



Lp-PLA₂ Controls for PLAC[®] Test
For use with the diaDexus PLAC Test

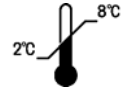


90104

REF

IVD FOR *IN VITRO* DIAGNOSTIC USE

STORE AT 2 TO 8°C



Intended Use

The Lp-PLA₂ Controls are intended for use with the diaDexus PLAC[®] test, an enzyme immunoassay for the quantitative determination of Lp-PLA₂ in human plasma and serum. The Lp-PLA₂ Controls are intended as a Quality Control tool to monitor Lp-PLA₂ clinical laboratory results. Two levels of Controls are provided to monitor the performance within the clinical range of the assay.

Package Components (Materials Supplied)

- **Control 1** (Low ~150 ng/mL) **1 bottle, 3.0 mL**
diaDexus recombinant Lp-PLA₂ antigen (DDX-RA) in a liquid, protein (BSA) buffered matrix
- **Control 2** (High ~400 ng/mL) **1 bottle, 3.0 mL**
diaDexus recombinant Lp-PLA₂ antigen (DDX-RA) in a liquid, protein (BSA) buffered matrix
- **Certificate of Analysis** **1 each**
The control ranges are indicated for every lot of controls – see Certificate of Analysis

Materials Required but not Supplied

- PLAC test – Catalog Number 90106
- See PLAC test package insert for further details

Warnings and Precautions

- For *In Vitro* Diagnostic Use.
- See the PLAC test package insert for assay details.
- It is recommended that both Control 1 and Control 2 be included in each patient run. If control values are not within acceptance limits, repeat the assay. Additional quality control testing may be necessary according to state and local requirements.
- The control ranges provided were derived from replicate testing of the specific control lots using PLAC test kits and should be used as guides. Individual laboratory means may vary from the values listed. Variations between laboratories may be caused by technique differences or reagent variability. It is recommended that each laboratory establish its own acceptable ranges.
- 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 diaDexus Lp-PLA₂ Controls.

Procedure

Store the controls at 2–8 °C until used. Mix gently to ensure homogeneity. Avoid foaming. Store any unused material at 2–8 °C. Controls should be assayed in the same manner as clinical samples. See the PLAC test reagent kit package insert for procedural instructions.

Storage and Stability

The Lp-PLA₂ Controls for PLAC Test are stable at 2–8 °C until the expiration date noted on the outer box.

Limitations

- Do not use the Lp-PLA₂ Controls past their expiration date.
- To avoid erroneous results, store the material as indicated. Follow the assay procedure as described in the package insert.
- If there is evidence of contamination, discard the vial.

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