CE IVD DIALAB

Lyophilized Calibration Serum

DIACAL AUTO

(Assayed Universal Calibration Serum)

Single Reagent

Lyophilized universal calibration serum for the use in tests for the quantitative in vitro determination of various analytes on photometric systems.

REF	Cont.	
D98485	**5 x 3 ml**	finished kit
D98485SV	**1 x 3 ml**	single vial
D98485VSV	**1 x 3ml**	unlabeled single vial (OEM)

COMPOSITION

COMPONENTS:

Pooled human serum
Bacteriostatic agents

CALIBRATOR PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 3 ml of dist. water (inaccurate reconstitution of the control and error in assay technique can cause erroneous results).
3. Close the vial carefully and let stand for 30 min.
4. Dissolve contents completely by swirling gently, avoiding the formation of foam.
5. Do not shake!

CALIBRATOR STABILITY AND STORAGE

Storage: at 2 – 8°C
Stability: until date of expiration

Stability after reconstitution:

	20–25°C	2 - 8°C	–20°C
Bilirubin (in the dark):	4 hours	8 hours	14 days
Acid Phosphatase:	2 hours	2 days	30 days
Other Analytes:	8 hours	2 days	30 days

CLOSE IMMEDIATELY AFTER USE

Do not use the product if there is visible evidence of microbial growth in the vial.

Improper handling and/or storage of the control can affect results.

FREEZE ONLY ONCE!

LOT SPECIFIC ASSAY DATA

Values and Expiry Date are LOT specific.
Please refer to table with Lot specific assay data.

ASSAY VALUES AND RANGES

The assay values and ranges provided for each analyte listed are derived using DIALAB reagents or reagents from other manufacturers.

WARNINGS AND PRECAUTIONS

Each individual donation intended for use in manufacture of DIACAL AUTO was tested for HbsAg, anti-HCV and anti-HIV 1and HIV 2 by FDA required tests.
Since no test method can assure that products derived from human blood do not contain HIV-1/2 and Hepatitis B and Hepatitis C virus, this material and all patient samples should be handled as though capable of transmitting infectious diseases.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Dati F. Reference materials and guidelines for standardization of methods in laboratory medicine. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Book Verlagsgesellschaft; 1998. p. 1404-26
2. Moss DW, Henderson AR. Enzymes. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia: WB Saunders Company; 1994 p. 735-896.
3. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)

IVD

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