

Leaders in Laboratory Medicine

Laboratory Bulletin

Date: June 17, 2022

To: Edmonton Zone – Physicians, Nurses, Laboratory Directors, and Managers From: Clinical Biochemistry, North Sector, Alberta Precision Laboratories (APL)

Re: Change in chemistry instruments at University of Alberta Hospital (UAH) and Sturgeon

Community Hospital (SCH)

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Key Messages:

- The newest generation of Roche Cobas Pro chemistry instruments will be implemented across Edmonton Zone urban hospitals (listed in Table 1) in a phased approach to replace current Beckman Coulter or Ortho Vitros instruments. Smaller suburban and rural sites will not be switching to Roche at this time and will remain with current instruments.
- In the first phase, the University of Alberta Hospital will go-live on Tuesday, June 21, 2022 at 11:00 AM, and the Sturgeon Community Hospital will go live on Thursday, June 23, 2022 at 10:00 AM.
- Table 1 outlines the go-live schedule. The Misericordia Community Hospital, the Grey Nuns
 Community Hospital, the Royal Alexandra Hospital, and the Cross Cancer Institute will stay on
 current instruments as an interim state until the designated go-live date. During this interim state,
 beta-hCG and other tests with different reference intervals are not comparable.

Table 1. Roche chemistry instrument implementation schedule in Edmonton Zone.

Site	Current instruments	New instrument	Go-Live date
*UAH	Beckman Coulter	Roche Cobas	June 21, 2022
*SCH	Beckman Coulter	Roche Cobas	June 23, 2022
MCH	Beckman Coulter	Roche Cobas	July 19, 2022
GNH	Beckman Coulter	Roche Cobas	July 21, 2022
RAH	Beckman Coulter	Roche Cobas	End of September, date TBD
CCI	Ortho Vitros	Roche Cobas	TBD

^{*}This bulletin applies to the University of Alberta Hospital and Sturgeon Community Hospital only. Other sites will remain with current instrumentation until designated go-live.

MCH = Misericordia Community Hospital; GNH = Grey Nuns Community Hospital; RAH = Royal Alexandra Hospital; CCI = Cross Cancer Institute

TBD = to be determined

- A number of changes will be adopted when sites switch to Roche instruments: cardiac biomarkers & quantitative beta-hCG test changes (Appendix A), reference interval (RI) changes (Appendix B), measuring unit changes (Appendix C), and blood/urine collection container type changes (Appendix D).
- Results for a number of Roche tests are expected to significantly change due to differences in reagent formulation and/or changes in blood collection container types (Appendix E). Long-term monitoring of patients for these select tests will require re-baselining to establish new trends.

Why this is important:

• This change is part of a large-scale provincial standardization effort to implement Roche chemistry platforms in urban hospital laboratories across Alberta, which will benefit patients by standardizing laboratory practice and reporting components such as tests, reference intervals and comments.

Action Required:

- Be aware of various changes outlined in Appendix A to D with implementation of Roche instruments at University of Alberta Hospital and Sturgeon Community Hospital.
- Be aware of the phased Roche implementation timeline at relevant urban sites and interim state where there will be differences in tests and reference intervals.
- Be aware of varying instruments, tests, and reference intervals across all Edmonton Zone urban, suburban, and rural sites.
- It is recommended to establish a new baseline for a number of Roche tests listed in Appendix E.
- Ordering in Epic will not be affected despite switch to new instruments.

Inquiries and feedback may be directed to:

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This bulletin has been reviewed and approved by:

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Appendix A: Changes to cardiac biomarkers and beta-hCG (see Table A)

Troponin T, high sensitivity

- The Roche high sensitivity troponin T (hs-TnT) assay will replace the Beckman high sensitivity troponin I (hs-TnI) assay. A new rapid chest pain protocol will also be implemented. See hs-TnT Survival Guide for further details.
- Results for hs-TnT are extremely different from hs-TnI and conventional troponin assays used at other suburban/rural sites in Edmonton and cannot be used interchangeably.
- When ordering troponin, the test will default to the local site test, which is hs-TnT. The Epic test order name remains the same ("Troponin").

