BECKMAN COULTER CE

SYNCHRON System(s)

Chemistry Information Sheet

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LACT

Lactate

REF A95550

For *In Vitro* Diagnostic Use

Rx Only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

LACT reagent, when used in conjunction with UniCel DxC 600/800 System(s) and Synchron Systems Multi Calibrator, is intended for the quantitative determination of Lactate concentration in human plasma and cerebrospinal fluid (CSF).

CLINICAL SIGNIFICANCE

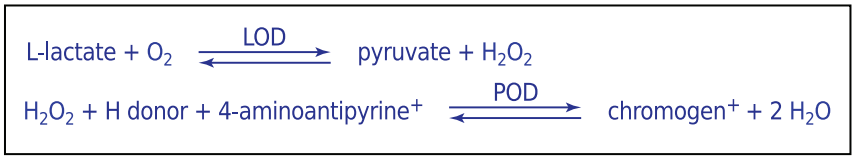
Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

METHODOLOGY

In the assay reaction, lactate oxidase (LOD) converts lactate to pyruvate with the concomitant generation of hydrogen peroxide (H_2O_2). The H_2O_2 formed reacts with a hydrogen donor and 4-aminoantipyrine (4-AAP) in a reaction catalyzed by peroxidase (POD) to form a chromophore. The lactic acid concentration is determined by measuring the absorbance due to the chromophore using an endpoint technique.

The SYNCHRON System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 100 parts reagent. The system monitors the change in absorbance at 560 nanometers. This change in absorbance is directly proportional to the concentration of lactic acid in the sample and is used by the System to calculate and express the lactate concentration.

CHEMICAL REACTION SCHEME



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SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[1] Freshly drawn plasma or cerebrospinal fluid are the preferred specimens. Chill the specimen immediately. Acceptable anticoagulants are listed in PROCEDURAL NOTES section of this chemistry information sheet. Whole blood, serum and urine are not recommended for use as a sample. Blood should be drawn without stasis because venous stasis may cause lactate elevation. Samples should remain on ice prior to analysis.

SPECIMEN STORAGE AND STABILITY

1. Tubes of blood are to be kept closed at all times and in a vertical, stopper-up position. Keep samples on ice. Plasma should be physically separated from contact with cells within 15 minutes of sample collection, and analyzed without delay.[2]
2. Plasma samples separated from cells are stable stored at: +15°C to +25°C up to 8 hours, +2°C to +8°C up to 14 days, -20°C up to 1 month. CSF samples are stable stored at:+15°C to +25°C up to 4 hours, +2°C to +8°C up to 3 days, -20°C up to 6 months.[3]

Additional specimen storage and stability conditions as designated by this laboratory:

SAMPLE VOLUME

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the Primary Tube Sample Template for your system.

CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

Criteria for sample rejection as designated by this laboratory:

PATIENT PREPARATION

Special instructions for patient preparation as designated by this laboratory:

SPECIMEN HANDLING

Special instructions for specimen handling as designated by this laboratory:

REAGENTS

CONTENTS

Each kit contains the following items:

Two Lactate Reagent Cartridges (each contains a minimum of 50 tests)

VOLUMES PER TEST

Sample Volume	3 µL
Total Reagent Volume	300 µL
Cartridge Volumes	
A	—
B	250 µL
C	50 µL

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Compartment B	
Reaction Buffer	15.7 mL
Compartment C	
Lactate Oxidase	3.7 mL
Peroxidase	
Sodium Azide (used as a preservative)	≤ 0.1 (w/w)

Also non-reactive chemicals necessary for optimal system performance.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Lactate Reagent (Compartment C)	EUH208	May produce an allergic reaction.
		Peroxidase < 0.1%
		Lactate Oxidase < 0.1%

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

Synchron Systems Multi Calibrator
At least two levels of matrix-specific control material
Saline

REAGENT PREPARATION

No preparation is required.

ACCEPTABLE REAGENT PERFORMANCE

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

REAGENT STORAGE AND STABILITY

LACT reagent, when stored unopened at +2°C to +8°C will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. Do not expose reagent to temperatures above +35°C or to direct sunlight. DO NOT FREEZE.

