



# Reference Manual

## Performance Verification Manual

For *In Vitro* Diagnostic Use

This manual is intended for  
UniCel DxC Systems  
AU Systems  
DxC AU Systems



PN A85514AF  
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## Performance Verification Manual

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Original Instructions

# Revision History

**A85514AF, 10/2023**

**CHANGES:**

**CHAPTER 1, *Performance Verification***

- Updated the *Chemistries to be Brought Online During Beckman Coulter AU/DxC AU Systems Installation* Section to add IgE, Clozapine, Kappa Free Light Chains, and Lambda Free Light Chains.

**CHAPTER 2, *Precision***

- Updated the *Precision Studies Protocol* to remove use of DAT quality controls.
- Updated Tables 2.7, 2.8, 2.9, and 2.10 to remove Test IDs.
- Updated Table 2.7 to remove Ammonia, Calcium oCPC, Lithium, T-Uptake, and Thyroxine. Added IgE.
- Updated Table 2.8 to remove Calcium oCPC.
- Updated Table 2.10 to add part number for HbA1c Advanced.

**CHAPTER 3, *Linearity***

- Updated the *Recommended Linearity Materials* section to add LGC Clinical Diagnostics.
- Updated Tables 3.6, 3.7, 3.8, and 3.9 to remove Test IDs.
- Updated Table 3.6 to remove Ammonia, Calcium oCPC, Lithium, T-Uptake, Thyroxine and obsolete AUs. Added IgE. Removed AMRs when vary by analyzer model and added note to refer to IFU.
- Updated Table 3.7 to remove Calcium oCPC.

**CHAPTER 4, *Method Comparison***

- Updated the *Method Comparison/Correlation Protocol Guidelines* section to refer to Data Innovations and latest CLSI procedure.

**CHAPTER 5, *Beckman Coulter Clinical System DATs***

- Updated the DAT AU/DxC AU Chemistries to remove Test IDs.

**A85514AE, 3/2021**

**CHANGES:**

Title page - Removed CE mark

Copyright page:

- Revised EC REP address
- Removed the Brazil address

**CHAPTER 1, *Performance Verification***

- Added a Note to the *Method comparison or correlation* section.

**A85514AD, 1/2019**

**CHANGES:**

**CHAPTER 1, *Performance Verification***

- Updated the *Chemistries to be Brought Online During Beckman Coulter Unicel DxC Systems Installation* because on this page HDLD-Cholesterol was changed to HDL.
- Updated the *Chemistries to be Brought Online During Beckman Coulter AU/DxC 700 AU Systems Installation* section.

**CHAPTER 2, *Precision***

- Added Whole Blood Chemistries, Use Whole Blood Controls to the *Precision Studies* section.
- Changed AMMON to AMM in Table 2.7.
- Changed Hemoglobin A1c to Hemoglobin A1c (B00389) in Table 2.7.
- Added the following two rows to Table 2.8.  
\*\* \*\* ng/mL 6-Acetylmorphine 6AM1G ng/mL \*\* \*\*  
\*\* \*\* ng/mL Buprenorphine BUP1G ng/mL \*\* \*\*
- Added *Table 2.10 DxC 700 AU Precision Guidelines Whole Blood Chemistry*.

**CHAPTER 3, *Linearity***

- Changed standard to commercial standards/material in the *Linearity* section.
- Changed Approximately 3.2% to 14.5% Hemoglobin A1c HbA1c 2.6 % - highest cal to 4-15 % Hemoglobin A1c (B00389) HbA1c 20-140 mmol/mol in Table 3.6.
- Changed AMMON to AMM in Table 3.6
- Added the following two rows to Table 3.7.  
NA 6-Acetylmorphine 6AM1G 2.9-20 ng/mL  
NA Buprenorphine BUP1G 0.7-25 ng/mL
- Added *Table 3.9 DxC 700 AU Whole Blood Analytical Range(s)*.
- Added the following address to the *Recommended Linearity Materials* section.  
Canterbury Scientific Ltd (+64 3 343 3345)  
71 Whiteleigh Ave  
Christchurch 8011  
New Zealand  
www.canterburyscientific.com

**CHAPTER 5, *Beckman Coulter Clinical System DATs***

- Added the following two rows to the *Qualitative Cutoff Levels* table.  
6-Acetylmorphine 10  
Buprenorphine 5

- Added 6-Acetylmorphine to the *Drugs of Abuse Concordance Data Summary* section.



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## Beckman Coulter Clinical Systems

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We are pleased to present the Beckman Coulter Clinical Systems Performance Verification manual, designed to assist you in making a smooth transition integrating your new Clinical System into your daily laboratory routine. Please take time to review this packet thoroughly with your Beckman Coulter Clinical Systems Engineer and Beckman Coulter Clinical Applications Specialist while they are installing your new system.

In addition to providing guidelines for evaluating precision and linearity, we have included some guidelines for performing method comparison studies. Performing a method comparison helps to evaluate any differences in recovery between different methods and/or different instrumentation, allowing adjustments of the reference interval, if necessary, when changing methods.

The Beckman Coulter Clinical Systems *Performance Verification Manual* provides you with a basic guideline for verifying the performance of your new Beckman Coulter System. However, your current laboratory policies and/or your local regulatory agency may dictate more specific guidelines for your laboratory to follow.

Beckman Coulter provides complimentary services including data reduction for Precision, Linearity, and Method Comparison studies. Beckman Coulter may be able to provide assistance in data reduction for additional studies. Contact your Beckman Coulter Representative for details.

We hope you will find the information contained in the *Performance Verification Manual* a useful tool for making a smooth transition to your new Beckman Coulter Clinical System.

## Chemistries to be Brought Online During Beckman Coulter UniCel DxC Systems Installation

Completed ✓

Critical Care	pa	L <sup>b</sup>	C <sup>c</sup>	General Chems	P	L	C	TDMs	P	L	C	Proteins Serology	P	L	C
Albumin				ALP				Acetaminophen				ASO			
Blood Urea Nitrogen				ALT				Carbamazepine				ApoA			
Calcium				Amylase/p-Amylase				Digoxin				ApoB			
Carbon Dioxide				AST				Gentamicin				C-Reactive Protein			
Chloride				Cholesterol				Phenobarbital				CRPH			
Creatinine				CK				Phenytoin				Complement C3			
Glucose				CR-S				Theophylline				Complement C4			
Phosphorus				Direct Bilirubin				Tobramycin				Haptoglobin			
Potassium				GGT				Valproic Acid				IgA			
Sodium				HDL				Vancomycin				IgG			
Total Protein				Iron								IgM			
Urea				IBCT				<b>DATs</b>				Prealbumin			
				LD				Amphetamines				Transferrin			
				LD-P				Barbiturates							
				LDLD Cholesterol				Benzodiazepines							
				Lipase				Cannabinoids 20ng				<b>UDRs</b>			
				Magnesium				Cannabinoids 50ng				AAG			
				MicroAlbumin				Cannabinoids 100ng				AMIK			
				Micro Total Protein				Cocaine Metabolite				Ceruloplasmin			
				Total Bilirubin				Methadone				Cholinesterase			
<b>Esoterics</b>				Triglyceride				Methaqualone				CKMB			
Alcohol				Uric Acid				Opiates 300ng				Cyclosporine			
Ammonia				Urea				Opiates 2000ng				Cystatin C			
CR-E								Phencyclidine				Homocysteine			
Lactate (LACT)								Propoxyphene				Quinidine			
Lithium				<b>Thyroids</b>								UIBC			
Hemoglobin				Thyroxin (T4)				<b>DAT UDR's</b>							
A1c				T-Uptake				Buprenorphine							
%HbA1c (calculation)								Ecstasy (MDMA)							
Salicylate								Oxycodone							
								Serum BARB							
								Serum BENZ							
								Tricyclics Serum Tox							

a. P = Precision b. L = Linearity c. C = Correlation

Not all chemistries are available in all geographies.

## Chemistries to be Brought Online During Beckman Coulter AU/DxC AU Systems Installation

Completed ✓

General Chems	P <sup>a</sup>	L <sup>b</sup>	C <sup>c</sup>	TDMs	P	L	C	Proteins Serology	P	L	C
ALT				Acetaminophen				AAG			
Albumin				Amikacin				AAT			
ALP				Caffeine				ASO			
Amylase				Carbamazepine				Apo A1			
AST				Digoxin				Apo B			
Bicarbonate				Disopyramide				B-2 Microglobulin			
Calcium				Ethosuximide				Ceruloplasmin			
Chloride				Gentamicin				Complement 3			
Cholesterol				Lidocaine				Complement 4			
Creatinine				Methotrexate				C Reactive Protein			
CK				NAPA				Ferritin			
Direct Bilirubin				Phenobarbital				Haptoglobin			
GGT				Phenytoin				IgA			
Glucose				Primidone				IgE			
HDL Cholesterol				Procainamide				IgG			
Iron				Quinidine				IgM			
LDL Cholesterol				Salicylic Acid				Prealbumin			
LDH				Theophylline				Rheumatoid Factor			
Lipase				Tobramycin				Transferrin			
Magnesium				Valproic Acid							
Inorganic Phosphorous				Vancomycin							
Potassium											
Sodium											
Total Bilirubin				<b>DATs</b>				<b>Esoteric</b>			
Total Protein				Amphetamines				Ammonia			
Triglyceride				Barbiturate				Cholinesterase			
UIBC				Benzodiazepine				Creatine Kinase MB			
Urea Nitrogen				Cannabinoid				D-Dimer			
Uric Acid				Cocaine Metabolite				HbA1c (B00389)			
Urinary/CSF Protein				Creatinine, Tox				HbA1c Advanced (B93009)			
Urine/CSF Albumin				Ecstasy				DxC AU only			
				Ethyl Alcohol				Lactate			
				LSD				Lithium			
<b>Thyroids</b>				Methadone				Procalcitonin (PCT)			
Thyroxine (T4)				Methaqualone				Homocysteine			
T-Uptake				Opiates				Kappa Free Light Chains			
				Oxycodone				Lambda Free Light Chains			
<b>Immunosuppressant Drugs</b>				Phencyclidine				Cystatin C			
Cyclosporine				Propoxyphene				Homocysteine			
Everolimus				Tricyclics, Tox				p-Amylase			
Mycophenolic Acid				6-Acetylmorphine				Procalcitonin			
Tacrolimus				Buprenorphine				ACE			
								Lipase NG*			
<b>Antipsychotic</b>											
Clozapine											

a. P = Precision b. L = Linearity c. C = Correlation  
 Not all chemistries are available in all geographies.  
 \* Not available on all analyzer models

## Performance Verification Studies

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### Purpose

The purpose of this section is to provide information to enable you to verify the performance of your Beckman Coulter Clinical System. We have included subject descriptions and forms to assist you with evaluating precision, interpreting calibration verification/linearity, and recording method comparison.