Natriuretic Peptides (BNP or NT-ProBNP)

- The Roche NT-proBNP assay will replace the Beckman BNP assay.
- Results for NT-proBNP are extremely different from BNP and cannot be used interchangeably.
- When ordering natriuretic peptides, the test will default to the local site test, which is NT-proBNP. The Epic test order name remains the same ("B-Natriuretic Peptide (BNP or NT-ProBNP)").
- Outpatient and community BNP samples collected at DynaLIFE or suburban rural centers within Edmonton Zone will be sent to the University of Alberta Hospital for NT-proBNP testing.

Beta-hCG

- The Roche beta-hCG assay is the same assay used at DynaLIFE, which will now allow serial monitoring between hospital and community settings.
- Suburban and rural sites that test hCG on-site will remain with the Beckman assay. Beckman and Roche results will not trend in Epic.
- This effectively solves the long-standing problem in the Edmonton Zone where the hospital and DynaLIFE assays were not interchangeable, and could not be used to directly monitor levels.

Table A: Summary of changes to cardiac biomarkers and hCG.

Test (units)	Ordering name	New RIs or critical limits	Notes
hs-TnT (ng/L)	Troponin	RI: <14 Critical limit (only phoned for outpatient/community results): >52	 See <u>hs-TnT Survival Guide</u> for rule in and rule out pathway. Results differ significantly from hs-TnI and other conventional troponin assays and should not be used interchangeably. Blood collection container type will not change Barricor lithium heparin plasma.
NT-proBNP (ng/L)	B-Natriuretic Peptide (BNP or NT- ProBNP)	<1 y: 54-556 1 to <2 y: 39-578 2 to <6 y: 20-565 6 to <12 y: 10-340 12 to <18 y: 6-216 ≥18 y: 0-300	 Results differ significantly from BNP and should not be used interchangeably. Blood collection container type will change from lavender top EDTA tubes to green top lithium heparin plasma (see Appendix D).
hCG (IU/L)	Beta hCG, quantitative	No change	 The Roche assay is the same assay used at DynaLIFE and will allow serial monitoring of results between hospital and community settings. The Beckman assay will remain in use at the suburban and rural sites that test hCG on-site. These assays will not trend in Epic.

RI = reference interval

y = Years

Appendix B: Changes to reference intervals (RIs)

Table B1. Changes to RIs for tests performed at UAH and SCH.

		Current RI		New standardized RI			
Test (units)	Age	Gender (M,F,U,X)	RI	Age	Gender (M,F,U,X)	RI	
	<18 y	All	<35	<18 y	All	<40	
ALT (U/L)	≥18 y	M/U/X	<60	≥18 y	M/U/X	<70	
	≥18 y	F	<40	≥18 y	F	<50	
Anion gap (mmol/L)	All	All	5 – 10	All	All	4 – 16	
	<30 d	All	<100	<30 d	All	<115	
	30 d - <1 y	All	<70	30 d – <1 y	All	<80	
AST (U/L)	1 - <6 y	All	<50	1 – <7 y	All	<60	
	7 - <18 y	All	35	7 – <18 y	All	<45	
	≥18 y	M/U/X	<45	≥18 y	M/U/X	<55	
	≥18 y	F	<35	≥18 y	F	<45	
Bilirubin, conjugated (µmol/L)	All	All	Critical limit for <31 d: >18	All	All	No critical limit	
Natriuretic peptides (ng/L)	 Test will change from BNP to NT-proBNP. See Appendix A 						
Lingae (LL/L)	All	All	≤60	<16 y	All	≤60	
Lipase (U/L)				≥16 y	All	≤80	
Total protein,	All	All	0.15 –	≤30 d	All	0.14 – 1.12	
CSF (g/L)	All	All	0.45	≥30 d	All	0.15 – 0.45	
Troponin T, hs (ng/L)	Test will of See Appears	change from hs-TnI to h endix A	ıs-TnT				

M = Male; F = Female; U = Unknown; X = non-binary

d= Days; m=Months; y= Years

RIs = reference intervals

Table B2: Changes to RIs for tests performed at UAH.

