

Setting Pass/Fail Limits for the 3M™ Clean-Trace™ Hygiene Monitoring and Management System

This Technical Bulletin describes best practices for setting your Relative Light Units (RLU) test result pass/fail limits for the 3M™ Clean-Trace™ Hygiene Monitoring and Management System and for reviewing and updating your RLU pass/fail limits to achieve your sanitation goals. When a technician uses the 3M Clean-Trace Hygiene Monitoring and Management System to sample and test an equipment surface (Test Point), the 3M™ Clean-Trace™ Luminometer immediately compares that RLU test result to your pass/fail limits, and it displays on screen “Pass,” “Fail” or “Caution” (for any value between the Pass and the Fail threshold).

- You can improve your cleaning effectiveness by setting your pass/fail limits close to the RLU value that indicates a clean surface as determined by your validation study to allow minimal margin of error.
- You can set the pass/fail limit further from the RLU value that indicates a clean surface if you want to maintain your current cleaning effectiveness by allowing a moderate margin of error.

Validation Study Using the 3M™ Clean-Trace™ Hygiene Monitoring Software

Conduct a validation study using the 3M Clean-Trace Luminometer to collect RLU test results by testing your equipment surfaces (Test Points). Analyze this data with the assumption that your cleaning processes are effective most of the time so that the most frequently occurring RLU test results indicate effectively cleaned equipment surfaces. Collect at least thirty test results for each Test Point. The level of cleanliness required for different Test Points can vary, so it's important to categorize the RLU test result data (raw, in-process, finished product area, etc.) and analyze Test Points for each category in its own dataset. This will prevent confounding the data, which could lead to misinterpreting the results of the analysis.

Since the 3M™ Clean-Trace™ Hygiene Monitoring Software requires you to enter a pass/fail limit for each Test Point when you create a Sample Plan, you can enter 150 RLU for the pass level and 300 RLU for the fail level as a starting point for most applications. Refer to the Technical Bulletins on 3M Clean-Trace System applications for more information on the recommended starting pass/fail limits for various applications (1, 2). Assuming that you use 150 as the pass limit and 300 as the fail limit, RLU test results are interpreted as follows:

- RLU test results less than 150 are in the Pass category.
- RLU test results between 150 and 299 are in the Caution category.
- RLU test results equal to or greater than 300 are in the Fail category.

User can also eliminate the Caution category by using 150 RLU for the pass level and 151 RLU for the fail level. We strongly recommend that you revise these initial pass/fail limits (150/300 RLU) after analyzing your validation study (3-6) RLU test result data and periodically thereafter. This will help ensure that the pass/fail values set are appropriate for the facility, products and cleaning processes.

The steps for a validation study:

- Locate and identify Test Points as outlined in Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practice (GMP), Sanitation Standard Operating Procedures (SSOP) for the facility.
 - Use the 3M Clean-Trace Hygiene Monitoring Software to create Sample Plans that contain your Test Points.
 - Send the Sample Plans to your 3M Clean-Trace Luminometer.
 - Use facility's standard cleaning procedure and clean Test Points to the highest standard of clean.
 - Test each Test Point 5-10 times (do not test same exact surface more than once). Use different 4 x 4 inch areas for large areas, such as a conveyor belt. For areas such as a fill nozzle, collect results over several days after cleaning.
 - Collect the RLU test results in the 3M Clean-Trace Hygiene Monitoring Software database.
 - Export data to Microsoft® Excel spreadsheet and confirm that the data is normally distributed.
- You can create a histogram as described below, and if the histogram shows the typical bell shaped curve, the data is normally distributed.
- Use the AVERAGE function to calculate the mean, and use the STDEV function to calculate the standard deviation of the RLU test results.
 - Calculate the mean \pm 3 standard deviations to set the pass/fail limit. The average RLU value is your Pass Limit for the Test Point and average RLU value + 3 standard deviation is the Fail Limit.
 - Based on the validation study, pass/caution/fail limits can be set up for each of Test Points.

Once validation study is complete follow the steps below to collect and analyze data on a routine basis.

