GOING LIVE WITH DAILY QC!!

This is a summary of how often we will run the DxC tests. Please review each attached QC page.

There will also be changes made to the QC charts on the instruments to aid you, and changes to the QC volumes.

There are a few important things to remember:

1. Be sure to load enough reagent to last 24 hours for those tests QC'd once a day.
2. QC every cartridge that you've loaded.
3. Mix the VPA cartridge each day BEFORE running QC.
4. BE SPARING OF THE CONTROLS!! Do not pour a full 0.5 mL cup of control for a few tests. Please review the updated QC volumes.

EVERY 1-2 HOURS	EVERY SHIFT	ONCE EACH DAY
NA	NA	AMM
K	K	AMY7
CL	CL	BHB
CO2	CO2	CRPH
CALC	CALC	DBIL
GLUCOSE	GLUCOSE	ETOH
	BUNm	FE
	CREAm	GGT
	PHOSm	LACT
	ALBm	LD
	TPm	LDLD
	ALP	LIP
	ALT	M-TP
	AST	MA
	CK	TRFN
	MG	URIC
	TBIL	ACTM
	TG	CARB
	CHOL	GEN
	HDL	LI
		PHE
		PHY
		SALY
		TOB
		THE
		VANC
		VPA**
		AMPH
		BARB
		BENZ
		COCM
		OP300
		C3
		C4
		HPT
		IgA
		IgG
		IgM
		PAB
***MIX VPA CARTRIDGE PRIOR TO RUNNING DAILY QC		
QC EVERY CARTRIDGE LOADED ON THE ANALYZER. FOR TESTS RUN DAILY, LOAD AND QC ENOUGH REAGENT TO LAST 24 HOURS.		

Traceability

The measurand (ACTM) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

SYNCHRON® Systems Drug Calibrator 2 is prepared using processed human serum to which weighed-in drug quantities are added,

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at –10°C to –20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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 800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

Quality Control

A minimum of two levels of control material are to be run each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C. Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

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 is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

Dilutions are programmed in Remisol. The final calculated result will be calculated by Remisol using the dilution factor that was entered in Remisol.

Reporting Results

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

Calibration

Calibration is not required.

Traceability

This measurand (ALP) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and controls onto the system, follow the protocols for system operation.

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

Calculations

UniCel DxC Systems 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.

Dilutions are programmed in Remisol. The final calculated result will be calculated by Remisol using the dilution factor that was entered in Remisol.

Reporting Results

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

Acceptable Reagent Performance

The acceptability of this reagent is determined by ensuring that quality control results are within acceptance criteria, as defined in the Clinical Chemistry Quality Control Procedure #3000.T.

Reagent Storage and Stability

ALT 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 30 days at 2°C to 8°C unless the expiration date is exceeded.

DO NOT FREEZE.

Equipment

This test is performed on the Beckman UniCel DxC 800 systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the UniCel DxC 800 systems *Reference Manual* for detailed instructions.

Calibration

Calibration is not required.

Traceability

This measurand (ALT) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and controls onto the system, follow the protocols for system operation.

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

Traceability

Ammonia measurand (analyte) in this calibrator is traceable to the manufacturer's selected measuring method.(2) The traceability process is based on prEN ISO 17511.

Ammonia set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON® System(s). Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

Two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

CONTROL	REF No.	STORAGE
Bio-Rad Liquichek ETOH/Ammonia Control Level 1 (3 mL)	544	+2°C to +8°C**
Bio-Rad Liquichek ETOH/Ammonia Control Level 3 (3 mL)	546	+2°C to +8°C**

**Control is stable until the expiration date when stored unopened at 2 to 8°C. Opened vials stored tightly capped are stable for 20 days.

Testing Procedure

1. If necessary, load reagent onto the system.
2. After reagent load is completed, calibration is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Traceability

The measurand (AMPH) in this calibrator is traceable to the GC/MS reference method. The traceability process is based on prEN ISO 17511. The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Drug Concentration in Calibrators

	Concentration (ng/mL)		
Drug Analyte	**DAT Negative Urine Calibrator**	**DAT Multi-Drug Low Urine Calibrator**	**DAT Multi-Drug High Urine Calibrator**
Amphetamines	0	1000	2000

Quality Control

A minimum of two levels of control material with levels 25% above and 25% below the cutoff threshold of each drug will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	**Concentration (ng/mL)**	**Storage**	**Reorder No.**
DAT Multi-Drug Low Urine Control	750	2°C to 8°C	**474976**
DAT Multi-Drug High Urine Control	1250	2°C to 8°C	**474979**

Quality Control Review

After the controls are run, the DAT Multi-Drug Low and High Urine Control results will be printed for review, and initialed by the person who has reviewed the results.

The rate units for the low control (25% below the cutoff) should be at least 10 rate units below the rate unit of the cutoff calibrator.

The rate units for the high control (25% above the cutoff) should be at least 10 rate units above the rate unit of the cutoff calibrator.

