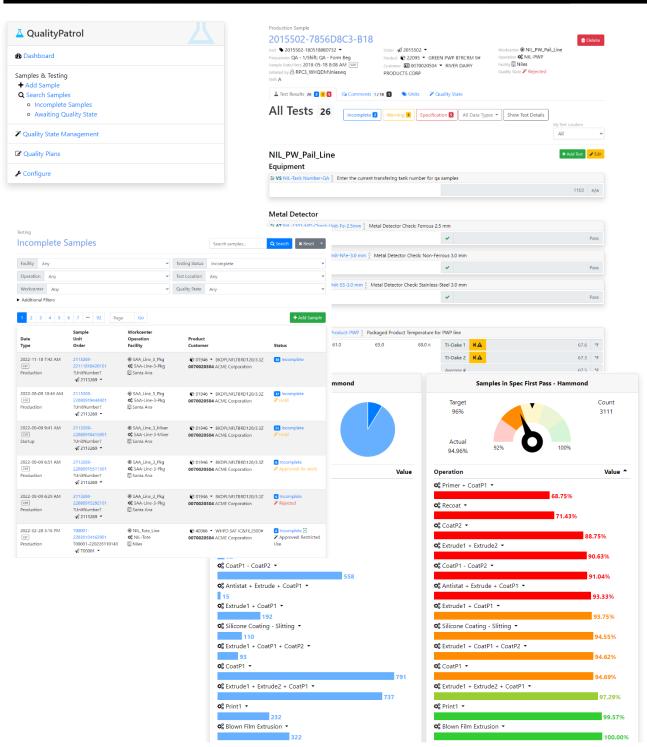
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Chapter 1: Introduction

Introduction

QualityPatrol™ is a PatrolSuite module that facilitates:

- ➤ The definition of the product quality plan, including process conditions and product testing requirements and the corresponding targets and specifications. In regulated industries such as medical devices, this is the design transfer step from the device master record (DMR) to manufacturing.
- ➤ The capture and storage of the information required by the quality plan (e.g. the test results) and the subsequent determination of the product's quality state. In regulated industries such as medical devices, this is the device history record (DHR).

This user guide covers the creation of samples, the testing thereof, and the assignment of the quality state for the sample. Configuration of the product quality plan and specifications are covered in a separate user guide.

Access

To access the PatrolSuite homepage, obtain the URL and login credentials from your IT department.

PatrolSuite module access is governed by both PatrolSuite and Active Directory security protocols. Therefore, users will see different homepage content and will have different access levels based on assigned roles. For assistance with security or permissions, contact your IT department.

Browser

PatrolSuite™ is accessed through a web browser. The platform and all its applications are certified for use with Google Chrome, Microsoft Edge, and Safari. To ensure full functionality and the best user experience, MAP strongly recommends using one of these supported browsers.

NEW Definitions

Business Partner – Customers and Suppliers.

Business Unit – Grouping of manufacturing facilities according to the market to which their products are sold.

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Comprehensive Testing – If an administrator has turned comprehensive testing "on" for a given test location, then all test results must be recorded before the user is allowed to save/close the edit test results window. This feature can be used to help ensure that all tests are performed as required.

Cost of Quality (CoQ) – The total cost of ensuring and maintaining product quality. It includes all costs involved in preventing defects, appraising product quality, and dealing with failures. CoQ is divided into four categories:

- 1. Prevention Costs (Quality Assurance)
 - o Costs to prevent defects before they happen such as training, process design, quality planning, policy and procedure documentation, and preventive maintenance.
- 2. Appraisal Costs (Quality Control)
 - Costs of measuring and monitoring product quality such as product inspection and testing, audits, calibration of instruments, statistical process control (SPC).
- 3. Internal Failure Costs (Nonconforming Product)
 - Costs of defects **found before** the product reaches the customer such as scrap, rework, downtime, re-inspection.
- 4. External Failure Costs (Customer Complaints)
 - Costs of defects **found after** the product is delivered to the customer such as customer complaints, warranty claims, returns, product recalls, loss of reputation.

Cost of Poor Quality (CoPQ) – Avoidable costs that result from delivering a substandard product or service. CoPQ = Internal Failure Costs + External Failure Costs. Accordingly, CoPQ is a subset of the CoQ often referred to as "the cost incurred when things go wrong."

Currency – A system of money in common use within a particular country or economic region, used as a medium of exchange, store of value, and unit of account in financial transactions.

Defect – Flaws, faults, or deviations in a manufactured item that prevent it from meeting design specifications, quality standards, or customer expectations.

Defect Category – Grouping of defects to help identify, analyze, and correct issues systematically. Common defect categories include:

- Aesthetic or Cosmetic Defects Visual imperfections that do not affect the product's functionality but can impact customer perception and marketability.
- Design Defects Flaws inherent in the product's design that make it unsafe, ineffective, or prone to failure, even if manufactured perfectly.
- Documentation/Labeling Defects Inaccurate or missing product information, which may lead to misuse, safety issues, or regulatory non-compliance.
- Functional Defects The product does not perform as intended or fails under specific conditions.
- Manufacturing Defects Flaws introduced during the production or assembly process, even when the design is correct.
- Material Defects Deficiencies in raw materials or components that affect product performance, safety, or durability.
- Packaging Defects Issues related to how the product is packaged for shipping, storage, or display.
- Process Defects Defects caused by errors in the manufacturing process settings, procedures, or conditions.

Department – An organized unit within a company that is responsible for managing a specific set of functions, processes, or activities that contribute to the organization's overall goals and operations.

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Disposition – The remediation instructions assigned to a product with a rejected quality state. The goal of the remediation is to minimize the financial loss due to making product that does not meet quality requirements.

Enterprise Resource Planning (ERP) – Software system that enables management of the day-to-day business activities such as accounting/finance, procurement, supply chain, human resources, sales order conversion to manufacturing orders, distribution, project management, compliance, and others.

