North Bristol NHS Trust

**Department of Clinical Biochemistry**
Core Clinical Services Directorate

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Dear Colleagues

**Clinical Biochemistry laboratory equipment changes week commencing 14/11/2022:**

This notification is to alert you to changes within Blood Sciences to our analytical platforms. Current Roche equipment has been in place for a number of years and following a tender process a new provider, Beckman Coulter UK (BCUK), has been awarded the contract. After a rigorous validation and training period the automated biochemistry service will be transferring to the new equipment on Monday November 14th 2022.

The majority of biochemistry assay reference ranges will stay the same, however some are different dependent on assay performance and evidence of provenance. Please see the later Table that summarises the key changes to the adult reference ranges. Changes to paediatric reference ranges will be available in due course on the Severn Pathology website.

Where there are changes in assay performance and/or associated changes in decision limits we will be adding comments to the reported results to aid your interpretation. In addition, we will be updating information to our website both in the test information and the quality sections for your reference. There are some key changes that we would like to highlight as follows.

- **Troponin I**
  Troponin T will be replaced by **Troponin I**, therefore a new Acute Coronary Syndrome pathway has been agreed by ED, Cardiology and Biochemistry departments across Bristol and Bath. This will be available on the 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 the clinical presentation and ECG findings. A single Troponin I below 18ng/L at presentation does not exclude acute coronary syndrome.

- **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 to/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

- **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 (FAI) and Free testosterone**
  The FAI reference range will be higher than many guidelines but the 5% quoted in many of these is not assay specific.
  - New FAI reference ranges: 0.8 – 9.0**%**

  There is little change to calculated free testosterone.

- **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.

- **Gonadotrophin and Oestradiol**
  There are new sex, age and menstrual cycle specific ranges. These will clearly be indicated on reports. Of note, the FSH reference range for peri-menopause is lower: >16 IU/L.

- **Prolactin**
  Results may be lower than previously. There is no change to the clinical decision limit of 700mIU/L

- **Haematinics**
  There are changes in assay performance (a notable significant negative bias in B12 results) and new reference ranges for Folate and Ferritin. A reference range will no longer be quoted for vitamin B12. Interpretative comments will be added to reports.

- **Tumour Markers**
  There are changes in the performance of some of the assays. These will clearly be indicated on reports together with notification of any change in upper reference limit.

As part of the transition we have taken the opportunity to review the telephone action limits that we currently use. Some changes will be made that will bring us into line with national guidelines for communicating critical results and with other biochemistry departments in the region.

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 nbn-tr.ClinicalBiochemistryNBT@nhs.net

Best regards

Michelle Young

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# ROUTINE BIOCHEMISTRY REFERENCE RANGE CHANGES (14/11/22)

| Analyte | Current NBT Adult Reference Range | NEW ADULT REFERENCE RANGE FROM 14/11/22 |
|---|---|---|
| **ACE** (angiotensin converting enzyme) | 8 – 52 U/L | 13 – 64 U/L |
| **AFP** (alpha-fetoprotein) | <6 kIU/L | <8 kIU/L |
| **AST** (aspartate aminotransferase) | 10 - 35 IU/L | Male: < 50 U/L<br>Female: < 35 U/L |
| **Vitamin B12** | 180 - 900 pg/mL | No Ref range quoted-comments added dependent on B12 level |
| **CA 15-3** | <25 kIU/L | <24 kIU/L |
| **CEA** (carcinoembryonic antigen) | <6 ug/L | <3 ug/L |
| **CRP** (c-reactive protein) | <6 mg/L | <5 mg/L |
| **Ferritin** | Male: 33 – 490 ug/L<br>Female: 15-445 ug/L | Male: 24-336 µg/L<br>Female: 11 -307 µg/ |
| **Folate** | 2.5 – 19.5 ug/L | 3 – 20 ug/L |
| **TSH** (thyroid stimulating hormone) | 0.27 – 4.2 mU/L | 0.38 -5.33 mU/L |
| **FT4** (thyroxine) | 12.0 – 22.0 pmol/L | 7.9 – 14.4 pmol/L |
| **FT3** (triiodothyronine) | 3.1 – 6.8 pmol/L | 3.8 – 6.0 pmol/L |
| **GGT** (gamma-glutamyl transferase) | Male: 10 – 71 IU/L<br>Female: 6 – 42 IU/L | Male: <55 IU/L<br>Female: <38 IU/L |
| **Iron** | 6 – 35 umol/L | 11 – 32 umol/L |
| **Lipase** | 13 – 60 U/L | <67 U/L |
| **PTH** (parathyroid hormone) | 1.60 – 6.90 pmol/L | 1.3 – 9.3 pmol/L |
| **SHBG** (sex hormone binding globulin) | Male: 20 – 75 nmol/L<br>Female: 30 – 130 nmol/L | Male: 13 – 90 nmol/L<br>Female: 17 – 136 nmol/L |
| **Testosterone** | Male: 8.7 – 29 nmol/L<br>Female: 0.2 – 1.7 nmol/L | Male: 6 -27 nmol/L<br>Female: <2.7 nmol/L |
| **Free Androgen Index** | 0.3 – 5.6% (18-49 years)<br>0.2 – 3.6% (50+ years) | 0.8 – 9.0% |
| **Calculated Free Testosterone** | 0.20 – 0.62 nmol/L | 0.17 – 0.66 nmol/L |
| **Transferrin Saturation** (threshold) | >45% | >50% males<br>>40% females<br>(BSH Guidelines) |
| **CSF Total Protein** | < 0.53 g/L | 0.15 – 0.45 g/L |