If either control is less than 10 rate units from the cutoff rate unit, the control(s) should be repeated. If the repeat control is still less than 10 rate units from the cutoff rate, the reagent should be re-calibrated and the controls checked again. If either or both control's rate units are still less than 10 rate units from the cutoff rate, load a new cartridge of reagent, calibrate and rerun controls again. If the controls still do not

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).

Materials Needed But Not Supplied With Reagent Kit

At least two levels of control material
Saline

Reagent Preparation

No preparation is required.
Document lot number in reagent log, date and initial every cartridge before loading.

Acceptable Reagent Performance

The acceptability of this reagent is determined by ensuring that quality control results are within acceptance criteria, as defined in the Clinical Chemistry Quality Control Procedure #3000.T.

Reagent Storage and Stability

AMY7 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 unless the expiration date is exceeded.

DO NOT FREEZE.

Equipment

This test is performed on the Beckman UniCel DxC 800 systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the UniCel DxC 800 systems *Reference Manual* for detailed instructions.

Calibration

Calibration is not required.

Traceability

AMY7 assay is traceable to the IFCC primary reference method.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

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 DxC800 System *Instructions for Use* (IFU) manual.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Ref. Number	Storage**
BHB Low Control (5 mL)*	2461	2°C to 8°C*
BHB High Control (5 mL)*	2463	2°C to 8°C*

*The measured amounts of ß-Hydroxybutyrate is in a synthetic serum substitute (SeraSub™) matrix.
**Store unopened vials in refrigerator (2°C to 8°C) until expiration date on label. Control solution is stable for 60 days in refrigerator (2°C to 8°C) after opening. Discard if turbidity or any change in appearance occurs or when there is a shift in control recovery.

Kit catalog (reorder) number: 2465-605

Testing Procedure

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

For dilutions programmed in Remisol: the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Acceptable Reagent Performance

The acceptability of this reagent is determined by ensuring that quality control results are within acceptance criteria, as defined in the Clinical Chemistry Quality Control Procedure #3000.T.

Reagent Storage and Stability

AST 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 30 days at 2°C to 8°C unless the expiration date is exceeded.

DO NOT FREEZE.

Equipment

This test is performed on the Beckman UniCel DxC 800 systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the UniCel DxC 800 systems *Reference Manual* for detailed instructions.

Calibration

Calibration is not required.

Traceability

This measurand (AST) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and controls onto the system, follow the protocols for system operation.

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

Traceability

The measurand (BARB) in this calibrator is traceable to the GC/MS reference method. The traceability process is based on prEN ISO 17511. The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Drug Concentration in Calibrators

	Concentration (ng/mL)		
Drug Analyte	**DAT Negative Urine Calibrator**	**DAT Multi-Drug Low Urine Calibrator**	**DAT Multi-Drug High Urine Calibrator**
Amphetamines	0	200	1000

Quality Control

A minimum of two levels of control material with levels 25% above and 25% below the cutoff threshold of each drug will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	**Concentration (ng/mL)**	**Storage**	**Reorder No.**
DAT Multi-Drug Low Urine Control	150	2°C to 8°C	**474976**
DAT Multi-Drug High Urine Control	300	2°C to 8°C	**474979**

Quality Control Review

After the controls are run, the DAT Multi-Drug Low and High Urine Control results will be printed for review, and initialed by the person who has reviewed the results.

The rate units for the low control (25% below the cutoff) should be at least 10 rate units below the rate unit of the cutoff calibrator.

The rate units for the high control (25% above the cutoff) should be at least 10 rate units above the rate unit of the cutoff calibrator.

If either control is less than 10 rate units from the cutoff rate unit, the control(s) should be repeated. If the repeat control is still less than 10 rate units from the cutoff rate, the reagent should be re-calibrated and the controls checked again. If either or both control's rate units are still less than 10 rate units from the cutoff rate, load a new cartridge of reagent, calibrate and rerun controls again. If the controls still do not

Traceability

The measurand (BNZG) in this calibrator is traceable to the GC/MS reference method. The traceability process is based on prEN ISO 17511. The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Drug Concentration in Calibrators

	Concentration (ng/mL)		
Drug Analyte	**DAT Negative Urine Calibrator**	**DAT Multi-Drug Low Urine Calibrator**	**DAT Multi-Drug High Urine Calibrator**
Benzodiazepines	0	200	1000

Quality Control

A minimum of two levels of control material with levels 25% above and 25% below the cutoff threshold of each drug will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	**Concentration (ng/mL)**	**Storage**	**Reorder No.**
DAT Multi-Drug Low Urine Control	100	2°C to 8°C	**474976**
DAT Multi-Drug High Urine Control	300	2°C to 8°C	**474979**

Quality Control Review

After the controls are run, the DAT Multi-Drug Low and High Urine Control results will be printed for review, and initialed by the person who has reviewed the results.

The rate units for the low control (25% below the cutoff) should be at least 10 rate units below the rate unit of the cutoff calibrator.