Facility – A physical location where raw materials are converted into finished or semi-finished products through various production processes, machinery, labor, and technology.

Manufacturing Execution System (MES) – Software system that tracks and documents the transformation of raw materials into finished goods, including inventory consumption and product genealogy. In a world class manufacturing environment, the MES is integrated to communicate bi-directionally with the ERP and the Quality System (PatrolSuite).

Market ("Customer Market") – Groups of consumers that a company targets to sell its products or services, based on shared needs, characteristics, or behaviors. These markets help companies focus their marketing, product development, and sales strategies by understanding who their customers are and what they need.

Operation – Location where a sample originates for which testing is performed.

Order – A set of data with a unique order number (typically originating from the MES or ERP) to identify a:

- Inbound Receiving order (often a "purchase order") for raw materials
- Manufacturing order and its related product and customer
- Outbound Shipping order for finished goods being shipped to customers

Product – A tangible output or item that is created through a controlled process involving raw materials, labor, machinery, and other inputs, intended for use, sale, or further processing. Types of products include:

- Finished Goods: Ready for sale to end users (e.g. computers, bicycles, paper).
- Semi-Finished Goods: Used as components in other products (e.g. engine parts, circuit boards).
- Raw Materials: Basic inputs for production (e.g., glue, steel, plastic pellets, lumber).

Product Group – A collection of related products that share common characteristics, functions, markets, manufacturing processes, or branding, and are managed together for strategic, operational, or marketing purposes.

Quality Assurance (QA) – A proactive process that focuses on preventing defects by ensuring that the processes used to manage and create deliverables are effective and followed correctly.

- Focus: Process-oriented
- Goal: Prevent defects before they happen
- When: Throughout the product development and prior to the manufacturing process
- Methods: Process audits, training, standard operating procedures (SOPs), continuous improvement
- Responsibility: Business management, quality management, and process engineers

Quality Control (QC) – A reactive process that focuses on identifying defects in the finished product through inspection and testing.

- Focus: Product-oriented
- Goal: Detect and fix defects after they occur
- When: After production or at specific checkpoints during production
- Methods: Inspections, measurements, product testing, sampling, statistical process control (SPC)
- Responsibility: Laboratory technicians, quality inspectors, or testing personnel

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Quality Plan – A formal set of electronic files or settings that define the specific quality practices, resources, standards, procedures, responsibilities, and inspection or testing methods to be applied to a particular product or process during manufacturing.

Quality State – The assessment of a sample's conformance to quality requirements. For example, a sample for which all tests are completed, and all are in spec, might have a quality state of "Approved."

Raw Material – A basic, unprocessed, or minimally processed substance that is used as the starting input in the production or manufacturing of goods and products.

Reasonable Data Limit (RDL) – The range in which all test results would normally be expected to fall. If an RDL is defined, and a test result is entered that exceeds the RDL, the user will get a warning message.

Sample – A QualityPatrol record reflecting a point in time at which product characteristics (i.e. test results) or process parameters (i.e. process conditions) are recorded. Samples are related to the Operation and Workcenter where they are being manufactured.

Sample Status "Incomplete" – A sample that has one or more data yet to be collected. For example, if a Sample requires 5 tests to be performed, but only 4 tests have been completed, then the sample is incomplete.

Sample Status "Completed" – A sample for which all tests are completed. Note that complete/incomplete has nothing to do with whether the results are in spec or out of spec.

Sample Location – A physical location on a single sample from which tests are performed for X-bar testing.

Sample Type "Start Up" – Identifies a sample of product that is not intended to be sold to a customer or used in further processing. Use Case: When a manufacturing line begins producing "Product 123," the first few samples are identified as Start Up and are used to determine when the product meets quality requirements. Once quality requirements are met, then the next sample is identified with the sample type "Production." Note: Start Up samples can be and are typically omitted from statistical analysis (DataPatrol & DashPatrol).

Sample Type "Production" – Identifies a sample of product that is expected to meet quality requirements and be sold to a customer or used in further processing.

Specification Limit – The product measurements within which confirm the acceptability of a product, or the process conditions within which likely result in the production of acceptable product. Product specification limits are typically defined by the customer. Process specification limits are typically defined by the manufacturer.

Specification Limit "Upper" – The highest value that a test result can be and still be considered acceptable to the customer.

Specification Limit "Lower" – The lowest value that a test result can be and still be considered acceptable to the customer.

Test Location – A physical location within the Facility where tests are completed.

Unit – The smallest measurable or sellable quantity of a product. Units are typically used for production, inventory, pricing, sales, and distribution purposes.

Unit of Measure – A standard quantitative unit used to specify, track, and manage the amount of a product,

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material, or resource in the manufacturing, inventory, sales, or procurement processes.

Warning Limit – A numerical value that, when exceeded, raises a flag prompting a timely, proactive response to eliminate or minimize the possibility of the parameter from reaching an alarm limit such as a specification.

Workcenter – A sub-division of an Operation. An Operation can have one or more Workcenters. Often, a workcenter reflects a unique manufacturing machine or asset.

Symbol Key

The following symbols are used in this user guide.

Typeface	Description
B	Indicates a "required" data entry field within a UI.
NEW	Indicates a new feature, or new information regarding existing functionality.
	Indicates rules regarding access security.
?	Click the help icon to view additional information.

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Chapter 2: Security

Roles & Permissions

See the "QualityPatrol – Configure" user guide for information regarding PatrolSuite security.



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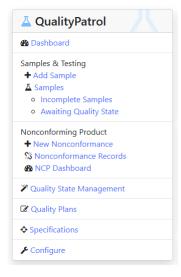
Chapter 3: Navigation

QualityPatrol Card

Users with the following permission can view QualityPatrol and its related pages.



The QualityPatrol card on the PatrolSuite homepage provides hyperlinks to the pages of the QualityPatrol module.



<u>Dashboard</u> – Enables a user to view the QualityPatrol dashboard.

