

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k052679

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Bilirubin

**D. Type of Test:**

N/A

**E. Applicant:**

Cliniqa Corporation

**F. Proprietary and Established Names:**

-Cliniqa Liquid QC Bilirubin Controls Levels 1, 2, & 3

-Cliniqa LiniCAL Bilirubin Calibration Verifiers Levels A - E for Olympus AU Systems

**G. Regulatory Information:**

1. Regulation section:

21 CFR § 862.1660

2. Classification:

Class I

3. Product code:

JJX, single (specified) analyte controls (assayed and unassayed)

4. Panel:

Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

Cliniqa Liquid QC Bilirubin Controls Levels 1, 2, & 3 are assayed, liquid, quality control products which may be used to evaluate the performance of clinical methods for Total and Direct Bilirubin.

Cliniqa LiniCAL Bilirubin Calibration Verifiers Levels A - E for Olympus AU Systems are assayed, liquid, quality control products which may be used to evaluate the performance of the Olympus AU Systems for Total and Direct Bilirubin.

2. Indication(s) for use:

See Intended Use section above

3. Special conditions for use statement(s):

Prescription Use Only

3. Special instrument requirements:

The calibration verifiers are to be used with the Olympus AU systems only. The liquid QC controls may be used with a number of automated chemistry analyzers.

**I. Device Description:**

Cliniqa Liquid QC Bilirubin Controls Levels 1, 2, & 3 are prepared from human serum and purified chemicals. Preservatives and stabilizers are added to maintain product integrity. Cliniqa LiniCAL Bilirubin Calibration Verifiers Levels A - E for Olympus AU Systems are human-serum based, containing constituents of human origin and are used in the clinical laboratory to verify calibration and/or assess linearity of the Olympus AU Systems. Five assayed levels of Bilirubin are provided to allow monitoring of the reportable range.

Each serum donor unit used to manufacture this product was tested for Hepatitis B Surface Antigen (HBsAg), HIV-1 antigen, antibody to Hepatitis C Virus (HCV), and antibody to HIV-1/2 and found non-reactive using FDA accepted test methods.

Cliniqa Liquid QC Bilirubin Controls Levels 1, 2, & 3 are 0.30, 7.76, and 22.6 mg/dL for total bilirubin respectively and 0.10, 3.20, and 8.07 mg/dL for direct bilirubin respectively.

The Cliniqa LiniCAL Bilirubin Calibration Verifiers Levels A - E for Olympus AU Systems have a series of analyte concentrations ranging from 0.30 mg/dL to 32 mg/dL for total bilirubin and 0.10 mg/dL to 10.6 mg/dL for direct bilirubin.

**J. Substantial Equivalence Information:**

1. Predicate device name(s): MAS Bilirubin Control and LiniCAL Chemistry Calibration Verifiers Levels A – E for Olympus AU Systems
2. Predicate 510(k) number(s): k031890 and k033162
3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicate
Intended Use	Bilirubin Control/Calibrator Verifier	Bilirubin Control/Multi-analyte Calibrator Verifier
Origin	Human serum	Human serum - Calibrator

<b>Differences</b>		
Item	Device	Predicate
Analyte	Control: Bilirubin Calibrator Verifier: Bilirubin	Control: Bilirubin Calibrator Verifier: N/A
Origin	Human serum	Bovine serum – Control
Stability	Both: Open vial at 2-8°C = 30 days	Both: Open vial at 2-8°C = 14 days

**K. Standard/Guidance Document Referenced (if applicable):** None Referenced

**L. Test Principle:** N/A

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:* N/A

b. *Linearity/assay reportable range:*

N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability

The Olympus instrument, reagents and calibrators are standardized to the NIST Standard Reference Material (SRM) 916a.

Stability

Stability characteristics of the Cliniqa Liquid QC Bilirubin Controls Levels 1, 2, & 3 and the of Cliniqa LiniCAL Bilirubin Calibration Verifiers Levels A - E for Olympus AU Systems were determined using the Arrhenius model of accelerated elevated temperature studies to predict estimated storage stability at 2 – 8 °C. Open vial stability was determined in a real time on board stability study at 2-8 °C on an Olympus AU 400 chemistry analyzer.

Expected Values

Expected values presented in each lot-specific insert of Cliniqa Liquid QC Bilirubin Controls Levels 1, 2, & 3 will be generated on the Olympus AU System.

Expected values presented in each lot-specific insert of Cliniqa LiniCAL Bilirubin Calibration Verifiers Levels A - E for Olympus AU Systems will be generated on the Olympus AU Systems.

Data points will be obtained from replicate assays obtained by multiple laboratories. At least two sets of data and a minimum of 12 data points will be used to determine the mean. Within and between assay Standard Deviations and Coefficient of Variations will be calculated for each set of data.

d. *Detection limit:* N/A

