The Freezerworks® Validation Verification Package

This Validation Verification Package is provided to help inform customers of the thorough validation process Dataworks uses to ensure only top quality products are released. This documentation of our development system offers customers a method to assess our dedication to quality product design and testing.

Commitment to Quality

Dataworks Development, Inc. has over 30 years of experience devoted to the design and continuous improvement of our Software Development LifeCycle, including program testing. We are committed to meeting or exceeding the software development requirements of the FDA, as well as our customers' quality standards. Every staff member at Dataworks is dedicated to providing our customers with the best products in the industry. This Validation Verification Package will illustrate some of the steps we take to provide the highest quality software possible.

Contents

- Software Development LifeCycle (SDLC) Summary
- Program Components Validated
- Samples of Completed Testing Artifacts
- Test Case Results
- Certificate of Validation

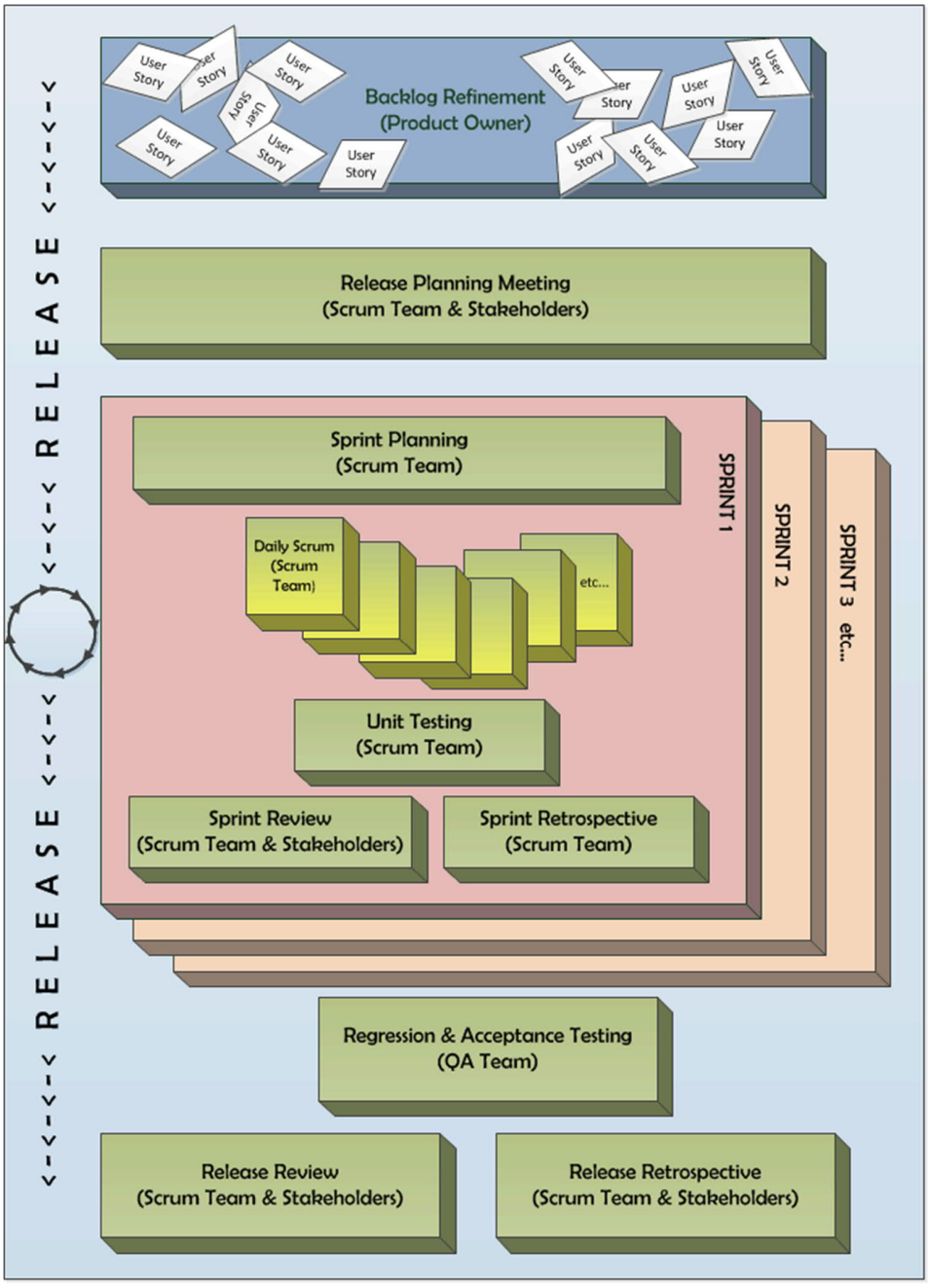
Please note that the testing procedures and artifacts, referenced below, are written to satisfy requirements of validation by a software development company. While Dataworks strives to include the most extensive variety of test cases and data ranges in our systems, they are in no way intended to replace the end-user validation required by the FDA. They are not a substitution for the laboratories' responsibility to assess their own unique needs (functional requirements) and risk levels.