We have included information to assist you with:

- Precision Evaluation
- Calibration verification and/or Linearity to verify Analytical Measuring Range
- Method Comparison: Quantitative and Qualitative (if applicable)

You will also find a summary form for your performance verification studies.

**IMPORTANT** Local regulatory agencies may dictate frequency and/or method of analysis.

### Overview

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Much has been said and written about the impact that the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) will have on the laboratory and method evaluation.<sup>1</sup> It is often confusing to determine what is needed for accreditation and certification for the different types of testing categories.

The following procedures will assist you in evaluating a new instrument or clinical test. Not all of these procedures are required by CLIA; however, some of them may be required by the College of American Pathologists (CAP), the Joint Commission of Accreditation of Healthcare Organizations (known as JCAHO), and/or individual state agencies. It is important to know state requirements as well as those of any other accrediting agencies that will impact your laboratory. The data generated from some of these procedures will help to establish the baseline performance of your Beckman Coulter Clinical System.

With these considerations in mind, the laboratory must compile its own policies and procedures manual for method evaluation. The method evaluation procedures can be included in the procedures manual. The laboratory is empowered to make its own decisions as to what procedures are appropriate and which performance limits or specifications are acceptable. The data must be maintained for as long as the procedure is used, plus two years.

The following is a synopsis of the performance characteristics to be verified at system installation. For more details, please refer to any text book on clinical chemistry or the various Clinical and Laboratory Standards Institute (CLSI) protocols available.

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<sup>1</sup> The Health Care Financing Administration (HCFA)'s State Operations Manual (Appendix C: Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services), published March 1993, details how to comply with the CLIA regulations.

## Precision Evaluation

Within-Run:

- Used to compare to manufacturer's published specifications or Total Allowable Error (TEa) when precision specifications are listed as "typical performance."
- Helpful for future troubleshooting of individual chemistries
- Uses a patient pool or control material

Precision can be monitored through use of Peer Group QC Programs such as Bio-Rad Unity Reports, and so forth.

## Linearity/CAL Verification

CAP requires linearities be performed on all methods and semiannually thereafter. Linearity is demonstrated when the data points from specimens relative to each other fall on or near a straight line.

Five levels, spanning the Analytical Measuring Range (AMR), are recommended. Typically 2-4 replicates are performed on each linearity sample/standard and plotted per the linearity material kit instructions. If the data points fall on a straight line, linearity is demonstrated.

## Method comparison or correlation:

- Comparison to a reference method
- Statistical equivalency of two methods or instrument systems
- Method Comparison like to like platforms
  - A minimum of 20-25 samples covering the Analytical Measuring Range. Refer to Westgard and Data Innovations.
- Method Comparison competitor platforms
  - A minimum of 40 samples covering the Analytical Measuring Range. Refer to EP09c.

**NOTE** Interpretive Guidelines for CLIA Standard 493.1253 “Establishment and Verification of Performance Specifications” gives the following guidance regarding performance verification<sup>1</sup>:

- Laboratories are responsible for verifying the performance specifications of test systems prior to reporting patient test results.
- The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate as determined by the laboratory director and clinical consultant.
- A laboratory may use the manufacturer’s performance specifications as a guideline but is responsible for verifying the manufacturer’s analytical claims before initiating patient testing.
- If a method was verified by someone other than the laboratory staff (for example, manufacturer representative), the laboratory must demonstrate that this verification correlates with its in-house test performance.
- Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.

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<sup>1</sup> State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. 3 Mar. 2017, [www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_c\\_lab.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_c_lab.pdf)

## Precision Studies Protocol

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### Precision Studies

#### Protocol

Precision studies should be completed prior to the method comparison study, to verify optimal performance of the instrument. The minimum number of replicates is 20 for the low and high controls.

#### 1. Instrument Statistics

A within run precision is performed using the batch/sequential mode on the analyzer.

#### 2. Prepare Sample

- A low and high control is used for precision studies with 20 replicates per control for within run precision studies.
- General Chemistries/TDM's  
Chemistry Controls and / or TDM controls.
- Esoteric Chemistries and UDR Chemistries  
Use specialty controls.
- Urine Chemistries  
Use Urine Controls.
- CSF Chemistries  
Use CSF Controls.
- DAT Chemistries  
Use DAT cutoff calibrator only. The cutoff level is the only Medical Decision Level that is important to be able to precisely report.
- Whole Blood Chemistries  
Use Whole Blood Controls.

#### 3. Precision Evaluation

Verify SD/CV results with the guidelines provided in this manual or with information found in the appropriate Synchron/AU Chemistry *Instructions for Use*.

For Chemistries that have only typical precision guidelines listed in the Synchron/ AU Chemistry *Instructions for Use*, use Total Allowable Error.

## Synchron Systems Precision Guidelines

### Precision Guidelines – Conventional Units (CU)

Table 2.1 Precision Guidelines - Serum/Plasma

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
<b>MC Side Tests</b>							
0.20	10	2.0	ALBm	g/dL	0.3	10	3.0
1.5	50	3.0	BUNm	mg/dL	2.3	51.1	4.5
0.20	10	2.0	CALC	mg/dL	0.3	10	3.0
2.0	100	2.0	CL	mmol/L	3.0	100	3.0
1.0	30.3	3.0	CO2	mmol/L	1.5	30.3	4.5
0.10	3.3	3.0	CREm	mg/dL	0.2	3.3	4.5
2.0	100	2.0	GLUCm	mg/dL	3.0	100	3.0
0.10	5	2.0	K	mmol/L	0.2	6.67	3.0
1.0	100	1.0	NA	mmol/L	1.5	100	1.5
0.15	7.5	2.0	PHOSm	mg/dL	0.23	7.7	3.0
0.20	10	2.0	TPm	g/dL	0.3	10	3.0
1.5	50	3.0	UREAm	mg/dL	2.3	51.1	4.5
<b>CC Side Tests</b>							
2.0	50.0	4.0	ACTM	µg/mL	3.0	50.0	6.0
0.2	6.7	3.0	ALB	g/dL	0.3	6.7	4.5
3.0	85.7	3.5	ALP	IU/L	4.5	85.7	5.3
3.0	85.7	3.5	ALT	IU/L	4.5	85.7	5.3
8.5	425.0	2.0	AMM	µg/dL	12.8	425	3.0
3.0	85.7	3.5	AMY7	U/L	4.5	85.7	5.3
5.0	100	5.0	Apo A	mg/dL	7.5	100	7.5
5.0	100	5.0	Apo B	mg/dL	7.5	100	7.5
10.0	250	4.0	ASO-	IU/mL	15.0	250	6.0
3.0	85.7	3.5	AST	IU/L	4.5	85.7	5.3
2.0	66.7	3.0	BUN	mg/dL	3.0	66.7	4.5
3.5	77.8	4.5	C3	mg/dL	5.25	77.8	6.75
2.0	44.4	4.5	C4	mg/dL	3.0	44.4	6.75
0.6	12	5.0	CAR	µg/mL	0.90	12	7.5

**Table 2.1** Precision Guidelines - Serum/Plasma (Continued)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
5.0	166.7	3.0	CHOL	mg/dL	7.5	166.7	4.5
5.0	142.9	3.5	CK	IU/L	7.5	142.9	5.3
0.2	10.0	2.0	CR-S	mg/dL	0.3	10.0	3.0
0.10	3.3	3.0	CR-E	mg/dL	0.15	3.3	4.5
0.20	4.0	5.0	CRP	mg/dL	0.3	4.0	7.5
0.005	0.1	5.0	CRPH	mg/dL	0.0075	0.1	7.5
		2.0	DATs	mA/min			
0.15	3.0	5.0	DBIL	mg/dL	0.23	3.0	7.5
0.1	2.0	5.0	DIGN	ng/mL	0.15	2.0	7.5
2.4	80.0	3.0	ETOH	mg/dL	3.6	80.0	4.5
3.5	140	2.5	FE	µg/dL	5.3	140	3.8
0.2	4.0	5.0	GEN	µg/mL	0.30	4.0	7.5
3.0	85.7	3.5	GGT	IU/L	4.5	85.7	5.3
2.0	100.0	2.0	GLUH	mg/dL	3.0	100.0	3.0
5.0 <sup>b</sup>	N/A	4.0 <sup>c</sup>	HbA1c-/HbA1c3	%	7.5 <sup>b</sup>	N/A	4.0 <sup>c</sup>
1.3	42	3.0	HDL	mg/dL	1.7	42	4.0
2.5	55.5	4.5	HPT	mg/dL	3.75	55.5	6.75
10.0	250	4.0	IBCT	µg/dL	15.0	250	6.0
5.0	100	5.0	IgA	mg/dL	7.5	100	7.5
20.0	400	5.0	IgG	mg/dL	30.0	400	7.5
5.0	100	5.0	IgM	mg/dL	7.5	100	7.5
1.2	40.0	3.0	LACT	mg/dL	1.8	40.0	4.5
5.0	143	3.5	LD	IU/L	7.5	143	5.3
2.0	100	2.0	LDLD	mg/dL	3.0	100	3.0
15.0	429	3.5	LD-P	IU/L	22.5	429	5.3
0.03	1.0	3.0 or 5.0 <sup>d</sup>	LI	mmol/L	0.045	1.0	4.5 or 7.5 <sup>d</sup>
7.0	100	7.0	LIP	U/L	10.5	100	10.5
0.125	2.3	5.4	MA	mg/dL	0.187	2.3	8.0
0.11	4.4	2.5	MG	mg/dL	0.17	4.4	3.8
2.0	50	4.0	M-TP	mg/dL	3.0	50	6.0
0.92	17.5	5.25	PAB	mg/dL	1.38	17.5	7.88
5.0	143	3.5	PAM	U/L	7.5	143	5.3

**Table 2.1** Precision Guidelines - Serum/Plasma (Continued)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
1.0	25	4.0	PHE	µg/mL	1.5	25	6.0
0.2	10	2.0	PHS	mg/dL	0.3	10.0	3.0
0.5	12.5	4.0	PHY	µg/mL	0.75	12.5	6.0
1.50	30	5.0	SALY	mg/dL	2.2	30	7.5
0.4	8.0	5.0	T4	µg/dL	0.6	8.0	7.5
0.15	5.0	3.0	TBIL	mg/dL	0.22	5.0	4.5
5.0	166.7	3.0	TG/TG-B	mg/dL	7.5	166.7	4.5
0.5	12.5	4.0	THE	µg/mL	0.75	12.5	6.0
0.2	5.0	4.0	TOB	µg/mL	0.3	5.0	6.0
0.3	10	3.0	TP	g/dL	0.5	10	4.5
5.0	100	5.0	TRFN	mg/dL	7.5	100	7.5
0.65	26	2.50	TU	%	0.98	26	3.75
4.3	143.3	3.0	UREA	mg/dL	6.5	143.3	4.5
0.15	7.5	2.0	URIC	mg/dL	0.22	7.5	3.0
1.3	33	4.0	VANC	µg/mL	2.0	33	6.0
3.6	60	6.0	VPA	µg/mL	4.5	60	7.5

- a. X-Over: When the mean of the test precision data is less than or equal to the x-over value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the x-over value, compare the test %CV to %CV guideline given above to determine acceptability.  
X-Over value = (SD guideline/CV guideline) X 100.
- b. < 5% HbA1c- NGSP or < 0.4 g/dL A1c
- c. ≥ 5% HbA1c- NGSP or ≥ 0.4 g/dL A1c
- d. ORDAC % CV.