	Current RI			New standardized RI		
Test (units)	Age	Gender (M,F,U,X)	RI	Age	Gender (M,F,U,X)	RI
Amylase (U/L)	All	All	30 – 150	All	All	30 – 110
C3 (g/L)	All	All	0.80 - 2.10	All	All	0.60 - 1.60
C4 (g/L)	All	All	0.15 - 0.50	All	All	0.10 - 0.40
Estradiol		to see Bulletin etive Commer		3, 2022: <u>Stanc</u>	dardization of	Estradiol Reference Intervals
				<2y		<8
	<10 y		<6.0	2 – <6y		<5
				6 – 10y		<4
FSH (IU/L)	≥10 y	F	Follicular: <7.0 Luteal: <7.0 Midcycle peak: 4.0 – 15.0 Postmenopausal: 16.0 – 80.0	≥11y	F	Follicular: <2 – 10 Luteal: <1 – 9 Midcycle peak: 3 – 33 Postmenopausal; 23 – 116
				<11y		<3
	All	М	<7.0	11 – <13y	М	<9
				≥13y		1-18
	<12 m		0.10 - 1.29	1 d – <3m		<1.21
	12 – 23 m	All	0.20 – 1.75	3 – <6 m	All	0.05 – 1.20
	2y		0.22 - 2.20	6m – <1y		0.10 – 1.20
	3 – 6 y		0.43 - 2.60	1 y		0.20 - 1.60
IgA (g/L)	7 –9 y		0.51 – 2.97	2 y		0.30 - 2.00
3 (3)	10 – 12 y		0.44 - 3.15	3 – <6 y		0.35 – 2.40
	13 –18 y		0.44 - 3.91	6 – <8y		0.40 - 2.80
	,			8 – <11y		0.45 – 3.20
	>18 y		0.70 - 4.00	11 – <16y		0.50 - 3.80
				≥16y		0.60 - 4.20
				1 d – < 3m		2.60 - 14.00
	<2 y		2.80 -14.80	3m – <1y		2.80 - 16.00
	-			1 – <3 y		4.00 – 16.00
IaC (a/L)	2 – 4 y	All	3.20 -15.60	3 – <6 y		5.40 - 16.00
IgG (g/L)	E 10 v		F 20 4F 00	6 – <8 y	All	5.80 - 16.00
	5 –18 y		5.30 – 15.90	8 – <11 y		6.20 - 17.00
				11 – <16 y		6.40 -17.00
	> 18 y		6.94 – 16.18	≥16 y		6.80 – 18.00
	< 1 y		0.12 – 1.25	< 5m		0.14 – 1.40
	1 – 4 y		0.20 - 1.96	5m – <4y] [0.20 - 1.60
IaM (a/L)	5 – 7 y	All	0.32 - 1.63	4 – <7 y		0.20 – 2.10
IgM (g/L)	8 – 18 y	All	0.48 - 2.26	7y – <12y	All	0.30 – 2.10
	>18 y		0.60 - 3.00	12y - <20y	[0.30 - 2.40
	>10 y		0.00 – 3.00	≥ 20 y		0.40 - 3.00
				0 – <3d		1.1 – 6.7
Lactate, CSF				3 –<11d] [1.1 – 4.4
(mmol/L)	All All	<2.8	≥11d	All	1.1 – 2.4	

