

ABSTRACT FORM ECAT SYMPOSIUM 15 – 16 SEPTEMBER 2022

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Abstract:

Clinicians trust medical laboratories to provide them with reliable results on which they base clinical decisions. Laboratories fulfil their responsibility for accurate and consistent results, by utilizing an arsenal of methodologies, ranging from validation and verification experiments to daily quality control procedures. All these procedures verify on different moments that the results of a certain examination method have analytical performance characteristics (APC) that meet analytical performance specifications (APS) that were set for a particular intended use. The APC can in part be determined by the long-term uncertainty u_{rw} , which comprises of both short-term and long-term components that each influence u_{rw} . To adequately maintain the adequacy of their measurement procedures, laboratories need to distinguish aspects that are manageable versus those that are not.

One of the aspects that influences u_{rw} is the momentary bias caused by using multiple reagent lots. This bias, when accepted or unnoticed, becomes part of the u_{rw} as long-term imprecision. However, even when acceptable, in combination with low short-term imprecision a momentary shift in measurement results could lead to misinterpretation of patient results. Therefore, reagent lot-variation affects the ability of laboratories to meet APS if reagent lot shifts are the most predominant contributing factor to the APC. We postulate a model for allocating a part of u_{rw} to between-lot variation, based on biological variation and the need for long term-consistency of an individual patient as part of the intended use. The allocation manages the ratio between short-term and long-term variation, and indicates laboratories when to reject or correct certain variations due to reagent lots.

We provide a formula to determine whether between reagent lot bias is (un)acceptable although other analytical performance characteristics may be still acceptable.