

PROCEDURE

Corewell Health East - Lipase Reagent Preparation c4000 - Taylor, Trenton, Wayne

This Procedure is Applicable to the following Corewell Health sites:

Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital

Applicability Limited to:	N/A
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Functional Area:	Clinical Operations, Laboratory
Lab Department Area:	Lab - Chemistry

1. Principle

This document provides the staff with directions to prepare Lipase reagent to be loaded on the Abbott Architect c4000 analyzer. Lipase reagent is manufactured by Abbott Diagnostics and requires special preparation before being placed on the chemistry analyzer.

The Lipase assay is used for the quantitation of lipase in human serum or plasma. Lipase belongs to a group of fat-splitting enzymes found in the blood, gastric juices, pancreatic secretions, intestinal juices, and adipose tissues. Lipases hydrolyze triglycerides (fats) into their component fatty acid and glycerol molecules.

2. Responsibility

Personnel who have completed the competency requirements will perform this testing.

3. Reagent/Equipment Needed

A. Lipase Reagent Handling

1. Remove air bubbles if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate.
2. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.
CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

B. Lipase Reagent Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C. Reagent stability is 11 days if the reagent is uncapped and on-board.

C. Lipase Indications of Deterioration

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, extreme turbidity, microbial growth, if calibration does not meet the appropriate package insert and/or Architect System Operations Manual criteria, or if controls do not meet the appropriate criteria.

4. Procedure

Entities will reference associated Documentation contained within this document as applicable
Printouts of this document may be out of date and should be considered uncontrolled.

- A. Prepare the Working Reagent by adding the contents of the R1 to the Lipase R1A. Use the funnel provided in the kit



- B. Replace the R1A reagent stopper and mix by gentle inversion to achieve complete dissolution.
C. Return the prepared Working Reagent to the R1 cartridge using the funnel provided in the kit, cap and mix again by gentle inversion. Remove air bubbles if present in the reagent cartridge, with a new applicator stick.
D. Place the R1 and R2 cartridges in the Reagent Supply Center.

5. Warnings

- A. For *In Vitro* Diagnostic Use.
B. Do not use components beyond the expiration date.
C. Do not mix materials from different kit lot numbers.
D. Do not mix reagents prepared at different times.
E. Do not reuse the reagent containers, bottles, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.

6. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

7. References

- A. Abbott Architect Lipase Package Insert, Revised February 2017

8. Procedure Development and Approval

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9. Keywords

Not Set