Wake Forest Baptist Medical Center	**Total Bilirubin CC-CH18**	**Dept:**	Clinical Core Lab/Cancer Center- Chemistry Section
		Effective Date:	July 15, 2009
		Revised Date:	02/04/2019
		Contact:	Clinical Core Lab/Cancer Center- Chemistry Management
Name & Title: Gregory J. Pomper, MD Medical Director of Pathology Laboratories		**Date:**	
Signature:			

1) General Procedure Statement:

a. **Scope:** To provide laboratory testing personnel with instructions for performing laboratory procedures as deemed appropriate by industry practices and regulatory agencies to assist in quality patient care.

b. **Responsible Department/Party/Parties:**

i.	Procedure owner:	Clinical Core Laboratory Management-Chemistry
ii.	Procedure:	Clinical Core Laboratory Personnel
iii.	Procedure prepared by:	Leigh Ann Jones / Emily Dockery
iv.	Supervision:	Clinical Core Laboratory Management-Chemistry Clinical Core Laboratory Specialist and Designees Medical Director Clinical Chemistry
v.	Implementation:	Clinical Core Laboratory Management-Chemistry Clinical Core Laboratory Specialist and Designees Medical Director Clinical Chemistry

2) Definitions: NA

3) Procedure:

This procedure is valid for the following analyzers:

- DXC600

PRINCIPLE:

Bilirubin measurements are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

INTENDED USE:

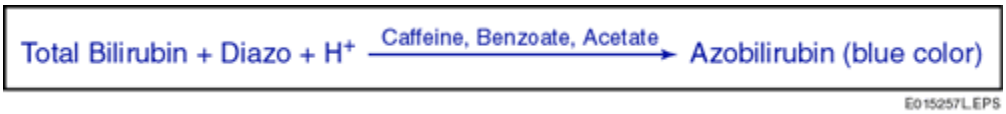
TBIL reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Bilirubin Calibrator, is intended for quantitative determination of Total Bilirubin concentration in human serum or plasma.

METHODOLOGY:

TBIL reagent is used to measure the total bilirubin concentration by a timed endpoint Diazo method.[1,2,3] In the reaction, the bilirubin reacts with diazo reagent in the presence of caffeine, benzoate, and acetate as accelerators to form azobilirubin.

The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 35 parts reagent. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of TBIL in the sample and is used by the System to calculate and express TBIL concentration.

CHEMICAL REACTION SCHEME



SPECIMEN:

PATIENT PREPARATION: None required.

Additional instructions for patient preparation as designated by this laboratory: None

TYPE OF SPECIMEN:

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[4] Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine 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 within two hours from the time of collection.[5]
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 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.[5]

3. Bilirubin is photosensitive. Protect samples from light.

ADDITIONAL SPECIMEN STORAGE AND STABILITY CONDITIONS AS DESIGNATED BY THIS LABORATORY:

None

SAMPLE PREPARATION:

Sample preparation is not required.

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 or the SPECIMEN REQUIREMENTS section of this manual for information on unacceptable specimens.

SPECIMEN HANDLING:

SPECIAL INSTRUCTIONS FOR SPECIMEN HANDLING AS DESIGNATED BY THIS LABORATORY:

None

REAGENTS:

CONTENTS

Each kit contains the following items:

Two Total Bilirubin Reagent Cartridges (2 x 300 tests) or (2 x 400 tests)
One Preparation Insert

VOLUMES PER TEST

Sample Volume	8 µL
Total Reagent Volume	280 µL
Cartridge Volumes	
A	255 µL
B	25 µL
C	– –

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Sodium Benzoate	347 mmol/L
Caffeine	173.9 mmol/L
Sulfanilic acid	27 mmol/L
HCl	50 mmol/L
Sodium Nitrite	0.36 mmol/L
Sodium Acetate	609 mmol/L

Also non-reactive chemicals necessary for optimal system performance.

CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/16/76).