Refer to UDR package inserts for Performance Characteristics information.

## Urine Chemistries Precision Guidelines

**Table 2.2** Precision Guidelines Urine Chemistries – Conventional Units (CU)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
<b>Modular (MC ) Chemistries</b>							
3.0	100	3.0	BUNm	mg/dL	4.5	100	4.5
0.3	10	3.0	CALC	mg/dL	0.45	10	4.5
3.0	100	3.0	CL	mmol/L	4.5	100	4.5
2.0	66.7	3.0	CREm	mg/dL	3.0	66.7	4.5
2.0	100	2.0	GLUCm	mg/dL	3.0	100	3.0
2.0	50	4.0	K	mmol/L	3.0	50	6.0
2.0	50	4.0	NA	mmol/L	3.0	50	6.0
2.0	100	2.0	PHOSm	mg/dL	3.0	100	3.0
1.1	37	3.0	UREAm	mmol/L	1.7	37.1	4.5
<b>Cartridge (CC) Chemistries</b>							
3.0	85.7	3.5	AMY7	U/L	4.5	85.7	5.3
3.0	100	3.0	BUN	mg/dL	4.5	100	4.5
1.0	33	3.0	CR-E	mg/dL	1.5	33	4.5
2.0	100	2.0	CR-S	mg/dL	3.0	100	3.0
2.4	80	3.0	ETOH	mg/dL	3.6	80	4.5
2.0	100	2.0	GLUH	mg/dL	3.0	100	3.0
0.125	2.3	5.4	MA	mg/dL	0.187	2.3	8.0
0.8	26.7	3.0	MG	mg/dL	1.2	26.7	4.5
2.0	50	4.0	M-TP	mg/dL	3.0	50	6.0
5.0	143	3.5	PAM	U/L	7.5	143	5.3
2.0	100	2.0	PHS	mg/dL	3.0	100	3.0
6.6	213	3.0	UREA	mg/dL	9.6	213	4.5
1.0	33	3.0	URIC	mg/dL	2.0	33	4.5

a. X-Over: When the mean of the test precision data is less than or equal to the x-over value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the x-over value, compare the test %CV to %CV guideline given above to determine acceptability. X-Over value = (SD guideline/CV guideline) X 100.

## CSF Chemistries Precision Guidelines

**Table 2.3** Precision Guidelines CSF Chemistries – Conventional Units (CU)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
2.0	100	2.0	CL	mmol/L	3.0	100	3.0
2.0	100	2.0	GLUCm	mg/dL	3.0	100	3.0
2.0	100	2.0	GLUH	mg/dL	3.0	100	3.0
1.2	40	3.0	LACT	mg/dL	1.8	40	4.5
2.0	50	4.0	M-TP	mg/dL	3.0	50	6.0
5.0	100	5.0	TPm	mg/dL	7.5	100	7.5

- a. X-Over: When the mean of the test precision data is less than or equal to the x-over value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the x-over value, compare the test %CV to %CV guideline given above to determine acceptability. X-Over value = (SD guideline/CV guideline) X 100.

## Synchron Systems Precision Guidelines

### Precision Guidelines – International Units (SI)

**Table 2.4** Precision Guidelines - Serum/Plasma (SI Units)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
<b>MC Side Tests</b>							
2.0	100	2.0	ALBm	g/L	3.0	100	3.0
0.5	16.7	3.0	BUNm	mmol/L	0.8	17.8	4.5
0.05	2.5	2.0	CALC	mmol/L	0.08	2.5	3.0
2.0	100	2.0	CL	mmol/L	3.0	100	3.0
1.0	30.3	3.0	CO2	mmol/L	1.5	30.3	4.5
9	300	3.0	CREm	μmol/L	13	300	4.5
0.1	5.6	2.0	GLUCm	mmol/L	0.2	5.6	3.0
0.10	5.0	2.0	K	mmol/L	0.20	6.67	3.0
1.0	100	1.0	NA	mmol/L	1.5	100	1.5
0.05	2.5	2.0	PHOSm	mmol/L	0.07	2.3	3.0
2.0	100	2.0	TPm	g/L	3.0	100	3.0
0.5	16.7	3.0	UREAm	mmol/L	0.8	17.8	4.5
<b>CC Side Tests</b>							
13.2	330	4.0	ACTM	μmol/L	19.9	330	6.0
2.0	66.7	3.0	ALB	g/L	3.0	66.7	4.5
0.05	1.43	3.5	ALP	μKat/L	0.08	1.43	5.3
0.05	1.43	3.5	ALT	μKat/L	0.08	1.43	5.3
5.0	250	2.0	AMM	μmol/L	7.5	250	3.0
0.03	0.72	3.5	AMY7	μKat/L	0.04	0.72	5.3
0.05	1.0	5.0	Apo A	g/L	0.08	1.0	7.5
0.05	1.0	5.0	Apo B	g/L	0.08	1.0	7.5
10	250	4.0	ASO-	IU/mL	15	250	6.0
0.05	1.43	3.5	AST	μKat/L	0.08	1.43	5.3
0.71	24.0	3.0	BUN	mmol/L	1.07	24.0	4.5
35.0	778	4.5	C3	mg/L	52.5	778	6.75
20.0	444	4.5	C4	mg/L	30.0	444	6.75
2.5	50.0	5.0	CAR	μmol/L	3.8	50.0	7.5
0.13	4.3	3.0	CHOL	mmol/L	0.20	4.3	4.5

**Table 2.4** Precision Guidelines - Serum/Plasma (SI Units) (Continued)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
0.08	2.29	3.5	CK	μKat/L	0.12	2.29	5.3
18	900	2.0	CR-S	μmol/L	27	900	3.0
8.8	291.7	3.0	CR-E	μmol/L	13.3	291.7	4.5
2.0	40.0	5.0	CRP	mg/L	3.0	40.0	7.5
0.050	1.0	5.0	CRPH	mg/L	0.075	1.0	7.5
		2.0	DATs	mA/min			
2.6	52.0	5.0	DBIL	μmol/L	3.9	52.0	7.5
0.128	2.56	5.0	DIGN	nmol/L	0.192	2.56	7.5
0.52	17.33	3.0	ETOH	mmol/L	0.78	17.33	4.5
0.6	25.1	2.5	FE	μmol/L	1.0	25.1	3.8
0.4	8.0	5.0	GEN	μmol/L	0.6	8.0	7.5
0.05	1.43	3.5	GGT	μKat/L	0.08	1.43	5.3
0.11	5.5	2.0	GLUH	mmol/L	0.17	5.5	3.0
5.0 <sup>b</sup>	N/A	4.0 <sup>c</sup>	HbA1c-/HbA1c3	%	7.5 <sup>b</sup>	N/A	4.0 <sup>c</sup>
0.03	1.1	3.0	HDL	mmol/L	0.04	1.1	4.0
25.0	555	4.5	HPT	mg/L	37.5	555	6.75
1.8	45.0	4.0	IBCT	μmol/L	2.7	45.0	6.0
0.05	1.0	5.0	IgA	g/L	0.08	1.0	7.5
0.20	4.0	5.0	IgG	g/L	0.30	4.0	7.5
0.05	1.0	5.0	IgM	g/L	0.08	1.0	7.5
0.13	4.33	3.0	LACT	mmol/L	0.20	4.33	4.5
0.08	2.3	3.5	LD	μKat/L	0.12	2.3	5.3
0.05	2.59	2.0	LDLD	mmol/L	0.08	2.59	3.0
0.25	7.1	3.5	LD-P	μKat/L	0.38	7.1	5.3
0.03	1.0	3.0 or 5.0 <sup>d</sup>	LI	mmol/L	0.045	1.0	4.5 or 7.5 <sup>d</sup>
0.12	1.67	7.0	LIP	μKat/L	0.18	1.67	10.5
1.25	23	5.4	MA	mg/L	1.87	23	8.0
0.04	1.6	2.5	MG	mmol/L	0.06	1.6	3.8
0.02	0.5	4.0	M-TP	g/L	0.03	0.5	6.0
9.2	175	5.25	PAB	mg/L	13.8	175	7.88
0.08	2.29	3.5	PAM	μKat/L	0.12	2.29	5.3
4.3	107.8	4.0	PHE	μmol/L	6.5	107.8	6.0
0.06	3.23	2.0	PHS	mmol/L	0.1	3.23	3.0
2.0	49.5	4.0	PHY	μmol/L	3.0	49.5	6.0

**Table 2.4** Precision Guidelines - Serum/Plasma (SI Units) (Continued)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
0.09	1.8	5.0	SALY	mmol/L	0.14	1.8	7.5
5.2	104.0	5.0	T4	nmol/L	7.8	104.0	7.5
2.6	86.7	3.0	TBIL	μmol/L	3.8	86.7	4.5
0.1	2.0	3.0	TG/TG-B	mmol/L	0.2	2.0	4.5
2.8	70.0	4.0	THE	μmol/L	4.2	70.0	6.0
0.4	10.0	4.0	TOB	μmol/L	0.6	10.0	6.0
3.0	100	3.0	TP	g/L	4.5	100	4.5
0.05	1.00	5.0	TRFN	g/L	0.08	1.00	7.5
0.65	26.0	2.50	TU	%	0.98	26.0	3.75
0.7	24.0	3.0	UREA	mmol/L	1.0	24.0	4.5
9.0	450.0	2.0	URIC	μmol/L	13.5	450.0	3.0
0.9	22.8	4.0	VANC	μmol/L	1.4	22.8	6.0
25.0	416	6.0	VPA	μmol/L	31.2	416	7.5

- a. Crossover (X-Over): When the mean of the test precision data is less than or equal to the x-over value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the x-over value, compare the test %CV to %CV guideline given above to determine acceptability.  
X-Over value = (SD guideline/%CV guideline) x 100.
- b. < 5% HbA1c- NGSP or < 0.4 g/dL A1c
- c. ≥ 5% HbA1c- NGSP or ≥ 0.4 g/dL A1c
- d. ORDAC % CV.

