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**Audit Template**

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| **Audit Title:**  Thames regional audit on Testosterone | |
| **Lead Auditor:**  **Funmi Akinlade** | **Audit date(s):**  May 2019 |
| Please indicate if **Regional**  Please indicate which hospital & location or region  **Queen's Hospital, Romford**  **Southern region** | **Report Author:**  Name: Funmi Akinlade  Email: [funmi.akinlade@nhs.net](mailto:funmi.akinlade@nhs.net) |
| **Aims of the Audit:** To review the use of testosterone assays across the region including the use of immunoassay and mass spectrometry assays. To identify any areas for improvement and/or harmonisation. | |
| **Audit Method and Outcome(s):**  An audit questionnaire was devised by the auditor and ratified by the committee of the Thames Audit Group (TAG). The questionnaire was distributed to members of the Southern region and a total of 15 responses were received. 2 thirds of responses were from laboratories in district general hospitals.  93% of laboratories measured testosterone by immunoassay, with 1 laboratory using mass spectrometry only for all female testosterone tests and 1 laboratory using both immunoassay and mass spectrometry. 40% of respondents used Roche immunoassay and 20% Abbott for the measurement of testosterone.  Although 60% of laboratories stated that the manufacturer was the source of their testosterone reference interval, reference intervals varied between laboratories, even amongst those using the same method. 53% of laboratories provide paediatric reference intervals for testosterone. Reference intervals for androstenedione, DHEAS and SHBG also varied between laboratories using the same method.  93% of laboratories provided imprecision data at testosterone concentrations < 2.0 nmol/L, the majority of laboratories provided data from internal QC, for 20% of laboratories the source of this data was the kit insert.  20% of laboratories automatically provide a free androgen index (FAI) on all female testosterone requests.  20% of respondents indicated that they do not offer testosterone confirmation by mass spectrometry. For those that do confirm female testosterone results by mass spectrometry the criteria for reflexing this test varied by testosterone concentrations:   1. All above the reference interval (1 lab), 2. Greater than 3 nmol/L (2 labs), 3. Greater than 3.5 nmol/L (4 labs), 4. Greater than 4 nmol/L (3 labs) or 5. At the discretion of the duty Biochemist (3 labs).   7 laboratories report a free testosterone result, 3 labs used the free androgen index, 3 labs report using the Vermeulen equation and 1 lab used the Nanjee and Wheeler equation. | |
| **Audit Recommendations / Standards:**   1. Reference intervals for testosterone should be based on those quoted by the manufacturer’s or should be locally derived by the laboratory. 2. Internal Quality Control should assess the performance of your laboratory testosterone assay at the low concentrations expected in females. 3. Testosterone confirmation by Mass Spectrometry (MS) for reliable measurement of testosterone should be part of the laboratory repertoire (may be sent to a referral laboratory). (Endocrine Society Hirsutism guidelines 2018) 4. Testosterone results above the immunoassay reference interval should be confirmed by mass spectrometry. 5. Reference intervals for androstenedione and SHBG should be based on those quoted by the manufacturer’s or should be locally derived by the laboratory. 6. Clinical symptoms should guide the measurement of 17OHP and not testosterone concentrations (Endocrine Society Hirsutism guidelines 2018). 7. Confirm low testosterone results in males on a repeat in the morning peak (on a fasting sample) (Endocrine Society Hypogonadism guidelines 2018/BSSM guidelines on Adult testosterone deficiency 2017). 8. Laboratories should be aware of the interference profile of their testosterone assay and should review this when there is a change or reformulation of the assay. | |
| **Please indicate to whom and when audit presented &/or circulated&/or published:**  Audit presented at the Thames Audit meeting on 14th May 2019. | |
| **Audit recommendations / standards ratified by … and when:**  Thames Audit Group May 2019 | |
| **Date of audit report: May 2019** | |
| **Audit documents for upload to http://www.acb.org.uk/whatwedo/science/audit.aspx**  *Please include as attachments with this Audit Summary form if authors and the organising committee would like information to be publicly accessible on the ACB website Audit section.*    Presentation  Standards/Recommendations  BlankSurvey Questionnaire | |