By comparing the Total Error (TE) to the Total Allowable Error (TEA), we can assess whether or not a new lot number of reagent provides clinically acceptable results. In this exercise you will be evaluating two different lot numbers and answering questions pertaining to your data.



|  |  |
| --- | --- |
|  | **Values (mmol/L) obtained with Control XYZ using the New Lot Number of Reagents** |
| **Reagent Lot Number A** | 5.73 | 5.74 | 5.75 | 5.73 | 5.71 | 5.73 | 5.72 | 5.73 |
| **Reagent Lot Number B** | 5.83 | 5.84 | 5.84 | 5.83 | 5.84 | 5.84 | 5.85 | 5.85 |

Complete the table using the information from the previous page.

|  |  |  |
| --- | --- | --- |
| Current Mean |  |  |
| Current SD |  |  |
| Target Value |  |  |
| Bias |  |  |
| Absolute Bias |  |  |
| Current TE |  |  |
| TEA |  |  |
|  | **Reagent Lot Number A** | **Reagent Lot Number B** |
| New Reagent Lot Number Mean |  |  |
| Current SD |  |  |
| Target Value |  |  |
| Bias |  |  |
| Absolute Bias |  |  |
| New Reagent Lot Number TE |  |  |
| TEA |  |  |
| TE < TEA (yes or no) |  |  |

By comparing the TE to the target value and TEA limit, we can conclude Reagent A is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

acceptable / unacceptable

By comparing the TE to the target value and TEA limit, we can conclude Reagent B is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

acceptable / unacceptable

Reagent B demonstrated a smaller shift from the current mean than Reagent A. Does this information support your conclusions regarding acceptability? Explain your answer.

Demonstrate your conclusions in the diagram below. Redraw the Gaussian curves into the diagram with relationship to TEA limits. Illustrate the reagents’ TE using arrows.