Refer to UDR package inserts for Performance Characteristics information.

## Urine Chemistries Precision Guidelines

**Table 2.5** Precision Guidelines Urine Chemistries – International Units (SI)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
<b>Modular (MC ) Chemistries</b>							
1.1	37	3.0	BUNm	mmol/L	1.7	37.1	4.5
0.08	2.5	3.0	CALC	mmol/L	0.11	2.5	4.5
3.0	100	3.0	CL	mmol/L	4.5	100	4.5
177	5900	3.0	CREm	μmol/L	265	5900	4.5
0.1	5.6	2.0	GLUCm	mmol/L	0.2	5.6	3.0
2.0	50	4.0	K	mmol/L	3.0	50	6.0
2.0	50	4.0	NA	mmol/L	3.0	50	6.0
0.6	30	2.0	PHOSm	mmol/L	0.96	32	3.0
1.1	37	3.0	UREAm	mmol/L	1.7	37.1	4.5
<b>Cartridge (CC) Chemistries</b>							
0.05	1.43	3.5	AMY7	μKat/L	0.08	1.43	5.3
1.07	35.7	3.0	BUN	mmol/L	1.61	35.7	4.5
88	2917	3.0	CR-E	μmol/L	133	2917	4.5
177	8850	2.0	CR-S	μmol/L	266	8866	3.0
0.25	17.33	3.0	ETOH	mmol/L	0.78	17.33	4.5
0.11	5.5	2.0	GLUH	mmol/L	0.71	5.5	3.0
1.25	23	5.4	MA	mg/L	1.87	23	8.0
0.3	10	3.0	MG	mmol/L	0.5	10	4.5
0.02	0.5	4.0	M-TP	g/L	0.03	0.5	6.0
0.08	2.29	3.5	PAM	μKat/L	0.12	2.29	5.3
0.65	32.3	2.0	PHS	mmol/L	0.97	32.3	3.0
1.1	35.7	3.0	UREA	mmol/L	1.6	35.7	4.5
60	1980	3.0	URIC	μmol/L	120	1980	4.5

- a. Crossover (X-Over): When the mean of the test precision data is less than or equal to the x-over value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the x-over value, compare the test %CV to %CV guideline given above to determine acceptability.  
 X-Over value = (SD guideline/%CV guideline) x 100.

## CSF Chemistries Precision Guidelines

**Table 2.6** Precision Guidelines CSF Chemistries – International Units (SI)

Within-Run			Test	Units	Total		
1SD	X-Over <sup>a</sup>	%CV			1SD	X-Over <sup>a</sup>	%CV
2.0	100	2.0	<b>CL</b>	mmol/L	3.0	100	3.0
0.1	5.6	2.0	<b>GLUCm</b>	mmol/L	0.2	5.6	3.0
0.11	5.5	2.0	<b>GLUH</b>	mmol/L	0.17	5.5	3.0
0.13	4.4	3.0	<b>LACT</b>	mmol/L	0.2	4.4	4.5
0.02	0.5	4.0	<b>M-TP</b>	g/L	0.03	0.5	6.0
50	1000	5.0	<b>TPm</b>	mg/L	7.5	1000	7.5

- a. Crossover (X-Over): When the mean of the test precision data is less than or equal to the x-over value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the x-over value, compare the test %CV to %CV guideline given above to determine acceptability.  
X-Over value = (SD guideline/%CV guideline) x 100.

## AU/DxC AU Systems Precision Guidelines

**Table 2.7** Precision Guidelines AU/DxC AU Chemistries - Serum/Plasma

CONVENTIONAL			Serum/Plasma Precision Specifications TEST NAME	SI UNITS		
WITHIN (%CV)	TOTAL (%CV)	UNIT		UNITS	TOTAL (%CV)	WITHIN (%CV)
< 5%	< 10%	mg/dL	α-1-Acidglycoprotein	g/L	< 10%	< 5%
< 5%	< 10%	mg/dL	α-1-antitrypsin	g/L	< 10%	< 5%
*	*	µg/mL	Acetaminophen	µmol/L	*	*
< 3%	< 3%	g/dL	Albumin	g/L	< 3%	< 3%
< 5%	< 10%	IU/L	Alkaline Phosphatase	µkat/L	< 10%	< 5%
< 5%	< 10%	IU/L	Alanine Aminotransferase	µkat/L	< 10%	< 5%
*	*	µg/mL	Amikacin	µmol/L	*	*
< 5%	< 10%	U/L	Amylase	µkat/L	< 10%	< 5%
< 5%	< 10%	mg/dL	Apolipoprotein A1	g/L	< 10%	< 5%
< 5%	< 10%	mg/dL	Apolipoprotein B	g/L	< 10%	< 5%
< 5%	< 10%	IU/mL	Anti-Streptolysin O	IU/mL	< 10%	< 5%
< 5%	< 10%	U/L	Aspartate Aminotransferase	µkat/L	< 10%	< 5%
< 5%	< 10%	mg/dL	β-2 Microglobulin	g/L	< 10%	< 5%
< 3% or < 1.0 <sup>a</sup>	< 7% or < 1.5 <sup>a</sup>	mEq/L	Bicarbonate	mmol/L	< 7% or < 1.5 <sup>a</sup>	< 3% or < 1.0 <sup>a</sup>
< 5% or ≤ 0.15 <sup>a</sup>	< 7.5% or ≤ 0.23 <sup>a</sup>	mg/dL	Bilirubin, D (OSR6x11)	µmol/L	< 7.5% or ≤ 3.9 <sup>a</sup>	< 5% or ≤ 2.6 <sup>a</sup>
< 7% or ≤ 0.07 <sup>a</sup>	< 8% or ≤ 0.21 <sup>a</sup>	mg/dL	Bilirubin, D (OSR6x181)	µmol/L	< 8% or ≤ 3.6 <sup>a</sup>	< 7% or ≤ 1.2 <sup>a</sup>
< 3% or ≤ 0.07 <sup>a</sup>	< 5% or ≤ 0.10 <sup>a</sup>	mg/dL	Bilirubin, T	µmol/L	< 5% or ≤ 1.7 <sup>a</sup>	< 3% or ≤ 1.2 <sup>a</sup>
< 3%	< 5%	mg/dL	Complement 3	g/L	< 5%	< 3%
< 3%	< 5%	mg/dL	Complement 4	g/L	< 5%	< 3%
*	*	µg/mL	Caffeine	µmol/L	*	*
< 3%	< 5%	mg/dL	Calcium Arsenazo	mmol/L	< 5%	< 3%
*	*	µg/mL	Carbamazepine	µmol/L	*	*

**Table 2.7** Precision Guidelines AU/DxC AU Chemistries - Serum/Plasma (Continued)

CONVENTIONAL			Serum/Plasma Precision Specifications TEST NAME	SI UNITS		
WITHIN (%CV)	TOTAL (%CV)	UNIT		UNITS	TOTAL (%CV)	WITHIN (%CV)
< 5%	< 10%	mg/L	Ceruloplasmin	mg/dL	< 10%	< 5%
< 3%	< 5%	mEq/L	Chloride	mmol/L	< 5%	< 3%
< 3%	< 3%	mg/dL	Cholesterol	mmol/L	< 3%	< 3%
< 5%	< 10%	kU/L	Cholinesterase	μkat/L	< 10%	< 5%
< 5%	< 10%	U/L	Creatine Kinase	μkat/L	< 10%	< 5%
< 5% or ≤ 2.3 <sup>a</sup>	< 6.5% or ≤ 3.0 <sup>a</sup>	U/L	Creatine Kinase MB	μkat/L	< 6.5% or ≤ 0.05 <sup>a</sup>	< 5% or ≤ 0.04 <sup>a</sup>
< 3%	< 6%	mg/dL	Creatinine	μmol/L	< 6%	< 3%
< 5% or ≤ 1.0 <sup>a</sup>	< 5% or ≤ 1.0 <sup>a</sup>	mg/L	C-Reactive Protein (OSR6x47)	mg/dL	< 5% or ≤ 0.1 <sup>a</sup>	< 5% or ≤ 0.1 <sup>a</sup>
< 5% or 0.02 <sup>a</sup>	< 10% or 0.02 <sup>a</sup>	mg/L	CRP High Sensitivity	mg/dL	< 10% or 0.002 <sup>a</sup>	< 5% or 0.002 <sup>a</sup>
< 5% or ≤ 0.20 <sup>a</sup>	< 10% or ≤ 0.25 <sup>a</sup>	mg/L	CRP Normal (OSR6x99)	mg/dL	< 10% or ≤ 0.025 <sup>a</sup>	< 5% or ≤ 0.020 <sup>a</sup>
*	*	ng/mL	Digoxin	nmol/L	*	*
< 10%	< 10%	μg FEU/mL	D-Dimer	μg FEU/mL	< 10%	< 10%
*	*	μg/mL	Disopyramide	μmol/L	*	*
*	*	μg/mL	Ethosuximide	μmol/L	*	*
< 8%	< 11%	ng/mL	Ferritin	μg/L	< 11%	< 8%
*	*	μg/mL	Gentamicin	μmol/L	*	*
< 5%	< 10%	U/L	Gamma Glutamyltransferase	μkat/L	< 10%	< 5%
< 3%	< 3%	mg/dL	Glucose	mmol/L	< 3%	< 3%
< 5%	< 10%	mg/dL	Haptoglobin	g/L	< 10%	< 5%
≤ 3%	≤ 4%	%	Hemoglobin A1c (B00389)	%	≤ 4%	≤ 3%
< 3%	< 5%	mg/dL	HDL Cholesterol	mmol/L	< 5%	< 3%
< 4.2%	< 8%	mg/dL	Immunoglobulin A	g/L	< 8%	< 4.2%
< 7.0% or ≤ 5.0 <sup>a</sup>	< 7.5% or ≤ 7.0 <sup>a</sup>	IU/mL	Immunoglobulin E	IU/mL	< 7.0% or ≤ 5.0 <sup>a</sup>	< 7.5% or ≤ 7.0 <sup>a</sup>