Reagent storage location:

CALIBRATION

CALIBRATOR REQUIRED

Synchron Systems Multi Calibrator

CALIBRATOR PREPARATION

No preparation is required.

CALIBRATOR STORAGE AND STABILITY

If unopened, the Synchron Systems Multi Calibrator should be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days unless the expiration date is exceeded.

> ⚠ **CAUTION**
>
> **Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.[4]**

Calibrator storage location:

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 LACT reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *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

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

Table 1.0 Quality Control Material

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

1. Load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operations.

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

CALCULATIONS

The SYNCHRON System(s) performs 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.

REPORTING RESULTS

Equivalency between the SYNCHRON LX and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The following reference intervals were taken from literature.[5]

Table 2.0 Reference intervals

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Literature	Plasma (Venous)	4.5 – 19.8 mg/dL	0.5 – 2.2 mmol/L
	CSF (Adult)	<25.2 mg/dL	<2.8 mmol/L

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Laboratory			

Refer to References (6, 2, 7) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

Only plasma obtained using sodium fluoride/potassium oxalate collection tubes is suitable for use with the Lactate Reagent.

LIMITATIONS

Samples with very high lactic acid could report as RX RATE LO or INIT RATE HI.

INTERFERENCES

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

Table 3.0 Interferences[a]

SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT
Bilirubin (unconjugated)	Bovine	30 mg/dL	NSI[b]
Bilirubin (Total)	Porcine	7.9 mg/dL DBIL	≤ -0.44 mmol/L or 10%
		25 mg/dL TBIL	
Hemoglobin	Human	500 mg/dL	NSI
Lipemia	Intralipid[c]	500 mg/dL	NSI
Ascorbic Acid	Sigma	6 mg/dL	NSI

Table 3.0 Interferences, Continued

SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT
Lactate Dehydrogenase	Chicken hearts	4,000 U/L	NSI
Pyruvate	Sigma	12 mg/dL	NSI

a Representative performance data obtained on LX20 PRO, DxC 600, and DxC 800 systems.
b NSI = No significant Interference (≤ ± 0.21 mmol/L or ≤ ± 4.8%).
c Registered trademarks are the property of their respective owners.

2. Venipuncture immediately after or during the administration of Metamizole (Dipyrone) may lead to falsely low results for LACT. Venipuncture should be performed prior to the administration of Metamizole.
3. Refer to References (8,9,10,11) for other interferences caused by drugs, disease and preanalytical variables.
4. Refer to References (12) for guidelines on performing interference testing.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

Representative performance data obtained on UniCel DxC 600/800 Systems.

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

Table 4.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Plasma or CSF	2.7 – 98.2 mg/dL	0.3 – 11.0 mmol/L

The low end of the analytical range represents the minimum level of detection. Samples exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

Sample results which are below the analytical range lower limit of 0.3 mmol/L (2.7 mg/dL) should be reported as "<0.3 mmol/L" ("<2.7 mg/dL").

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 5.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

SENSITIVITY

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for LACT determination is 0.3 mmol/L (2.7 mg/dL).

Refer to References (13) for guidelines on performing sensitivity testing.

EQUIVALENCY

Equivalency was assessed by Deming regression analysis of patient samples to an accepted clinical method.

Plasma (in the range of 0.5 to 10.3 mmol/L):

X (Synchron Systems Lactate LAC on UniCel DxC 600)	
Y (Synchron Systems Lactate LACT on UniCel DxC 600)	
Slope	0.92
Intercept	-0.02
CORRELATION COEFFICIENT (R^2)	0.998
Number of samples	117
Range (mg/dL)	4.5 – 92.8

Plasma (in the range of 0.5 to 9.5 mmol/L):

X (Synchron Systems Lactate LAC on UniCel DxC 800)	
Y (Synchron Systems Lactate LACT on UniCel DxC 800)	
Slope	0.90
Intercept	0.02
CORRELATION COEFFICIENT (R^2)	0.999
Number of samples	116
Range (mg/dL)	4.5 – 85.6

