LABQUALITY DAYS

The SKML Multi-sample Approach for the Exactly Right EQA

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According to ISO15189 medical laboratories have to participate in an inter-laboratory comparison such as an external quality assessment program. Purpose of such participation is to verify whether the laboratory results meet the intended quality goals. As a consequence an EQA program should be able to report to its participants whether the intended goals are met. Since laboratories are also obligated to imply corrective actions if goals are not met, an EQA program should also give insight in the sources of error in order to give direction to such corrective action. These goals for a useful EQA define requirements for EQA programs that are not met by many. Firsts, in order to be presentative for the accuracy of the patient samples, the EQA samples need to be commutable. Secondly, value assignment should be performed in reference laboratories using reference methods, rather than based on consensus which may be biased by large groups of potentially biased methods. Finally, the described purposes of EQA lead to requirements for the EQA reports that depict how successful criteria have been met. For this purpose most EQA providers have reports with method statistics which allow to distinguish between errors in an individual laboratory and problems in a method that affect all users of a method. This is not enough however; reports should also equip participants with information on bias and imprecision, since both sources of inaccuracy require different types of corrective action. For that purpose SKML has introduced MUlti Sample Evaluation (MUSE) that judges performance in the light of desirable specifications for total error according to the EFLM Milan criteria. For the root cause analysis of the total error, bias and imprecision are calculated from multi sample regression analysis.