Lactate Dehydrogenase (LDH) using Abbott Architect ci4100

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Department:	STAT Lab	**Effective Date:**	8/24/18
Policy, Procedure, or Both:	Procedure	**Revision Date(s):**	
Author:	Kim Clark, MT (ASCP)	**Version:**	1

Applicable Standards	
Standard	Organization
COM.10000	CAP
Related Documents	

Version History		
Version	Effective Date	Retired Date
1	08/24/2018	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By
8/22/18	1	**New Policy/Procedure**	System Laboratory Medical Director, Joe A. Lewis. M.D., F.C.A.P.

Distribution
Christus Spohn Shoreline STAT Lab

TECHNICAL PROCEDURE MANUAL
CHRISTUS Spohn Hospital Corpus Christi Shoreline STAT Lab
Lactate Dehydrogenase (LDH) Abbott Architect ci4100
Proc #: HSL0310.01

Intended Use

The Lactate Dehydrogenase (LDH) assay is used for the quantitation of lactate dehydrogenase in human serum or plasma.

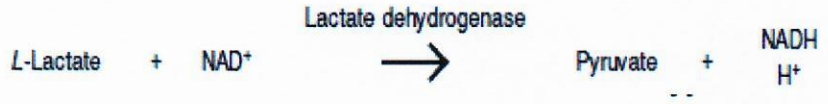
Clinical Significance

LDH is an enzyme found in the cells of many body tissues, including the heart, liver, kidneys, skeletal muscle, brain, red blood cells, and lungs. It is responsible for converting muscle lactate into pyruvate, an essential step in producing cellular energy. It is composed of four peptide chains of two subunits (M form and H form) which results in up to five different isoenzymes which can be separated and quantitated by electrophoresis. Measurement of the total LDH activity in serum or plasma is non-specific and cannot differentiate the tissues of origin of the component isoenzymes.

LDH is used in the differential diagnosis of hemolytic anemia and as a tumor marker in some malignancies, such as germ cell tumors. LDH is elevated in hepatitis, glomerular nephritis, pulmonary embolism, muscle disease, and many leukemias and lymphomas. As LDH is a non-specific marker, it is used in combination with other markers in diagnosis and patient management.

Principle

Lactate dehydrogenase is a hydrogen transfer enzyme that catalyzes the oxidation of *L*-lactate to pyruvate with the mediation of NAD+ as a hydrogen acceptor.



Methodology: This method uses the IFCC recommended forward reaction - Lactate to Pyruvate.

Specimen Collection and Handling

Suitable Specimens

Verified specimen types to be used with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Glass or plastic tubes with or without gel barrier	The STD (1:3) dilution or UNDILUTED protocols may be used with serum samples.
Plasma	Glass or plastic tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin	The STD (1:3) dilution protocol reduces pre-analytical variability as described in literature.[11-15] This pre-analytical phenomenon is due to platelets and other cellular aggregates present in a layer at the top of heparin plasma samples following centrifugation. For this reason, the UNDILUTED protocol is not recommended for plasma samples. **NOTE:** Plasma from primary tubes handled according to the manufacturer's instructions may still contain cells, leading to elevated results. For optimal plasma performance, transfer the plasma from the primary tube to a secondary sample tube after centrifugation. To ensure accurate results, the plasma specimen tube should be filled with the prescribed minimum volume for an appropriate anticoagulant to specimen ratio.

Specimen Storage

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Serum and Plasma

Temperature	Maximum Storage
20 to 25°C	7 days
2 to 8°C	4 days
-20°C*	6 weeks

*A temperature variation of +/- 10% at -20°C (+/- 2°C) is assumed not to change the stability of the specimen (W. Guder, personal communication, August 6, 2001).
Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.
NOTE: The various LDH isoenzymes differ in stability at different temperatures. LDH-4 and LDH-5 are most susceptible to refrigeration or freezing.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

Materials and Equipment Required

TEST INSTRUMENT: Abbott ARCHITECT System

MATERIALS PROVIDED

2P56 Lactate Dehydrogenase Reagent Kit

MATERIALS REQUIRED BUT NOT PROVIDED

- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Reagent Handling and Storage:

***CAUTION*:**

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix reagents prepared at different times.
4. Do not pool reagents within a kit or between kits.

- Hemolyzed specimens must not be used.
- Plasma samples may exhibit pre-analytical variability. Refer to the SPECIMEN COLLECTION AND HANDLING, Plasma section of the package insert

CAUTION: This product requires the handling of human specimens.
It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

The following warnings and precautions apply to R1	
	
DANGER.	Contains diethanolamine and sodium azide.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure.
H318	Causes serious eye damage.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P201	Obtain special instructions before use.
P260	Do not breathe mist / vapors / spray.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice / attention.
P310	Immediately call a POISON CENTER or doctor / physician.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Reagent Handling

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. 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.