<u>Samples & Testing</u> – Enables a user to create a sample, to record test results, and to assign a quality state (formerly the QDMS Console).

- Add Sample. Enables a user to create a sample.
- Samples. Enables a user to search for samples by testing status.
- Incomplete Samples. Enables a user to search for incomplete samples and add test results.
- Awaiting Quality State. Enables a user to search for completes samples that were not assigned a
 quality state (likely because one or more test results are out of specification).

NEW Nonconforming Product – Provides access to the nonconforming product pages. Note that this module may not be active depending on the organization's use of these features.

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Quality State Management – Enables a user to:

- Assign a quality state to multiple samples from the same production order.
- Send a quality state code to the MES/ERP for units that were not samples in QualityPatrol.

Quality Plans – Enables a user to find, view, and manage quality plans and specifications.

NEW Specifications – Enables a user to access the search specifications page.

Configure – Enables a user to access the QualityPatrol configuration pages.



Chapter 4: Add a Sample

NEW Introduction

A "sample" is a QualityPatrol record reflecting a point in time at which product characteristics (i.e. test results) or process parameters (i.e. process conditions) are recorded. Samples are related to the Operation and Workcenter where they are being manufactured.

QualityPatrol does not manage "when" samples need to be created. This functionality is managed by a manufacturing execution system (MES). If the organization does not have a MES, then the organization should consider creating a "sample initiation guide" to define when samples need to be created at each manufacturing operation.

Page: {PatrolSuite URL}/Quality/AddSample

The following permissions govern adding and deleting samples. Deleting a sample is covered in a subsequent chapter.

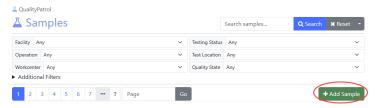


Add Sample

- 1. NEW There are three ways to begin adding a sample. Click on the desired hyperlink or button.
 - a. The "Add Sample" hyperlink on the QualityPatrol card.



b. The 'Add Sample' button on the search samples page.



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c. The 'Add Sample' button on the DashPatrol "Line Details" page.

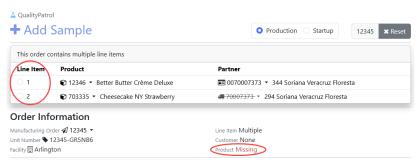


2. Click on the radio button to indicate the sample type (Production or Startup), enter the unit number being tested (depending on the manufacturing process, some organizations will enter a manufacturing order number instead of a unit number), and click the 'Search' button.

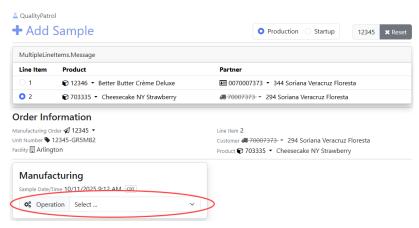


3. QualityPatrol supports multi-line item orders (i.e. an order that has multiple products, or one product related to multiple business partners). If there are multiple line items in the order, QualityPatrol will prompt the user to select a line item. Select the applicable line item.

Note: In the screen shot below, the product is labeled as "Missing" because the order has two line items for different products.



4. Select the operation.



Note: If a corresponding quality plan does not exist, a warning will be displayed advising the user that a





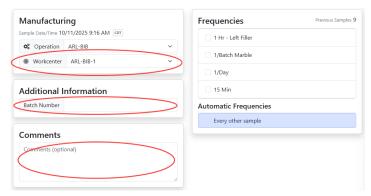
sample can still be created, and test methods will need to be added in an ad hoc manner.



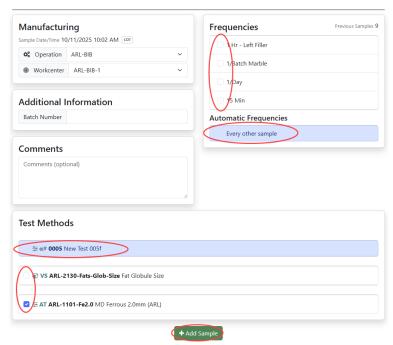
5. Select the workcenter, add Additional Information if requested, and add comments about the sample if desired.

Note: If only one workcenter exists for the operation, then it will automatically be selected.

Note: The Additional Information feature is defined in QualityPatrol Configure at the Operation level and is based on the "UDFs." See the "QualityPatrol - Configure" user guide for more information.



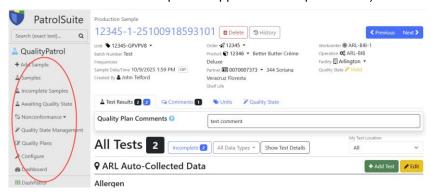
- 6. Select the applicable sample frequency(ies) and click the 'Add Sample' button.
 - Note: When a frequency is selected, the required test methods will be highlighted in blue.
 - Note: If "Automatic Frequencies" are chosen in the quality plan, then those frequencies will be automatically selected, and they cannot be unselected.
 - Note: Prior to clicking the 'Add Sample' button, the user can add additional test methods that are not required based on the chosen frequencies by checking the checkbox of the test methods that are not highlighted in blue.







7. The sample will be created, and the sample page will automatically open to enable the user to enter test results. If the user is not ready to enter test results, click on one of the hyperlinks in the main menu to navigate to a different page (e.g. Click on the "Incomplete Samples" hyperlink to view the Incomplete Samples page where the most recent sample will appear at the top of the list).





Chapter 5: Search Samples

Introduction

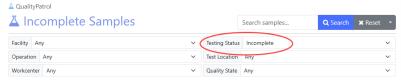
The search samples page enables user to locate and open QualityPatrol samples.

There are three hyperlinks to access the Search Samples page:

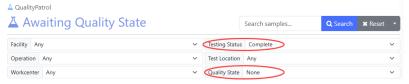


Samples – Opens the Search Samples page without any filters pre-selected.