EUROPEAN HAZARD CLASSIFICATION

Total Bilirubin (Compartment C)	Reagent	T;R25	Toxic if swallowed.
		S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

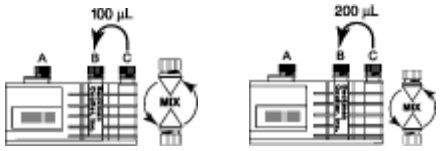
SYNCHRON® Systems Bilirubin Calibrator
Deionized water (low level calibrator)
At least two levels of control material
Human serum albumin (azide free)
Protective Equipment: lab coat, gloves

REAGENT PREPARATION

For P/N 442745 (300 tests): Quantitatively transfer 100 microliters (0.1 mL) of the contents from the smallest compartment (C) into the center compartment (B).

For P/N 476861 (400 tests): Quantitatively transfer 200 µL (0.2 mL) of the contents from the smallest compartment (C) into the center compartment (B).

Replace the cartridge caps and **gently** invert the cartridge several times to ensure adequate mixing. Thorough mixing is necessary for successful calibration.



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, as defined in the CONTROL PROCEDURES section of this manual.

REAGENT STORAGE AND STABILITY

TBIL reagent when stored unopened at room temperature will obtain the shelf-life indicated on the cartridge label. Once prepared, the reagent cartridge is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

REAGENT STORAGE LOCATION:

Room Temperature in the Cancer Center Lab.

CALIBRATION:

CALIBRATOR REQUIRED

SYNCHRON® Systems Bilirubin Calibrator
Deionized water (low level calibrator)

CALIBRATOR PREPARATION

No preparation is required.

CALIBRATOR STORAGE AND STABILITY

If unopened, the SYNCHRON® Systems Bilirubin Calibrator may 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 24 hours 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.[6]

CALIBRATOR STORAGE LOCATION:

Freezer/Refrigerator #2 in Cancer Center Lab.

CALIBRATION INFORMATION

NOTICE

Since Total Bilirubin is a calibrated chemistry and also requires "quantitative" reagent preparation it is important to follow proper reagent handling, preparation and storage procedures, especially when utilizing the within-lot calibration feature. Before reporting patient results on successive within-lot cartridges, always analyze and review calibration and quality control data.

1. The system must have a valid calibration curve in memory before control or patient samples can be run.
2. Under typical operating conditions the TBIL reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the SYNCHRON LX *Maintenance Manual and Instrument Log*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.
3. For detailed calibration instructions, refer to the SYNCHRON LX *Operations Manual*, or 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 SYNCHRON LX *Diagnostics and Troubleshooting Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

DxC 600 Calibration Procedure

From the **Rgts/Cal** dialog box, check the Calibration Time Left column shown in days:hours:minutes and the Cal Status Column to see which chemistries require calibration.

1. Select **Rgts/Cal** from the menu bar.

2. Select the chemistries to be calibrated. If necessary, use the up and down arrows to select more chemistries.

3. Select **Cal F4**.

4. Select **List F5** to review the calibrator load list. Make sure the same lot number on the calibrator bottle is the same as the lot number in the screen.

5. Get the bar coded calibrator racks listed on the screen and place nesting cups into the assigned rack positions as shown on the load list.

   - For Aqua Cals 1, 2, and 3, use 2mL nesting cups.
   - For all other chemistries use a 0.5mL nesting cup.

6. Place calibrators into appropriate nesting cups.

7. Place the rack(s) in the autoloader with the rack bar code label to the right. Press **Run** on the analyzer.

Calibrations will print out automatically upon completion. File all printouts in the provided calibration notebook for each DxC.

Follow all passed calibrations with the appropriate quality control material for each chemistry that was calibrated.

If there is a failure during the calibration for either a modular or a chemistry calibration, there is a pop-up message which shows the chemistry that failed and the associated error code(s).

For failed calibrations refer to the DxC's IFU (on the DxC computer - **ALT F1**) *CHAPTER 12, Troubleshooting Calibration and Result Errors* for more information.

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 work load and work flow.

The following controls should be prepared and used in accordance with the package inserts. Copies of these inserts can be found in the CONTROL PROCEDURES section of this manual. Discrepant quality control results should be evaluated and handled as described in the CONTROL PROCEDURES section of this manual.

