DXC (LIP) LIPASE

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PURPOSE

To provide instructions for the quantitative determination of lipase on the DXC 600/800.

PRINCIPLE

LIP reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Enzyme Validator Set, is intended for the quantitative determination of Lipase activity in human serum or plasma in random access mode.

BACKGROUND

Clinical Significance

Lipase measurements are used primarily in the diagnosis and treatment of pancreatic disorders.

Methodology

The Random Access Lipase reagent utilizes the methodology of Panteghini to determine pancreatic lipase activity in serum and plasma. The SYNCHRON® System(s) monitors the rate of formation of methylresorufin which forms spontaneously from two coupled reactions which utilize a 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin)-ester as a substrate. The measured rate of color formation at 560 nm is directly proportional to the pancreatic lipase activity.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 54 parts reagent. The system monitors the change in absorbance at 560 nanometers. The rate of formation of the methylresorufin is directly proportional to the activity of LIP in the sample and is used by the System to calculate and express the LIP activity.
One unit (U) is defined as the amount of enzyme activity which liberates 1 µmol of methylresorufin from 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6`-methylresorufin)-ester per minute at +37°C.

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
J-F-CH0826	DXC 800 Calibrators
J-F-CH1940	DXC 800 (AMR) Analytical Measurement Range
M-F-CH0820	Chemistry Controls
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range
R-W-CH0815	DXC Reagent Lot to Lot Correlations
R-F-CH0814	Lot-to-Lot Correlation

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma is the preferred specimen. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet.
Whole blood, urine, ascitic, and pleural fluids are not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells as soon as possible. A maximum limit of eight hours from the time of collection is recommended.

2. Separated serum or plasma should not remain at room temperature longer than 4 hours. If assays are not completed within 4 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5ml	• 4 hours at 18-26**° C** • 48 hours at 2-8**° C** • After 48 hours, freeze at -15 to -20° C

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

SAMPLE VOLUME

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two Lipase Reagent Cartridges, kit 476851 (2 x 30 tests) or (2 x 60 tests)

Volume per Test	
Sample Volume	4 µL
ORDAC Sample Volume	2 uL
Total Reagent Volume	217 µL
Cartridge Volumes	A 660 µL (for cuvette and probe washing) B 167 µL Buffer C 50 uL Substrate

Reactive Ingredients	
Tris Buffer	31 mmol/L
Colipase (porcine pancreas)	1.2 mg/L
Taurodeoxycholic Acid, Sodium Salt	5.4 mmol/L
Deoxycholic acid, Sodium salt	1.4 mmol/L
1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin)-ester	0.3 mmol/L
Sodium tartrate	3.4 mmol/L
Calcium Chloride	0.2 mmol/L

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by ensuring that quality control results are within your facility`s acceptance criteria.

New lots of reagent require lot to lot correlation studies. Refer to the DXC Reagent Lot To Lot Correlations R-W-CH-0815.

Reagent Storage and Stability

LIP reagent when stored unopened at +2°C to +8°C will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 21 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE

CALIBRATION

Calibrator Required

SYNCHRON® Systems Enzyme Validator Set

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems Enzyme Validator Set when stored unopened at -15°C to -20°C will remain stable until the expiration date printed on the label. Once opened, resealed calibrators are stable for 60 days at -15°C to -20°C. Do not use beyond the manufacturer's expiration date.

Calibration Information

1. The system must have a valid calibration in memory before controls or patient samples can be run.

2. Under typical operating conditions the LIP reagent cartridge must be calibrated every 5 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

The following anticoagulants were assessed by Deming regression analysis with a minimum of 50 paired serum and plasma samples. Values of serum (X) ranging from 24 U/L to 219 U/L were compared with the values for plasma (Y) yielding the following results.

Anticoagulant	Level of Anticoagulant Tested
Lithium Heparin	14 Units/mL
Sodium Heparin	14 Units/mL

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Conventional Units
Serum or Plasma	7-60 U/L

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum or Plasma	10 – 200 U/L
Serum or Plasma (ORDAC)	180 – 400 U/L

Samples with activities exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with a patient sample of low Lipase value, and reanalyzed.

Reporting results outside of analytical range

Lower limit of range	10 U/L	Results below 10, report as < 10 U/L.
Upper limit of range	400 U/L	Results >400 U/L should be diluted with patient sample of known low lipase (<30U/L) to a maximum dilution of X5 and reanalyzed. Results >2000 U/L should be reported as >2000 U/L. NOTE: Lipase values of >400 U/L will be reported as >400 U/L and will also reflex to a test called LIPASE R in the LIS. The manual dilution should be resulted in the LIPASE R field.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for LIP determination is 10 U/L.

LIMITATIONS

EDTA was found to report results 15% lower than serum.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin	Porcine	30 mg/dL INDEX 20	NSI
Hemoglobin	RBC hemolysate	200 mg/dL INDEX 5	NSI
Lipemia	Human	320mg/dl INDEX 8 Ultrafuging Recommended	NSI

2. Lipemic samples greater than Index of 8 should be ultracentrifuged and the analysis performed on the infranate.

3. Refer to References (8,9,10) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Standardized formatting using small tables. Added Maximum dilution. Incorporated Updated Index information.			
Committee Approval Date	☒ Date: 1/8/2015 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 7/30/15