The rate units for the high control (25% above the cutoff) should be at least 10 rate units above the rate unit of the cutoff calibrator.

If either control is less than 10 rate units from the cutoff rate unit, the control(s) should be repeated. If the repeat control is still less than 10 rate units from the cutoff rate, the reagent should be re-calibrated and the controls checked again. If either or both control's rate units are still less than 10 rate units from the cutoff rate, load a new cartridge of reagent, calibrate and rerun controls again. If the controls still do not

Calibration

Calibrator Required

SYNCHRON® Systems AQUA CAL 1, 2 and 3 (**Kit Reorder #s 471288, 471291, 471294**)

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

Unopened calibrators should be stored at 2°C to 8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.

Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

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

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

Under typical operating conditions the BUNm assay must be calibrated every 72 hours or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

Urea Nitrogen (analyte) in this calibrator is traceable to NIST* 912a.
**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions For Use* (IFU) manual for information on this feature.

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

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 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (C3) in this calibrator is traceable to the IFCC reference preparation for plasma proteins. BCR-470* (16,17) Traceability process is based on prEN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS Immunology 1	2°C to 8°C
MAS Immunology 2	2°C to 8°C

Controls are received and stored at 2°C to 8°C and once opened are good for 30 days.

Testing Procedure

1. If necessary, load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.
2. After reagent load is completed, calibration is 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 UniCel DxC 800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions For Use* (IFU) manual for information on this feature.

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

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 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (C4) in this calibrator is traceable to the new IFCC reference preparation for plasma proteins, ERM- DA470k (formerly CRM470)* (16,17) Traceability process is based on prEN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS Immunology 1	2°C to 8°C
MAS Immunology 2	2°C to 8°C

Controls are received and stored at 2°C to 8°C and once opened are good for 30 days.

Testing Procedure

1. If necessary, load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.
2. After reagent load is completed, calibration is 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 UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the calibrators should be stored at 2°C to 8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days unless the expiration date is exceeded.

Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

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

Under typical operating conditions the CALC assay must be calibrated every 24 hours or with each new bottle of reagent and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/ 800 System *Instructions for Use* (IFU) manual.

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

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

Calcium (analyte) in this calibrator is traceable to NIST* SRM 915a.

**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material are to be run each day of patient testing. Control material for this test will be analyzed using the following schedule:

Monday – Friday, 0000 – 0800: Run controls every two (2) hours.
Monday – Friday, 0800 – 2300: Run controls every (1) hour.
Weekends and holidays, all hours: Run controls every two (2) hours.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

Traceability

The measurand (CAR) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

SYNCHRON® Systems Drug Calibrator 1 is prepared using processed human serum to which weighed-in drug quantities are added,

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

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.(7)

Calibration Information

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

Under typical operating conditions the CHOL reagent cartridge must be calibrated every 14 days or with each new lot of reagent, and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions for Use* (IFU) manual for information on this feature.

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

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (CHOL) in this calibrator is traceable to each reference material for each analyte. The traceability process is based on prEN ISO 17511. The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

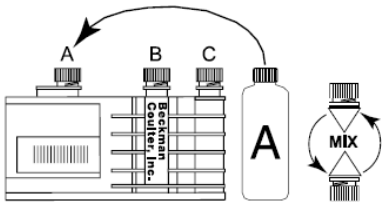
In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Reagent Preparation



Transfer all the contents of one CK A-reagent bottle into the largest reagent compartment (A).

Replace cartridge caps and gently invert the cartridge several times to ensure adequate mixing.

Date and initial cartridge and document in reagent log before loading each new cartridge.

Acceptable Reagent Performance

The acceptability of this reagent is determined by ensuring that quality control results are within acceptance criteria, as defined in the Clinical Chemistry Quality Control Procedure #3000.T.

Reagent Storage and Stability

CK 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 30 days at 2°C to 8°C unless the expiration date is exceeded.

DO NOT FREEZE.

Equipment

This test is performed on the Beckman UniCel DxC 800 systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the UniCel DxC 800 systems *Reference Manual* for detailed instructions.

Calibration

Calibration is not required.

Traceability

This measurand (AST) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Calibrator Storage and Stability

If unopened and stored capped in the original containers at 2°C to 8°C, the calibrators are stable until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days unless the expiration date is exceeded.

Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

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

Under typical operating conditions the Cl assay must be calibrated every 24 hours or with each new bottle of reagent and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/ 800 System *Instructions for Use* (IFU) manual.

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

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

Chloride (analyte) in this calibrator is traceable to NIST* SRM 918a/919a.

**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material are to be run each day of patient testing. Control material for this test will be analyzed using the following schedule:

Monday – Friday, 0000 – 0800: Run controls every two (2) hours.
Monday – Friday, 0800 – 2300: Run controls every (1) hour.
Weekends and holidays, all hours: Run controls every two (2) hours.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

Calibrator Storage and Stability

If unopened, the calibrators should be stored at 2°C to 8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.

Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

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

Under typical operating conditions the CO_2 assay must be calibrated every 24 hours or with each new bottle of reagent, and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/ 800 System *Instructions for Use* (IFU) manual.

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

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

Carbon dioxide (analyte) in this calibrator is traceable to NIST* SRM 351a.
**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material are to be run each day of patient testing. Control material for this test will be analyzed using the following schedule:

Monday – Friday, 0000 – 0800: Run controls every two (2) hours.
Monday – Friday, 0800 – 2300: Run controls every (1) hour.
Weekends and holidays, all hours: Run controls every two (2) hours.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

Quality Control

A minimum of two levels of control material with levels 25% above and 25% below the cutoff threshold of each drug will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Concentration (ng/mL)	Storage	Reorder No.
DAT Multi-Drug Low Urine Control	225	2°C to 8°C	**474976**
DAT Multi-Drug High Urine Control	375	2°C to 8°C	**474979**

Quality Control Review

After the controls are run, the DAT Multi-Drug Low and High Urine Control results will be printed for review, and initialed by the person who has reviewed the results.

The rate units for the low control (25% below the cutoff) should be at least 10 rate units below the rate unit of the cutoff calibrator.

The rate units for the high control (25% above the cutoff) should be at least 10 rate units above the rate unit of the cutoff calibrator.

If either control is less than 10 rate units from the cutoff rate unit, the control(s) should be repeated. If the repeat control is still less than 10 rate units from the cutoff rate, the reagent should be re-calibrated and the controls checked again. If either or both control's rate units are still less than 10 rate units from the cutoff rate, load a new cartridge of reagent, calibrate and rerun controls again. If the controls still do not meet the cut off rate limits, testing of this assay should not be used on the analyzer and service may be required.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program samples and controls for analysis as directed in the as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.
4. After loading samples and controls onto the system, follow the protocols for system operation as directed in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	+2°C to +8°C*
MAS ChemTrak 3	+2°C to +8°C*
MAS Urine Chemistry Control 1	+2°C to +8°C**
MAS Urine Chemistry Control 2	+2°C to +8°C**

*Controls are received frozen and stored at –15°C to –25°C. Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.
**Bottles of controls are stored at 2°C to 8°C. Once opened, controls are good for 30 days when stored at 2°C to 8°C.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

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 Controls' Biosafety Level 2 guidelines. (22)

Calibration Information

The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

Under typical operating conditions the CRPH reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual for information on this feature.

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. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (CRPH) in this calibrator is traceable to the reference materials as listed below. The traceability process is based on prEN ISO 17511.

CRPH—BCR* 470 (32,33)

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias. System specific values are provided on a value assignment sheet.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

Three levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

Two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 3	2°C to 8°C*
MAS Bilirubin Control 3	2°C to 8°C**

*MAS control is received frozen and stored at -15°C to -20°C. Each bottle of control in use is thawed and stored at 2°C to 8°C and is good for 14 days.
**Mas Bilirubin Control 3 is stored at 2°C to 8°C and opened vials are stable for 14 days. DO NOT FREEZE this control.

Testing Procedure

1. If necessary, load 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Reporting Results

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

Traceability

The measurand (ETOH) in this calibrator is traceable to Manufacturer's Working Calibrator. Working Calibrator is prepared gravimetrically from USP grade 200-proof ethanol. The traceability process is based on prEN ISO 17511.

The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Cal1 = 0 (zero) mg/dL Ethyl Alcohol in Tris buffer with 0.09% Sodium Azide

Cal2 = 100 mg/dL (22 mmol/L) Ethyl Alcohol in Tris buffer with 0.09% Sodium Azide

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand (FE) to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at +2°C to +8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Traceability

The measurand (GEN) in this calibrator is traceable to the Manufacturer's Working Calibrator. The Working Calibrator is prepared using processed human serum to which weighed-in quantities of gentamicin are added. The calibrator set is designed for generation of a six-point calibration curve which defines the analytical range for gentamicin. The traceability process is based on prEN ISO 17511.

The values were verified using representative samples from this lot of Calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be prepared and used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems perform all calculations internally to produce the final reported result.

Equipment

This test is performed on the Beckman UniCel DxC 800 systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the UniCel DxC 800 systems *Reference Manual* for detailed instructions.

Calibration

Calibration is not required.

Traceability

This measurand (GGT) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and controls onto the system, follow the protocols for system operation.

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

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

Glucose (analyte) in this calibrator is traceable to NIST* SRM 917a.
**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material are to be run each day of patient testing. Control material for this test will be analyzed using the following schedule:

Monday – Friday, 0000 – 0800: Run controls every two (2) hours.
Monday – Friday, 0800 – 2300: Run controls every (1) hour.
Weekends and holidays, all hours: Run controls every two (2) hours.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –10°C to –20°C. Bottles of controls in use are thawed and stored at +2°C to +8°C and are good for 14 days.