Incomplete Samples – Opens the Search Samples page with the Testing Status filter pre-selected to "Incomplete." Accordingly, samples with one or more tests that have not been completed are displayed.



Awaiting Quality State – Opens the Search Samples page with the Testing Status filter pre-selected to "Complete" and the Quality State filter pre-selected to "None." Accordingly, samples with all test completed but no quality state assigned (most likely because a test failed or exceeded specification limits) are displayed. Samples on this page require daily review and processing by quality management.



The search samples page is located on Page: {PatrolSuite URL}/Quality/Samples



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Search

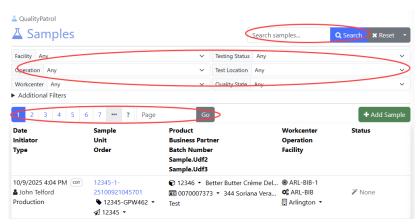
8. To view QualityPatrol samples, click one of the three hyperlinks in the QualityPatrol card.



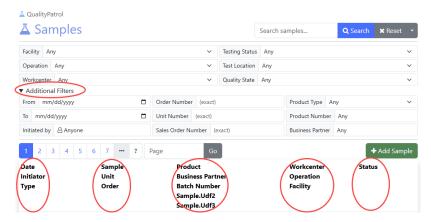
9. To find a sample, enter the sample number into the "Search samples..." cell and click 'Search," or use the filters to filter the samples displayed in the sample grid. Use the page numbers to navigate to different pages of the sample grid.

Note: The sample grid is sorted to display the most recent sample at the top.

Note: If a user previously selected his/her "My Test Location" from within an open sample, then this filter will display the chosen My Test Location. If My Test Location is set to "Any" (which means that a My Test Location has not been chosen), then this dropdown acts like a normal filter for all test locations.



- a. Click on the 'Additional Filters' test to expose additional filters.
- b. Click on the desired column heading to sort the data grid.



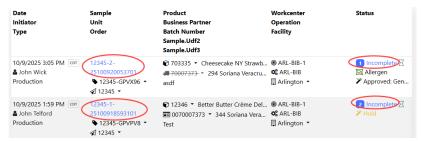
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Open a Sample

10. To open a sample, click on the sample number.

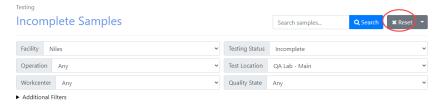
Note: For incomplete samples, click on the status hyperlink to open the sample page pre-filtered to view only the incomplete tests visible.



Reset Filters

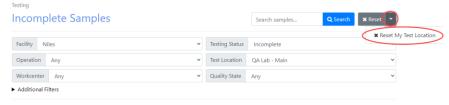
The 'Reset' button has two actionable areas:

11. "Test Location" filter. Click the left side of the 'Reset' button to clear chosen filters.



Note: On the Incomplete Samples page, the 'Reset' button clears all filters except the Testing Status. This allows a user who is on the Incomplete Samples page to stay on the Incomplete Samples page when the filters are cleared. Changing the "Incomplete" testing status to "Any" will take the user to a different page: the Search Samples page.

12. "My Test Location" filter. Click the arrow on the right side of the 'Reset' button to expose the submenu. Click 'Reset My Test Location' to change the user's My Test Location to 'Any.' Resetting the My Test Location will result in the dropdown displaying the previously chosen Test Location filter (if any).



Note: If a user selects a "My Test Location" from within an open sample, then that My Test Location will persist onto this page and supersede any previously selected Test Location filter.



Chapter 6: Edit Sample - Test Results

Introduction

This chapter provides functional details regarding the Test Results tab. Most importantly, this is where test results are recorded.

Note: If the applicable quality plan has comments, those comments are displayed below the tabs.



Sample Header

The sample header shows the metadata about the sample.

- 13. To delete the sample, click on the "Delete" button and click on the "Delete" button in the confirmation window.
- 14. **NEW** To see the audit trail of changes to the sample, click the 'History' button.
- 15. To view other samples from the same manufacturing order, click the 'Previous' or 'Next' buttons.

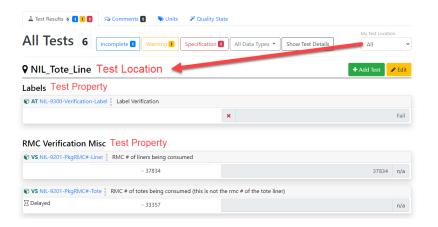


Test Results Layout

The test results tab organizes the sample's required tests by Test Location and Test Property.

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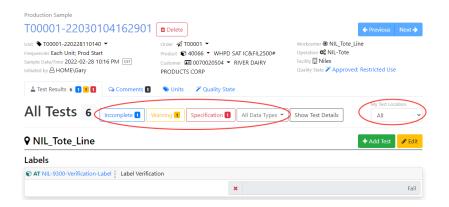
Test Methods Filter Buttons

- 16. Click on one of the test method filter buttons to change the test methods displayed on the page.
 - a. **Incomplete** Filters the test methods to display only those that have not been completed. The blue badge shows the number of incomplete test methods.
 - b. **Warning** Filters the test methods to display only those that have a result that violates a warning limit. The yellow badge shows the number of test methods that exceed a warning limit.
 - c. **Specification** Filters the test methods to display only those that have a result that violates a specification limit. The red badge shows the number of test methods that exceed a specification limit.
 - d. Data Types Filters the test methods to display only those for the chosen data type.
 - e. My Test Location Formerly "My Location At" in QDMS. Choosing a My Test Location:
 - Sorts the test methods so the My Test Location methods appear at the top of the Test Results tab.
 - ii. Enables the user to enter/edit test results for the chosen My Test Location. The remaining test methods for other test locations are still displayed, but the user cannot enter/edit test results for other test locations.
 - iii. Persists the My Test Location onto the Search Samples pages.