Summary

Only when all development and testing procedures have been completed satisfactorily will the Head of Quality Assurance certify a version of the software for public release. A Certificate of Validation is included at the conclusion of this document. Please contact Dataworks if further information or documentation is needed.

The SDLC Process

The Dataworks Software Development LifeCycle (SDLC) was created in accordance with FDA Guidelines and other current industry technology standards. This extensive SDLC system governs the creation of our software from start to finish; from user input and requirements analysis through production and release. We routinely evaluate our SDLC processes with an eye towards continual improvement. The quality objectives of the SDLC will be regularly communicated and reviewed with the employees who fulfill them. In support of the Dataworks Mission Statement, we are dedicated to making high quality software through this SDLC.



Agile Software Development Methodology

In August of 2017 Dataworks began implementation of a new style SDLC for our Freezerworks product line. The new methodology is based on the Agile approach and takes full advantage of the scrum team, product development sprints, and stakeholder involvement. The Agile Development Team is comprised of the software developers, representatives from the QA Department, and the Technical Writer. Jira, the issue and project tracking database is used to trace all feature requests and error reports through this SDLC process.

As illustrated above, the SDLC is comprised of the following elements:

Backlog Refinement

The Product Owner(s) are responsible for the maintenance of the backlog of User Stories. They will evaluate each Feature Request, assigning a Priority value to it: Must Have, Should Have, and Could Have. Likewise, they will evaluate each Error Report and determine its Impact and Urgency. These evaluations will determine the placement of the issue on the backlog. Feature Requests and Error Reports are submitted by employees on behalf of customers and are linked to the customer's record in the Customer Relationship Management system.

Release Planning Meeting

At the beginning of each new Release cycle, a meeting will be convened with all members of the Agile Development Team including internal stakeholders representing Sales, Marketing, IT, and Support. A limited number of large User Stories (Epics) will be selected for completion during the Release. The Agile Development Team and Stakeholders will discuss each Epic and Story selected and assign Story Points to it based on the anticipated complexity. The number of Stories selected will depend on the estimated Story Points and the current known velocity of the Agile Development Team.

Sprint Planning

Each Release will be comprised of multiple two or three week Sprints. At the beginning of each Sprint, the Agile Development Team will meet to select issues from the backlog to be completed during the Sprint. The number of issues will depend upon the capacity of the team members for that Sprint. The team will discuss each issue and estimate the time required to complete it.

Daily Scrum

The members of the Agile Development Team will meet daily to report on activity progress, including any blocking problems. The Scrum Master will facilitate the meeting and assist with clearing any reported blockers.

Unit Testing

Each developer will be responsible for writing Test Cases to use in Unit Testing. He will also be responsible for initial validation of all code written to satisfy the Acceptance Criteria. Special attention will be paid to any needed regression testing. The QA department will assemble and execute test case runs to verify and qualify that each issue meets the Acceptance Criteria. Test results are documented in the TestRail test case

management system with traceability to each User Story in the Jira issue tracking database. Unit Testing is to be completed and the Acceptance Criteria should be satisfied by the end of each Sprint.

Test Cases & Validation

The QA department will assemble and execute test case runs to verify and qualify the issues during each Sprint based on the test cases created by development during Unit Testing. QA will also identify edge cases and ancillary testing beyond the basic functionality specified in the Acceptance Criteria. Test Cases specify inputs, execution conditions, and expected results for a particular objective. The objective of the test cases is to determine if the program meets the acceptance criteria and to find errors via high yield testing (those cases with the highest probability of finding errors and reducing the number of test cases needed). At least one person performing validation must not have participated in the programming of the project being tested. Performance of the program is documented at each step of the Test Case. All test results are documented in the TestRail test case management system and Jira issue tracking database. Any errors found during validation are entered in JIRA, corrected by the development team, and tested again in the next testing round.

Code Review

After initial validation is completed, the developer will set the Status of the Issue to "Code Review Requested" and assign it to another developer for review. Code Review will check for some or all of the following:

- Adherence to SOP and Best Practice
- Completion of Test Cases
- Appropriateness of techniques for scalability and performance
- Check for errors, omission, and opportunities for improvement

Any errors, omissions, or suggestions will be noted in the Jira issue and assigned back to the developer. When complete, the developer will assign the Issue to the QA Department for inclusion in the formal validation.

Sprint Review

At the conclusion of each Sprint, the Agile Development Team will meet with the internal stakeholders to review the completed product for that Sprint. Any errors or suggested changes will be documented for inclusion on the backlog.

Sprint Retrospective

Following the Sprint Review, the Agile Development Team will meet to discuss what went well during the Sprint, what did not go well, and what changes should be made in the process to address these points.

Stakeholder Involvement

Regular involvement of both internal and external stakeholders is considered critical for the success of the product development. Internal stakeholders will include representatives from Sales, Marketing, and Support. External stakeholders will be selected from our active customer base, determined by expressed interest in the area of the program being modified or written.