TABLE 1 QUALITY CONTROL MATERIAL

CONTROL NAME	SAMPLE TYPE	STORAGE
BC SYNCHRON LIQUID COMP.CHEM CONTROL 1,2,3 REF.657365 LIS QC CODES: LEVEL 1 : C - SYN1C4 LEVEL 2 : C - SYN2C4 LEVEL 3 : C - SYN3C4	SERUM/PLASMA	UNOPENED: FREEZER OPENED: REFRIGERATOR

DxC 600 Quality Control Procedure

Running Control Samples with Auto Generation and Multiple Cartridge

This procedure is used when daily QC is run. The instrument automatically runs chemistries that are defined for the control, loaded and calibrated, and contain sufficient volume to run the controls.

1. Clear previous control orders.

    - Select **Samples** from the menu bar.
    - Select **Clear F7**.
    - Under Sample ID(s) type *From* **C-A** *To* **C-Z**.
    - Select **OK** to continue clearing. A confirmation screen appears. Select **OK**.

2. Get the bar coded quality control racks and place nesting cups into the assigned rack positions.

    - For Synchron Controls 1 and 3 use 2 mL nesting cups.
    - For all other controls use a 0.5 mL nesting cup.

3. Place controls into the appropriate nesting cups.

4. Place the rack(s) in the autoloader with the rack bar code label to the right. Press **Run** on the analyzer.

Manually Programming Control Samples

This procedure is used when only specific tests need quality control testing (i.e. post calibration)

1. Clear previous control orders.

    - Select **Samples** from the menu bar
    - Select **Clear F7**
    - Type the QC sample ID into the **Sample ID(s)** field.
    - Select **OK**.
    - Select **OK** to confirm.

2. Select **Control F5**.

3. Select the number next to the **Control name** field (by using the touch screen) to select from predetermined Control names.

4. The **Program Control** screen opens. Touch the drop down key next to the Control ID to populate the field.

5. Select chemistries to be run. To access duplicate or specific cartridges, select **Rgt Cart F8**. Then select the desired cartridges and select **OK**.

6. Select **Save F10** to save the control programming.

7. Get the bar coded quality control racks and place nesting cups into the assigned rack positions.

- Use 0.5 mL nesting cups for all chemistries.

8. Place controls into the appropriate nesting cups.

9. Place the rack(s) in the autoloader with the rack bar code label to the right. Press **Run** on the analyzer.

10. When Quality Control is completed it will be review by the tech manning Command Central. When QC is successful then patients can be ran on the instrument. If any Quality Control does not meet our lab's quality control policies then the failed test will have to have the QC repeated on it. It is possible that the test may have to be recalibrated before running QC. That will be determined by looking at that test's previous QC results - is QC shifting one direction or another, etc…)

TESTING PROCEDURE(S):

NOTICE
When using the within-lot calibration feature it is highly recommended that recovery be confirmed on subsequent cartridge(s) from the same lot number by analyzing quality control material prior to analyzing or reporting any patient results.

1. If necessary prepare reagent as defined in the Reagent Preparation section of this chemistry information sheet and 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 operation.

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

DxC 600 Sample Programming and Processing

Processing Bar Coded and centrifuged Samples

1. Refer to Beckman Coulter's Primary Tube Sample Template to identify which rack(s) to load samples on and to determine if nesting cups are necessary. Template is located at each DxC 600.

2. Load tube(s) into appropriate rack(s) with the bar code labels visible through the slot on the same side of the rack as the rack bar code label.

3. Place rack(s) on the autoloader with the rack bar code label to the right. Load priority samples first then routines.

5. Press **RUN** on the analyzer.

For a STAT sample:

If the system is running and there are other racks on the autoloader, press **PRIORITY**. The rack pusher moves back one space so the STAT rack can be placed in front of the other racks. Press **RUN.**

Processing Samples Manually

The following items require manual programming:

- Samples without bar codes and no sample programming.
- Samples with bar codes and no sample programming.
- Short / Pediatric Samples

1. Refer to Beckman Coulter's Primary Tube Sample Template to identify which rack(s) to load samples on and to determine if nesting cups are necessary. Template is located at each DxC 600.

2. Select **Samples** from the menu bar.

3. Identify samples using the list below:

    - If the sample has a readable bar code - type in the Sample ID.
    - If the sample has no bar code or bar code cannot be read - Type in the sample ID and type numbers in the **Rack** and **Pos** fields.