Note: Resetting the My Test Location to "Any" will enable the user to record test results for all testing locations in each sample.

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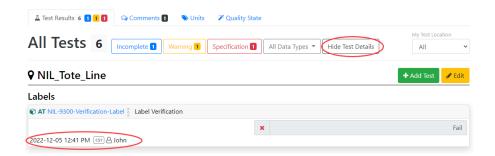


Test Method Details

17. Click on the 'Show Test Details' button to display the date/time the test was completed and the user who performed the test.



18. Click on the 'Hide Test Details' button to hide the test details.

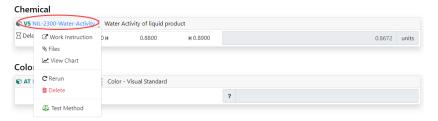


Test Method Menu

19. To access the test method submenu, click on the test method name or the ellipses adjacent to the test method name.

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- a. Click on the desired submenu link.
 - i. **Work Instruction** If a work instruction has been associated with the test method, then the Work Instruction menu choice will appear. Click to open the work instruction.
 - ii. Files Click to attach files to the test results.
 - iii. **View Chart** Click to view the results for the applicable test method for all samples in the same manufacturing order in DashPatrol.
 - Users with the following permission can view charts in DashPatrol.



- v. **Delete** Click to delete the sample and its test results.
 - Users with the following permissions can delete samples.



vi. **Test Method** – Click to view the test method details page.

Specifications

For test methods that have an upper, lower, or target specification defined, the specs are displayed in the test method card.







20. Click on the specification values to display the detailed specification information.



Files

Users with the following permissions can attach files to test results.



Note: If a test method requires a file to be attached before results can be saved, then the yellow "Required" icon will appear.



Note: Files can be attached to the results of any test method, including those test methods that do not require files.

Note: Once a file is attached, a file badge appears to indicate the number of attached files.



21. To attach a file to a test result, click on the desired test method name and click "Files" in the submenu.

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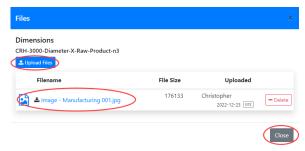




a. Click the 'Upload Files' button.



- b. Select a file from a network location and click the operating system's upload button. The file will appear in the dialogue window.
 - i. To view the file, click on the file name.
 - ii. To upload another file, click the 'Upload Files' button.
 - iii. To delete an existing file, click the 'Delete' button.
 - iv. To close the dialogue window, click 'Close.'



22. To view a test method's existing files, click on the desired test method name. The Files submenu will display the number of attached files in the badge. Click on the Files submenu.



Add a Test

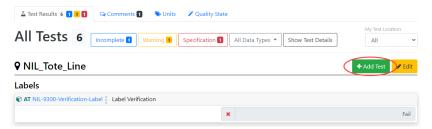
Users with the following permissions can add a test to an existing sample.



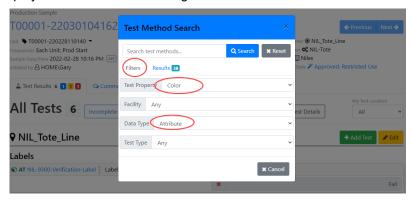
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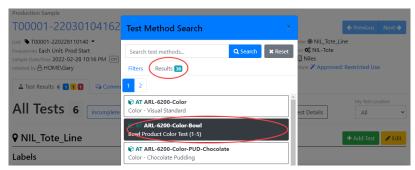
23. To add a test that is not already listed on the sample page, click the 'Add Test' button.



a. On the Filters tab, enter the test method name or number into the search cell and click the 'Search' button. Alternatively, use the filters to find a test method. As filters are selected, the badge on the Results tab displays the number of matching test methods.



b. Click on the Results tab and click on the desired test method.



Record Test Results - Alphanumeric

Users with the following permissions can record test results (all data types).

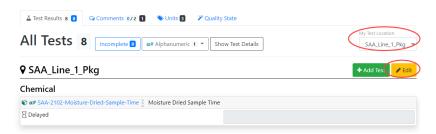


24. To record test results, first select your My Test Location. This will filter the list of test methods to display only those test methods that are performed at your location. Locate the desired test and click the 'Edit'

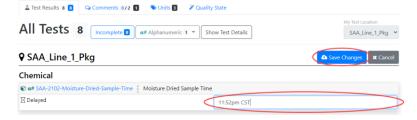




button.

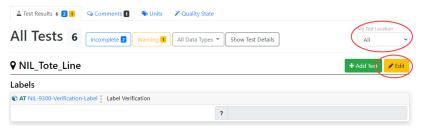


a. Click into the results cell, enter the result, and click the 'Save Changes' button.

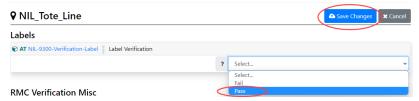


Record Test Results - Attribute

25. To record test results, first select your My Test Location. This will filter the list of test methods to display only those test methods that are performed at your location. Locate the desired test and click the 'Edit' button.



a. Select the applicable attribute option from the dropdown and click 'Save Changes.'



Note: Attribute options that "Fail" are displayed with a red "X."

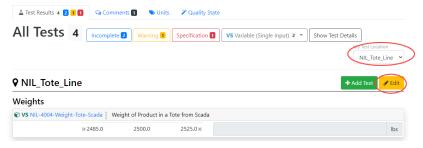


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Record Test Results - Variable Single Input

26. To record test results, first select your My Test Location. This will filter the list of test methods to display only those test methods that are performed at your location. Locate the desired test and click the 'Edit' button.

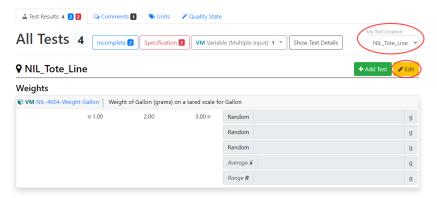


a. Click into the results cell, enter the test result, and click the 'Save Changes' button.'



