

**IMPORTANT NOTE**

**6<sup>th</sup> September 2018**

**CHANGE OF MEASURING SYSTEM FOR ROUTINE CHEMISTRY AND IMMUNOASSAY**

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On Sunday 2nd September SydPath changed to new instruments for the majority of routine chemistry and immunoassay testing. The previous system was in use for over 8 years reached end-of-life and was replaced with a system from Beckman-Coulter. There are changes to results for some assays. Reference intervals have also been reviewed. These changes are marked on pathology reports. Where relevant recommended Australian Common Reference Intervals were retained or adopted.

TEST	CHANGE	CURRENT ADULT RI	PROPOSED ADULT RI
Sodium	~1 mmol/L lower	137 – 146	135 – 145 #
Chloride	~3 mmol/L higher	95 – 110 #	No change
Bicarbonate	~2 mmol/L higher	22 – 32 #	No change
Creatinine	No change	M: 60 – 120 umol/L F: 40 – 90 umol/L	M: 60 – 110 umol/L F: 45 – 90 umol/L #
Urea (female)	No change	3.0 – 8.5 mmol/L	<50 years: 3.0 – 7.0 50-69 years: 3.5 – 8.0 70+ years: 4.0 – 9.0 #
Urea (male)	No change	3.0 – 8.5 mmol/L	<50 years: 3.5 – 8.0 50-69 years: 4.0 – 9.0 70+ years: 4.5 – 10.0 #
Total Protein	~3 g/L lower	60 – 82 g/L	60 – 80 g/L #
Albumin	~ 4 g/L lower	36 – 52 g/L	33 – 48 g/L
Globulins	~ 1 g/L lower	22 – 38 g/L	15 – 30 g/L
AST	~12% higher	0 – 30 U/L	M: 0 – 35 U/L F: 0 – 30 U/L #
ALT	~12% higher	0 – 30 U/L	M: 0 – 40 U/L F: 0 – 35 U/L #
GGT (female)	~15% higher	0 – 35 U/L	M: 0 – 50 U/L F: 0 – 35 U/L #
Alkaline Phosphatase	~8% higher	19y+: 30 -100 U/L	19y+: 30 – 110 U/L #
Total Bilirubin	~15% higher	0-18 umol/L	1 – 20 umol/L #
Direct Bilirubin	~25% lower	0 – 10 umol/L	0 – 5 umol/L

# RCPA/AACB Australian recommended common reference intervals.

No significant change in results and no change in reference intervals for the following tests:

Serum: Potassium, Glucose, Urate, Iron, Calcium, Magnesium, Phosphate, Transferrin, Amylase, Lipase, Creatine Kinase, LDH, CRP, Lactate, Cholesterol, HDL cholesterol, Triglycerides, eGFR, creatinine clearance, HbA1c, NT-proBNP, therapeutic drugs (eg Gentamicin, Digoxin, Phenytoin, Vancomycin).

Urine and CSF: no change in results for any tests (eg creatinine, protein, albumin, glucose), or testing for urine drugs of abuse.

