# Seradyn QMS® Amikacin Assay Application for: BECKMAN COULTER™ UniCel® DxC & SYNCHRON® Systems

Beckman Coulter Reagent Part Number A45384

**Homogeneous particle-enhanced turbidimetric immunoassay for the quantitative determination of Amikacin in human serum or plasma.**

For In Vitro Diagnostic Use Only

## Intended Use

**The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen storage, quality control, and additional performance data.**

## Ordering Information

The following materials are available from your local Beckman Coulter Representative.

| Item | Beckman Coulter Reorder Number |
|---|---|
| Seradyn QMS Amikacin Assay Kit | A45384 |
| Seradyn QMS Amikacin Calibrator Kit (6x1.0 mL) | A45385 |
| User-Defined Reagent Cartridge (pkg. of 12) | 442835 |

## Technical Support

For Technical Support please contact your local Beckman Coulter Representative.

## Reagent Storage

Refer to the package insert for information on reagent storage.

**Note:**
It is not recommended to leave the Amikacin reagent on-board for more than 40 days on the Synchron CX, more than 35 days on the Synchron LX or more than 35 days on the UniCel DxC.

# Instructions For Use

**Analyzer Operating Procedures**

Refer to the instrument specific operator's manual for information on analyzer operation.

To prepare the Amikacin reagent, separately mix the Antibody Reagent **R1** and Microparticle Reagent **R2** bottles by gentle inversion. Dispense one bottle of each **R1** and **R2** into appropriate compartments of a User Defined Cartridge (P/N 442835).

The following table outlines reagent preparation.

| | **User Defined Cartridge** | |
|---|---|---|
| **Seradyn QMS Amikacin** | Compartment A | Compartment B |
| Antibody Reagent **R1** | One bottle | |
| Microparticle Reagent **R2** | | One bottle |

**Calibrator Information**

Refer to the package insert for calibration information. Calibration is to be performed every 14 days on the Synchron CX or as indicated by control recovery. The Synchron LX requires calibration to be performed every 10 days and the UniCel DxC requires calibration to be performed every 10 days or as indicated by control recovery.

**Recommended Controls**

The following controls are recommended for use with the QMS Amikacin Assay:

- Bio-Rad Liquichek™ Immunoassay Plus
- Bio-Rad Liquichek™ TDM

# Application Parameters

**Parameters**

The following table outlines the QMS Amikacin Assay chemistry parameters for use on the UniCel and Synchron Systems.

| INSTRUMENT PARAMETERS | SYNCHRON CX | UNICEL DXC SYNCHRON LX |
|---|---|---|
| Test Name | AMKX | AMKX |
| Reaction Type: | Rate 1 | Rate 1 |
| Units | µg/mL | µg/mL |
| Decimal Precision/Precision: | X.XX | X.XX |
| Reaction Direction: | Positive | Positive |
| Calculation Factor: | 0 | 1 |
| Math Model: | 8 | 8 |
| Calibration Time Limit: | 336 | 240 |
| Number of Calibrators: | 6 | 6 |
| # 1 | 0.0 | 0.0 |
| # 2 | 3.0 | 3.0 |
| # 3 | 10.0 | 10.0 |
| # 4 | 20.0 | 20.0 |
| # 5 | 35.0 | 35.0 |
| # 6 | 50.0 | 50.0 |
| Primary Wavelength: | 520 nm | 520 nm |
| Secondary Wavelength: | 700 nm | 700 nm |
| Sample Volume: | 3 µL | 3 µL |

| REAGENTS | SYNCHRON CX | UNICEL DXC SYNCHRON LX |
|---|---|---|
| **PRIMARY INJECT (FIRST)/FIRST INJECT** | | |
| Compartment/Component: | A | A |
| Volume/Dispense Volume: | 250 µL | 250 µL |
| Add Time/Inject Time: | NA[a] | NA[a] |
| **PRIMARY INJECT (FIRST)/SECOND INJECT** | | |
| Compartment/Component: | None | None |
| Volume/Dispense Volume: | NA[a] | NA[a] |
| Add Time/Inject Time: | NA[a] | NA[a] |
| **SECOND INJECT/THIRD INJECT** | | |
| Compartment/Component: | B | B |
| Volume/Dispense Volume: | 75 µL | 75 µL |
| Add Time/Inject Time: | 496 sec | 176 sec |