Record Test Results - Variable Multi Input

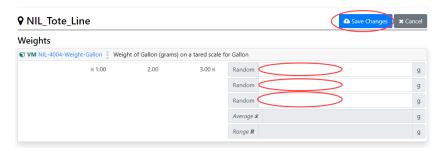
27. To record test results, first select your My Test Location. This will filter the list of test methods to display only those test methods that are performed at your location. Locate the desired test and click the 'Edit' button.



a. Click into the results cell for the applicable sample location, enter the test result, and click the 'Save Changes' button.

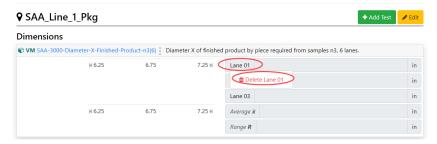






Note: The Average and Range values are not calculated until 'Save Changes' is clicked.

28. To delete a Variable Multi Input test location, click on the test location name and click on "Delete Location" in the submenu.



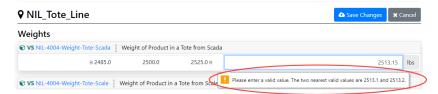
a. Click the 'Delete' button in the confirmation window.



Record Test Results – Indicators & Warnings

The following indicators and warnings apply to variable single input (VSI) and variable multi input (VMI) test methods.

> If a result is entered using the incorrect decimal places, then a warning will prompt the user to enter a result with the correct decimal places.



If a result exceeds specification limits, then a red out of spec icon will appear, and the cell will be outlined in red.



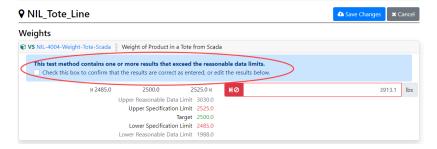




If a result exceeds warning limits, then a yellow warning limit icon will appear, and the cell will be outlined in yellow.



- If a result exceeds a reasonable data limit (RDL), then then a blue dialogue box will appear. The user will not be allowed to save the result until one of two actions are completed:
 - a. Change the value entered.
 - b. Check the acknowledgement checkbox.



If a test location is "comprehensive" and the user saves results before all results are entered, then a dialogue box will appear asking the user to enter the test results for incomplete test methods.



If a test method requires a file to be attached before results can be saved, then the yellow Required icon will appear.



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If a sample is initiated that does not have a corresponding test plan, then the Test Results tab will not contain any test methods.

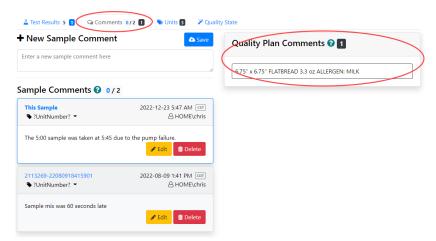




Chapter 7: Edit Sample - Comments

Quality Plan Comments

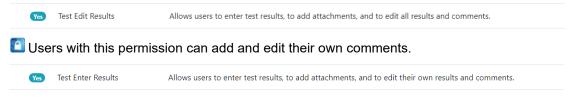
29. Click on the Comments tab. The quality plan comments are displayed in a read-only manner. Quality Admins typically use quality plan comments to communicate important information to the operators and laboratory technicians regarding the sampling plan, the testing requirements, or health and safety concerns.



Sample Comments

This section displays the comments made when samples for the applicable manufacturing order are initiated.

Users with this permission can edit other user's comments.



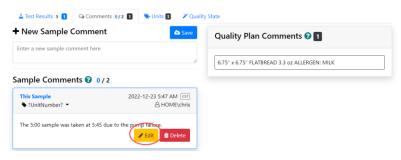
30. To add a new comment, enter the comments and click 'Save.'



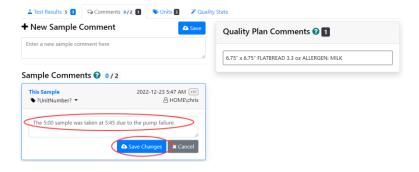




31. To edit a comment, click the 'Edit' button.



a. Edit the sample and click 'Save Changes,'





Chapter 8: Edit Sample - Units

Introduction

The Units tab displays the input units that were consumed at the applicable step of the manufacturing process. If PatrolSuite is integrated with an MES that tracks genealogy, then the input units will be displayed automatically. If no MES exists, then users can manually record genealogy using the 'Add Unit' feature.

Users with this permission are allowed to add and remove input units.

Sample Edit Genealogy Allows users to edit the sample genealogy (consumed units).

Add Input Units

32. Click on the Units tab. Enter the unit number and click on the 'Add Unit' button.



Remove Input Units

33. Click on the 'Remove' button for the desired unit.



34. In the confirmation window, click on the 'Remove' button.





Chapter 9: Quality State Assignment

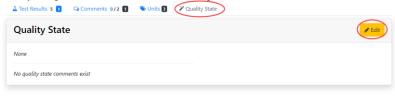
Introduction

The Quality State tab is used to manage the quality state assigned to the sample. Typically, if all testing is complete and all results are within specification limits, QualityPatrol will automatically assign the quality state "Approved – General use."



Edit

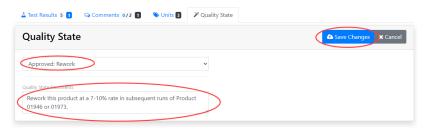
35. To edit the sample's quality state, click on the Quality State tab and click the 'Edit' button.



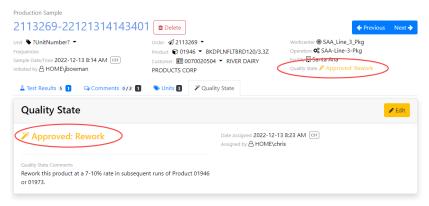
36. Choose the applicable quality state, enter any comments related to the further processing of the product.

