04955161001V5.0

TPLA Calibrator Set

SEKISUI

REF **04955161** 190 → 5 x 1 mL Calibrator

English

System information

For use on Roche/Hitachi MODULAR P and **cobas c** analyzers the calibrator codes are 941-945.

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

TPLA Calibrator Set contains 5 lyophilized calibrators for use in the calibration of the Sekisui "Mediace TPLA" immunoturbidimetric assay (Cat. No. 04955137).

Summary

The TPLA Calibrator Set contains 5 lyophilized calibrators based on human serum and bovine serum albumin (BSA).

The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the Sekisui "Mediace TPLA" assay on clinical chemistry analyzers.

Reagents – working solutions

Reactive components in the lyophilizate:

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
Anti-Treponema pallidum antibodies	human

Non-reactive components in the lyophilizate:

BSA; gelatin; stabilizers and preservatives.

The antibody levels are lot-specific. The exact calibrator values are given on the label of each vial and in the electronically available or enclosed value sheets.

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

For the **cobas c** analyzers (except for the **cobas c** 111 analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Calibrator values[1]

The calibrator values were determined using the Sekisui Mediace TPLA immunoturbidimetric method.

Traceability information is given in the relevant Method Sheets for the system reagents.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
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.[2,3]

Handling

Carefully open each bottle and pipette in exactly 1 mL of distilled/deionized water. Carefully close the bottles and dissolve contents within 30 minutes by occasional gentle swirling.

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

Storage and stability[1]

Store at 2-8 °C.

Criterion for the stability data stated:

Recovery within ± 15 % of initial value.

Stability of the lyophilized calibrator:	up to the stated expiration date at 2-8 °C
Stability of the reconstituted calibrator:	24 hours at 15-25 °C 7 days at 2-8 °C 2 weeks at (-15)-(-25) °C.

Store calibrator 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

Use TPLA Calibrator Set as specified in the relevant Method Sheet for the system reagents.

References

1 Data on file at Sekisui.

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

3 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.

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
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing

CE

Sekisui Medical Co. Ltd.
13-5, Nihombashi 3-chome, Chuo-ku
Tokyo, 103-0027, Japan

EC REP

Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
D-30175 Hannover, Germany

European Distributor:
Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim, Germany

Roche