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

SYNCHRON® Systems Multi Calibrator
At least two levels of control material
Saline

Reagent Preparation

No preparation is required.
Date and initial reagent container and document in reagent log before loading each new cartridge.

Acceptable Reagent Performance

The acceptability of this reagent is determined by successful calibration and 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

CHOL reagent when stored unopened at 2°C to 8°C will attain 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

Calibrator Required

SYNCHRON® Systems Multi Calibrator **Kit Reorder # 442600**

Calibrator Preparation

No preparation is required.

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
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

SYNCHRON® Systems Multi-Cal Calibrator
At least two levels of control material
Saline

Reagent Preparation

No preparation is required.
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 successful calibration and 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

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

DO NOT FREEZE.

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

Calibrator Required

SYNCHRON Systems Multi Calibrator **Kit Reorder # 442600**

Calibrator Preparation

No preparation is required.

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.

Calibration Information

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

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

Calibrator Required

SYNCHRON® Systems Multi Calibrator **Kit Reorder # 442600**

Calibrator Preparation

No preparation is required.

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.(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 MG reagent cartridge must be calibrated every 7 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.

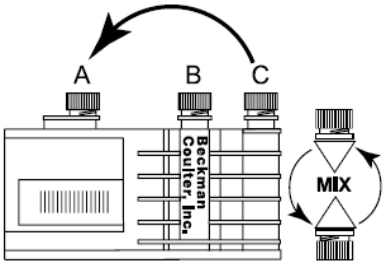
For detailed calibration instructions, refer to the UniCel DxC 600/ 800 System *Instructions for Use* (IFU) manual.

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.

Materials Needed But Not Supplied With Reagent Kit

SYNCHRON Systems Multi Calibrator
At least two levels of control material
Saline

Reagent Preparation



Qualitatively transfer all the contents of compartment C (smallest compartment) into compartment A (largest compartment).

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

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

Acceptable Reagent Performance

The acceptability of this reagent is determined by successful calibration and 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

TG reagent when stored unopened at 2°C to 8°C will attain the shelf-life indicated on the cartridge label. Once prepared, 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

Calibrator Required

SYNCHRON® Systems Multi Calibrator **Kit Reorder # 442600**

Calibrator Preparation

No preparation is required.

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.

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.