

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

A. 510(k) Number:

K032665

B. Analyte:

Multi-Analyte Calibrator

C. Type of Test:

Not Applicable

D. Applicant:

OLYMPUS AMERICA, INC.

E. Proprietary and Established Names:

OLYMPUS LYOPHILIZED CALIBRATOR, MODELS DR0070 AND DR0071

F. Regulatory Information:

1. Regulation section:
21CFR §862.1150 -Calibrator.
2. Classification:
2
3. Product Code:
JIX
4. Panel:
Chemistry (75)

G. Intended Use:

1. Indication(s) for use:
The Olympus Lyophilized Calibrator is a two level general purpose chemistry calibrator designed to provide suitable calibration levels for OLYMPUS analyzers employing the OLYMPUS Methodologies.
2. Special condition for use statement(s):
Not Applicable
3. Special instrument Requirements:
Olympus series of chemistry analyzers

H. Device Description:

The Olympus Lyophilized Multi-Analyte calibrator is a Two Level, Liquid Human Serum based product for use on the Olympus family of Clinical Chemistry Analyzers. The calibrator is supplied in two formats.

DR0070	DR0071
6x5mL Level I Lyophilized Human Serum	6x10mL Level I Lyophilized Human Serum
6x6mL Level I Diluent	6x11mL Level I Diluent
6x5mL Level II Lyophilized Human Serum	6x10mL Level II Lyophilized Human Serum
6x6mL Level II Diluent	6x11mL Level II Diluent

Both kit formats (DR0070 and DR0071) contain the same mixture of constituents in different volumes. Both formats are manufactured in one batch and the assigned values are the same regardless of the fill volume in the vials. The diluent and lyophilized vial labels are clearly marked with the level number. The assigned values in each level of calibrator are determined by Olympus for each production lot using a documented test and validation protocol.

The current validated constituents and target values are as follows:

Constituent	Units	Level I Target Value and (Range)	Level II Target Value and (Range)
Albumin	g/dL	2.4 (2.1-2.7)	4.0 (3.6-4.4)
Bicarbonate	mEq/L	20 (18-22)	40 (36-44)
Bilirubin, Direct	mg/dL	2.5 (2.25-2.75)	
Bilirubin, Total	mg/dL	6.5 (5.85-7.15)	
Calcium (Arsenazo Application)*	mg/dL	8.0 (7.2-8.8)	12.0 (11.5-12.5)
Calcium (OPC Application)	mg/dL	8.0 (7.2-8.8)	12.0 (11.5-12.5)
Cholesterol	mg/dL		220 (198-242)
Creatinine	mg/dL		6.0 (5.4-6.6)
Creatinine STAT*	mg/dL		6.0 (5.4-6.6)
Glucose	mg/dL		250 (225-275)
Glucose STAT*	mg/dL		250 (225-275)
Inorganic Phosphorous	mg/dL		5.0 (4.5-5.5)
Iron	ug/dL	300 (270-330)	
Magnesium	mg/dL mEq/L		3.0 (2.7-3.3) 2.5 (2.25-2.75)
Total Protein	g/dL		7.2 (6.5-7.9)
Triglyceride	mg/dL		250 (225-275)
UIBC	ug/dL		270 (243-297)
Urea Nitrogen (BUN)	mg/dL		50 (45-55)
Urea Nitrogen STAT*	mg/dL		50 (45-55)
Uric Acid	mg/dL		8.0 (7.2-8.8)

*These assays not available for AU5200 Analyzer

These target calibrator values are set near the medical decision point as well as across and above the expected normal reference range.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Olympus Liquid Multi-Analyte Calibrator predicate device
2. Predicate K number(s):
K863095
3. Comparison with predicate:

	Olympus Lyophilized Multi-Analyte Calibrator	Olympus Liquid Multi-Analyte Calibrator (PREDICATE)	Olympus Lyophilized Multi-Analyte Calibrator (PREDICATE)
Intended Use	Calibrator	Calibrator	Calibrator
Analyte Constituents	Albumin Bicarbonate Bilirubin, Direct Bilirubin, Total Calcium (Arsenazo) Calcium (OPC) Cholesterol Creatinine Creatinine STAT Glucose Glucose STAT Inorganic Phosphorous Iron Magnesium Total Protein Triglyceride UIBC Urea Nitrogen (BUN) Urea Nitrogen STAT Uric Acid	Albumin Bicarbonate Calcium (Arsenazo) Calcium (OPC) Cholesterol Creatinine Creatinine STAT Glucose Glucose STAT Inorganic Phosphorous Magnesium Magnesium Total Protein Triglyceride Urea Nitrogen (BUN) Urea Nitrogen STAT Uric Acid	Albumin Bicarbonate Bilirubin, Direct Bilirubin, Total Calcium Chloride Cholesterol Creatinine Creatinine STAT Glucose Glucose STAT Inorganic Phosphorous Iron Magnesium Potassium Sodium Total Protein Triglyceride UIBC Urea Nitrogen (BUN) Urea Nitrogen STAT Uric Acid
Matrix Base	Human Serum	Bovine Serum	Human Serum
Form	Lyophilized Human Serum with diluent mixture	Liquid	Lyophilized Human Serum with diluent mixture
Volume	5 mL per vial (DR0070) 10 mL per vial (DR0071)	5 mL per vial	25mL per vial
Levels	2 Levels	1 Level	2 Levels

J. Standard/Guidance Document Referenced (if applicable):

Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators

K. Test Principle:

Not Applicable

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability (controls, calibrators, or method):*

Olympus purchases calibrator material manufactured by outside vendors. The required number of samples of the lot is to be forwarded to Olympus' Technical Operations and Product Support (TOPS) with a copy of the certificate of analysis. Any calibrator that is derived, or has components derived, from a human source (serum, plasma, etc) must be tested for reactivity to HIV-1 and Hepatitis B. The Certificate of Analysis must contain a statement of the non-reactivity of the calibrator for these infectious agents. The calibrators are intended to be used on the various Olympus clinical chemistry analyzers as a means for establishing reference values for Olympus clinical chemistry system assays. The following procedures are to be followed when assigning chemistry values for these calibrators. The assigned values are published in the package insert accompanying the product upon approval at DSG.

Prepare the calibrator material as per the manufacturer's instructions. Calibrate the chosen analyzer with the current calibrator (traceable to a national standard) and immediately follow with 10 replicates of the unknown calibrator for each analyte. Include any other appropriate material in duplicate to confirm proper functioning of analyzer and assay (Olympus assayed controls, linearity material, etc.)

A run is defined as 10 replicates for each analyte. Perform at least five separately calibrated runs for a minimum total of 50 data points for the calibrator and 10 data points for each control. Retain all printouts for the batch file.

The current lot of calibrator should be assayed over the open shelf life of the material and this stability verified by the manufacturer for subsequent lots.

At the conclusion of the testing period, calculate the mean, the standard deviation (SD), and coefficient of variation (CV) for each analyte and each material analyzed. The SD and CV are measurements of the precision of the test mean and reflect the performance of the testing; Olympus America has established performance goals for total precision for each analyte that must be met. Total precision goals are 33% of total allowable error goals from CLIA and CAP.

The data used to generate the preliminary calibrator value will be reviewed and evaluated in detail by the Senior TOPS Associate. This person may choose to make adjustments or normalizations to the published value of the primary reference material and/or the current calibrator published value. This adjustment will be for all materials within a single calibrated run by the use of a constant factor or addend traceable to the primary reference material or the current calibrator.

Confirmation of Final Assigned Values:

Calibrate the chosen analyzer using the preliminary calibrator values for the new lot of calibrator.

Run, in replicates of 10, the preliminary calibrator, and, in triplicate as unknowns, the primary standard, current assayed controls in use, linearity standards, and any NIST or CAP reference material that is available.

Calibrator values are acceptable if recovery of NIST traceable reference material standards and the calibrator run as an unknown recovers $100\% \pm 5\%$.

Repeat a run with the assigned calibrator ($n=10$) as an unknown at least once more, recalibrating each time, giving a minimum of 20 data points for the calibrator.

- d. *Detection limit:*
Not Applicable
- e. *Analytical specificity:*
Not Applicable
- f. *Assay cut-off:*
Not Applicable

2. Comparison studies:

- a. *Method comparison with predicate device:*
Not Applicable
- b. *Matrix comparison:*
Not Applicable

3. Clinical studies:

a. Clinical sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Not Applicable

M. Conclusion:

The information and data provided by OLYMPUS AMERICA, INC. supports a Substantial Equivalence (SE) determination to other CALIBRATOR, MULTI-ANALYTE MIXTURE regulated under 21 CFR §862.1150 - Calibrator.