Reagent Storage

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	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2-8°C	Until expiration date	
On board	System temperature	30 days (720 hours)	After 30 days (720 hours), the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

Reagents may be stored on or off the ARCHITECT cSystem.
If reagents are removed from the system, store at 2-8°C (with replacement caps) in their original boxes. When reagent is placed back on the system, run controls and if appropriate criteria are not met, recalibration may be required. For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Reagent Preparation:

LDH is supplied as a liquid, ready-to-use, reagent kit which contains: R1 & R2

Reactive Ingredients		Concentration
R1	Diethanolamine	380 mmol/L
	L-Lithium lactate	76 mmol/L
R2	β-NAD	33 mmol/L

Inactive ingredients: R1 contains sodium azide (≤ 0.1%).

Calibration : Blank Calibration Using on board Deionized water

Frequency:
Calibration is stable for 30 days (720 hours) for any one lot.

A new calibration is required:

1. If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
2. Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

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Calibration Procedure:
The calibration factor was established based on the IFCC methodology.

Troubleshooting and Overall Acceptance Criteria Failure

See ARCHITECT Operations Manual for further calibration troubleshooting.

Quality Control:

Controls are tested according to each location/site Quality Control Procedure.

- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Procedure
For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

The Lactate Dehydrogenase assay file must be installed on the ARCHITECT cSystem prior to performing the assay. For detailed information on assay file installation and viewing
and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
For information on printing assay parameters or for a detailed description of system procedures, refer to the ARCHITECT System Operations Manual, Section 5.

Calculations
Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

Reporting Results
The Conventional result units for the LDH assay is U/L. The corresponding SI result unit is U/L.

Specific Performance Characteristics
Reference Ranges
It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Serum/Plasma (Abbott Package Insert)

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	Range (U/L)
Adult	125 to 220

Serum/Plasma (this facility)

Critical Values ***:Refer to Critical Value Policy Procedure***

Performance Characteristics

Measuring Interval

The measuring interval of Lactate Dehydrogenase STD (1:3) dilution protocol is 30 to 2,000 U/L and the UNDILUTED protocol is 10 to 2,000 U/L (10 to 4,500 U/L if Flex Rate is used).

Linearity

Lactate Dehydrogenase is linear up to 2,000 U/L within } 9.0% or 20 U/L, whichever is greater with 95% confidence.

Flex Rate Linearity is 4,500 U/L (UNDILUTED protocol only).

Dilution:

Specimens with LDH values exceeding 2,000 U/L (4,500 U/L for Flex Rate Linearity) are flagged and may be diluted by following the Automated Dilution Protocol 1:5.

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the enzyme activity value by multiplying the result by the appropriate dilution factor.

Limit of Quantitation (LOQ), Limit of Detection (LOD), Limit of Blank, (LOB)

	STD 1:3	UNDILUTED
LoB	7	2
LoD	14	5
LoQ*	14	5

*If the LoD meets the total error of the assay, then LoQ = LoD.

Limitation of Procedure:

N/A

Precision:

The imprecision of the LDH assay is ≤ 4.7% Total CV.

Serum/Plasma:

STD (1:3) Dilution Protocol

Control		Level 1	Level 2
N		80	80
Mean (U/L)		135.18	377.19
Within Run	SD	3.87	5.06
	%CV	2.86	1.34
Between Run	SD	1.16	2.48
	%CV	0.86	0.66
Between Day	SD	2.30	4.13
	%CV	1.70	1.10
Total	SD	4.64	6.99
	%CV	3.44	1.85

UNDILUTED Protocol

Control		Level 1	Level 2
N		80	80
Mean (U/L)		134.64	380.87
Within Run	SD	1.15	1.88
	%CV	0.85	0.49
Between Run	SD	1.44	0.75
	%CV	1.07	0.20
Between Day	SD	1.24	3.85
	%CV	0.92	1.01
Total	SD	2.22	4.34
	%CV	1.65	1.14

Interfering Substances:

Interfering Substances

Interference studies were conducted using an acceptance criteria of ≤ 9.0% of the target value. Interference studies were conducted using CLSI protocol NCCLS EP7-P. Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Interfering Substance	Interferent Concentration	N	Target (U/L)	Observed (% of Target)*
Unconjugated Bilirubin	60 mg/dL	8	239.3	102
Conjugated Bilirubin	20 mg/dL	8	241.6	101
Intralipid	2,000 mg/dL	8	229.6	97
Lipemia	2,014 mg/dL	8	312.4	92

* Percentages have been rounded to whole numbers.

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NOTE: Hemolyzed specimens must not be used because erythrocytes contain approximately 150 times more LDH activity.

Alternative method

Send to sister facility if unable to perform at this site.

Effective date

Effective Date for this procedure:

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Revised By: Kimberlee J. Clark, MT(ASCP)