**Precision**

AU/DxC AU Systems Precision Guidelines

**Table 2.7** Precision Guidelines AU/DxC AU Chemistries - Serum/Plasma (Continued)

CONVENTIONAL			Serum/Plasma Precision Specifications TEST NAME	SI UNITS		
WITHIN (%CV)	TOTAL (%CV)	UNIT		UNITS	TOTAL (%CV)	WITHIN (%CV)
< 3.5%	< 6%	mg/dL	Immunoglobulin G	g/L	< 6%	< 3.5%
< 4.2%	< 10%	mg/dL	Immunoglobulin M	g/L	< 10%	< 4.2%
< 3%	< 5%	ug/dL	Iron	µmol/L	< 5%	< 3%
< 5%	< 5%	mg/dL	Lactate	mmol/L	< 5%	< 5%
< 5%	< 10%	U/L	Lactate Dehydrogenase	µkat/L	< 10%	< 5%
< 3%	< 5%	mg/dL	LDL Cholesterol	mmol/L	< 5%	< 3%
*	*	µg/mL	Lidocaine	µmol/L	*	*
< 5%	< 10%	U/L	Lipase	µkat/L	< 10%	< 5%
< 3%	< 5%	mg/dL	Magnesium	mmol/L	< 5%	< 3%
*	*	µmol/L	Methotrexate	mol/L	*	*
*	*	µg/mL	N- Acetylprocainamide	µmol/L	*	*
*	*	µg/mL	Phenobarbital	µmol/L	*	*
*	*	µg/mL	Phenytoin	µmol/L	*	*
< 3%	< 5%	mg/dL	Phosphorus (Inorganic)	mmol/L	< 5%	< 3%
< 3%	< 5%	mEq/L	Potassium	mmol/L	< 5%	< 3%
< 5%	< 10%	mg/dL	Prealbumin	g/L	< 10%	< 5%
*	*	µg/mL	Primidone	µmol/L	*	*
*	*	µg/mL	Procainamide	µmol/L	*	*
< 3%	< 4%	g/dL	Protein, Total	g/L	< 4%	< 3%
*	*	µg/mL	Quinidine	µmol/L	*	*
<10% for values ≤ 20 IU/ mL or <5% for values >20 IU/ mL	< 10%	IU/L	Rheumatoid Factor	IU/L	< 10%	<10% for values ≤ 20 IU/ mL or <5% for values >20 IU/ mL
*	*	mg/dL	Salicylic Acid	µmol/L	*	-
< 3%	< 5%	mEq/L	Sodium	mmol/L	< 5%	< 3%

**Table 2.7** Precision Guidelines AU/DxC AU Chemistries - Serum/Plasma (Continued)

CONVENTIONAL			Serum/Plasma Precision Specifications TEST NAME	SI UNITS		
WITHIN (%CV)	TOTAL (%CV)	UNIT		UNITS	TOTAL (%CV)	WITHIN (%CV)
*	*	µg/mL	Theophylline	µmol/L	*	*
*	*	µg/mL	Tobramycin	µmol/L	*	*
< 3%	< 5%	mg/dL	Transferrin	g/L	< 5%	< 3%
< 3%	< 5%	mg/dL	Triglyceride	mmol/L	< 5%	< 3%
< 2%	< 3%	mg/dL	Uric Acid	µmol/L	< 3%	< 2%
< 3%	< 5%	mg/dL	Urea Nitrogen	mmol/L	< 5%	< 3%
< 8%	< 10%	µg/dL	Unsaturated Iron Binding Capacity	µmol/L	< 10%	< 8%
*	*	µg/mL	Valproic Acid	µmol/L	*	*
*	*	µg/mL	Vancomycin	µmol/L	*	*

\* Installation performance criteria is based on Total Allowable Error (TEa).

Refer to reagent package inserts for Performance Characteristics information.

For third party reagents, refer to supplier's package inserts for Performance Characteristics information.

**Table 2.8** AU/DxC AU Precision Guidelines Urine Chemistries

CONVENTIONAL			Urine Precision Specifications TEST NAME	SI UNITS		
WITHIN (%CV)	TOTAL (%CV)	UNIT		UNITS	TOTAL (%CV)	WITHIN (%CV)
**	**	U/L	Amylase	μkat/L	**	**
**	**	mg/dL	Calcium Arsenazo	mmol/L	**	**
**	**	mEq/L	Chloride	mmol/L	**	**
**	**	mg/dL	Creatinine (OSR6x78)	μmol/L	**	**
**	**	mg/dL	Glucose	mmol/L	**	**
**	**	mg/dL	Magnesium	mmol/L	**	**
**	**	mg/dL	Phosphorus (Inorganic)	mmol/L	**	**
**	**	mEq/L	Potassium	mmol/L	**	**
< 4%	< 5%	mg/dL	Urinary/ CSF Protein	g/L	< 5%	< 4%
**	**	mEq/L	Sodium	mmol/L	**	**
≤ 5% or 1 <sup>a</sup>	≤10% or 2 <sup>a</sup>	mg/L	Urine/CSF Albumin	mg/dL	≤ 10% or 0.2 <sup>a</sup>	≤ 5% or 0.1 <sup>a</sup>
**	**	mg/dL	Urea Nitrogen	mmol/L	**	**
< 3%	< 5%	mg/dL	Uric Acid	μmol/L	< 5%	< 3%
**	**	ng/mL	6-Acetylmorphine	ng/mL	**	**
**	**	ng/mL	Buprenorphine	ng/mL	**	**

\*\* Installation performance criteria is based on Total Allowable Error (TEa).

Refer to DAT package inserts for Performance Characteristics information.

For third party reagents, refer to supplier's package inserts for Performance Characteristics information.

**Table 2.9** AU/DxC AU Precision Guidelines CSF Chemistries

CONVENTIONAL			CSF Precision Specifications TEST NAME	SI UNITS		
WITHIN (%CV)	TOTAL (%CV)	UNIT		UNITS	TOTAL (%CV)	WITHIN (%CV)
***	***	mg/dL	Glucose	mmol/L	***	***
< 6 % or < 0.4 <sup>a</sup>	< 7.5 % or < 0.5 <sup>a</sup>	mg/dL	Immunoglobulin G	g/L	< 7.5 % or < 0.005 <sup>a</sup>	< 6 % or < 0.004 <sup>a</sup>
< 5%	< 5%	mg/dL	Lactate	mmol/L	< 5%	< 5%
< 4%	< 5%	mg/dL	Urinary/ CSF Protein	g/L	< 5%	< 4%
≤ 5% or 1	≤10% or 2 <sup>a</sup>	mg/L	Urine/CSF Albumin	mg/dL	≤ 10% or 0.2 <sup>a</sup>	≤ 5% or 0.1

a. Compare the % CV to the SD guideline and use the greater number.

\*\*\* Installation performance criteria is based on Total Allowable Error (TEa).

For third party reagents, refer to supplier’s package inserts for Performance Characteristics information.

**Table 2.10** DxC AU Precision Guidelines Whole Blood Chemistry

NGSP			Whole Blood Precision Specifications* TEST NAME	IFCC		
WITHIN (%CV)	TOTAL (%CV)	UNIT		UNITS	TOTAL (%CV)	WITHIN (%CV)
≤ 1.5% CV or SD ≤ 0.1	≤ 2% CV or SD ≤ 0.13	%	HbA1c Advanced (B93009)	mmol/ mol	≤ 2.9% CV or SD ≤ 1.4	≤ 2.3% CV or SD ≤ 1.1

\* Precision specifications are based on a 20-day precision study following the CLSI EP05 guideline - Evaluation of Precision Performance of Clinical Chemistry Devices.



## Linearity Protocol

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### Purpose

#### Linearity:

Linearity is typically performed with five or more interrelated samples, with 2-4 replicates for each level. Data is plotted against the expected value or standard number. Commercially prepared commercial standards/material or multiple dilutions of a high patient sample may be used.

#### Procedure:

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- 1 Verify adequate volume of reagents.

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  - 2 Verify calibrations have been completed and will not time out in the middle of procedure.

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  - 3 Verify controls have been completed and are within acceptable limits.

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  - 4 Program the instruments to run the selected analytes in 2 - 4 replicates.

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  - 5 For Linearity studies, plot the instrument values versus the linearity material kit instructions.
-

## Recommended Linearity Materials

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**LGC Clinical Diagnostics (Maine Standards) (1-800-377-9684)**

221 US Route 1  
Cumberland Foreside, ME 04110  
Fax: 207-892-2266  
[www.mainestandards.com](http://www.mainestandards.com)

**Sekisui Diagnostics, LLC (1-781-652-7800)**

4 Hartwell Place  
Lexington, MA 02421  
[www.sekisuidiagnostics.com](http://www.sekisuidiagnostics.com)

**Verichem Laboratories (1-800-552-5859)**

90 Narragansett Avenue  
Providence RI 02907  
[www.verichemlabs.com](http://www.verichemlabs.com)

**Canterbury Scientific Ltd (+64 3 343 3345)**

71 Whiteleigh Avenue  
Christchurch 8011  
New Zealand  
[www.canterburyscientific.com](http://www.canterburyscientific.com)

## Serum/Plasma Analytical Measuring Ranges - Synchron Systems

### Modular (MC) Chemistries – Synchron Systems

**Table 3.1** Synchron MC Chemistries Serum/Plasma Analytical Measuring Ranges

Modular (MC) Chemistry Serum/Plasma	Analytical Measuring Ranges Serum/Plasma Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
Albumin (ALBm)	1-7 g/dL	NA <sup>a</sup>	10-70 g/L	NA
Blood Urea Nitrogen (BUNm)	1-150 mg/dL	130-300 mg/dL	0.4-53.6 mmol/L	46.4-107.1 mmol/L
Calcium	2-20 mg/dL	NA	0.5-5 mmol/L	NA
Carbon Dioxide	5-50 mmol/L	NA	5-50 mmol/L	NA
Chloride	50-200 mmol/L	NA	50-200 mmol/L	NA
Creatinine (CREm)	0.1-25 mg/dL	NA	8.8-2210 µmol/L	NA
Glucose (Oxidase) (GLUCm)	10-600 mg/dL	300-1200 mg/dL	0.55-33.3 mmol/L	16-7-66.7 mmol/L
Phosphorus (PHOSm)	0.5-12 mg/dL	NA	0.2-3.9 mmol/L	NA
Potassium	1-15 mmol/L	NA	1-15 mmol/L	NA
Sodium	100-200 mmol/L	NA	100-200 mmol/L	NA
Total Protein (TPm)	1-12g/dL	NA	10-120 g/L	NA
Urea (UREAm)	1-150 mg/dL	130-300 mg/dL	0.4-53.6 mmol/L	46.4-107.1 mmol/L

a. NA = Not Applicable

### Cartridge (CC) Chemistries – Synchron Systems

**Table 3.2** Synchron CC Chemistries Serum/Plasma Analytical Measuring Ranges

Cartridge Chemistry (CC) Serum/Plasma	Analytical Measuring Ranges Serum/Plasma Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
Acetaminophen	10-300 µg/mL	NA <sup>a</sup>	66-1986 µmol/L	NA
Alanine Aminotransferase (ALT)	5-400 IU/L	350-2600 IU/L	0.09-6.80 µkat/L	5.8-43.0 µkat/L
Albumin	1-7 g/dL	NA	10-70 g/L	NA
Alkaline Phosphatase (ALP)	5-1000 IU/L	800-1650 IU/L	0.1-16.7 µkat/L	13.3-27.5 µkat/L
Ammonia	16-1700 µg/dL	NA	9-1000 µmol/L	NA
Amylase G7 (AMY7)	5-1200 U/L	1000-2000 U/L	0.08-20.00 µkat/L	16.67-33.34 µkat/L