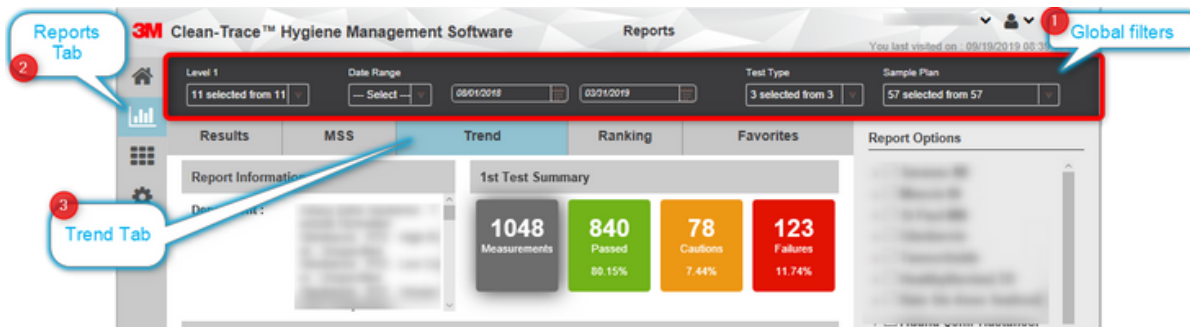
- Use the 3M Clean-Trace Hygiene Monitoring Software to create Sample Plans that contain your Test Points and the pass/fail limits.
- Send the Sample Plans to your 3M Clean-Trace Luminometer.
- Sample and test the Test Points.
 - Collect the RLU test results in the 3M Clean-Trace Hygiene Monitoring Software database.
- Analyze the data.

Refer to the 3M Clean-Trace Hygiene Monitoring Software User Manual for more details on each of these steps.

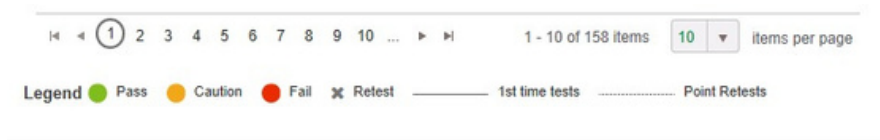
Graphical Analysis Using 3M Clean-Trace Hygiene Monitoring Software Test Point Trend Graph

There are several steps to analyze the RLU test results from the validation study and routine sampling. The first step is to use the Test Point Trend graph in the 3M Clean-Trace Hygiene Monitoring Software to create a visual representation of the RLU test results in the form of a run chart. This is a graphical display of the RLU test results in time series and in relation to the current pass/fail limits. To create a Test Point Trend graph using the 3M Clean-Trace Hygiene Monitoring Software, follow the following steps:

1. Log in to 3M Clean-Trace Hygiene Monitoring Software.
2. Set the global filters at the top of the page to include the Test Points of interest.
3. Select the Reports Tab, then click on Trend Tab.



4. In the Trend screen, scroll down to the Test Points details area.
5. A graphical display of the RLU test results in time series and in relation to the current pass/fail limits will be displayed for all selected Test Points. Depending on the selection, this may take multiple pages to view all data.



Analyze time series trend for the Test Points of interest. Figure 1 is an example of a Test Point Trend graph chart showing that most RLU test results are significantly lower than the pass limit, with exception of few. The green line indicates the pass limit, currently set at 150 RLU. In this case, lowering the pass limit could be a way to force improvements in the cleaning process.

Sample Plan: Test Point Name: Location: Test Type

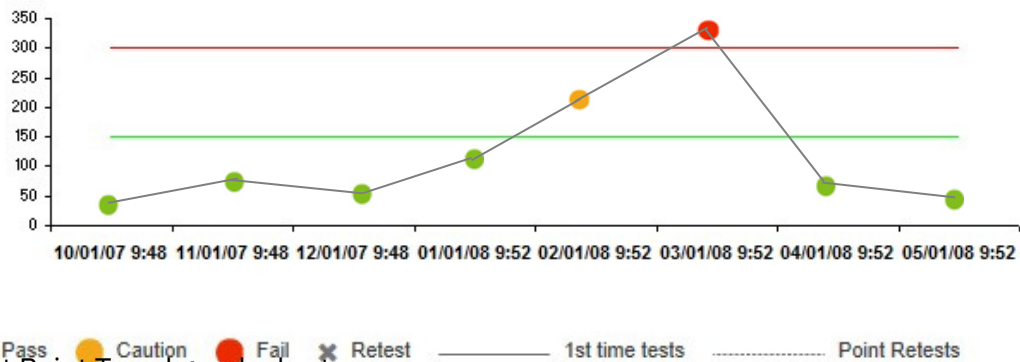


Figure 1. Test Point Trend graph chart.

