

YUMIZEN G CAL



CALIBRATOR PLASMA FOR COAGULATION TESTS

Cat. No.: 1300036416

12 x 1 ml

PRODUCT NAME

Yumizen G CAL calibrator.

INTENDED USE**(For In Vitro Diagnostic Use Only)**

Yumizen G CAL calibrator plasma is intended to calibrate of the following coagulation tests:

- antithrombin (AT).
- fibrinogen (FIB)
- prothrombin time (PT)

SUMMARY AND PRINCIPLE

Yumizen G CAL calibrator is dedicated for calibration of coagulation tests. There are test specific calibrator target values in the issued sheet for the given reagents.

The percentage values in the issued sheet relate to pooled, fresh, anticoagulated, human plasma values, while other values to WHO standard.

ACTIVE INGREDIENTS

Yumizen G CAL calibrator is derived from human, anticoagulated, freeze-dried, pooled human plasma from healthy donors with stabilizer.

PRECAUTIONS

- Person installing the Yumizen G CAL calibrator must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Yumizen G CAL calibrator, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Calibrator coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the calibrator otherwise erroneous results may occur!
- Each lot of this calibrator tested by the presence of HIV 1/2, HBsAg, HCV, lues and found to be negative.
- All calibrator, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the calibrator beyond the expiration date printed on the label!

PREPARATION

Yumizen G CAL calibrator is dissolved with 1 ml distilled water. Allow them to stand at room temperature (20-25°C) for at least 30 minutes. The gently horizontal mixing is recommended during the reconstitution. Swirl the vial gently and horizontal again before use, but do not shake!

TEST PROCEDURE

Prepare dilution series from Yumizen G CAL calibrator.

Follow the procedure as described in the instruction for use of the corresponding tests to measure the required parameter. Enter the target values of the calibrator (lot number specific values sheet) into the appropriate menu following the manual of the concerned instrument.

STORAGE AND STABILITY

Yumizen G CAL calibrator in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in below table:

T (°C)	20-25	≤ -20
Time	4 hours	30 days

The reconstituted calibrator can be frozen and thawed back only once. Thawed calibrator should be used within two hours, when stored at 20-25°C.

EXPECTED RESULTS

The test specific calibrator target values for each of the parameters may vary from lot to lot. Check the lot specific target values in the issued sheet in the box. Normal and pathological controls are recommended for verified calibration curve.

LIMITATIONS

The calibration curve is valid for the actual lot of the used reagent. New calibration is necessary, if the lot of reagent and/or the measurement circumstances are changed.

In case of unexpected control values, new calibration is needed.

MATERIALS REQUIRED BUT NOT PROVIDED**On Yumizen G line:**

- For calibration of AT test:
 - Yumizen G AT; Cat. No.: 1300036390

On other systems:

- For calibration of AT test:
 - Yumizen G AT; Cat. No.: 1300036390
- For calibration of PT test:
 - Yumizen G PT 5; Cat. No.: 1300036338
 - Yumizen G PT Liq 4; Cat. No.: 1300036373
 - Yumizen G PT Reco 10; Cat. No.: 1300036376
- For calibration of FIB test:
 - Yumizen G FIB 2; Cat. No.: 1300036383
 - Yumizen G FIB 5; Cat. No.: 1300036384
- For dilution of PT, FIB calibration: Yumizen G IMIDAZOL; Cat. No.: 1300036385
- Different levels of control for quality control (Yumizen G CTRL I & II; Cat. No.: 1300036412)
- Optical coagulation analyser for measuring, Horiba Medical analysers (Yumizen G line) are recommended.



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