ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MED 002

Specific Criteria for Urinalysis Section

Technical Notes MED 002 – Urinalysis, 29 March 2019
The SAC Accreditation Programme is managed by Enterprise Singapore

1. Introduction & Scope

1.1 a) This document describes the specific requirements to be complied by urinalysis sections to be accredited.

b) The International Standard 'ISO 15189 Medical laboratories – Particular requirements for quality and competence', other MEDICAL Series Technical Notes published by SAC-SINGLAS shall be studied in conjunction with this document.

2. General Technical Note : Medical 001

2.1 Please refer **General Technical Note: Medical - 001** for the following:

- Personnel
- Accommodation & Environmental Conditions
  - Physical Facilities and Laboratory Safety
- Laboratory Equipment – Calibration & Maintenance
- Pre-examination Procedures
  – Requisitions, Collection and Handling of Specimens
- Examination Procedures
  - Test Methods and Method Validation
- Assuring Quality of Examination Procedures
  - Quality Control, Proficiency Testing, Reagents and Reference Materials
- Post-examination Procedures
  - Retained Samples and Waste Disposal
- Reporting of Results

3. Personnel

3.1 Refer to Personnel in **General Technical Note: Medical - 001**.

4. Accommodation and Environmental Conditions

4.1 Refer to Accommodation & Environmental Conditions - Physical Facilities and Laboratory Safety in **General Technical Note: Medical - 001**.

5. Laboratory Equipment

5.1 Refer to Laboratory Equipment in **General Technical Note: Medical - 001**. In addition to that the following is applicable to urinalysis section.

5.2 Refractometers or dipsticks with specific gravity capability shall be checked periodically with standard solutions. Osmometers shall be checked each day of use with controls of know osmolality.

5.3 The laboratory shall have a written routine maintenance and function verification schedule for all instruments and equipment including clinical microscopy section.

6. Pre-examination Procedures

6.1 Specimen Collection and Handling

6.1.1 Refer to Pre-examination Procedures in **General Technical Note: Medical - 001**. **.** In addition to that the following is applicable to urinalysis section.

6.1.2 Written Instructions shall be provided to patients for proper collection of clean voided specimens.

6.1.3 Written instructions shall be given for proper preservation and storage when specimens are collected for special tests and when specimens cannot be examined within 2 hours of collection.

6.14 Written instructions shall be provided for the rejection of unacceptable specimens or the special handling of sub-optimal specimens.

7. Examination Procedures

7.1 Refer to Examination Procedures in **General Technical Note: Medical - 001.** In addition to that the following is applicable to urinalysis section.

7.2 Procedure Manual

7.2.1 The manual shall include the principle, clinical significance, specimen type, required reagents, calibration, quality control, procedural steps, calculations, reference ranges, and interpretation.

7.2.2 It shall provide the descriptions of urine sediment elements and be available to the bench technologists. It should be reviewed annually by the LD or supervisor to ensure that the technical protocol is complete and current.

7.2.3 The laboratory has a written procedure defining the criteria under which the microscopic examination may be omitted.

8. Assuring Quality of Examination Procedures – Quality Control and Proficiency Testing

8.1 Refer to Quality Control and Proficiency testing in **General Technical Note: Medical - 001**. **.** In addition to that the following is applicable to the urinalysis section:-

8.2 There is a written procedure for the laboratory to follow manufacturer's instructions for quality control, calibration and related functions.

8.3 The laboratory has a written procedure for correlation of macroscopic results with microscopic sediment findings.

8.4 Review of quality control results at least weekly by section supervisor and monthly by Laboratory Director (LD)/ however named, or designate, shall be documented.

8.5 Corrective action taken in response to unacceptable results shall also be recorded.

8.6 The elements of a urinalysis vary according to the patient populations served and the needs of clinicians. Urinalysis may include the following: glucose, protein, blood/haemoglobin, leukocyte esterase, nitrite, specific gravity, bilirubin, ketones, pH and urobilinogen. Their utility should be reviewed periodically by the laboratory.

8.7 The laboratory has a written procedure defining criteria used for assessing morphologic observation among personnel performing urine sediment microscopy.

8.8 Controls and Standards

8.8.1 Reference materials (atlases, charts or photomicrographs) shall be available to assist in the microscopic identification of sediment constituents. Microscopic findings should be correlated with macroscopic results.

8.8.2 A protocol for processing quality control materials of known compositions should be available. Controls shall be used regularly to check reactivity and accuracy of the qualitative procedures (protein, glucose, etc.).

8.8.3 Control specimens shall be tested in the same manner as patient samples and results of controls should be verified for acceptability before reporting results.

8.8.4 Control samples shall be integrated within the routine laboratory workload to be analysed by personnel who routinely test patient samples.

9. Post-examination Procedures

9.1 Refer to Post-examination Procedures - Retained Samples and Waste Disposal in **General Technical Note: Medical - 001**.

10. Reporting of Results

10.1 Refer to Reporting of Results in **General Technical Note: Medical - 001.** In addition to that, the urinalysis tests, where possible, shall contain all results with reference intervals.