

Improving the laboratory result release process in the light of ISO 15189:2012 standard

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Abstract

The ISO 15189:2012 standard section 5.9.1 requires laboratories to review results before release, considering quality control, previous results, and clinical information, if any, and to issue documented procedures about it. While laboratory result reporting is generally regarded as part of the post-analytical phase, the result release process requires a general view of the total examination process. Reviewing test results may follow with troubleshooting and test repetition, including reanalyzing an individual sample or resampling. A systematic understanding of the result release may help laboratory professionals carry out appropriate test repetition and ensure the plausibility of laboratory results. In this paper, we addressed the crucial steps in the result release process, including evaluation of sample quality, critical result notification, result reporting, and recommendations for the management of the result release, considering quality control alerts, instrument flags, warning messages, and interference indexes. Error detection tools and plausibility checks mentioned in the present paper can support the daily practice of results release.

Keywords: Accreditation; ISO 15,189; Laboratory errors; Quality control; Result release.