4. If the sample is STAT, select the **STAT** check box.

5. Select **Sample type** from the pull-down menu. Serum is the default.

6. Select each chemistry and/or select panel. It may be necessary to use the up and down arrows to access additional chemistries.

7. Select **Next F10**.

8. To program additional samples repeat steps 2-6.

9. Place samples into assigned rack postions.

10. Remove caps from sample(s).

11. Place rack(s) on the autoloader with the rack bar code label to the right. Load priority samples first then routines.

12. Press **RUN** on the analyzer.

For a STAT sample:

If the system is running and there are other racks on the autoloader, press **PRIORITY**. The rack pusher moves back one space so the STAT rack can be placed in front of the other racks. Press **RUN.**

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.

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 reference intervals listed below were taken from literature.[7]

TABLE 2 REFERENCE INTERVALS

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Literature	Serum or Plasma	0.3 – 1.2 mg/dL	5.1 – 20.5 µmol/L

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS		S.I. UNITS
Laboratory	SERUM / PLASMA	>=1M	0.1-1.2 mg/dL	
		14D up to 1M	0.5-4.0 mg/dL	
		7D up to 14D	1.0-5.0 mg/dL	
		4D up to 7D	2.0-12.0 mg/dL	
		3D up to 4D	6.0-13.0 mg/dL	
		2D up to 3D	3.0-12.5 mg/dL	
		1D up to 2D	3.5-7.5 mg/dL	
		0D up to 1D	1.5-3.2 mg/dL	

Refer to References (8,9,10) for guidelines on establishing laboratory-specific reference intervals.

Procedures for reporting results to the appropriate personnel can be found in the HOW TO REPORT RESULTS section of this manual.

ADDITIONAL REPORTING INFORMATION AS DESIGNATED BY THIS LABORATORY:

Results are autoverified by the Beckman DL2000 software. Failed verify and critical values are held to be reviewed by the DL operator who will take action before results are validated. For quick help, refer to "DATALINK OPERATIONAL GUIDE ".

Serum Total Bili >18.0 mg/dL is considered CRITICAL for NEWBORNS ONLY and needs to be called to the appropriate personnel and documented on the LIS.

PROCEDURAL NOTES:

ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Table 3 Acceptable Anticoagulants[a]

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL)
Sodium Heparin	29 Units/mL	NSI[b]
Lithium Heparin	29 Units/mL	NSI
Ammonium Heparin	29 Units/mL	NSI
EDTA	3.0 mg/mL	NSI

2. The following anticoagulants were found to be incompatible with this method:

Table 4 Incompatible Anticoagulants[c]

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	PLASMA-SERUM BIAS (mg/dL)[d].
Sodium Citrate	1.7 mg/mL	≤ -0.8
Potassium Oxalate/Sodium Fluoride	4.0 / 5.0 mg/mL	≤ -0.4

LIMITATIONS

None identified.

INTERFERENCES

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

Table 5 Interferences[e]

SUBSTANCE	SOURCE	MAXIMUM LEVEL TESTED	OBSERVED EFFECTe
Hemoglobin	RBC hemolysate	100 mg/dL	≤ +0.63 mg/dL
Lipemia	Intralipid	200 mg/dL	≤ -0.24 mg/dL
Azide	NAi	5 mg/dL	≤ +0.24 mg/dL
Citrate	NA	900 mg/dL	≤ ±0.20 mg/dL
Oxalate	NA	1000 mg/dL	≤ ±0.20 mg/dL
Gentisic Acid	NA	5 mg/dL	≤ +0.24 mg/dL
Acetoacetate	NA	0.2 mg/mL	≤ +0.7 mg/dL
		1.08 mg/mL	≤ +3.7 mg/dL

2. Lipemic samples >2+ should be ultra-centrifuged and the analysis performed on the infranate.
3. The Naproxen metabolite, O-desmethylnaproxen, has demonstrated a positive interference with the Jendrassik-Grof method for total Bilirubin measurement.**Error! Reference source not found.**
4. Refer to References (11,12,13) for other interferences caused by drugs, disease and preanalytical variables.
5. N-acetyl-p-benzoquinone imine (NAPQI), a metabolite of acetaminophen (paracetamol), may generate erroneously low results in samples for patients that have taken toxic doses of acetaminophen (paracetamol).

