

Yumizen G CTRL DDi I & II



Control plasmas for Latex D-dimer tests

Cat. No: 1300036414 5 x 1 ml Yumizen G CTRL DDi I
5 x 1 ml Yumizen G CTRL DDi II

PRODUCT NAME

Yumizen G CTRL DDi I & II

INTENDED USE

(Only for in vitro diagnostic purposes)

The D-dimer two levels controls are intended to control measurements of Yumizen G DDi 2 test.

SUMMARY AND EXPLANATIONS

Yumizen G CTRL DDi I & II controls are dedicated for internal quality control of Yumizen G DDi 2 test (Cat. No.: 1300036391). They are instrument and lot specific control. Control ranges are specified in the value sheet for the given **reagents**.

ACTIVE INGREDIENTS

Yumizen G CTRL DDi I & II controls are derived from human, anticoagulated, freeze-dried, pooled human plasma from healthy donors with preservative. Yumizen G CTRL DDi I & II contains D-dimer antigen from human plasma with enzymatic digestion. Yumizen G CTRL DDi I & II controls represent two different measuring ranges.

CAUTIONS AND WARNINGS

- Yumizen G CTRL DDi I & II controls are to be used exclusively by properly trained laboratory professional.
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- The Yumizen G CTRL DDi I & II should be treated with caution due to its ingredients; regulation on handling of hazardous materials should be followed.
- Controls should be considered as potentially infectious as they may get in contact with laboratory samples and other materials; precautionary measures should be taken.
- Caution is required to prevent microbiological contamination of controls as this may possibly lead to false results during measurements.
- Each donor unit used in the preparation of this control tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.

- All controls, 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 controls after the expiry date indicated on the label of the product.

PREPARATION

Yumizen G CTRL DDi I & II controls should be dissolved in 1 mL (1000 µL) 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

Yumizen G CTRL DDi I & II controls are to be used as patients' plasmas as investigated with D-dimer test.

STORAGE AND SHELF LIFE

The unopened Yumizen G CTRL DDi I & II controls in intact packaging are stable until the expiry date when stored at 2 - 8°C. After opening the stability of the controls kept in the original vial is presented in the table below.

T [°C]	20-25	15-19	2-8
Time [hours]	8	24	48

The control should not be frozen.

EXPECTED RESULTS

The instrument specific control ranges may vary from lot to lot. Compare the measured values with the declared one on the value sheet. The obtained results:

- have to be inside the reference range declared, but to get the exact mean is not obligatory,
- should be considered as a guidance, but every laboratory should determine its own control ranges.

INSTRUCTION FOR USE

LIMITS OF USE

To check the accuracy of the reported result perform external quality assurance program at regular intervals.

In case of unexpected control values check that all components of the test system are functioning correctly.

INSTRUMENTS AND MATERIALS NEEDED FOR OPERATION

- Optical analyzer for the measurements. The use of Horiba Medical devices (Yumizen G line) is recommended.
- For controlling DDi test: Yumizen G DDi 2 (Cat. No.: 1300036391)



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