Graphical Analysis Using a Microsoft® Excel Histogram

The next step you can take is to analyze the data from your validation study by exporting the RLU test results into a spreadsheet, and then using the Microsoft® Excel features to create a histogram chart. Follow directions in the 3M Clean-Trace Hygiene Monitoring Software User Manual (see section Viewing or Printing Reports) to export data. A histogram is a bar graph that shows the number of RLU test results that fall into each range (for example the ranges can include 0-10 RLU, then 11-20 RLU, etc.). The cumulative percentage plot shows the percentage of RLU test results in each range and all ranges below it. For example the cumulative percentage displayed for the 31-40 RLU range is the percentage of RLU test results in the 31-40 range + 21-30 range + 11-20 range + 0-10 range.

1. Use the Filter Results Table feature in the 3M Clean-Trace Hygiene Monitoring Software to display only the RLU test results that you expect to have the same pass/fail limits because they require the same level of cleanliness. Refer to the “Filtering the Data” section of the 3M Clean-Trace Hygiene Monitoring Software User Manual for more details.
2. Use the Export Data feature to export the RLU test results to a spreadsheet. Refer to the “Exporting Data” section of the 3M Clean-Trace Hygiene Monitoring Software User Manual for more details.
3. Use Microsoft® Excel to create a histogram chart to review and analyze the RLU test results:
 - a. Use Microsoft® Excel to open the spreadsheet you created in step 2 above. Create a new column named “RLU bins” in column AI, and enter 10 into cell AI1, enter 20 into cell AI2, enter 30 into cell AI3, etc. until you have entered 300 into cell AI31. This assumes that 300 is the highest RLU test result in the data you’re analyzing in the spreadsheet.
 - b. Select the Data tab in Microsoft® Excel, and then click Data Analysis in the Analysis group. If Data Analysis does not appear in the Analysis group, you need to add the Data Analysis Add-in:
 - i. Click the Microsoft® Office button in the upper left corner of the screen, and then select Excel Options at the bottom of the menu. Select Add-Ins on the left edge of the dialog box.
 - ii. Select Analysis ToolPak in the Name column, and then click Go.
 - iii. Click the check box for Analysis ToolPak, and then click OK .

- c. Select Histogram in the Analysis Tools menu.
 - i. Select the Results in column H for the Input Range, and select the contents of the “RLU bins” column for the Bin Range. Select the Cumulative Percentage option and the Chart Output option and the New Worksheet ply option, and then click OK.
 - d. A histogram chart similar to the example in figure 2 appears.
 - i. Expand the histogram chart by grabbing the edge of the graph with the cursor and dragging it out.
 - ii. Right-click on a bar in the Frequency graph, and select Add Data Labels to add the data labels.
 - iii. Float the cursor over the Cumulative % line to display the data at each data point.
 - e. Analyze the histogram chart to determine the optimal pass/fail limits.
 - i. The Frequency bar graph shows the number of RLU tests results that are in each RLU bin. For example, in figure 2 below there are 268 RLU test results in the first RLU bin (0-10 RLU). Use the Frequency bar graph to find the most frequently occurring RLU test result values, because they should represent clean surfaces assuming your cleaning processes are effective most of the time. Then decide how large a margin of error you want to allow between the RLU test results that represent clean surfaces and your pass/fail limit.
 - ii. The Cumulative % line shows the percent of RLU test results that are equal to or less than each RLU bin. For example, in figure 2 below, 95.44% of the RLU test results are equal to or less than 150 RLU pass limit. Use the Cumulative % plot to find out the percentage of RLU test results that are equal to or less than the pass/fail limit you’re considering. This assumes that the “More” RLU bin contains an insignificant number of RLU test results, since this RLU bin contains the RLU test results that are above the pass category.
 - iii. If the number of RLU test results in the “More” RLU bin is significant compared to the total number of RLU test results, investigate this by increasing the number of RLU bins and creating another histogram chart.
 - If most of the RLU test results in the new RLU bins are not significantly higher than your proposed pass/fail limit, consider increasing your pass/fail limit.
 - If most of the RLU test results in the new RLU bins are significantly higher than your proposed pass/fail limit, investigate to find out the reason for the high RLU test results.
4. The example histogram in Figure 2 shows a single peak in the frequency of RLU test result values (RLU = 268) at a low RLU range (0-10 RLU), which is expected if your cleaning process is effective.
5. Decreasing the pass/fail limit could be a tool for improving the effectiveness of your cleaning processes. Assuming the pass/fail limit in this example is 150 RLU, you could change the pass/fail limit to 120 RLU, for example. After making this change, new RLU test result values

between 121 and 150 will not be in the pass category, and the sanitation team will have to re-clean and re-test until the RLU test result values are less than 121 RLU. Lowering a pass/fail limit may tend to increase the frequency of re-cleaning and re-testing until the cleaning process at those Test Points become more effective. As a result, RLU test result values that are less than 120 will tend to increase and the number of RLU test results values that are greater than 121 will tend to decrease.

