

Standard AOP.03.07

Established norms and ranges are used to interpret and to report clinical laboratory results.

Intent of AOP.03.07

Norms and ranges are needed to interpret test results; these norms and ranges are included with the test results so health care providers can interpret test results.

The laboratory establishes reference intervals or “normal” ranges for each test performed. The range is included in the medical record, either as part of the report or by including a current listing of such values approved by the laboratory leader. Ranges are provided when a contracted laboratory service performs the test. The reference ranges are appropriate to the hospital’s geography and patient demographics. The reference ranges are reviewed and updated when testing methods change and to reflect current scientific evidence.

Measurable Elements of AOP.03.07

1. © The laboratory establishes reference ranges for each test performed.
2. The range is included in the medical record at the time test results are reported.
3. Ranges are provided when tests are performed by contracted laboratory services.
4. Ranges are appropriate to the hospital’s geography and patient demographics.
5. The laboratory reviews and updates ranges as needed.

Standard AOP.03.08

The hospital has implemented processes for quality control and proficiency testing of laboratory services.

Intent of AOP.03.08

Well-designed quality control processes and proficiency testing are essential to providing accurate laboratory services.

Quality control procedures are used to validate test methods and results. Quality control also includes daily surveillance to ensure that testing is completed according to procedure. Rapid corrective actions are implemented when deficiencies are identified.

The laboratory participates in an approved proficiency testing program or external quality assessment when available. Proficiency testing determines how well an individual laboratory’s results compare with other laboratories that use the same methods. Proficiency testing can identify performance problems not recognized by internal mechanisms.

Quality control processes include the following:

- Validation of the test methods used for accuracy, precision, and reportable range
- Daily surveillance of results by qualified laboratory staff
- Rapid corrective action when a deficiency is identified
- Documentation of results and corrective actions

If an approved proficiency testing program or external quality assessment is not available, the laboratory exchanges samples with a laboratory in another hospital for purposes of peer comparison. Proficiency testing, or an alternative, is carried out for all specialty laboratory programs.

The laboratory maintains documentation of participation in a proficiency testing program.

Measurable Elements of AOP.03.08

1. ① The hospital establishes and implements a written quality control program for the clinical laboratory.
2. The program includes the validation of test methods for accuracy, precision, and reportable range.
3. The program includes the daily surveillance and documentation of test results.
4. The program includes rapid correction and documentation of deficiencies.
5. The laboratory participates in a proficiency testing program or an alternative for all laboratory tests when external quality assessments are not available.
6. The laboratory's proficiency testing results meet satisfactory performance criteria in accordance with laws and regulations.

Standard AOP.03.09

The hospital ensures the quality of services provided by contracted laboratories.

Intent of AOP.03.09

The hospital has a responsibility to ensure that any service provided by contracted services meets all licensing and legal requirements and meets quality expectations developed by the hospital.

If the hospital uses the services of a contracted laboratory, the hospital has a responsibility to make certain that the contracted laboratory is licensed, accredited, or certified by recognized authorities.

Contracted laboratories must participate in proficiency testing to determine how the contracted laboratory's results compare with other laboratories that use the same testing methods.

The hospital identifies measures to monitor the quality of services provided by all contracted laboratories. Qualified individuals review and act on the results of quality monitoring. This information is used to identify potential process improvements and to make decisions about future contracts with the contracted laboratories.

To be certain the contracted laboratory is licensed and accredited or certified, and participates in an outside proficiency testing program, the hospital must obtain a copy of a license from a recognized licensing authority and of the certificate or letter of accreditation or certification from a recognized laboratory accreditation or certification program.

The hospital defines what measures the contracted laboratory is required to collect and submit to the hospital, as well as how often data are submitted to the hospital. Examples of measures collected to evaluate contracted laboratories include the following:

- Turnaround times for tests, meaning the time it takes for the laboratory to report a result following receipt of the specimen
- Critical results reporting
- Problems with specimens such as missing identifiers or specimen rejections

Measurable Elements of AOP.03.09

1. ① The hospital maintains a copy of the license and the certificate or letter of accreditation or certification, from a recognized authority, for all contracted laboratories used by the hospital.
2. ① The hospital maintains documentation that any contracted laboratory used by the hospital participates in a proficiency testing program.
3. The hospital determines the frequency and type of performance expectation data from contracted laboratories. (*See also* GLD.05.00, MEs 4 and 5)
4. The individual responsible for the laboratory or a designee reviews the performance data from contracted laboratories and takes action based on the results. (*See also* GLD.05.00, MEs 4 and 5)
5. ① An annual report of the data from contracted laboratories is provided to the leaders responsible for the management and renewal of contracts.