Traceability

HDL Cholesterol measurand (analyte) in this calibrator is traceable to NIST* SRM 911b. The traceability process is based on prEN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*NIST – National Institute of Standards and Technology.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

For dilutions programmed in Remisol: the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Lipid Panel Calculations are performed in the LIS

Calibrator Storage and Stability

The SYNCHRON® Systems CAL 1 is stable until the expiration date printed on the calibrator bottle if stored capped in the original container at 2°C to 8°C. DO NOT FREEZE.

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.(8)

Calibration Information

The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

Under typical operating conditions the HPT reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions For Use* (IFU) manual for information on this feature.

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

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 800 System *Instructions For Use* (IFU) manual.

Traceability

Each measurand in this calibrator is traceable to the IFCC reference preparation for plasma proteins. BCR-470* (18,19) Traceability process is based on prEN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

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.(8)

Calibration Information

The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

Under typical operating conditions the Ig-A reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions For Use* (IFU) manual for information on this feature.

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

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 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (IgA) in this calibrator is traceable to the IFCC reference preparation for plasma proteins. BCR-470* (18,19) Traceability process is based on prEN ISO 17511

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Calibration Information

The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

Under typical operating conditions the Ig-G reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions For Use* (IFU) manual for information on this feature.

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

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 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (IgG) in this calibrator is traceable to the IFCC reference preparation for plasma proteins. BCR-470*(18,19) Traceability process is based on prEN ISO 17511

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS Immunology 1	2°C to 8°C
MAS Immunology 2	2°C to 8°C

Controls are received and stored at 2°C to 8°C and once opened are good for 30 days.

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

The SYNCHRON® Systems CAL 1 is stable until the expiration date printed on the calibrator bottle if stored capped in the original container at 2°C to 8°C. DO NOT FREEZE.

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.(8)

Calibration Information

The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

Under typical operating conditions the Ig-M reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions For Use* (IFU) manual for information on this feature.

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

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 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (Ig-M) in this calibrator is traceable to the IFCC reference preparation for plasma proteins. BCR-470*(18,19) Traceability process is based on prEN ISO 17511

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS Immunology 1	2°C to 8°C
MAS Immunology 2	2°C to 8°C

Controls are received and stored at 2°C to 8°C and once opened are good for 30 days.

Testing Procedure

1. If necessary, load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.
2. After reagent load is completed, calibration is 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 UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

For dilutions programmed in Remisol: the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Reporting Results

Equivalency between the SYNCHRON LX and UniCel DxC 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 interval values listed below were taken from literature and a study performed on SYNCHRON Systems.(6)

Reference Intervals

Intervals	Sample Type	Conventional Units
Literature	Serum or Plasma	50 - 300 mg/dL
SYNCHRON	Serum or Plasma	43 - 279 mg/dL
UCDMC	Serum or Plasma	43 - 279 mg/d

Refer to References (7,8,9) for guidelines on establishing laboratory-specific reference intervals

Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

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

Under typical operating conditions the K assay must be calibrated every 24 hours or with each new bottle of reagent and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/ 800 System *Instructions for Use* (IFU) manual.

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

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

Potassium (analyte) in this calibrator is traceable to NIST* SRM 918a.

**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material are to be run each day of patient testing. Control material for this test will be analyzed using the following schedule:

Monday – Friday, 0000 – 0800: Run controls every two (2) hours.
Monday – Friday, 0800 – 2300: Run controls every (1) hour.
Weekends and holidays, all hours: Run controls every two (2) hours.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Under typical operating conditions the LACT reagent cartridge must be calibrated every 30 days or with each new lot of reagent, and also with certain parts replacements or maintenance procedures, as defined in the as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual for information on this feature.

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

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (LACT) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by intermethod bias.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage*
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 1	2°C to 8°C

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at +2°C to +8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration is required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operation.

Calibration

Calibration is not required.

Traceability

This measurand (LD) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

Testing Procedure

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and controls onto the system, follow the protocols for system operation.

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

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Reporting Results

Reference Intervals

The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.(5)

Calibrator Assigned Values

The assigned value for LDLD Calibrator was established by multiple instruments using representative samples from each lot of calibrator. The calibrator value is specific to the assay methodology on UniCel DxC 800 Systems. Values by other methodologies may be different.

The assigned value is traceable to the National Cholesterol Education Program (NCEP) reference methodology for LDL CHOLESTEROL.(5)

Calibrator Summary

The LDLD Calibrator is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including low-density lipoproteins. The LDLD calibrator is designed for generation of a two-point calibration curve using deionized water as a low-level calibrator.

Calibrator Constituents

1.0 mL (after reconstitution with D.I water.)
Human serum
Sodium azide (0.1%)

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).

Calibrator Limitations

The SYNCHRON® Systems LDLD Calibrator should be used only in conjunction with UniCel DxC 800 Systems and SYNCHRON LDLD reagents.