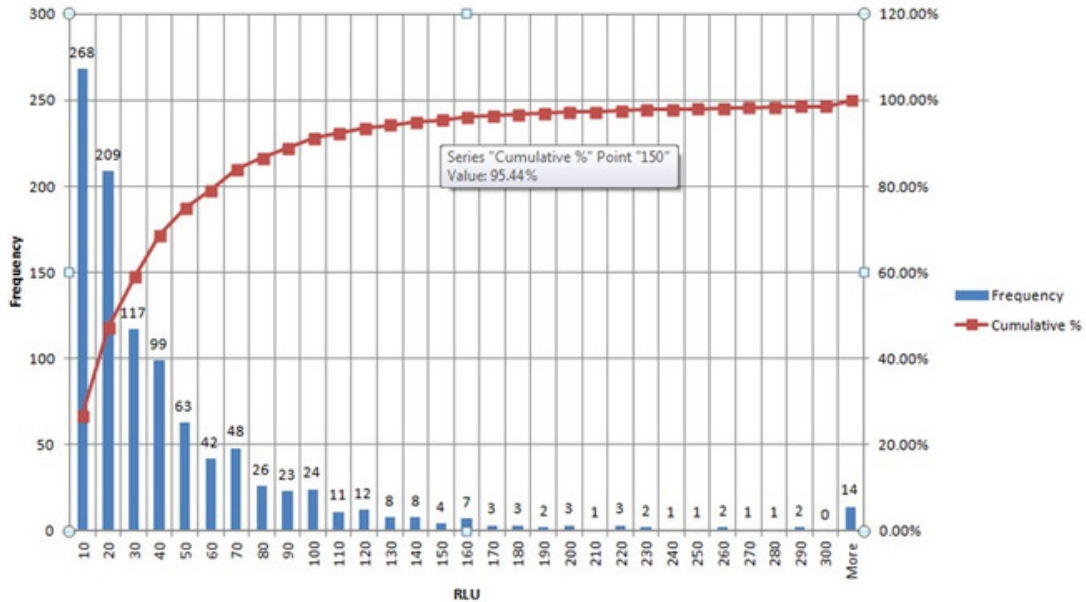


Figure 2. Example of a histogram chart showing RLU test results for a table top surface from the demo database results.

6. The example histogram in figure 3 shows multiple peaks in the frequency of RLU test result values at 20 RLU, 60 RLU, and 120 RLU, which could indicate the cleaning process is sometimes achieving the level of cleanliness indicated by 120 RLU, and other times achieving the level of cleanliness indicated by 60 RLU, and yet other times achieving the level of cleanliness indicated by 20 RLU. This may indicate that the cleaning process is not consistent, and you should investigate the cause of this inconsistency. Another potential cause is that the data has been confounded by including Test Points expected to have three different levels of cleanliness (20 RLU, 60 RLU, and 120 RLU).

