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A SYNLAB pathology partnership

Guy's & St Thomas' Hospital
Blood Sciences Laboratories

15th September 2023

Dear Laboratory user,

Re: Changes to biochemistry lab reporting with EPIC from 5th October 2023

We are writing to inform you that from **05/10/23**, the Synnovis Blood Sciences Laboratories at Guys and St Thomas' sites will be making changes to some tests with the introduction of EPIC electronic health records system**.** In all cases no changes to the analytical methodology or UKAS accreditation will occur. These changes are summarised below:

A full list is available at **www.synnovis.co.uk/gstt-refranges**.

Changes to units

Test	Current Units	New Units
Total Urine Protein	g/L	mg/L
Macroprolactin	Percentage recovery (%) and bioactive monomeric prolactin (mIU/L)	Monomeric prolactin (mIU/L)

New comments

Test	Previous Comment	New Comment
Urine albumin to creatinine ratio (ACR)	NICE CG182 (2014): KDIGO ACR categories in CKD: Normal < 3 Microalbuminuria 3-30 Macroalbuminuria >30	NICE CKD Guidelines NG203: < 3 mg/mmol: normal to mildly increased 3-30 mg/mmol: moderately increased >30 mg/mmol: severely increased
AKI 2 & 3	N/A	Rise in creatinine may indicate Acute Kidney Injury stage (1, 2 or 3). This patient needs to be reviewed urgently. If AKI exists and clinically appropriate please initiate and complete the AKI Pathway (Pathway 2407) as soon as possible.

Macroprolactin	• If monomeric prolactin above reference interval but prolactin recovery ≤60%: **First screen**: suggest repeat to confirm and also request immunoglobulins to exclude rare but possibly confounding effect if they are elevated **Second screen:** This confirms previous positive/equivocal screens on xx.xx.xx. Macroprolactin should be requested whenever prolactin is measured on this patient and the estimated bioactive prolactin used for interpretation.	• If monomeric prolactin above reference interval but prolactin recovery ≤60%: After removal of macroprolactin complexes the estimated monomeric prolactin is above the reference interval. Other causes for hyperprolactinaemia should be investigated.
	• If monomeric prolactin above reference interval but prolactin recovery ≥ 60%: Macroprolactin not detected. The significantly raised prolactin level therefore needs further investigation for both secondary and primary causes.	• If monomeric prolactin above reference interval but prolactin recovery ≥ 60%: No significant amount of macroprolactin complexes present thus the estimated monomeric prolactin result is elevated. Other causes for hyperprolactinaemia should be investigated.
	• Monomeric prolactin within/above reference interval: This is not elevated	• If monomeric prolactin within reference interval: After removal of macroprolactin complexes the estimated monomeric prolactin is within the reference interval. No further investigation is required.
Macroprolactin – if reflexed more than once within a 12 month period	N/A	If the previous result had no significant macroprolactin present the test will be cancelled with the following comment: Test cancelled. Macroprolactin screen not required as previously analysed within last 12 months and found to have no significant macroprolactin present.

New reference intervals

Following an internal review of some of our reference intervals, the below tests will have the following changes.

Test	Current Reference Interval(s)	New Reference Interval(s)
Transferrin saturation (%)	N/A - previously risk related comment: Please note new Abbott transferrin saturation results are not trendable compared to pre-Nov 22. This is a calculated test that now uses direct measurement of transferrin compared to previous use of total iron binding capacity. Transferrin saturation (>45% females, >50% male) with a raised ferritin (>200 mg/L in females, >300 mg/L in males) suggests iron overload (EASL 2010 HFE Hemochromatosis).	20-45
High sensitive Troponin I (ng/L)	No previous paediatric reference ranges Male >19 years: <35 Female >19 years: <16	0 to <6 months: <55.8 6 months to <19 years:<5.5 Male >19 years: <35 Female >19 years: <16
NT pro BNP (ng/L)	No previous paediatric reference ranges	0 to < 1 year: 29.6-1594.0 1 to < 19 years: 11.0-214.0

New equations for three calculated tests

The below tests will be calculated using different formula to previous and so cannot be trended pre and post EPIC go live.

Test	Current formula	New formula
Estimated Glomerular Filtration Rate (eGFR)	4v MDRD	CKD-EPI (2009) minus ethnicity [NG203]
Adjusted calcium	Payne	James
LDL cholesterol	Friedewald	Sampson NIH2

(i) *<u>Change to eGFR calculation explained</u>*

The NICE Chronic kidney disease: assessment and management [NG203] 2021 guidelines recommend the use of the CKD Epidemiology Collaboration creatinine (CKD-EPI) equation to estimate GFR. We will use the 2009 CKD-EPI and not 2021 as this has not been validated in a UK population. Until now we have used the 4 variable Modification of Diet in Renal Disease (MDRD) formula. Several studies have shown that the MDRD equation systematically underestimates the GFR, particularly in low-risk patients with a high-normal serum creatinine

level. This results in the labelling of some people with CKD who do not have significant kidney disease, particularly in the earlier stages of CKD.

As a result of this change in equation please be aware of the following:

- The new equation will more accurately assess eGFR, reducing the over-diagnosis of CKD in low-risk patients and improving diagnostic performance in patients aged over 80 years.
- Serum creatinine results are not affected by this change and will continue to be comparable over time. If the creatinine has not changed significantly, then true renal function will not usually have altered and any eGFR change can be attributed to the change in equation. Likewise, a change in creatinine that is significant could be masked by a seemingly stable eGFR.

(ii) Change to adjusted calcium equation explained

The Payne equation used to calculate adjusted calcium was derived using a bromocresol green (BCG) method for albumin measurement. A clinical review was prompted when the albumin method changed to bromocresol purple (BCP) following the introduction of the Abbott Allinity analysers (November 2022). This review showed that the BCG Payne based formula is not suitable for use with BCP-based albumin methods unlike the James equation which has been externally validated on BCP-based albumin methods as well as on internal GSTT patient data.

(iii) Change to calculated LDL equation explained

LDL cholesterol has historically been calculated using the Friedewald equation, however, this has several limitations and is not valid in samples with triglycerides >4.5 mmol/L. The Sampson-National Institutes of Health 2 equation is more accurate than the Friedewald equation, particularly in patients with low LDL, and can also be used with triglycerides up to 9 mmol/L.

Changes to critical phoning limits

Test	Previous limits	New limits
AKI alerts 2 & 3	N/A	All AKI alerts 2 & 3 will be phoned

Just as a reminder the following reference ranges were changed November 2022 when we went live with the Abbott Alinity analysers and will not be changing.

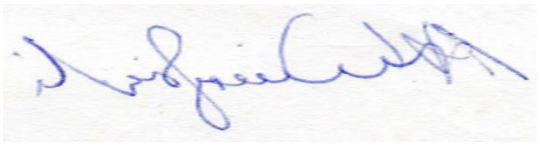
Test	Reference range
Albumin (g/L)	0 to 4 days: 28-44 4days to 14 years: 38-54 15-59 years: 35-50 60-90 years: 32-46

	>90 years: 29-45
Alanine transaminase (U/L)	0-55

The full list is available at www.synnovis.co.uk/gstt-refranges.

Should you have questions related to these changes please do not hesitate to contact us.

Yours faithfully,



Professor Anthony Wierzbicki
Consultant Chemical Pathologist
Department of Blood Sciences
Guys and St Thomas' Hospital
Tony.Wierzbicki@gstt.nhs.uk

Dr Sunita Sardiwal
Consultant Clinical Scientist
Department of Blood Sciences
Guys and St Thomas' Hospital
sunita.sardiwal@gstt.nhs.net