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| Document Contact | Kelly Walewski: Medical Technologist Lead |
| Area | Laboratory-Chemistry |
| Applicability | All Beaumont Hospitals |

# Laboratory Chemistry Total Error Allowable



Document Type: Procedure

## I. PURPOSE AND OBJECTIVE:

A. This document identifies Total Error Allowable (TEA) is the amount of error that can be tolerated without invalidating the medical usefulness of the analytical result. U.S.Clinical Laboratory Improvement Amendment (CLIA) requirements for a Quality Control (QC) program call for in-house data to conduct a risk assessment of the testing process.

## II. BACKGROUND:

A. Clinical Laboratory Improvement Act (CLIA) requirements for a Quality Control (QC) program call for in-house data to conduct a risk assessment of the testing process. To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error.

B. In-house data, established by the laboratory in its own environment and by its own personnel, must be included to demonstrate that the stability of the test system supports the number and frequency of QC documented in the Quality Control Plan (QCP). Data from verification or establishment of performance specifications and historical QC data can be included. Published data or data from manufacturers (e.g., package inserts) may be taken into consideration, but may not be used as the sole criteria for decision-making.

C. The concept of “total error allowable” was investigated by Westgard over a quarter century ago for use in laboratory medicine; it comprises bias as well as random elements.

D. Bias: Inaccuracy or systematic error is determined during method validation studies from a comparison of methods experiment. Laboratories perform these experiments to verify a manufacturer’s claim after installation of new test systems. After initial validation, labs are

required to monitor bias using EQA (external quality assessment)/Patient samples with target values established by reference methods, the mean of a survey group or the mean of a survey peer group.

E. Imprecision (random error) is determined from a replication experiment during method validation studies or SQC (statistical quality control) data collected during routine operation. The coefficient of variation (CV) is the ratio of the standard deviation to the mean and shows the extent of variability in relation to the mean.

F. **Formula to calculate TEA**: %TEA =%bias+2CV

# III. RECOMMENDED USE OF TEA CRITERIA:

A. Evaluation criteria for lot-to-lot comparison using patient samples. Difference between lots generally should not exceed TEA.

B. Evaluation criteria for method validation and verification. Bias between methods generally should not exceed 1/2 of TEA. Imprecision generally should not exceed 1/2 of TEA.

C. The target CV for QC ranges generally should not exceed 1/2 of TEA.



## Attachments

Total Allowable Error (TEA) Reference Guide rev 9.2022.pdf

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Directors | Vaishali Pansare: Chief, Pathology | 6/15/2023 |
| Medical Directors | Jeremy Powers: Chief, Pathology | 6/8/2023 |
| Medical Directors | Ann Marie Blenc: System Med Dir, Hematopath | 6/7/2023 |
| Medical Directors | Muhammad Arshad: Physician | 5/31/2023 |
| Medical Directors | Ryan Johnson: OUWB Clinical Faculty | 5/31/2023 |
| Medical Directors | John Pui: Chief, Pathology | 5/31/2023 |
| Policy and Forms Steering Committee Approval (if needed) | Colette Kessler: Mgr, Division Laboratory | 5/31/2023 |

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| Caitlin Schein: Staff Physician | 5/26/2023 |
| Nga Yeung Tang: Tech Dir, Clin Chemistry, Path | 5/25/2023 |
| Qian Sun: Tech Dir, Clin Chemistry, Path | 5/24/2023 |
| Colette Kessler: Mgr, Division Laboratory | 5/11/2023 |