[a] NA=Not applicable

*Continued on next page*

## Application Parameters, continued

| INSTRUMENT PARAMETERS | SYNCHRON CX | UNICEL DXC SYNCHRON LX |
|---|---|---|
| **REAGENTS:** | | |
| **BLANK** | | |
| Start Read: | 350 sec | 30 sec |
| End Read: | 420 sec | 100 sec |
| **REACTION 1** | | |
| Start Read: | 211 sec | 196 sec |
| End Read: | 483 sec | 468 sec |
| **REACTION 2** | | |
| Start Read: | NA[a] | NA[a] |
| End Read: | NA[a] | NA[a] |
| **USABLE RESULT RANGE:** | | |
| Lower Limit: | NA[a] | NA[a] |
| Upper Limit: | NA[a] | NA[a] |
| **ERROR DETECTION LIMITS:** | | |
| **REAGENT BLANK/BLANK** | | |
| ABS Low Limit: | -1.5[b] | -1.5[b] |
| ABS High Limit: | 1.5[b] | 2.200[b] |
| Rate Low Limit: | -1.5[b] | -1.5[b] |
| Rate High Limit: | 1.5[b] | 2.200[b] |
| Mean Deviation: | 1.5[b] | 2.200[b] |
| **REACTION/REACTION 1** | | |
| ABS Low Limit: | -1.5[b] | -1.5[b] |
| ABS High Limit: | 2.0 | 2.200[b] |
| Rate Low Limit: | -1.5[b] | -1.5[b] |
| Rate High Limit: | 1.5[b] | 2.200[b] |
| Mean Deviation: | 1.5[b] | 2.200[b] |
| **REACTION 2** | | |
| ABS Low Limit: | -1.5[b] | -1.5[b] |
| ABS High Limit: | 1.5[b] | 2.200[b] |
| Rate Low Limit: | -1.5[b] | -1.5[b] |
| Rate High Limit: | 1.5[b] | 2.200[b] |
| Mean Deviation: | 1.5[b] | 2.200[b] |
| **SUBSTRATE DEPLETION** | | |
| Initial Rate: | 99.999[b] | 99.999[b] |
| Delta ABS: | 1.5[b] | 2.2[b] |
| **MULTIPOINT SPAN:** | | |
| Cal 1 - Cal 2 | -0.0030 | -0.0030 |
| Cal 2 - Cal 3 | -0.0030 | -0.0030 |
| Cal 3 - Cal 4 | -0.0030 | -0.0030 |
| Cal 4 - Cal 5 | -0.0030 | -0.0030 |
| Cal 5 - Cal 6 | -0.0030 | -0.0030 |
| Cal 6 - Cal 1 | -0.0400 | -0.0400 |

[a] NA=Not applicable

[b] Denotes default value

# Results and Data

**Performance Data**

Refer to the QMS Amikacin reagent package insert for additional performance data.

**Typical Precision**

Properly operating UniCel and Synchron systems should exhibit precision values comparable to the following:

| Within Run Precision | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | CX | | | DxC | | | LX | | |
| µg/mL | Mean | SD | %CV | Mean | SD | %CV | Mean | SD | %CV |
| Low Control (4.6 µg/mL) | 4.68 | 0.150 | **3.2** | 4.50 | 0.096 | **2.1** | 4.49 | 0.161 | **3.6** |
| Medium Control (14 µg/mL) | 14.10 | 0.169 | **1.2** | 13.60 | 0.127 | **0.9** | 13.92 | 0.285 | **2.0** |
| High Control (28 µg/mL) | 27.61 | 0.389 | **1.4** | 27.01 | 0.254 | **0.9** | 27.72 | 0.613 | **2.2** |
| **Total Run Precision** | | | | | | | | | |
| | CX | | | DxC | | | LX | | |
| µg/mL | Mean | SD | %CV | Mean | SD | %CV | Mean | SD | %CV |
| Low Control (4.6 µg/mL) | 4.68 | 0.158 | **3.4** | 4.50 | 0.123 | **2.7** | 4.49 | 0.191 | **4.3** |
| Medium Control (14 µg/mL) | 14.10 | 0.273 | **1.9** | 13.60 | 0.178 | **1.3** | 13.92 | 0.452 | **3.2** |
| High Control (28 µg/mL) | 27.61 | 0.391 | **1.4** | 27.01 | 0.602 | **2.2** | 27.72 | 0.661 | **2.4** |

**Method Comparison**

A total of 59 clinical samples were tested on the UniCel and Synchron systems and the results compared with the Hitachi™ 717 analyzer method. The data were analyzed and are presented in the table below.

| CX | |
|---|---|
| Slope | 0.963 |
| y-intercept | 0.230 |
| R | 0.996 |

| DxC | |
|---|---|
| Slope | 0.978 |
| y-intercept | 0.339 |
| R | 0.996 |

| LX | |
|---|---|
| Slope | 0.959 |
| y-intercept | -0.104 |
| R | 0.998 |

# Additional Information

**Important**

This application has undergone limited technical evaluation and is intended to provide guidance only for the use of the QMS Amikacin reagent on the UniCel® DxC, SYNCHRON LX® and CX® Clinical Systems. You should perform additional testing before reporting diagnostic results.

Information on sample preparation, expected values, quality control, as well as warnings and precautions related to the use of this reagent may be obtained from the package insert.

Instrument operating instructions are contained in the SYNCHRON LX® Operations Manual, SYNCHRON CX® Operating Instructions, or UniCel® DxC Systems Instructions For Use (IFU) Manual.

Since Beckman Coulter does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the manufacturer.

**Shipping Damage**

If damaged product is received, notify your Beckman Coulter Clinical Support Center.



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EC REP

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