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

Beckman Coulter Reagent Part Number A45390

Homogeneous particle-enhanced turbidimetric immunoassay for the quantitative determination of Quinidine 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 Quinidine Assay Kit	A45390
Seradyn QMS Quinidine Calibrator Kit (6x1.0 mL)	A45391
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 Quinidine reagent on-board for more than 38 days on the Synchron CX, more than 28 days on the Synchron LX or more than 31 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 Quinidine 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 Quinidine	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 3 days on the Synchron CX and Synchron LX or as indicated by control recovery. The UniCel DxC requires calibration to be performed every 3 days or as indicated by control recovery.

Recommended Controls

Item	**Beckman Coulter Reorder Number**
Beckman Coulter Triad® LINK Comprehensive Unassayed Chemistry Control Serum	465400, 465405, 465410
Beckman Coulter Triad® NYSSPATH Comprehensive Unassayed Chemistry Control Serum	667005, 667006, 667007

Application Parameters

Parameters

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

INSTRUMENT PARAMETERS	SYNCHRON CX	UNICEL DXC SYNCHRON LX
Test Name	QINX	QINX
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:	72	72
Number of Calibrators:	6	6
# 1	0.0	0.0
# 2	0.5	0.5
# 3	1.0	1.0
# 4	2.0	2.0
# 5	4.0	4.0
# 6	8.0	8.0
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

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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:	499 sec	452 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	-0.0040	-0.0040
Cal 2 - Cal 3	-0.0040	-0.0040
Cal 3 - Cal 4	-0.0040	-0.0040
Cal 4 - Cal 5	-0.0040	-0.0040
Cal 5 - Cal 6	-0.0040	-0.0040
Cal 6 - Cal 1	-0.0100	-0.0100

[a] NA=Not applicable

[b] Denotes default value

Results and Data

Performance Data

Refer to the QMS Quinidine 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 (1.06 µg/mL)	0.98	0.067	**6.8**	0.92	0.034	**3.7**	0.96	0.042	**4.4**
Medium Control (3.0 µg/mL)	2.92	0.061	**2.1**	2.89	0.033	**1.1**	2.88	0.051	**1.8**
High Control (5.0 µg/mL)	4.88	0.056	**1.1**	4.84	0.044	**0.9**	4.82	0.104	**2.2**
Total Run Precision									
	CX			DxC			LX		
µg/mL	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Low Control (1.06 µg/mL)	0.98	0.072	**7.3**	0.92	0.050	**5.4**	0.96	0.046	**4.8**
Medium Control (3.0 µg/mL)	2.92	0.065	**2.2**	2.89	0.045	**1.6**	2.88	0.058	**2.0**
High Control (5.0 µg/mL)	4.88	0.127	**2.6**	4.84	0.096	**2.0**	4.82	0.128	**2.7**

Method Comparison

A total of 56 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	1.022
y-intercept	-0.040
R	0.996

DxC	
Slope	1.005
y-intercept	-0.042
R	0.997

LX	
Slope	1.035
y-intercept	-0.154
R	0.995

Additional Information

Important

This application has undergone limited technical evaluation and is intended to provide guidance only for the use of QMS Quinidine 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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