PERFORMANCE CHARACTERISTICS:

Analytic Range

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

TABLE 6 ANALYTICAL RANGE

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma	0.1 – 30.0 mg/dL	1.7 – 513.0 µmol/L

Samples with concentrations outside the analytical range will be reported as "<0.1 mg/dL" ("<1.7 µmol/L") or ">30.0 mg/dL" (">513.0 µmol/L").

Samples reported out as greater than the analytical range may be confirmed by diluting with human serum with a known bilirubin value and reanalyzing. The appropriate dilution factor should be applied to the reported result.

REPORTABLE RANGE (as determined on site):

TABLE 7 REPORTABLE RANGE

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum /Plasma	0.0- 30.0	

SENSITIVITY

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for TBIL determination is 0.1 mg/dL (1.7 µmol/L).

EQUIVALENCY

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

Serum or plasma (in the range of 0.2 to 28.2 mg/dL):

Y (SYNCHRON LX Systems)	= 0.96X + 0.31
N	= 79
MEAN (SYNCHRON LX Systems)	= 6.75
MEAN (SYNCHRON CX7 DELTA)	= 6.69
CORRELATION COEFFICIENT (r)	= 0.9997

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 8 PRECISION VALUES

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[i].		% CV
		mg/dL	µmol/L	mg/dL	µmol/L	
Within-run	Serum/Plasma	0.15	2.6	5.0	86.7	3.0
Total	Serum/Plasma	0.22	3.8	5.0	86.7	4.5

Comparative performance data for a SYNCHRON LX® System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.[15] Each laboratory should characterize their own instrument performance for comparison purposes.

TABLE 9 NCCLS EP5-T2 PRECISION ESTIMATE METHOD

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[j].	Test Mean Value (mg/dL)	EP5-T2 Calculated Point Estimates	
						SD	%CV
Within-run	Serum	Control 1	1	80	1.7	0.1	6.1
	Serum	Control 2	1	80	5.9	0.1	1.7
	Serum	Control 3	1	80	8.9	0.1	1.2
	Serum	Control 4	1	80	17.5	0.2	1.1
Total	Serum	Control 1	1	80	1.7	0.1	6.1
	Serum	Control 2	1	80	5.9	0.1	1.9
	Serum	Control 3	1	80	8.9	0.1	1.3
	Serum	Control 4	1	80	17.5	0.2	1.23

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON LX® System and are not intended to represent the performance specifications for this reagent.

ADDITIONAL INFORMATION:

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

SHIPPING DAMAGE

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

4) Review/Revision/Implementation:

a. Review Cycle: 2 years
b. Office of Record: Department of Clinical Core Laboratory-Chemistry
c. All new procedures and procedures that have major revisions must be signed by the Laboratory Director.
d. All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.

5) Related Procedures: None

6) References:

REFERENCES:

1. Malloy, H. T., Evelyn, K. A., *J. Biol. Chem.*, 119 481 (1937).
2. Jendrassik, L., Grof, P., *Biochem. Z.*, 297:81 (1937).
3. U.S. Patent No. 4,672,041.
4. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1994).
5. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens*, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
6. CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Government Printing Office, Washington, D.C. (1984).
7. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
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9. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1987).
10. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 18th Edition, W. B. Saunders Company, Philadelphia, PA (1991).
11. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D. C. (1995).
12. Friedman, R. B., Young, D. S., *Effects of Disease on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D.C. (1997).
13. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D. C. (1997).

14. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Approved Guideline, NCCLS publication EP9-A, Villanova, PA (1995).

15. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992).

ENDNOTES

a Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

b NSI = No Significant Interference (within ±0.3 mg/dL or 6%).

c Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

d Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

e Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

f Plus (+) or minus (-) signs in this column signify positive or negative interference.

g Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

h NA = Not applicable.

i 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.

j 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.

7) Attachments: None

8) Revision Dates:

Review/Revision Date	Review/Revision Description	Signature
02/04/2020	Possible Tylenol interference added on pg. 15	