Traceability

LDL Cholesterol measurand (analyte) in this calibrator is traceable to the National Cholesterol Education Program (NCEP) reference methodology which uses the LDL Beta Quantification method (ultracentrifugation method). The traceability process is based on prEN ISO 17511. The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias. System specific values are found in the value assignment sheet.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON Systems. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias. System specific values are found on the value assignment sheet.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
- Upon loading a new reagent cartridge.
- Following each new calibration.
- Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

When a *Lipid Panel with reflex* is ordered, the collection must be noted as Fasting or Non-Fasting if a reflex for a Direct LDL is desired. The comment should be entered when the specimen is requisitioned.

The fasting comment will be automatically populate the Fasting result field of the Lipid Panel when the specimen results are opened for review or result entry.

If the fasting result is "NO", the LDL(calc) will be calculated if the Triglyceride is **≤150 mg/dL**.

When the triglyceride result is >150 mg/dL and <1000 mg/dL for a non-fasting sample, a direct LDL can be reflexed or added and the calculated LDL result in the LIS will be "TEST NOT PERFORMED". The comment "Non-Fasting specimen may affect the Triglyceride result and the LDL is not calculated" will be appended to the LDL(calc) result.

If the triglyceride result is > 1000 mg/dL, the LDLD is not performed.

If the Fasting "result" is "YES" and the triglyceride result is **≤400 mg/dL**, the LDL cholesterol is calculated.

If the patient specimen was a fasting sample, but the triglyceride result is **>401 and <1000 mg/dL**, the calculated LDL result in the LIS will be "TEST NOT PERFORMED" and the comment "Unable to calculate LDL due to elevated triglycerides" will be appended to the result. These samples will be saved for 5 days to be run for Direct LDL Cholesterol (LDLD) if a physician requests it. An additional comment will be attached to the LDL(calc) result line to call the chemistry department within 5 days to perform the Direct LDL assay.

If the Lipid Panel was ordered with an LDL Cholesterol reflex, the Direct LDL Cholesterol will be reflex ordered in the LIS and the LDLD test will be downloaded to Remisol as a pending test to be run.

If the patient was fasting and the triglyceride is **> 1000 mg/dL**, neither the calculated LDL nor the Direct LDL assay can be done. In this case, the calculated LDL result in the LIS will be "TEST NOT PERFORMED" and the comment "Unable to calculate LDL due to elevated triglycerides" will be placed in the LDL(calc) comment field. The LDLD result in the LIS will also be "TEST NOT PERFORMED" and the comment "Unable to perform LDLD due to elevated triglycerides" will be appended to the result.

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. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (lipase) in this calibrator is traceable to the reference method (IFCC*) 6'-methylresorufin ester substrate.(15) The traceability process is based on prEN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*IFCC-The international Federation of Clinical Chemistry and Laboratory Medicine.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

The SYNCHRON System(s) Random Access lipase (LIP) reagent is designed for human pancreatic lipase. Control materials consisting of porcine lipase do not perfectly mimic the performance of the reagent with patient samples.

Due to human pancreatic lipase specificity, excessive lot-to-lot shifts with animal based control materials may occur.

To aid you in ensuring consistent reagent quality for human samples, run several known patient samples on both the new and old lots. Alternatively, you may contact the Clinical Support Center at 1-800-854-3633 from the United States and Canada, or your local Beckman Coulter Representative for the results of human patient samples performed during manufacture.

The lipase reagent is intended for use with human pancreatic lipase. Animal-based control materials may not accurately demonstrate reagent performance.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at –10°C to –20°C.
MAS ChemTrak bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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 800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

Reference Intervals

The pharmacological response to serum lithium level is subject to considerable individual variation. (1,2)

The physician should determine the appropriate therapeutic interval for each patient.

Traceability

Total Protein in this Calibrator is traceable to the NIST* SRM 927. Traceability process is based on prEN ISO 17511.

**NIST=National Institute of Standards and Technology*

Quality Control

A minimum of two levels of control material will be analyzed for urine and CSF controls each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage	Catalog No.
MAS UriChemTrak 1	+2°C to +8°C*	UR11001
MAS UriChemTrak 2	+2°C to +8°C*	UR22002

*Unopened vials are stable until the expiration date on the label. Once opened, vials of control are stable for 30 days when stored tightly capped at +2°C to +8°C. Do not freeze. Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

Testing Procedure

1. If necessary, 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 UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (MA) in this calibrator is traceable to the IFCC reference preparation for plasma proteins. BCR-470* (1,2) Traceability process is based on prEN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

Two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage	Catalog No.
MAS UriChemTrak 1	2°C to 8°C*	UR11001
MAS UriChemTrak 2	2°C to 8°C*	UR22002

*Unopened vials are stable until the expiration date on the label. Once opened, vials of control are stable for 30 days when stored tightly capped at 2°C to 8°C. **Do not freeze**. Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

Testing Procedure

1. If necessary, load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.
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 UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in the DataLink, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by the DataLink.