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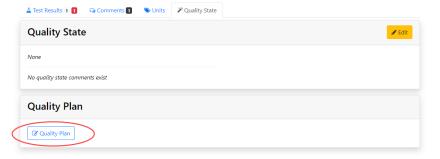
37. Click 'Save Changes.' The chosen quality state will be applied and displayed.



Note: If PatrolSuite is integrated to communicate bi-directionally with the ERP or MES, then the assigned quality state and the quality state comments are automatically sent to the ERP or MES so that the ERP or MES can manage further processing of the unit.

Quality Plan

38. Click on the Quality Plan button to access the applicable quality plan.





Chapter 10: Quality State Management

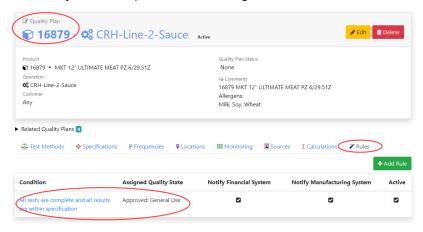
Introduction

The following permissions govern the ability to manage the quality state assigned to a sample.



Quality State Rules

Quality state rules govern what happens to a sample when certain tests are performed. For example, once all tests are complete, and if all of those results are within specification limits, then a QualityPatrol rule can be configured (within the applicable quality plan) to automatically assign a quality state such as "Approved – General Use" to the sample. If PatrolSuite is integrated to communicate with your ERP or MES, then the quality state rule can also automatically send the corresponding quality state information to the ERP or MES. See the QualityPatrol – Quality Plans & Specifications user guide for more information.



Note: Quality State Rules and Quality State Management are two separate apps that are not related (except for the fact that both apps are used to manage quality states.

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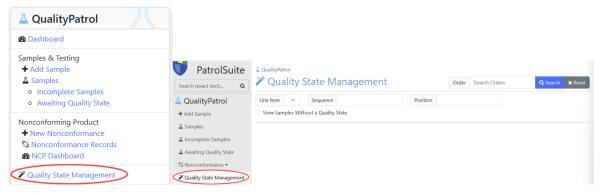


- Quality State Rules Located on the Rules tab of the quality plan. Used to automatically assign a
 quality state to a sample once certain criteria are met. See the "Quality Plans & Specifications" user
 guide.
- Quality State Management Located on its own page in QualityPatrol. Used to manually assign a
 quality state to one or more samples from the same manufacturing order.

Quality State Management

This page enables a user to manage the quality state assigned to units that have a sample in QualityPatrol.

Use Case: If the first 14 units of a manufacturing order meet quality requirements, but the remaining 6 units fail a quality requirement, then quality state management can be used to quickly place all 20 units on, for example, "Hold."



- 39. To access the quality state management page, click on the "Quality State Management" hyperlink in the QualityPatrol card on the homepage, or in the navigation menu.
- 40. To edit the quality state of samples in an order, enter the desired order number and click Search.



a. Click on the Samples tab and use the filters to locate the sample(s) of interest.

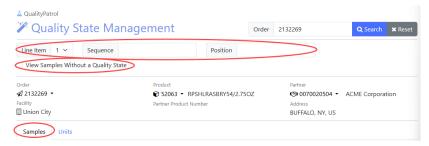
Note: Choose the order line item, if applicable.

Note: Enter the sample Sequence and Position, if applicable. This requires integration with an MES to exchange sequence or position data regarding units.

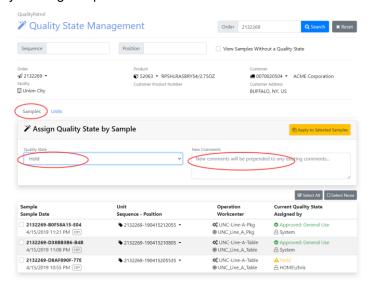
Note: Click the "View Samples Without a Quality State" checkbox to view only those samples without a quality state.

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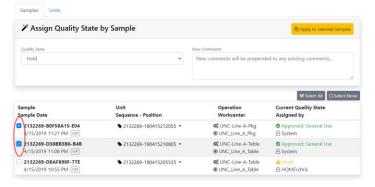




b. Choose the desired quality state and enter any new comments. The new comments will be prepended to any existing sample comments.



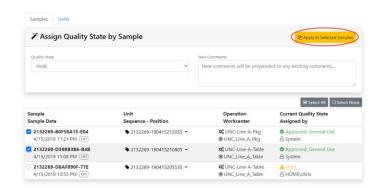
c. Check the checkbox that corresponds to the desired sample(s).



d. Click the Apply to Selected Samples button.

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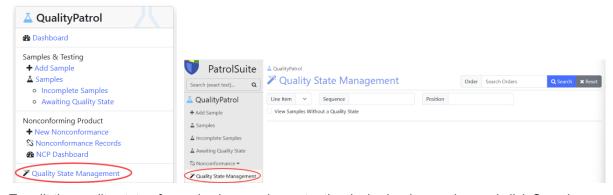
Quality State Management – Units Tab

This tab enables a user to manage the quality state code sent from QualityPatrol to the MES for units that do not have a sample in QualityPatrol.

Note: The units tab applies only to instances where QualityPatrol is configured to communicate bi-directionally with a manufacturing execution system (MES).

Use Case: If the 1st unit and every 10th unit are sampled and tested in QualityPatrol, then this tab enables a user to send a desired quality state code for the unsampled units (i.e. units 2-9) to the MES.

41. To access the quality state management page, click on the "Quality State Management" hyperlink in the QualityPatrol card on the homepage, or in the navigation menu.



42. To edit the quality state of samples in an order, enter the desired order number and click Search.



a. Click on the Units tab and use the filters to locate the sample(s) of interest.

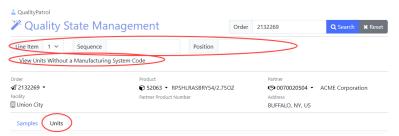
Note: Choose the order line item, if applicable.