CSF (in the range of 0.6 to 9.7 mmol/L):

X (Synchron Systems Lactate LAC on UniCel DxC 600)	
Y (Synchron Systems Lactate LACT on UniCel DxC 600)	
Slope	0.93
Intercept	-0.07
CORRELATION COEFFICIENT (R^2)	0.999
Number of samples	119
Range (mg/dL)	5.4 – 87.4

CSF (in the range of 0.6 to 9.9 mmol/L):

X (Synchron Systems Lactate LAC on UniCel DxC 800)	
Y (Synchron Systems Lactate LACT on UniCel DxC 800)	
Slope	0.92
Intercept	-0.03
CORRELATION COEFFICIENT (R^2)	0.998
Number of samples	119
Range (mg/dL)	5.4 – 89.2

Refer to References (14) for guidelines on performing equivalency testing.

PRECISION

A properly operating SYNCHRON System(s) should exhibit precision values less than or equal to the following:

Table 6.0 Precision Values

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[a]		% CV
		mmol/L	mg/dL	mmol/L	mg/dL	
Within-run	Plasma/CSF	0.13	1.2	4.4	40.0	3.0
Total	Plasma/CSF	0.20	1.8	4.4	40.0	4.5

a When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Comparative performance data for Synchron Systems evaluated using the CLSI/NCCLS Approved Guideline EP5-A2 appears in the table below.[15] Each laboratory should characterize its own instrument performance for comparison purposes.

Refer to References (15) for guidelines on performing precision testing.

Table 7.0 CLSI/NCCLS EP5-A2 Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[a]	Test Mean Value (mmol/L)	EP5-A2 Calculated Point Estimates	
						SD	%CV
Within-run	Plasma	Control Level 1	1	80	1.8	0.036	2.0
(DxC 600)	Plasma	Control Level 2	1	80	3.9	0.049	1.3
	Plasma	Control Level 3	1	80	6.6	0.078	1.2
	PPHI		1	80	9.8	0.106	1.1
	PPMID		1	80	7.0	0.092	1.3
	PPLO		1	80	2.4	0.039	1.6
	CSF	Control Level 1	1	80	2.1	0.030	1.4
	CSF	Control Level 2	1	80	4.2	0.060	1.4
Total	Plasma	Control Level 1	1	80	1.8	0.036	2.0
(DxC 600)	Plasma	Control Level 2	1	80	3.9	0.057	1.5
	Plasma	Control Level 3	1	80	6.6	0.091	1.4
	PPHI		1	80	9.8	0.136	1.4
	PPMID		1	80	7.0	0.110	1.6
	PPLO		1	80	2.4	0.041	1.7
	CSF	Control Level 1	1	80	2.1	0.036	1.7
	CSF	Control Level 2	1	80	4.2	0.072	1.7
Within-run	Plasma	Control Level 1	1	80	1.7	0.027	1.6

Table 7.0 CLSI/NCCLS EP5-A2 Precision Estimate Method, Continued

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[a]	Test Mean Value (mmol/L)	EP5-A2 Calculated Point Estimates	
						SD	%CV
(DxC 800)	Plasma	Control Level 2	1	80	3.9	0.056	1.4
	Plasma	Control Level 3	1	80	6.6	0.065	1.0
	PPHI		1	80	9.7	0.115	1.2
	PPMID		1	80	6.9	0.080	1.1
	PPLO		1	80	2.4	0.046	1.9
	CSF	Control Level 1	1	80	2.1	0.049	2.4
	CSF	Control Level 2	1	80	4.2	0.053	1.3
Total	Plasma	Control Level 1	1	80	1.7	0.031	1.8
(DxC 800)	Plasma	Control Level 2	1	80	3.9	0.063	1.6
	Plasma	Control Level 3	1	80	6.6	0.093	1.4
	PPHI		1	80	9.7	0.139	1.4
	PPMID		1	80	6.9	0.092	1.3
	PPLO		1	80	2.4	0.048	2.0
	CSF	Control Level 1	1	80	2.1	0.052	2.5
	CSF	Control Level 2	1	80	4.2	0.062	1.5