**Table 3.2** Synchron CC Chemistries Serum/Plasma Analytical Measuring Ranges (*Continued*)

Cartridge Chemistry (CC) Serum/Plasma	Analytical Measuring Ranges Serum/Plasma Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
Antistreptolysin-O (ASO-)	25-800 IU/mL	640-1600 IU/mL	25-800 IU/mL	640-1600 IU/mL
Apolipoprotein A (ApoA)	25-300 mg/dL	NA	0.25-3.00 g/L	NA
Apolipoprotein B (ApoB)	35-300 mg/dL	NA	0.35-3.00 g/L	NA
Aspartate Aminotransferase (AST)	5-400 IU/L	350-2600 IU/L	0.1-6.7 $\mu$ kat/L	5.8-43.0 $\mu$ kat/L
Blood Urea Nitrogen	5-100 mg/dL	NA	1.8-35.7 mmol/L	NA
Carbamazepine	2-20 $\mu$ g/mL	NA	8.5-84.6 $\mu$ mol/L	NA
Cholesterol	5-750 mg/dL	600-1000 mg/dL	0.13-19.43 mmol/L	15.54-25.90 mmol/L
Compliment C3	10-350 mg/dL	NA	100-3500 mg/L	NA
Compliment C4	5-120 mg/dL	NA	50-1200 mg/L	NA
C-Reactive Protein	0.5-20 mg/dL	15.0-48.8 mg/dL	5.0-200.0 mg/L	150.0-488.0 mg/L
High Sensitivity C-Reactive Protein	0.02-8.0 mg/dL	6.0-38 mg/dL	0.2-80.0 mg/L	60-380.0 mg/L
Creatine Kinase	5-1200 IU/L	860-4100 IU/L	0.1-20.0 $\mu$ kat/L	14.3-.68.3 $\mu$ kat/L
Creatinine (CR-S)	0.3-25 mg/dL	NA	27-2210 $\mu$ mol/L	NA
Creatinine Enzymatic (CR-E)	0.1-25 mg/dL	NA	9-2210 $\mu$ mol/L	NA
Digoxin	0.2-4.5 ng/mL	NA <sup>a</sup>	0.256-5.76 nmol/L	NA
Direct Bilirubin	0.1-10 mg/dL	NA	1.7-171.0 $\mu$ mol/L	NA
HDL (HDL)	5-135 mg/dL	NA	0.13-3.49 mmol/L	NA
Direct LDL (LDLD)	10-550 mg/dL	NA	0.26-14.2 mmol/L	NA
Ethanol (ETOH)	5-600 mg/dL	NA	1.1-130 mmol/L	NA
Gamma Glutamyl Transferase (GGT)	5-750 IU/L	550-3000 IU/L	0.1-12.5 $\mu$ kat/L	9.2-50.0 $\mu$ kat/L
Gentamicin	0.5-12 $\mu$ g/mL	NA	1.0-25.1 $\mu$ mol/L	NA
Glucose (Hexokinase, GLUH)	5-700 mg/dL	NA	0.3-38.8 mmol/L	NA
Haptoglobin	15-300 mg/dL	1.0-25 mg/dL 240.0-1200 mg/dL	150-3000 mg/L	10-25 mg/L 2400-12000 mg/L

**Table 3.2** Synchron CC Chemistries Serum/Plasma Analytical Measuring Ranges (Continued)

Cartridge Chemistry (CC) Serum/Plasma	Analytical Measuring Ranges Serum/Plasma Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
HbA1c-/HbA1c3	Hb-/Hb3: 6-24 g/dL A1c-/A1c3: 0.3 g/dL-Cal 5 %HbA1c: 4 - 17%	NA	Hb-/Hb3: 3.7 - 14.9 mmol/L A1c-/A1c3: 0.19 – Cal 5 mmol/L %HbA1c: 4 - 17%	NA
IBCT Total Iron Binding Capacity	10-1000 µg/dL	NA	1.8-179.1 µmol/L	NA
Immunoglobulin A	40-700 mg/dL	6.50 mg/dL 560-8000 mg/dL	0.4-7.0 g/L	0.06-0.5 g/L 5.6-80.0 g/L
Immunoglobulin G	200-3200 mg/dL	2560-12,000 mg/dL	2.0-32.0 g/L	25.6-120.0 g/L
Immunoglobulin M	25-2400 mg/dL	1920-12,000 mg/dL	0.3-24.0 g/L	19.2-120.0 g/L
Iron (FE)	5-500 µg/dL	NA	0.9-89.5 µmol/L	NA
Lactate (LACT)	2.7-98.2 mg/dL	NA	0.3-11.0 mmol/L	NA
Lactate Dehydrogenase (LD)	5-750 IU/L	600-2700 IU/L	0.1-12.5 µkat/L	10.0-45.0 µkat/L
Lactate Dehydrogenase (LD-P)	20-2500 IU/L	1800-3800 IU/L	0.3-41.7 µkat/L	30.0-63.3 µkat/L
Lipase (LIP)	10-200 U/L	180-400 U/L	0.17-3.40 µkat/L	3.06-6.80 µkat/L
Lithium	0.06 - 3.0 mmol/L	3.0-7.0 mmol/L	0.06-3.0 mmol/L	3.0-7.0 mmol/L
Magnesium	0.1-7 mg/dL	NA	0.04-2.88 mmol/L	NA
p-Amylase (PAM)	7-600 U/L	480-1800 U/L	0.12-10 µkat/L	8-30 µkat/L
Phenobarbital (PHE)	5-80 µg/mL	NA	21.5-345.0 µmol/L	NA
Phenytoin (PHY)	2.5-40 µg/mL	NA	9.9-158.4 µmol/L	NA
Phosphorus (PHS)	1-12 mg/dL	NA	0.3-3.9 mmol/L	NA
Prealbumin	2-60 mg/dL	NA	20-600 mg/L	NA
Salicylate	4-100 mg/dL	NA	0.3-7.2 mmol/L	NA
T-Uptake (TU)	Calibrator Dependent	NA	Calibrator Dependent	NA
Theophylline	2-40 µg/mL	NA	11.1-222.0 µmol/L	NA
Thyroxine (T4)	2 µg/dL-High Cal Value	NA	25.8 mmo/L-High Cal Value	NA
Tobramycin	0.5-12 µg/mL	NA	1.1-25.7 µmol/L	NA
Total Bilirubin	0.1-30 mg/dL	NA	1.7-513.0 µmol/L	NA

**Table 3.2** Synchron CC Chemistries Serum/Plasma Analytical Measuring Ranges (*Continued*)

Cartridge Chemistry (CC) Serum/Plasma	Analytical Measuring Ranges Serum/Plasma Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
Total Protein	3.0-12 g/dL	NA	30-120 g/L	NA
Transferrin	70-850 mg/dL	NA	0.7-8.5 g/L	NA
Triglyceride	10-1000 mg/dL	NA	0.1-11.3 mmol/L	NA
Urea	10.7-213.8 mg/dL	NA	1.8-35.7 mmol/L	NA
Uric Acid	0.5-12 mg/dL	9.0-21 mg/dL	30-714 $\mu$ mol/L	536-1250 $\mu$ mol/L
Valproic Acid	10-150 $\mu$ g/mL	NA	69-1040 $\mu$ mol/L	NA
Vancomycin	3.5-40 $\mu$ g/mL	30-60 $\mu$ g/mL	2.4-27.6 $\mu$ mol/L	20.7-41.4 $\mu$ mol/L

a. NA = Not Applicable

## Urine Analytical Measuring Ranges – Synchron Systems

**Table 3.3** Synchron MC Chemistries Urine Analytical Measuring Ranges

Modular (MC) Chemistry Urine	Analytical Measuring Ranges Urine Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
Blood Urea Nitrogen (1:10 Dilution) (BUNm)	10-1500 mg/dL	1300-3000 mg/dL	3.57-535.7 mmol/L	464.3-1071.4 mmol/L
Calcium	2-30 mg/dL	NA <sup>a</sup>	0.5-7.5 mmol/L	NA
Chloride	15-300 mmol/L	NA	15-300 mmol/L	NA
Creatinine (CREm)	10-400 mg/dL	NA	0.88-35.36 mmol/L	NA
Glucose (Oxidase) (GLUCm)	10-600 mg/dL	300-1200 mg/dL	0.55-33.3 mmol/L	16.7-66.7 mmol/L
Phosphorus (1:10 Dilution) (PHOSm)	5-140 mg/dL	NA	1.6-45.5 mmol/L	NA
Potassium	2-300 mmol/L	NA	2-300 mmol/L	NA
Sodium	10-300 mmol/L	NA	10-300 mmol/L	NA
Urea (1:10 Dilution) (UREAm)	10-1500 mg/dL	1300-3000 mg/dL	3.57-535-7 mmol/L	464.3-1071.4 mmol/L

a. NA = Not Applicable

**Table 3.4** Synchron CC Chemistries Urine Analytical Measuring Ranges

Cartridge (CC) Chemistry Urine	Analytical Measuring Ranges Urine Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
Alcohol (ETOH)	5-600 mg/dL	NA	1.1-130 mmol/L	NA
Amylase G7 (AMY7)	5-1200 U/L	1000-2000 U/L	0.08-20.0 $\mu$ kat/L	16.67-33.34 $\mu$ kat/L
Blood Urea Nitrogen (BUN)	50-1000 mg/dL	NA <sup>a</sup>	17.9-357.0 mmol/L	NA
Creatinine (CR-S)	10-400 mg/dL	NA	884-35360 $\mu$ mol/L	NA
Creatinine Enzymatic (CR-E)	10-400 mg/dL	NA	884-35360 $\mu$ mol/L	NA
Glucose (Hexokinase, GLUH)	5-700 mg/dL	NA	0.3-38.8 mmol/L	NA
Magnesium	1-70 mg/dL	NA	0.4-28.8 mmol/L	NA
MicroAlbumin	0.2-30 mg/dL	24-97 mg/dL	2-300 mg/L	240-970 mg/L
Micro Total Protein (M-TP)	6-150 mg/dL	NA	0.06-1.50 g/L	NA
p-Amylase (PAM)	7-600 U/L	480-1800 U/L	0.12-10 $\mu$ kat/L	8-30 $\mu$ kat/L
Phosphorus (PHS)	10-120 mg/dL	NA	3.2-38.7 mmol/L	NA
Urea	107.2-2138.4 mg/dL	NA	17.9-357.0 mmol/L	NA
Uric Acid	5-120 mg/dL	NA	300-7140 $\mu$ mol/L	NA

## CSF Analytical Measuring Ranges- Synchron Systems

**Table 3.5** Synchron CSF Analytical Measuring Ranges

Modular Chemistry (MC) and Cartridge (CC) Chemistry CSF	Analytical Measuring Ranges CSF Chemistry			
	Conventional Units (CU)	ORDAC (CU)	International Units (SI)	ORDAC (SI)
Chloride MC	50-200 mmol/L	NA <sup>a</sup>	50-200 mmol/L	NA
Glucose (Oxidase) (GLUCm) MC	3-600 mg/dL	300-1200 mg/dL	0.55-33.3 mmol/L	16.7-66.7 mmol/L
Total Protein (TPm) MC	10-1500 mg/dL	NA	100-15000 mg/L	NA
Glucose (Hexokinase) (GLUH) CC	5-700 mg/dL	NA	0.3-38.8 mmol/L	NA
Lactate (LACT) CC	2.7-98.2 mg/dL	NA	0.3-11.0 mmol/L	NA
Micro Total Protein (M-TP) CC	6-300 mg/dL	NA	0.06-3.0 g/L	NA

a. NA = Not Applicable

Refer to UDR package inserts for Analytical Measuring Range information.