Traceability

The measurand (MG) in this calibrator is traceable to each reference material for each analyte. The traceability process is based on prEN ISO 17511. The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

For dilutions programmed in Remisol: the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

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

Under typical operating conditions the NA assay must be calibrated every 24 hours or with each new bottle of reagent and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/ 800 System *Instructions for Use* (IFU) manual.

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

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

Sodium (analyte) in this calibrator is traceable to NIST* SRM 919a.

**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material are to be run each day of patient testing. Control material for this test will be analyzed using the following schedule:

Monday – Friday, 0000 – 0800: Run controls every two (2) hours.
Monday – Friday, 0800 – 2300: Run controls every (1) hour.
Weekends and holidays, all hours: Run controls every two (2) hours.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Drug Concentration in Calibrators

	Concentration (ng/mL)		
Drug Analyte	**DAT Negative Urine Calibrator**	**OP 300 Low Urine Calibrator**	**OP 300 High Urine Calibrator**
Opiates	0	300	1000

Quality Control

A minimum of two levels of control material with levels 25% above and 25% below the cutoff threshold of each drug will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Concentration (ng/mL)	Storage	Reorder No.
OP 300 Low Urine Control	225	2°C to 8°C	**474988**
OP 300 High Urine Control	375	2°C to 8°C	**474991**

Quality Control Review

After the controls are run, the OP300 Low and High Urine Control results will be printed for review, and initialed by the person who has reviewed the results.

The rate units for the low control (25% below the cutoff) should be at least 10 rate units below the rate unit of the cutoff calibrator.

The rate units for the high control (25% above the cutoff) should be at least 10 rate units above the rate unit of the cutoff calibrator.

If either control is less than 10 rate units from the cutoff rate unit, the control(s) should be repeated. If the repeat control is still less than 10 rate units from the cutoff rate, the reagent should be re-calibrated and the controls checked again. If either or both control's rate units are still less than 10 rate units from the cutoff rate, load a new cartridge of reagent, calibrate and rerun controls again. If the controls still do not meet the cut off rate limits, testing of this assay should not be used on the analyzer and service may be required.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS Immunology 1	2°C to 8°C
MAS Immunology 2	2°C to 8°C

Controls are received and stored at 2°C to 8°C and once opened are good for 30 days.

Testing Procedure

1. If necessary, load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.
2. After reagent load is completed, calibration is 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 UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Reporting Results

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

Traceability

The measurand (PHE) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

SYNCHRON® Systems Drug Calibrator 1 is prepared using processed human serum to which weighed-in drug quantities are added,

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

Traceability

Phosphorus (measurand) in these calibrators are traceable to the NIST* SRM 3139a.

**NIST - National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The set point values for Phosphorus were established by human sample correlation to isotope dilution mass spectroscopy.

The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

NOTICE

Benzoic acid crystal formation may result at lower temperatures in Cal 1 and Cal 2. Crystals may be redissolved by warming or maintaining at 18°C to 26°C for 24 to 48 hours.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C. Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

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 is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC800 System *Instructions For Use* (IFU) manual for information on this feature.

For detailed calibration instructions, refer to the UniCel DxC800 System *Instructions For Use* (IFU) manual.

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

The measurand (PHY) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

SYNCHRON® Systems Drug Calibrator 1 is prepared using processed human serum to which weighed-in drug quantities are added,

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calibrator Summary

SYNCHRON® Systems Salicylate Calibrator is prepared in an aqueous solution by weighing the appropriate amount of sodium salicylate to achieve 20.7 mg/dL. The calibrator is designed for generation of a two-point calibration curve using saline as a low-level calibrator.

The SYNCHRON® Systems Salicylate Calibrator should be used only in conjunction with SYNCHRON Systems and SYNCHRON SALY reagents.

Traceability

The measurand (Salicylate) in this calibrator is traceable to the manual Trinder method.(4) The traceability process is based on prEN ISO 17511.

The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON® System(s). Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS OmniImmune 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at –10°C to –20°C.
MAS ChemTrak bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.
OMNI Immune bottles of controls in use are thawed and stored at +2°C to +8°C and are good for 30 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (TOB) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

SYNCHRON® Systems Drug Calibrator 3 Plus is prepared using processed human serum to which weighed-in drug quantities are added,

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

The 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.

Calibration Information

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

Under typical operating conditions the TBIL reagent cartridge must be calibrated every 14 days or with each new lot of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions for Use* (IFU) manual for information on this feature.

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

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

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.

Traceability

SYNCHRON Systems Bilirubin calibrator matrix is derived from stabilized human defibrinated serum. Bilirubin measurand in this calibrator is traceable to NIST* SRM 916. The traceability process is based on prEN ISO 17511.

**NIST=National Institute of Standards and Technology*

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

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.(7)

Calibration Information

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

Under typical operating conditions the TG reagent cartridge must be calibrated every 14 days or with each new lot of reagent, and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration enabled. Refer to the UniCel DxC 800 System *Instructions for Use* (IFU) manual for information on this feature.

