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Dear Colleagues

Laboratory equipment and result changes 10th January 2023

We are writing to alert you to changes underway in the blood science laboratory. Our current haematology, immunology and biochemistry analysers are about to change. We have been using our current equipment for over 9 years and like any equipment it is in vital need of an upgrade. The current equipment contract is ending and after a tender process a new provider has been awarded the contract. Haematology has already moved to using Beckmann Coulter UK and the biochemistry laboratory will make this move in January 2023.

The importance of this change is that whilst the majority of tests will maintain the current reference ranges some will change. We will be adding comments to any that are significantly different therefore at the time of go-live we would encourage **all** results to be viewed along with the reference ranges and clinical comments.

We will upload a full list of adult and paediatric reference range changes to the RUH pathology website. Most of the basic electrolytes, liver function and bone profiles will remain the same.

There are some particular changes we would like to alert you to:

Troponin I

Troponin T will be replaced by a new test, Troponin I, therefore the acute coronary syndrome pathway has been updated to reflect this. It will be available on our website. The 99th centile of the normal population reference range for Troponin I is 18ng/L but interpretation is only possible in the context of understanding the clinical presentation and ECG findings.

A single Troponin I below 18ng/L does not exclude ischaemic chest pain.

Troponin testing has a limited role in primary care and should ONLY be requested in the following scenarios:

- low-risk patients in whom symptoms have completely resolved 24 hours prior to presentation
- atypical symptoms with a low likelihood of ACS, where troponin testing may essentially 'exclude' ACS to cover clinical uncertainty
- secondary care request

Cortisol

- To exclude adrenal insufficiency, 9am Cortisol should be greater than 350nmol/L

- After synacthen, a 30 or 60 minute cortisol should be greater than 450nmol/L
- In pregnant ladies, or those taking the oral contraceptive pill, a higher threshold of 600nmol/L applies
- To exclude Cushings after a dexamethasone suppression test the cortisol should be equal/less than 50nmol/L (unchanged)
- Please note that the new assay cross reacts with prednisolone more so it is essential that levels are taken 24hrs after the last prednisolone dose

Thyroid function

The reference ranges are changing with a notable narrowing of the FT4 range and lowering of the upper limit of normal.
Clinical comments will continue to be added to results but correct interpretation will rely upon the correct clinical indication being selected at requesting.

New ranges are:

- TSH 0.38-5.3mIU/L
- FT4 7.86-14.4pmol/L
- FT3 3.8-6.0pmol/L

Testosterone

- At low testosterone concentrations (i.e. normal female and hypo-gonadal male) results will be higher than previously
- The adult female reference range is higher to account for this: <2.7 nmol/L
- At high testosterone concentrations results may be slightly lower than previously
- The adult male reference range is lower to account for this: 6 – 27 nmol/L
- The new assay does not cross react with norethisterone

Free Androgen index and Free testosterone

Reference range will be higher than many guidelines but the 5% quoted in many of these is not assay specific but rather a clinical tradition. It will be important to use these new thresholds to avoid over diagnosis of PCOS and to avoid under treatment in post-menopausal women taking testosterone.

- New FAI reference ranges: 0.8 – 9.0**%**

There is little change to calculated free testosterone

FSH

Post-menopausal ranges are much lower, a FSH >16 IU/L is consistent with a peri- or post-menopausal state

Progesterone

Luteal progesterone levels greater than 30nmol/L have traditionally supported ovulation although this is largely a clinical threshold rather than an evidenced assay specific cut off. The new analysers suggest that ovulation may have occurred at levels greater than 12nmol/L but good practice would be to repeat to confirm.

- Follicular phase: <4nmol/L
- Luteal phase: >12nmol/L

Tumour markers

There will be significant change in all reference ranges, please ensure you take account of the new ranges. The main impact of this may be for those patients being monitored for progression or reoccurrence. The specialist clinical teams are being notified and being advised that a new baseline

in tumour marker will need establishing and more frequent monitoring may be required initially. We will be supporting the specialist teams with this.

B12

There will be a significant negative bias in in B12 results therefore BSW clinical guidance will be updated to reflect this and new diagnostic thresholds will need adopting. We have agreed this with haematology colleagues.

The following will apply:

- B12>250 ng/L: Vitamin B12 deficiency not likely to be present
- B12 180-250 ng/L: May still indicate deficiency. If strong clinical suspicion suggest discussion with a clinical biochemist or haematologist
- B12 100-180ng/L: Possible deficiency. If clinical findings suggest deficiency consider a trial of therapy and assessment of response
- B12<100ng/L: Consistent with B12 deficiency, commence treatment

Folate

The new reference range is 3.0 – 20.0 ug/L

At levels 3.0 - 4.5 ug/L, consider other causes of macrocytosis but if clinical suspicion remains high, consider a trial of therapy after B12 levels have been investigated. Monitor FBC/MCV for response. (Discussed with haematology)

Ferritin

There is a significant negative bias in comparison to the previous method

The new reference ranges are: Males: 24 – 336 ug/L and Females: 11 – 307 ug/L

In otherwise well individuals ferritin level below 30 ug/L will still be considered consistent with iron deficiency (discussed with haematology)

At levels 30-100 ug/L where deficiency is suspected we continue to suggest transferrin saturation

Transferrin Saturation

The methodology for iron studies is changing whereby we will be measuring transferrin rather than measuring the unsaturated iron-binding capacity and calculating the total iron-binding capacity

We will be moving to gender specific cut-off values; 50% for males and 40% for females. As referenced in British Journal of Haematology systematic review:
https://onlinelibrary.wiley.com/doi/full/10.1111/bjh.15164

All the biochemistry tests, which were previously accredited by UKAS to ISO 15189:2012, will be undergoing an Extension to Scope process. Throughout this transition period please be assured that the quality of our services will remain the same.

Your patience will be much appreciated as the laboratory embarks on this period of change. If you have any concerns or queries, please do not hesitate to contact us via our main email address ruh-tr.biochemistry@nhs.net

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