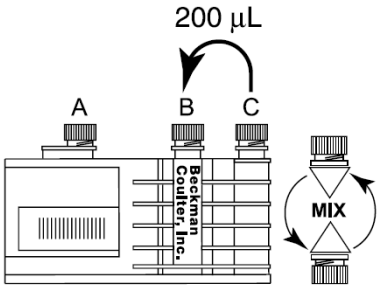
Reagent Preparation



Quantitatively transfer 200 µL of the contents from the smallest compartment (C) into the center compartment (B).

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

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

TBIL reagent when stored unopened at room temperature will obtain 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 Bilirubin Calibrator (**Kit Reorder # 465915**)
Deionized water (low level calibrator)

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Bilirubin Calibrator may be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at 2°C to 8°C are stable for 24 hours unless the expiration date is exceeded.

CAUTION

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.(6)

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 Bilirubin Calibrator (**Kit Reorder # 465915**)
Deionized water (low level calibrator)

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON Systems Bilirubin Calibrator may be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are aliquoted, protected from light and stored at -15°C to20°C are stable for 24 hours.

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.
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Calibration Information

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

Under typical operating conditions the DBIL 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

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*