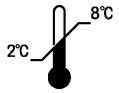
PLAC® Test Calibrator Kit

For use with the diaDexus PLAC® Test Reagent Kit

REF 90108

IVD



Symbol Key	
REF	Catalog Number
IVD	*In vitro* diagnostic medical device
LOT	Batch
	Expiration Date
	Store at 2 to 8 °C
CAL	Calibrator
	Consult Instructions for Use
	Manufacturer

Read this package insert completely before using the product. Follow instructions carefully when performing tests. Failure to follow the instructions may result in inaccurate results.

Intended Use

The PLAC® Test Calibrator Kit is intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA_2 by the PLAC® Test Reagent Kit.

Package Components (Materials Supplied)

Five levels of calibrators are provided for calibration of the PLAC Test Reagent Kit assay. Calibrators contain diaDexus recombinant Lp-PLA_2 antigen (DDX-RA) in a protein (BSA) buffered matrix with 0.01% sodium azide.

CAL	**0 ng/mL**	**1 bottle, 2.0 mL**	REF	**60015**
CAL	**50 ng/mL**	**1 bottle, 2.0 mL**	REF	**60016**
CAL	**100 ng/mL**	**1 bottle, 2.0 mL**	REF	**60017**
CAL	**250 ng/mL**	**1 bottle, 2.0 mL**	REF	**60018**
CAL	**500 ng/mL**	**1 bottle, 2.0 mL**	REF	**60019**

Materials Required but not Supplied

- PLAC Test Reagent Kit
- See PLAC Test Reagent Kit package insert for further details

Warnings and Precautions

- For *In Vitro* Diagnostic Use.
- See the PLAC Test Reagent Kit package insert for assay details.
- Treat calibrators as potentially biohazardous material.
- Dispose of calibrators in a manner consistent with relevant regulations.
- Do not use calibrators past their expiration dates.
- Do not mix components from other lots of PLAC Test Calibrator Kits.
- Do not switch caps on calibrator vials as this may lead to contamination or inaccurate results.

Procedure

Calibrators are ready to use. Mix gently to ensure homogeneity. Avoid foaming. Calibrators should be assayed using the same procedure as the samples. It is recommended that each laboratory determine a suitable calibration frequency. A new calibration curve should be generated at least monthly and whenever there is a reagent lot change or substantive instrument change such as maintenance or repair. See the PLAC Test Reagent Kit package insert for procedural instructions.

Storage and Stability

Store the PLAC Test Calibrator Kit at 2 to 8 °C until used. Promptly return calibrators to 2 to 8 °C storage after use. The unopened PLAC Test Calibrator Kit is stable at 2 to 8 °C until the expiration date printed on the outer box. Opened bottles are stable for three months provided that they are free from contamination, that the cap is replaced immediately after each use, and that the calibrators are stored at 2 to 8 °C and used before the expiration date.

Indications of Deterioration

Deterioration may be indicated if there are visible signs of microbial growth, turbidity or precipitate in the container. If deterioration is observed, discontinue use.

Limitations

- Accurate and reproducible results are dependent upon properly functioning instruments, properly stored reagents and good laboratory technique.
- Follow the assay procedure as described in the package insert for the PLAC Test Reagent Kit.

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