

When purchasing assayed or unassayed quality control material, CLIA regulations require the laboratory to perform replicate analysis for each analyte stated within the product's package insert so as to ascertain that particular laboratory's acceptable range. There are no specific guidelines for the number of times quality control material must be tested to establish statistical limits. In general, twenty (20) replicate tests should be considered the minimum for determining a standard deviation.¹ However, your laboratory can use the following model as the basis for its own method of establishing each level of quality control material's acceptable range:

Day One:	Tech A runs 3 to 5 replicates of each level
Day Two:	Tech B runs 3 to 5 replicates of each level
Day Three:	Tech C runs 3 to 5 replicates of each level
Day Four (optional):	Tech D runs 3 to 5 replicates of each level
Day Five (optional):	Tech E runs 3 to 5 replicates of each level

This provides anywhere from 9 to 25 data points per level of quality control material to be evaluated and statistical parameters (mean and standard deviation) to be calculated. The lab would then decide on whether the acceptable range for each specific analyte should fall within ± 1 standard deviation (SD), $\pm 2SD$ or $\pm 3SD$.

The laboratory may, however, use the stated value of a commercially **assayed** control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is **verified** (multiple replicates) by the laboratory. If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits.²

Statistical parameters for **unassayed** control materials must be **established** over time by the laboratory through concurrent testing of control materials.³ (see model above)

For more information, please contact AUDIT MicroControls' Technical Service at (866) 252-8348.

¹Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1256(d)(10) - Interpretative Guidelines

²Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1256(d)(10)(ii) and §493.1256(d)(10) - Interpretative Guidelines

³Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1256(d)(10)(iii)