## Serum/Plasma Analytical Measuring Ranges - AU/DxC AU Systems

**Table 3.6** AU/DxC AU Serum/Plasma Analytical Measuring Ranges

<b>AU Analytical Measuring Ranges Serum/Plasma Chemistry</b>		
<b>Conventional</b>	<b>TEST NAME</b>	<b>SI</b>
20-200 mg/dL	<b>α-1-Acidglycoprotein</b>	0.2-2 g/L
30-500 mg/dL	<b>α-1-antitrypsin</b>	0.3-5 g/L
0.1-200 µg/mL	<b>Acetaminophen</b>	0.7-1324 µmol/L
1.5-6.0 g/dL	<b>Albumin</b>	15-60 g/L
5-1500 IU/L	<b>Alkaline Phosphatase</b>	0.1-25.0 µkat/L
3-500 IU/L	<b>Alanine Aminotransferase</b>	0.05-8.33 µkat/L
2.5-50 µg/mL	<b>Amikacin</b>	4.3-85.5 µmol/L
10-2000 U/L	<b>Amylase</b>	0.2-33.3µkat/L
40-250 mg/dL	<b>Apolipoprotein A1</b>	0.4-2.5 g/L
40-200 mg/dL	<b>Apolipoprotein B</b>	0.4-2.0 g/L
100-1000 IU/mL	<b>Anti-Streptolysin O</b>	100-1000 IU/mL
3-1000 U/L	<b>Aspartate Aminotransferase</b>	0.05-16.7 µkat/L
0.05-1.6 mg/dL	<b>β-2-Microglobulin</b>	0.0005-0.016 g/L
2-45 mEq/L	<b>Bicarbonate</b>	2-45 mmol/L
0-10 mg/dL	<b>Bilirubin, D (OSR6x11)</b>	0-171 µmol/L
0.05-10 mg/dL	<b>Bilirubin, D (OSR6x181)</b>	0.9-171 µmol/L
0-30 mg/dL	<b>Bilirubin, T</b>	0-513 µmol/L
15-500 mg/dL	<b>Complement 3</b>	0.15-5.0 g/L
8-150 mg/dL	<b>Complement 4</b>	0.08-1.5 g/L
1-30 µg/mL	<b>Caffeine</b>	5-155 µmol/L
4-18 mg/dL	<b>Calcium Arsenazo</b>	1-4.5 mmol/L
*-20 µg/mL	<b>Carbamazepine</b>	*-84.6 µmol/L
60-2000 mg/L	<b>Ceruloplasmin</b>	6-200 mg/dL
50-200 mEq/L	<b>Chloride</b>	50-200 mmol/L
25-700 mg/dL	<b>Cholesterol</b>	0.6-18.1 mmol/L
1-15 kU/L	<b>Cholinesterase</b>	17-250 µkat/L
10-2000 U/L	<b>Creatine Kinase</b>	0.17-33.3 µkat/L

**Table 3.6** AU/DxC AU Serum/Plasma Analytical Measuring Ranges (Continued)

<b>AU Analytical Measuring Ranges Serum/Plasma Chemistry</b>		
<b>Conventional</b>	<b>TEST NAME</b>	<b>SI</b>
10-2000 U/L	<b>Creatine Kinase MB</b>	0.17-33.3 $\mu$ kat/L
0.2-25.0 mg/dL	<b>Creatinine</b>	18-2210 $\mu$ mol/L
5-300 mg/L	<b>C-Reactive Protein (OSR6x47)</b>	0.5-30 mg/dL
AU480/680: 0.2 to 160 mg/L AU5800/DxC AU: 0.2 to 80 mg/L	<b>CRP High Sensitivity</b>	AU480/680: 0.02 to 16 mg/dL AU5800/DxC AU 0.02 to 8 mg/dL
*-480 mg/L	<b>CRP Normal (OSR6x99)</b>	*-48 mg/dL
0.25-8.0 $\mu$ g FEU/mL	<b>D-Dimer</b>	0.25-8.0 $\mu$ g FEU/mL
*-5.0 ng/mL	<b>Digoxin</b>	*-6.4 nmol/L
0.5-8 $\mu$ g/mL	<b>Disopyramide</b>	1.5-23.6 $\mu$ mol/L
10-150 $\mu$ g/mL	<b>Ethosuximide</b>	71-1062 $\mu$ mol/L
8-450 ng/mL	<b>Ferritin</b>	8-450 $\mu$ g/L
0.25-10 $\mu$ g/mL	<b>Gentamicin</b>	0.5-20.9 $\mu$ mol/L
3-1200 U/L	<b>Gamma-Glutamyltransferase</b>	0.05-20 $\mu$ kat/L
30- 400 mg/dL	<b>Haptoglobin</b>	0.3-4.0 g/L
4-15 %	<b>Hemoglobin A1c (B00389)</b>	20-140 mmol/mol
2.5-200 mg/dL	<b>HDL Cholesterol</b>	0.07-5.17 mmol/L
10-700 mg/dL	<b>Immunoglobulin A</b>	0.1-7.0 g/L
20-500 IU/mL	<b>Immunoglobulin E</b>	20-500 IU/mL
75-3000 mg/dL	<b>Immunoglobulin G</b>	0.75-30 g/L
20-500 mg/dL	<b>Immunoglobulin M</b>	0.2-5.0 g/L
10-1000 $\mu$ g/dL	<b>Iron</b>	1.8-178.6 $\mu$ mol/L
2-90 mg/dL	<b>Lactate</b>	0.2-10 mmol/L
25-1200 U/L	<b>Lactate Dehydrogenase</b>	0.4-20.0 $\mu$ kat/L
7-400 mg/dL	<b>LDL Cholesterol</b>	0.2-10.3 mmol/L
1-12 $\mu$ g/mL	<b>Lidocaine</b>	4.3-51.2 $\mu$ mol/L
3-600 U/L	<b>Lipase</b>	0.05-10 $\mu$ kat/L
0.5-8.0 mg/dL	<b>Magnesium</b>	0.2-3.3 mmol/L

**Table 3.6** AU/DxC AU Serum/Plasma Analytical Measuring Ranges (Continued)

<b>AU Analytical Measuring Ranges Serum/Plasma Chemistry</b>		
<b>Conventional</b>	<b>TEST NAME</b>	<b>SI</b>
0.3-2.0 µmol/L	<b>Methotrexate</b>	0.3-2.0 µmol/L
*-16 µg/mL	<b>N-Acetylprocainamide</b>	*-57.8 µmol/L
*-80 µg/mL	<b>Phenobarbital</b>	*-345 µmol/L
*-40 µg/mL	<b>Phenytoin</b>	*-158 µmol/L
1-20 mg/dL	<b>Phosphorus (Inorganic)</b>	0.3-6.5 mmol/L
1-10 mEq/L	<b>Potassium</b>	1-10 mmol/L
3-80 mg/dL	<b>Prealbumin</b>	0.03-0.80 g/L
2.5-20 µg/mL	<b>Primidone</b>	11-92 µmol/L
*-12 µg/mL	<b>Procainamide</b>	*-51 µmol/L
3-12 g/dL	<b>Protein, Total</b>	30-120 g/L
*-8 µg/mL	<b>Quinidine</b>	*-25 µmol/L
10-120 IU/mL	<b>Rheumatoid Factor</b>	10-120 IU/mL
*-80 mg/dL	<b>Salicylic Acid</b>	*-5792 µmol/L
50-200 mEq/L	<b>Sodium</b>	50-200 mmol/L
*-40 µg/mL	<b>Theophylline</b>	*-222 µmol/L
*-10 µg/mL	<b>Tobramycin</b>	*-21.4 µmol/L
75-750 mg/dL	<b>Transferrin</b>	0.75-7.5 g/L
10-1000 mg/dL	<b>Triglyceride</b>	0.1-11.3 mmol/L
2-130 mg/dL	<b>Urea Nitrogen</b>	0.7-46.4 mmol/L
1.5-30 mg/dL	<b>Uric Acid</b>	89-1785 µmol/L
55-450 µg/dL	<b>Unsaturated Iron Binding Capacity</b>	9.8-80.4 µmol/L
*-150 µg/mL	<b>Valproic Acid</b>	*-1040 µmol/L
2-50 µg/mL	<b>Vancomycin</b>	1.3-34 µmol/L

\*Analyzer model specific. Refer to Instructions for Use or Application Sheet.

For third party reagents, refer to supplier's package inserts for Analytical Measuring Range information.

## Urine Chemistry Analytical Measuring Ranges- AU/DxC AU Systems

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**Table 3.7** AU/DxC AU Urine Analytical Measuring Ranges

<b>AU Analytical Measuring Ranges Urine Chemistry</b>		
<b>Conventional</b>	<b>TEST NAME</b>	<b>SI</b>
10-1500 U/L	<b>Amylase</b>	0.1-25 $\mu$ kat/L
0.1-40 mg/dL	<b>Calcium Arsenazo</b>	0.025-10 mmol/L
15-400 mEq/L	<b>Chloride</b>	15-400 mmol/L
1-300 mg/dL	<b>Creatinine</b>	88-26520 $\mu$ mol/L
10-700 mg/dL	<b>Glucose</b>	0.6-39 mmol/L
0.5-10.0 mg/dL	<b>Magnesium</b>	0.2-4.1 mmol/L
10-200 mg/dL	<b>Phosphorus (Inorganic)</b>	3.2-64.5 mmol/L
2.0-200 mEq/L	<b>Potassium</b>	2.0-200 mmol/L
4-200 mg/dL	<b>Protein</b>	0.04-2 g/L
10-400 mEq/L	<b>Sodium</b>	10-400 mmol/L
20-1300 mg/dL	<b>Urea Nitrogen</b>	7-464 mmol/L
1-100 mg/dL	<b>Uric Acid</b>	60-5950 $\mu$ mol/24 hrs
7-450 mg/dL	<b>Urine/CSF Albumin</b>	0.7-45 mg/dL

For third party reagents, refer to supplier’s package inserts for Analytical Measuring Range information.