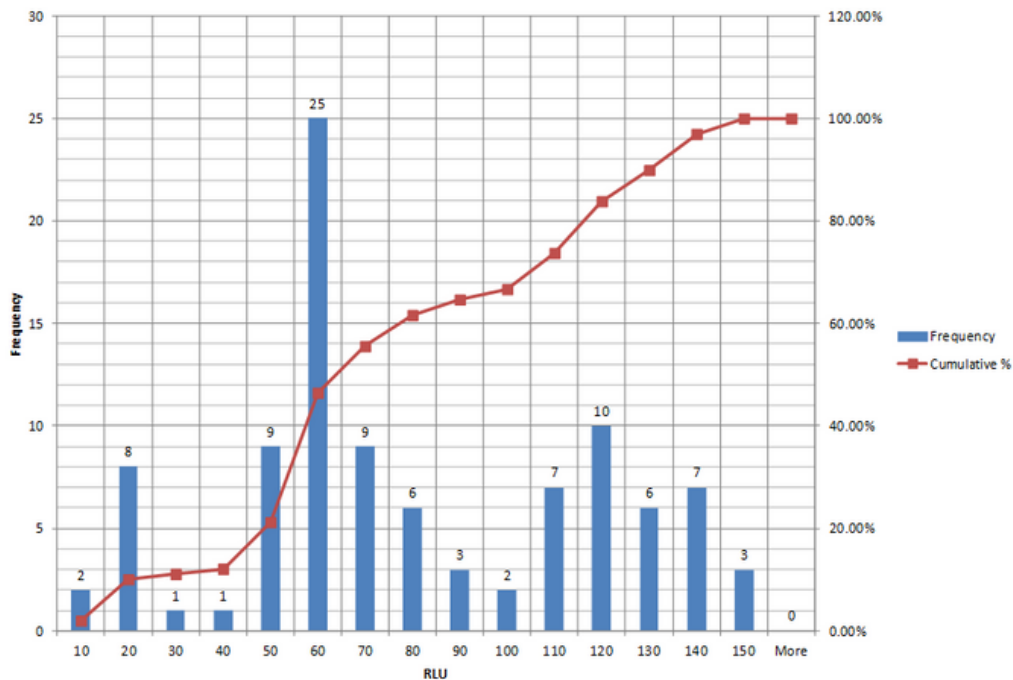


Figure 3. Example of a histogram chart showing RLU test results for pizza line from the demo database results.

Statistical Analysis Using Microsoft® Excel Formulas

Statistical Analysis of the Validation Study Data Using Microsoft® Excel Functions

You may also analyze the data from your validation study by conducting a statistical process control analysis and set the pass/fail limits based on the normal variation observed in a clean process. See steps below:

1. Export test result data into a spreadsheet as described in the “Exporting Data” section of the 3M Clean-Trace Hygiene Monitoring Software User Manual.
2. Do a time series analysis and investigate any trends before proceeding.
3. Review the distribution of the data. You can create a histogram as described in step 3 above, and if the histogram shows the typical bell shaped curve, the data is normally distributed.
4. If does not show a normal distribution, conduct a mathematical transform on the data, such as a Box-Cox transformation, to achieve a normal distribution.
5. Calculate the mean + 3 standard deviations or + 2 standard deviations, based on your process control procedure.
6. Transform the data back to determine the RLU pass/fail limit to use in the 3M Clean-Trace Hygiene Monitoring Software.

If you’re using 3M™ Clean-Trace™ Water Plus – Total ATP Test Swab to confirm a clean-in-place (CIP) cleaning process, you can do a validation study by measuring the background count RLU test results of the rinse water before it’s used in the CIP process as a basis for setting your pass/fail limits.

1. Use 3M Clean-Trace Water Plus – Total ATP Test Swab to test at least 30 samples of the rinse water before it’s used in the CIP process. Record the RLU test results for each sample.

2. Enter the RLU test results into a Microsoft® Excel spreadsheet, and confirm that the data is normally distributed. You can create a histogram as described in step 3 above, and if the histogram shows the typical bell shaped curve, the data is normally distributed.

3. Use the AVERAGE function to calculate the mean, and use the STDEV function to calculate the standard deviation of the RLU test results.

4. Calculate the mean \pm 3 standard deviations (or \pm 2 standard deviations, based on your process control procedure) to set the pass/fail limit. You can assume that RLU test values greater than this pass/fail limit are not background counts; instead they indicate Test Points that have not been cleaned effectively.

User should analyze, and if necessary update your pass/fail limits using the methods described in this Technical Bulletin on a periodic basis and any time you change cleaning processes. To update pass/fail limits, use the 3M Clean-Trace Hygiene Monitoring Software to edit your pass/fail limits for the Test Points in your Sample Plans, and then send your Sample Plans to your 3M Clean-Trace Luminometer. Refer to the 3M Clean-Trace Hygiene Monitoring Software User Manual for more details on editing your Sample Plans and sending your Sample Plans to your 3M Clean-Trace Luminometer. Always collect all results from your 3M Clean-Trace Luminometer before editing your Sample Plans.

If you would like assistance with reviewing your pass/fail limits, please contact your local 3M Food Safety Professional Services Representative.

References:

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3M Food Safety

3M Center
Building 275-5W-05
St. Paul, MN 55144-1000 USA
1-800-328-6553
www.3M.com/foodsafety

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02 9099 5988
info@haccpplus.com.au
www.haccpplus.com.au