	<2 y		180 – 430	1 d – <5 y	Δ.11	125 – 320
LD (U/L)	2 – <12 y	All	110 – 300	6 - <10 y	All	125 – 300
LD (O/L)	≥12 y		100 – 225	11 – <15 y		115 – 260
	≥12 y		100 – 223	≥16 y		100 – 235
	<10y		<10.0	<11y		0 – 6
LH (IU/L)	≥10y	F	Follicular: <15.0 Luteal: <15.0 Mid-cycle peak: 30.0-100.0 Postmenopausal: <3.0	≥11y	F	Follicular: 1 – 13 Luteal: 1 – 17 Mid-cycle peak: 8 – 76 Postmenopausal: 16 – 54
	<10y		<10.0	<11y		0 – 6
	≥10y M	M	<12.0	11 – <71 y ≥71 y	М	1 – 9 3 – 35
Prealbumin (g/L)	All	All	0.100 - 0.400	All	All	0.200 – 0.400
	All		<7.0	<12 y		<0.6
Progesterone (nmol/L)	≥14 y	F	Follicular: <5.0 Luteal: 15.0 – 90.0 Postmenopausal: <3.0	≥12y	F	Follicular: <2.9 Luteal: 5.0 – 76.0 Postmenopausal: <0.6
	All	M	<3.0	All	M	<0.6
Prolactin	<31 d	All	n/a	All	М	4.0 – 15.0
(ug/L)	≥31 d	ΛII	<21	All	F/U/X	4.0 – 25.0
Thyroid function tests (TSH, FT4, and FT3)	Click here to see Bulletin distributed on June 13, 2022: <u>Update to thyroid hormone reference intervals</u> and to the progressive TSH algorithm					

M = Male; F = Female; U = Unknown; X = non-binary

d= Days; m=Months; y= Years

RIs = reference intervals

Appendix C: Changes to measuring units for intraoperative PTH (IOPTH)

Table C: Summary of measuring unit changes for IOPTH

Test	Relevant site	Current units	New units	Notes
IOPTH	UAH	pmol/L	ng/L	 Routine PTH performed at DynaLIFE will temporarily remain with pmol/L until further notice. Be aware of differences in units used across different testing locations.

Appendix D: Changes to default collection container types for select blood and urine collections

Table D1: Summary of changes to default collection container type for ammonia and NT-proBNP.

Test	Site	Current container type	New container type	Notes
Ammonia	All	Lithium heparin plasma (green top tubes)	EDTA plasma (lavender top tubes)	See Appendix E for expected changes to test results due to instrument and container type changes.
NT-proBNP	All	EDTA plasma (lavender top tubes) for BNP	Lithium heparin plasma (green top)	NTpro-BNP will replace BNP as indicated in Appendix A.

Table D2: Changes to default collection container type for 24 hour urine phosphate and magnesium.

Test	Site	Current container type	New container type	Notes
Magnesium, Urine, 24 Hour	All	24 Hr Urine Container – Plain 24 Hr Urine Container – Acid	24 Hr Urine Container – Acid	Specimens must be collected in a container preserved with acid
Phosphate, Urine, 24 Hour	All	24 Hr Urine Container – Plain	24 Hr Urine Container – Acid	Specimens must be collected in a container preserved with acid

Appendix E: Approximate changes expected to results with the new Roche instruments Table E1. Approximate range of result changes across all sites

Test	Approximate range of result changes	Notes
Acetaminophen	-15% to -30%	N/A
ALP	+20% to +30%	See Appendix B for RI changes.
ALT	-5% to +10%	See Appendix B for RI changes.
Ammonia	-5% to -15%	N/A
AST	+10% to +30%	See Appendix B for RI changes.
Bilirubin, conjugated	+20% to +40%	N/A
Bilirubin, total	-5% to -20%	N/A
Chloride	+3 mmol/L	See Appendix B for RI changes.
hCG	-25% to -35%	This is now the same assay used at DynaLIFE and can be used for serial monitoring. See Appendix A.
LD	+20% to +30%	See Appendix B for RI changes.
Lipase	+20% to +45%	See Appendix B for RI changes.
NT-proBNP	+130% to +800%	See Appendix A and B for reporting and RI changes.
Troponin T, high sensitivity	-100% to + 800%	See Appendix A and B for reporting and RI changes.

Table E2. Approximate changes in results for tests performed at UAH.

Test	Approximate result changes	Notes
C4	-25%	See Appendix B for RI changes.
Ferritin	+50%	N/A
Folate	-20%	N/A
FSH	-10%	N/A
Gentamicin	-15%	N/A
GGT	-15%	N/A
LH	+20%	N/A
Prealbumin	-10%	See Appendix B for RI changes.
Prolactin	+30%	See Appendix B for RI changes.
TSH	TSH Click here to see Bulletin distributed of hormone reference intervals and to	
Tobramycin	-25%	N/A
Vitamin B12	+40%	N/A