Note: Enter the sample Sequence and Position, if applicable. This requires integration with an MES to exchange sequence or position data regarding units.

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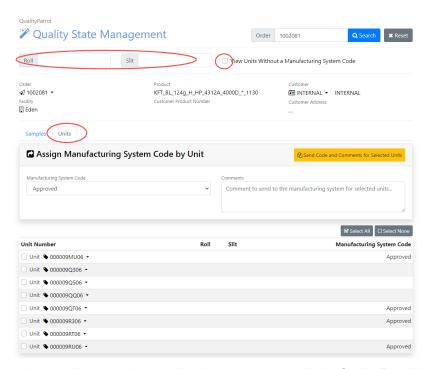


Note: Click the "View Samples Without a Quality State" checkbox to view only those samples without a quality state.



- 43. The units without samples in QualityPatrol are displayed. Additionally, if a quality state code was previously sent to the MES, then the code will be displayed.
 - Note: Click the "View Units Without a Manufacturing System Code" checkbox to view only those units that have not had a quality state code sent to the MES.

Note: If PatrolSuite is integrated with the MES to exchange sequence or position data regarding units, then the Sequence and Position filters can be used to filter the displayed samples.



Note: In the above image, there are 4 units that do not have samples in QualityPatrol but already have had the "Approved" code sent to the MES.

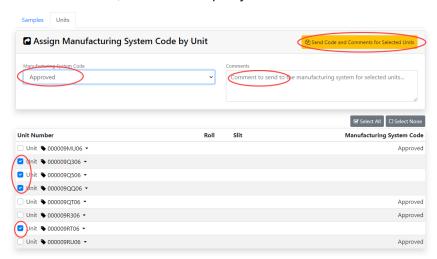
Note: Units with QualityPatrol samples are not selectable and will not have a checkbox.

- 44. Choose the desired manufacturing system code, enter any related comments, select the desired units, and click the "Send Code and Comments for Selected units" button.
 - Note: The manufacturing system code is not the "quality state." All quality states that are defined in QualityPatrol are related to a code (Approved, Delayed, Hold, Rejected, or Restricted). This page





sends the code to the MES, not the actual quality state.





Chapter 11: Dashboard

The following permission enables users to view the QualityPatrol dashboard.

NEW Allows users to view the QualityPatrol dashboard.

Dashboard Homepage

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The QualityPatrol dashboard provides a set of metrics related to the sampling and testing process. Filters and breakdown variables enable the production of thousands of unique metrics.

45. Click on the "Dashboard" hyperlink in the QualityPatrol card. The dashboard homepage will open and display "All Metrics."



- 46. Use the filters to filter the data reflected in the metrics.
- 47. Use the Previous/Next button to navigate between filter choices.
- 48. Click the Reset button to reset the filters.

Note: The targets are determined and set based on an analysis of the historical data. A future version of the dashboard will enable management of the targets.

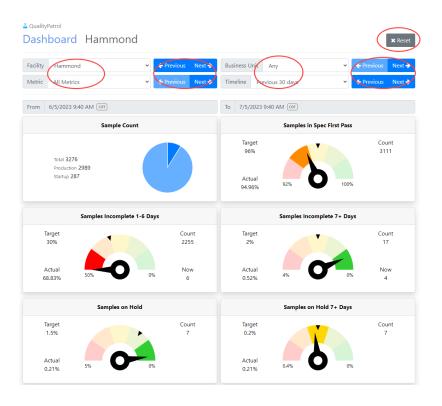
Note: The range of data ("the scale") displayed in the color-coded dials are determined and set based on an analysis of the historical data. A future version of the dashboard will enable management of the scale. Green reflects good performance while red reflects poor performance.

Note: The metric data are based on "samples" or "tests." Look at the metric title to determine the nature of the data.

Note: "Samples in Spec First Pass" measures the number of samples where, for each individual sample, all tests were completed and all results were within specification, and no tests were re-run.

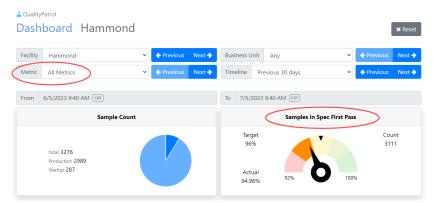
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Metric Details Page

49. Choose an individual metric from the Metrics dropdown or click on a desired metric title to access the metric details page.

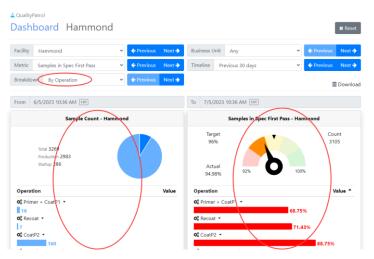


The metric details page introduces a "breakdown" variable that categorizes the data by the chosen variable. The Pareto diagram on the right displays the worst performing items at the top and the corresponding data "count" is displayed on the left.

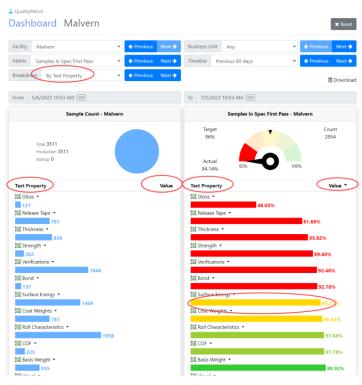
50. Choose a desired breakdown variable.

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- 51. Click on the Pareto diagram headers to change the sort order of the data displayed.
- 52. Click on the desired bar to see related samples in QualityPatrol Search for Samples. Note that not all breakdown variables are related to filterable sample meta data (such as Test Property shown below).



53. If the amount of breakdown items exceeds the number of data rows displayed in the Pareto chart, then a message will appear at the bottom of the chart to advise the user as such.

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a. To download all the data, click on the "Download" hyperlink.