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

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (TG) in this calibrator is traceable to each reference material for each analyte. The traceability process is based on prEN ISO 17511. The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Lipid Panel Calculations are performed in the LIS

Calculation of LDL-c: This is only calculated on fasting specimens with triglyceride levels less than or equal to 400 mg/dL and non-fasting specimens with triglyceride levels less than or equal to 150 mg/dL. Friedewald, Levy, and Fredrickson in 1972 established and validated a formula to calculate LDL cholesterol (LDLcalc). The formula is based on the assumption the VLDL cholesterol is present in a concentration equal to one-fifth of the triglyceride concentration. This assumption is valid for triglyceride concentrations of less than or equal to 400 mg/dL. Above this level, inconsistencies in the VLDL triglyceride/cholesterol ratio occur and the formula cannot be used. It is also not valid for Type III and certain other lipid disorders. To calculate LDL-c (for triglycerides ≤ 400 mg/dL[fasting] and for triglycerides ≤150 mg/dL[non-fasting]):

$$LDL(calc) = Cholesterol_{TOTAL} - [HDL + Triglyceride/5]$$

Total cholesterol/HDL ratio:

$$\text{Total cholesterol/HDL ratio} = \frac{\text{Total Cholesterol (mg/dL)}}{\text{HDL (mg/dL)}}$$

Calculation of VLDL-C (not part of current lipid panel): This can be calculated when the triglyceride level is ≤ 400 mg/dL and when a direct LDL result is obtained on a sample with the triglyceride result between 401 and 1000 mg/dL:

$$VLDL(calc) = \text{Total Cholesterol} - HDL - \text{Direct LDL}$$

LDL/HDL ratio: this can be calculated as Friedewald LDL - HDL when the triglyceride level is ≤ 400 mg/dL. When a Direct LDL assay is performed, the LDL-D value is used in the ratio instead of the calculated LDL.

Traceability

The measurand (THE) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

SYNCHRON® Systems Drug Calibrator 1 is prepared using processed human serum to which weighed-in drug quantities are added,

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

The 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.

Quality Control

A minimum of two levels of control material are to be run each shift.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE
Do not use controls containing diethylamine HCl.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C. Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

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 is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

Dilutions are programmed in Remisol. The final calculated result will be calculated by Remisol using the dilution factor that was entered in Remisol.

Reporting Results

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

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (TRFN) in this calibrator is traceable to the IFCC reference preparation for plasma proteins. BCR-470* (15,16) Traceability process is based on prEN ISO 17511.

The assigned value was established using representative samples from this lot of calibrator and is specific to the assay methodologies of the SYNCHRON LX and the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

*BCR is a registered trademark of EC-JRC-IRMM

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

Calibrator Storage and Stability

If unopened, the calibrators 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 or when calibration and quality control recoveries have shifted.

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.(5)

Calibration Information

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

Under typical operating conditions the URIC reagent cartridge must be calibrated every 14 days or with each new lot of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration enabled. For detailed calibration instructions, refer to the UniCel DxC 600/ 800 System *Instructions For Use* (IFU) manual.

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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

The measurand (URIC) in this calibrator is traceable to each reference material for each analyte. The traceability process is based on prEN ISO 17511. The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*
MAS Urine Chemistry 1	2°C to 8°C**
MAS Urine Chemistry 2	2°C to 8°C**

*Controls are received frozen and stored at –15°C to –25°C. Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.
**Urine controls are received and stored at 2°C to 8°C. Bottles of controls in use are stored at 2°C to 8°C and are good for 30 days.

Testing Procedure

1. If necessary, load reagent onto the system.
2. After reagent load is completed, calibration is 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems 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.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

24 hr timed urine specimens are calculated from the following equation:

$$\text{Urine uric acid } \frac{\text{mg}}{\text{dL}} \text{ X } \frac{\text{dL}}{\text{100mL}} \text{ X Total volume collected (mL) = mg/24hr}$$

Calculations are only performed on 24 hour collections (±15 minutes) and reported as mg/24hr.

Do not round off total collection time.

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

The measurand (VANC) in this calibrator is traceable to the Manufacturer's Working Calibrator. The Working Calibrator is prepared by diluting the concentrate gravimetrically. The concentrate is prepared from USP grade Vancomycin2. The traceability process is based on prEN ISO 17511.

The values were verified using representative samples from this lot of Calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.

Calculations

The 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.

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

The measurand (VPA) in this calibrator is traceable to the Manufacturer's Working Calibrator. The traceability process is based on prEN ISO 17511.

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration. The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

SYNCHRON® Systems Drug Calibrator 1 is prepared using processed human serum to which weighed-in drug quantities are added,

Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:
Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

Mix VPA cartridges prior to running controls each day.

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C
MAS ChemTrak 3	2°C to 8°C

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, 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 UniCel DxC800 System *Instructions For Use* (IFU) manual.