



Title: Reviewing Pass/Fail Levels when Switching from AQT100 3M™ Clean-Trace Water – Total to AQT200 3M™ Clean-Trace™ Water Plus – Total

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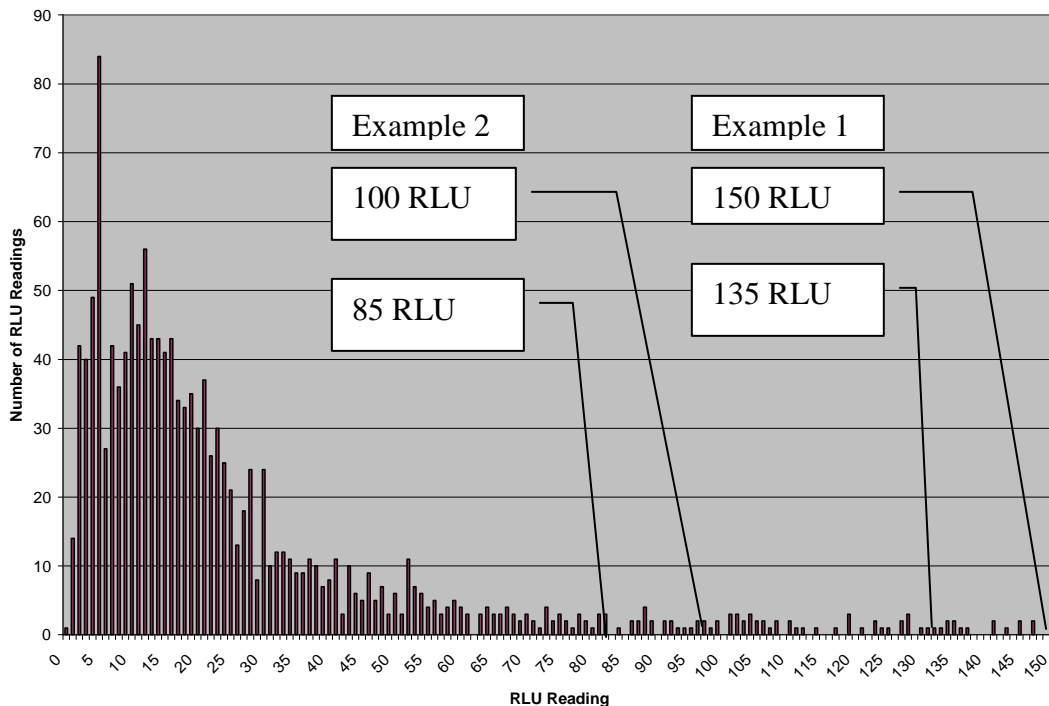
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Supersedes: New

Technology Platform: Hygiene Monitoring

Originating Location: St. Paul, Minnesota

Although the background RLU levels for AQT200 are lower, the change does not require a re-evaluation of your current pass/fail limits set in your 3M™ Clean-Trace™ NG Luminometer since most customers set their pass/fail limits at much higher levels. However, customers who have set their pass/fail limits low to improve their cleaning efficiency may wish to review their pass/fail limits.



3M Food Safety Technical Bulletin

This graph shows the number of occurrences of each RLU reading in the “pass” category (0-150 RLU) for an example set of AQT100 data (n=1,071). Verification test results show that switching from AQT100 to AQT200 could be expected to decrease the RLU reading by an estimated 15 RLU due to the decreased background level of AQT200.

1. With the pass/fail level set at 150 RLU, decreasing all the RLU readings by 15 RLU has minimal effect, since there are only a few occurrences of RLU readings between 150 RLU and 135 RLU. In this case, it would not be necessary to review and modify the pass/fail levels.
2. With the pass/fail level set at 100 RLU, decreasing all the RLU readings by 15 RLU has a greater effect, since more occurrences of RLU readings are between 100 RLU and 85 RLU. In this case, it would be appropriate to review and possibly modify the pass/fail levels.

Count of Result	Result Status Changed?		
What-if Result Status	No	Yes	Grand Total
Caution	32	3	35
Fail	91		91
Pass	941	4	945
Grand Total	1064	7	1071

This is a what-if spreadsheet analysis of the same example AQT100 data set (n=1,071) that shows if the RLU readings all decreased by 15 RLU due to switching from AQT100 to AQT200 these are the effects on the result statuses (pass/caution/fail). This analysis quantifies the graphical analysis shown above:

- 7 of the 1,071 RLU readings (0.7%) would shift from one pass/fail level category to another.
 - 4 of the 1,071 RLU readings (0.4%) would shift from the “caution” category (151-299 RLU) to the “pass” category (0-150 RLU)
 - 3 of the 1,071 RLU readings (0.3%) would shift from the “fail ” category (300 and higher) to the “caution” category (151-299 RLU)

In summary, the vast majority of samples are well within the pass zone, and will not be affected by the change in backgrounds. For lower pass/fail limits of 100 RLU, it would be appropriate to review and possibly modify the pass/fail levels, although this is not essential.

It is important to note that the improved lower and less variable RLU backgrounds seen with AQT200 in essence makes the test more sensitive due to improved signal to noise ratios, and less likely to produce false positive results.