a The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

Table 8.0 CLSI/NCCLS EP5-A2 Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[a]	Test Mean Value (mg/dL)	EP5-A2 Calculated Point Estimates	
						SD	%CV
Within-run	Plasma	Control Level 1	1	80	15.9	0.321	2.0
(DxC 600)	Plasma	Control Level 2	1	80	35.3	0.442	1.3
	Plasma	Control Level 3	1	80	59.4	0.702	1.2
	PPHI		1	80	87.9	0.957	1.1
	PPMID		1	80	62.7	0.828	1.3
	PPLO		1	80	21.6	0.347	1.6
	CSF	Control Level 1	1	80	18.9	0.269	1.4
	CSF	Control Level 2	1	80	38.1	0.545	1.4
Total	Plasma	Control Level 1	1	80	15.9	0.325	2.0

Table 8.0 CLSI/NCCLS EP5-A2 Precision Estimate Method, Continued

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[a]	Test Mean Value (mg/dL)	EP5-A2 Calculated Point Estimates	
						SD	%CV
(DxC 600)	Plasma	Control Level 2	1	80	35.3	0.515	1.5
	Plasma	Control Level 3	1	80	59.4	0.817	1.4
	PPHI		1	80	87.9	1.229	1.4
	PPMID		1	80	62.7	0.989	1.6
	PPLO		1	80	21.6	0.368	1.7
	CSF	Control Level 1	1	80	18.9	0.326	1.7
	CSF	Control Level 2	1	80	38.1	0.645	1.7
Within-run	Plasma	Control Level 1	1	80	15.7	0.243	1.6
(DxC 800)	Plasma	Control Level 2	1	80	35.1	0.500	1.4
	Plasma	Control Level 3	1	80	59.1	0.584	1.0
	PPHI		1	80	87.7	1.039	1.2
	PPMID		1	80	62.4	0.717	1.1
	PPLO		1	80	21.3	0.415	1.9
	CSF	Control Level 1	1	80	18.6	0.440	2.4
	CSF	Control Level 2	1	80	37.8	0.478	1.3
Total	Plasma	Control Level 1	1	80	15.7	0.284	1.8
(DxC 800)	Plasma	Control Level 2	1	80	35.1	0.565	1.6
	Plasma	Control Level 3	1	80	59.1	0.838	1.4
	PPHI		1	80	87.7	1.249	1.4
	PPMID		1	80	62.4	0.832	1.3
	PPLO		1	80	21.3	0.428	2.0
	CSF	Control Level 1	1	80	18.6	0.468	2.5
	CSF	Control Level 2	1	80	37.8	0.560	1.5

a The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

ADDITIONAL INFORMATION

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

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May be covered by one or more pat. -see www.beckmancoulter.com/patents.

SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

REVISION HISTORY

Revision AB

Remove Not for distribution in the USA.

Revision AC

Revised Reagent Storage and Stability section.

Revision AD

Added Revision History

Revision AE

Revised Interferences section.

Revision AF

Added new language requirement: Czech, and Korean.

Revision AG

Removed references to CX and LX systems as they are discontinued effective 12/2013.

Added Beckman Coulter trademark statement and disclaimer.

Revision AH

Added GHS Classification information

Revision AJ

Added GHS Classification information

Revision AK

Updates to comply with requirements per Beckman Coulter Global Labeling Policy.

New statement (item #2) added under INTERFERENCES section.

Revision AL

Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

Revision AM

Update to Symbols Key

Revision AN

Added new language requirement: Bulgarian, Romanian, Serbian, and Vietnamese. Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

SYMBOLS KEY

Table 9.0

REF	Catalogue Number	IVD	In Vitro Diagnostic
CONTENTS	Contents		Temperature limit
	Manufacturer		Expiration Date
LOT	Batch code	SDS	Safety Data Sheet
CE	CE Mark		Consult Instructions for Use
EC REP	Authorized Representative in the European Community		Date of Manufacture
	Do Not Freeze		Do not reuse
Made in Germany	Made in Germany		

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