**Judging Acceptability Worksheet 14C05**

**Directions:**

1. Determine your Medical Decision Point (Xc).
2. Calculate the allowable total error at Xc.
3. Provide the estimate of random error at Xc from your long-term precision experiment.
4. Provide the estimate of systematic error (difference) at Xc from your comparison of methods experiment.
5. Calculate the total error and the sigma-metric.
6. Determine the Sigma performance for each Xc using the Sigma table located on the following page.
7. Evaluate acceptability at each Medical Decision Point using the pre-defined quality requirement for the new method.

**Quality Requirement**

The Cobas c501 Chemistry Analyzer may be judged acceptable for the AST analyte if one of the following conditions is met:

1. Manufacturer’s claims for linearity, precision and accuracy have been verified.
2. The total error calculation (bias + 3 sd or %bias + 3CV) for the test method is less than the CLIA total allowable error for each Medical Decision Point (Xc).
3. The Sigma-metric is > 3.0 for each Medical Decision Point (Xc).

**In Units of U/L**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Concentration of Xc | AST TEA at concentration of Xc  (%TEA \*Xc) /100% | Long-term Precision  (in SD) | Bias or Difference with Comparative Method | Total Error  (bias + 3(SD)) | Sigma Metric  ([TEA – bias]/SD) | Sigma Performance  (See Sigma table on following page) | Acceptability |
| 35 U/L |  |  |  |  |  |  |  |
| 120 U/L |  |  |  |  |  |  |  |

**In Percent**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Concentration of Xc | AST %TEA at concentration of Xc | Long-term Precision  (in %CV) | %Bias or %Difference with Comparative Method | Total Error  (%bias + (3%CV)) | Sigma Metric  ([%TEA-%bias]/%CV) | Sigma Performance  (See Sigma table below) | Acceptability |
| 35 U/L |  |  |  |  |  |  |  |
| 120 U/L |  |  |  |  |  |  |  |

**Sigma Performance Table**

|  |  |
| --- | --- |
| **If** | **Then** |
| The Sigma metric less than 2.0 | * The method has **unacceptable performance** and does not meet your requirement for quality, even when the method is working properly. * It is not acceptable for routine operation. |
| The Sigma metric is between 2.0-3.0 | * The method has **marginal performance** and provides the necessary quality when everything is working correctly. * This method will require:   + 4-8 controls per run   + well-trained operators   + reduced rotation of personnel   + more aggressive preventive maintenance   + careful monitoring of patient test results   + continual efforts to improve method performance |
| If the Sigma metric is between 3.0-4.0 | * The method has **fair performance** and meets your requirement for quality and can be managed in routine operation. * This method will require a multirule procedure with 4-6 control measurements per run. |
| If the Sigma metric is between 4.0-6.0 | * The method has **good performance** and is clearly acceptable and can be well-managed in routine operation with 2-4 control measurements per run, using standard Westgard QC rules. |
| If the Sigma metric is >6.0 | * The method has **Six Sigma performance** and can be managed using a single control rule with wide limits (i.e. 1:3s, 1:3.5s). |