

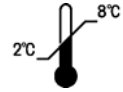






Lp-PLA₂ Control Kit
For use with the diaDexus PLAC[®] Test Reagent Kit



REF 90109

IVD



Symbol Key	
REF	Catalog Number
IVD	<i>In vitro</i> diagnostic medical device
LOT	Batch
	Expiration Date
	Store at 2 to 8 °C
CONTROL	Control
	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 Lp-PLA₂ Control Kit is intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC[®] Test Reagent Kit, a turbidimetric immunoassay for the quantitative determination of Lp-PLA₂.

Package Components (Materials Supplied)

Two levels of Controls are provided to monitor performance within the clinical range of the assay. Controls contain diaDexus recombinant Lp-PLA₂ antigen (DDX-RA) in a protein (BSA) buffered matrix with 0.01% sodium azide. The assayed control ranges are indicated above for each lot of controls. Concentration levels are determined by assay with the PLAC Test Reagent Kit.

- **CONTROL** Low (<200 ng/mL) 1 bottle, 2.0 mL **REF 65005**
- **CONTROL** High (>300 ng/mL) 1 bottle, 2.0 mL **REF 65006**

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 all patient samples and controls as potentially biohazardous material.
- Dispose of controls in a manner consistent with relevant regulations.
- Do not use controls past their expiration dates.
- Do not mix components from other lots of Lp-PLA₂ Controls.

Assigned Target Values and Ranges

The control ranges provided were derived from replicate testing of the specific control lots using Hitachi 917, PLAC Test Reagent Kits and calibrators. Verify that the lot numbers on the Control vials correspond to the lot numbers shown on this package insert. Values listed are specific for each lot and should be used as guides. Individual laboratory means may vary from the values listed. Variations between laboratories may be caused by technique or equipment differences. It is recommended that each laboratory establish its own acceptable ranges.

Frequency for QC

It is recommended that both Controls be included in each assay run. If control values are not within acceptance limits, repeat the assay. Additional quality control testing may be necessary according to local, state and/or federal regulations or accreditation requirements.

Procedure

Controls are ready to use. Mix gently to ensure homogeneity. Avoid foaming. Controls should be assayed using the same procedure as the samples. See the PLAC Test Reagent Kit package insert for quality control procedural instructions.

Storage and Stability

Store the Lp-PLA₂ Control Kit at 2 to 8 °C until used. Promptly return controls to 2 to 8 °C storage after use. The unopened Lp-PLA₂ Control 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 controls 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

- The ranges given are intended only as guidelines. Laboratories should determine ranges based on their own test system and tolerance limits.
- 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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*This product is covered by U.S. Patent Nos. 5532152, 5641669, 5968818, 5981252 and 7045329.
Additional patents pending.*

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