## CSF and Whole Blood Chemistry Analytical Measuring Ranges- AU/DxC AU Systems

**Table 3.8** AU/DxC AU CSF Analytical Measuring Ranges

<b>AU Analytical Measuring Ranges CSF Chemistry</b>		
<b>Conventional</b>	<b>TEST NAME</b>	<b>SI</b>
10-800 mg/dL	<b>Glucose</b>	0.6-44.4 mmol/L
2-50 mg/dL	<b>Immunoglobulin G</b>	0.02-0.50 g/L
2-90 mg/dL	<b>Lactate</b>	0.2-10 mmol/L
4-200 mg/dL	<b>Protein</b>	0.04-2 g/L
10-450 mg/dL	<b>Urine/CSF Albumin</b>	1.0-45 mg/dL

**Table 3.9** DxC AU Whole Blood Analytical Measuring Range(s)

<b>DxC AU Analytical Measuring Range(s) Whole Blood Chemistry</b>		
<b>NGSP</b>	<b>TEST NAME</b>	<b>IFCC</b>
4-15% HbA1c	<b>HbA1c Advanced (B93009)</b>	20-140 mmol/mol HbA1c

# Linearity Study

Beckman Coulter System: \_\_\_\_\_ SN: \_\_\_\_\_ Date: \_\_\_\_\_

Analyte: \_\_\_\_\_ Analytical Measuring Range: \_\_\_\_\_

Sample Level	Expected/ Factor	Rep 1	Rep 2	Rep 3	Comments

Analyte: \_\_\_\_\_ Analytical Measuring Range: \_\_\_\_\_

Sample Level	Expected/ Factor	Rep 1	Rep 2	Rep 3	Comments

Analyte: \_\_\_\_\_ Analytical Measuring Range: \_\_\_\_\_

Sample Level	Expected/ Factor	Rep 1	Rep 2	Rep 3	Comments



## Method Comparison/Correlation Protocol

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### Protocol

The sample population should cover the entire Analytical Measuring Range (AMR).

- To accomplish the above, samples should be saved for non-naturally occurring analytes. For other analytes, it may be necessary to either spike or dilute a sample. Refer to the appropriate Beckman Coulter Clinical Systems Chemistry Information Sheet (CIS) / Reagent *Instructions for Use* (IFU) for the appropriate system diluent. Note on the worksheet if the sample was altered.
- Particular attention should be made to keep the spiked or diluted sample matrix as close to the original sample matrix as possible.
- Controls, Survey material, or standards should not be used as samples, but may be used for spiking or diluting samples.

Use split samples to ensure samples run at the same time on each instrument.

The sample population should include abnormal low, abnormal high, and normal range patients. Evaluate data and rerun samples with discrepant values on both instruments to determine the correct values. Always investigate the results (that is, patient diagnosis, drugs, sample integrity, was the sample “spiked” with outside material).

Method Comparison: When current and comparative methods are the equivalent, that is, replacing existing AU Systems or Synchron Systems, a minimum of 20-25 samples are analyzed covering the AMR. Refer to Westgard and Data Innovations.

Method Comparison: When current and comparative methods are different, a minimum of 40 samples are analyzed covering the AMR. Refer to CLSI EP09c.

During data analysis, the reference method is considered the comparative system currently in use in the laboratory. Reference method is labeled 'X'. Beckman Coulter method is labeled 'Y'.

## Terminology for Correlation/Method Comparison Studies

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### Terminology

A correlation study is the evaluation of samples to determine the equivalency of two methods or instrument systems. The same samples are run on both systems and a correlation graph is made of the values obtained. Conventionally, the values from the reference method/system go on the X axis and the values from the new or test method/system go on the Y axis.

A regression analysis is performed to determine the best linear relationship between two variables. A correlation study uses Demming Regression – a statistical analysis that distributes error evenly to X and Y values. A regression analysis comparing two methods is expressed in the form of a linear equation:

$$Y = mX + b$$

m = Slope

b = y-intercept

#### **Slope (m)**

Ratio of Y units to X units.

Provides the angle of the best fit line of the graph.

Deviation from a slope of 1 (ideal condition) defines the amount of proportional error.

It is industry practice to have an acceptable Slope equal to  $1.0 \pm 0.1$  [acceptable range 0.9 to 1.1].

#### **Intercept (b)**

The point where the regression line falls on the Y axis, or where the X value is zero.

Deviation from intercept of zero defines amount of constant error.

#### **Correlation Coefficient (R)**

Indicates the degree of agreement between the two variables or sets of data.

Calculated as a range between -1 and 1.

Equal to 1 when all the data points fall directly on the regression line.

Proportional to random error, it decreases as random error increases.

#### **Standard Error of Estimate (S.E.E.)**

"Standard deviation of the residual" and indicates the dispersion of the data points about the regression line.

Residual is the difference between the actual Y for any X and the calculated Y from the regression line.

Standard error is expressed in units of concentration having an ideal value of zero.

Deviation from the ideal is representation of the random error between methods.

## Patient Correlation Data Worksheet

Beckman Coulter System: \_\_\_\_\_

SN: \_\_\_\_\_ # Reference System: \_\_\_\_\_

Reagent Lot #: \_\_\_\_\_ Reagent Lot #: \_\_\_\_\_

Calibrator Lot #: \_\_\_\_\_ Calibrator Lot #: \_\_\_\_\_

Reference Range: \_\_\_\_\_ Reference Range: \_\_\_\_\_

Analytical Range: \_\_\_\_\_ Analytical Range: \_\_\_\_\_

Sample #	Reference System	Beckman Coulter System	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			



# Beckman Coulter Clinical System DATs

## Drugs of Abuse Chemistries

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### DAT Testing – Synchron Systems

#### Qualitative Cutoff Levels

DAT Synchron Chemistries	Beckman Coulter Cutoff Level ng/mL
Amphetamines (AMPH)	1000
Barbiturates (BARB)	200
Benzodiazepine (BNZG)	200
Cannabinoid 20 ng (THC2)	20
Cannabinoid 50 ng (THC5)	50
Cannabinoid 100 ng (THC)	100
Cocaine Metabolite (COCM)	300
Methadone (METD)	300
Methaqualone (METQ)	300
Opiate (OP)	300
Opiate 2000 ng (OP2)	2000
Phencyclidine (PCP)	25
Propoxyphene (PROX)	300
Buprenorphine (BUPX)	10
Ecstasy (MDMA)	500
Oxycodone (OXYX)	300
Serum Barb (SRBX)	1000
Serum BENZ (SBZX)	50
Tricyclics (STCX)	300

**NOTE** Refer to Chemistry Information Sheets for Semi-Quantitative and Quantitative cutoffs.

## DAT Testing – AU/DxC AU Systems

### Qualitative Cutoff Levels

DAT AU/DxC AU Chemistries	Beckman Coulter Cutoff Level ng/mL
Amphetamines	300, 500, 1000
Barbiturate	200, 300
Barbiturate, Tox	NA <sup>a</sup>
Benzodiazepine	200, 300
Benzodiazepine, Tox	NA
Cannabinoid	20, 50, 100
Cocaine Metabolite	150, 300
Creatinine, Tx	NA
Ecstasy	300, 500
Ethyl Alcohol	NA
LSD	0.5
Methadone	150, 300
Methaqualone	300
Opiates	300, 2000
Oxycodone	100, 300
Phencyclidine	25
Propoxyphene	300
Tricyclics, Tox	NA
6-Acetylmorphine	10
Buprenorphine	5

a. NA = Not Applicable

## Concordance/Method Comparison Protocol

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When assessing quantitative assays, a correlation study is used to evaluate the equivalency of two methods by comparing the recovered results for a sample set. Similarly, when comparing qualitative tests, such as the DAT assays, a concordance study is used. Known positive and negative samples are run on both systems and the results compared. Two systems or assays that agree on all samples are said to be 100% concordant.

- A minimum of 20 and a maximum of 40 specimens should be evaluated using both systems (Beckman Coulter Analyzer and the reference analyzer) at the same time.
- The sample population should include at least 20% positive specimens.
- Use the tables provided on next page for data analysis (refer to table below for an example).
- The positive/positive, negative/negative, and positive/negative sample matches should be summarized for each assay and entered into the Concordance Data Summary sheets.

Example: N = 98 samples

25 Positive/Positive matches

70 Negative/Negative matches

3 positive on the Beckman Coulter Analyzer, Negative on Reference system

Overall Agreement =  $95/98 \times 100 = 97\%$

Example:

Amphetamine		Reference:		
N = 98		POS	NEG	Overall Agreement =
Beckman Coulter System	POS	25	3	97%
	NEG	0	70	

## Drugs of Abuse Concordance Data Summary

Amphetamine		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Barbiturates		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Benzodiazepine		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Cocaine		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Methadone		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Methaqualone		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Opiates		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Phencyclidine		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Cannabinoids		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Buprenorphine		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Ecstasy (MDMA)		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

Oxycodone		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

LSD		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

6-Acetylmorphine		Reference:		
N =		POS	NEG	Overall Agreement =
Beckman Coulter System	POS			
	NEG			

## DAT Concordance Studies

Account: \_\_\_\_\_

Reference: (R) \_\_\_\_\_

Date: \_\_\_\_\_

Beckman Coulter System: (S) \_\_\_\_\_

	Sample ID	AMPH		BARB		BNZG		COCM		METD		METQ		OP		PCP		PROX		THC		Notes
		R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	
1	1234																					
2	1235	+	+																		+	+
3	1236																					
4	1237																				+	+
5	1238	+	-																			AMPH- Borderline
6																						
7																						
8																						
9																						
10																						
11																						
12																						
13																						
14																						
15																						
16																						
17																						
18																						
19																						
20																						
	<b>Total Sample</b>																					

Example

Only Positive results posted in format of Reference/Beckman Coulter System

## DAT Concordance Studies

Account: \_\_\_\_\_

Reference: (R) \_\_\_\_\_

Date: \_\_\_\_\_

Beckman Coulter System: (S) \_\_\_\_\_

	Sample ID	AMPH		BARB		BNZG		COCM		METD		METQ		OP		PCP		PROX		THC				Notes
		R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	
1																								
2																								
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18																								
19																								
20																								
	<b>Total Sample</b>																							

Only Positive results posted in format of Reference/Beckman Coulter System.



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