materials required (but not provided)

- System reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

The controls should be run daily in parallel with patient samples and after every calibration. Control intervals must be adapted to individual laboratory’s requirements.

Follow the applicable government regulations and local guidelines for quality control.

References

1 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

3 Data on file at Sekisui Medical Co., Ltd.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

RPR Control Set

SEKISUI

Additions, deletions or changes are indicated by a change bar in the margin.

CE

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EC REP

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Roche