**IMMUNOASSAY**

TEST	CHANGE	CURRENT ADULT RI	NEW ADULT RI
TSH	~12% lower	0.4 – 4.2 mIU/L	0.4 – 4.8 mIU/L
Free T4	~4 pmol/L lower	11 – 22 pmol/L	8.0 – 16.0 pmol/L
Free T3	Minor changes	3.0 – 6.2 pmol/L	4.0 – 6.0 pmol/L
Ferritin	~ 30 % lower	M: 30 – 400 ug/L F<55y: 15 – 150 ug/L F>55y: 30-400 ug/L	M: 30 – 400 ug/L F<55: 15 – 150 ug/L F>=55y: 30 – 300 ug/L
Vitamin B12 (pmol/L) (active B12 if<200)	~ 25% lower	Deficient: <120 Indeterm'ate: 120-180 Replete: >180 pmol/L	Deficient: <90 Indeterm'ate: 90-140 Replete: >140 pmol/L
Folate – Serum	~10% higher	>8.8 nmol/L	>10 nmol/L
Folate – Red Cell	~ 600 nmol/L lower	>1400 nmol/L	>800 nmol/L
Insulin	~ 20% lower	2 – 15 mIU/L	0 – 15 mIU/L
Prolactin (mU/L)	~ 30% Lower	M: 50 – 350 F: 50 – 500	M: 50 – 300 mU/L F<55: 50 – 500 mU/L F55+: 50 – 300 mU/L
hCG	~ 25% higher	<10 U/L	F<40 & M: 0 - 5 IU/L F>=40: 0 - 10 U/L
4 g/L lower 33 – 48 g/L	Similar values	Follicular: 50 - 800 Mid-cycle: 150 – 1500 Luteal: 150 – 1000 Postmenop: 0 - 100 M: 0 - 150	Follicular: 50 - 420 Mid-cycle: 120 – 2000 Luteal: 130 – 1000 Postmenop: 0 - 100 M: 0 - 150
Progesterone (nmol/L)	Similar values	Mid-follicular: <3.0 Mid-luteal: >20 Postmenopausal: <0.6 M: <0.6	Mid-follicular: 0 - 5.0 Mid-luteal: >15 Postmenop: 0 - 2.5 M: 0 - 6.5
LH (IU/L)	~15% lower	Follicular: 2.4 – 13 Mid-cycle: 14 - 97 Luteal phase: 1 – 12 Postmenop: 7.7 - 60 M: 1.7 – 8.6	Follicular: 2 - 12 Mid-cycle: 15 - 100 Mid-luteal: 1 – 13 Postmenop: 7.0 - 60 M: 1.0 – 9.0
FSH (IU/L)	~10% higher	Follicular: 3.5 – 13 Mid-cycle: 4.7 - 22 Luteal phase: 1.7 – 7.7 Postmenop: 25 - 140 M: 1.5 – 13	Follicular: 4.0 – 9.0 Mid-cycle: 4.0 - 23 Mid-luteal: 1.5 – 5.0 Postmenop: 17 - 115 M: 1.0 – 9.0
SHBG (nmol/L)	~ 25% lower	M 15-49y: 15 – 50 M 50+: 20 – 90 F: 20 - 110	M: 15-49y: 12 – 50 M 50+: 15 - 80 F: 15 - 130
Testosterone (nmol/L)	Concentration dependent	M 18-49: 10 – 32 M 50+: 8 – 32 F: 0 – 1.8	M 18 - 40: 8 – 25 M 40+: 6 – 22 F: 0 – 2.0
Free Testosterone (calculated, pmol/L)	~20% higher	F 18-50y: 0 – 24 F 50+: 0 – 17 M 18-50y: 200 - 700 M 50+: 150 - 400	F 18-50y: 0 – 30 F 50+: 0 – 22 M 18-50y: 200 - 600 M50+: 150 - 500
Free Androgen Index	~25% higher	0 – 4.0	0 – 5.0
Troponin I	Change from Trop'n T		F: 0 – 10 ng/L M: 0 – 20 ng/L
PTH	~ 10% higher	1.5 – 7.0 pmol/L	2.0 – 9.0 pmol/L

## TUMOUR MARKERS

TEST	CHANGE (1)	CURRENT ADULT RI	NEW ADULT RI
AFP	Good correlation. Results ~10% lower	0 – 7.0 ug/L	0 – 9.0 ug/L (2)
CA 125	Some patient-specific variation. Overall similar results.	0 - 35 kU/L	0 – 35 kU/L
CA 15-3	Considerable patient specific variation.	< 30 kU/L	0 – 24 kU/L
CA 19-9	Some patient-specific variation at higher values. Overall similar results.	0 – 34 kU/L	0 – 35 kU/L
CEA	Some patient-specific variation. Overall similar results.	0 – 5 ug/L	0 – 5 ug/L
PSA (3)	Good correlation. Results 0 – 10% higher	Age-related	No change
Free / Total PSA (3)	Good correlation. Similar results.		No change
hCG	Good correlation. Results ~30% higher.	<10 IU/L	F <40y: 0 – 5 IU/L F 40y+: 0 – 10 IU/L M: 0 – 5 IU/L

(1) Due to the use of different detection antibodies in some methods the relationship between results from the two measurement systems may show some patient specific differences as well as some systematic differences for some assays. The table above below summarises the relationship between the new and old methods as well as any change in population reference intervals (RI).

All samples for tumour marker testing from patients with previous results will be measured on both the new and old methods to allow a re-baselining for ongoing monitoring. Samples from patients without previous results will only be measured on the new Beckman-Coulter system.

(2) AFP interval is changed from approximately 95<sup>th</sup> centile of a healthy population to a 99<sup>th</sup> centile.

(3) PSA and free PSA are using the Hybritech calibration. This minimises change in results and is consistent with the current reference intervals.

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