Regularly scheduled calls with external stakeholders will be conducted to demonstrate the product as it is in development and obtain feedback regarding the functionality and user interface. External stakeholders are also essential for fleshing out User Stories.
Internal stakeholders will be invited to attend the meetings with the external stakeholders. Additionally, they will be asked to review User Interface in the middle of Sprints, discuss functionality issues as they arise, etc.

Regression & Acceptance Testing

With the assistance of the developers, the QA department will identify those areas of the program that require regression testing as a result of the changes made during a Sprint. Test cases will be defined and executed to ensure that all required regression testing is completed. Additional Acceptance Testing will be conducted to ensure that the Acceptance Criteria is continued to be met for all Stories conducted during the release. Acceptance Testing will also include sanity testing on the basic functionality of the program as well as any other areas deemed a high risk.

Release Review

At the completion of a defined Release cycle, all stakeholders will be invited to attend a final review meeting at which all of the product changes are demonstrated. Any errors or modifications identified will be added to the Product Backlog.

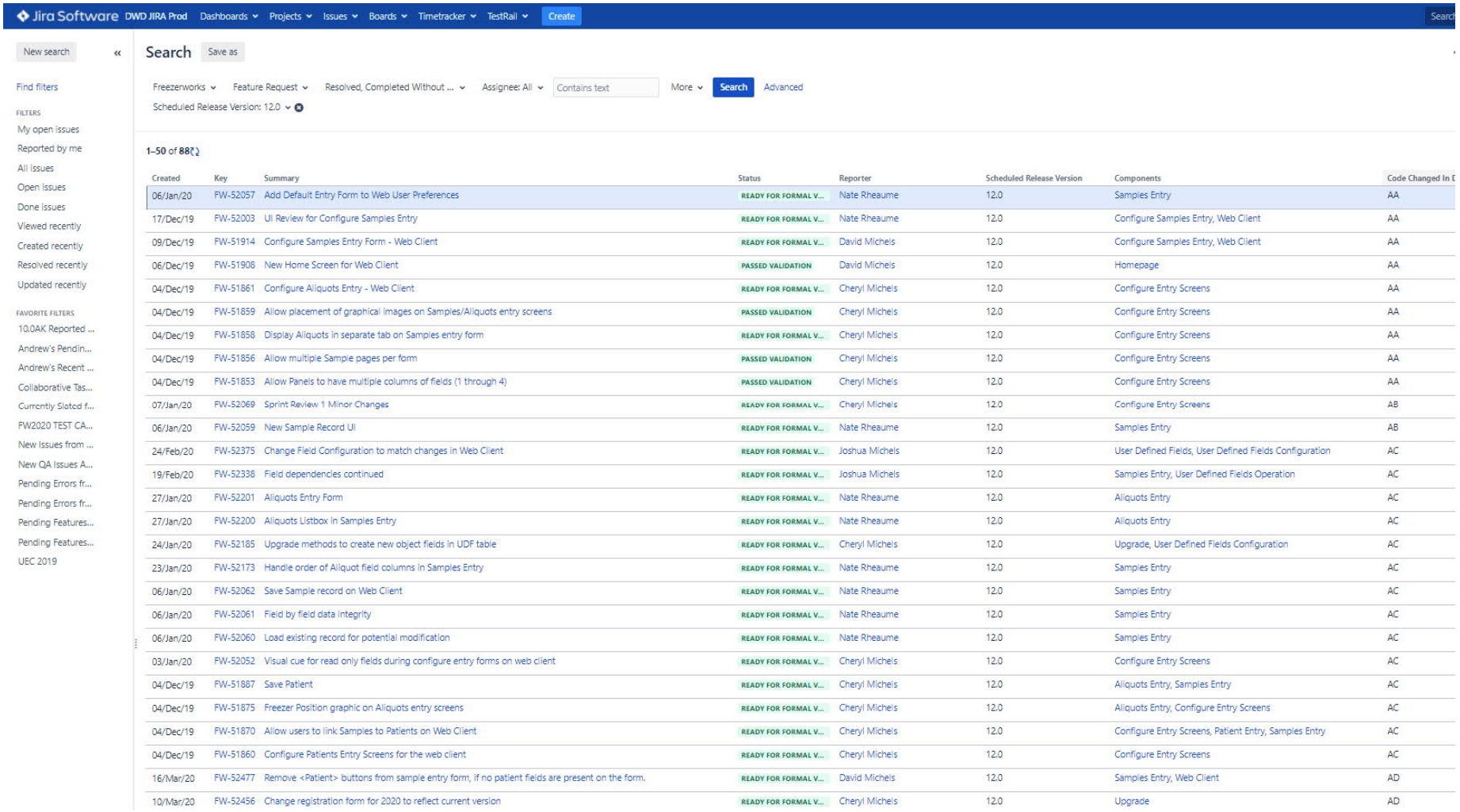
Release Retrospective

After the Release Review, internal stakeholders will meet with the Agile Development Team to discuss what went well during the Release cycle, what went poorly, and what changes need to be made to the process.

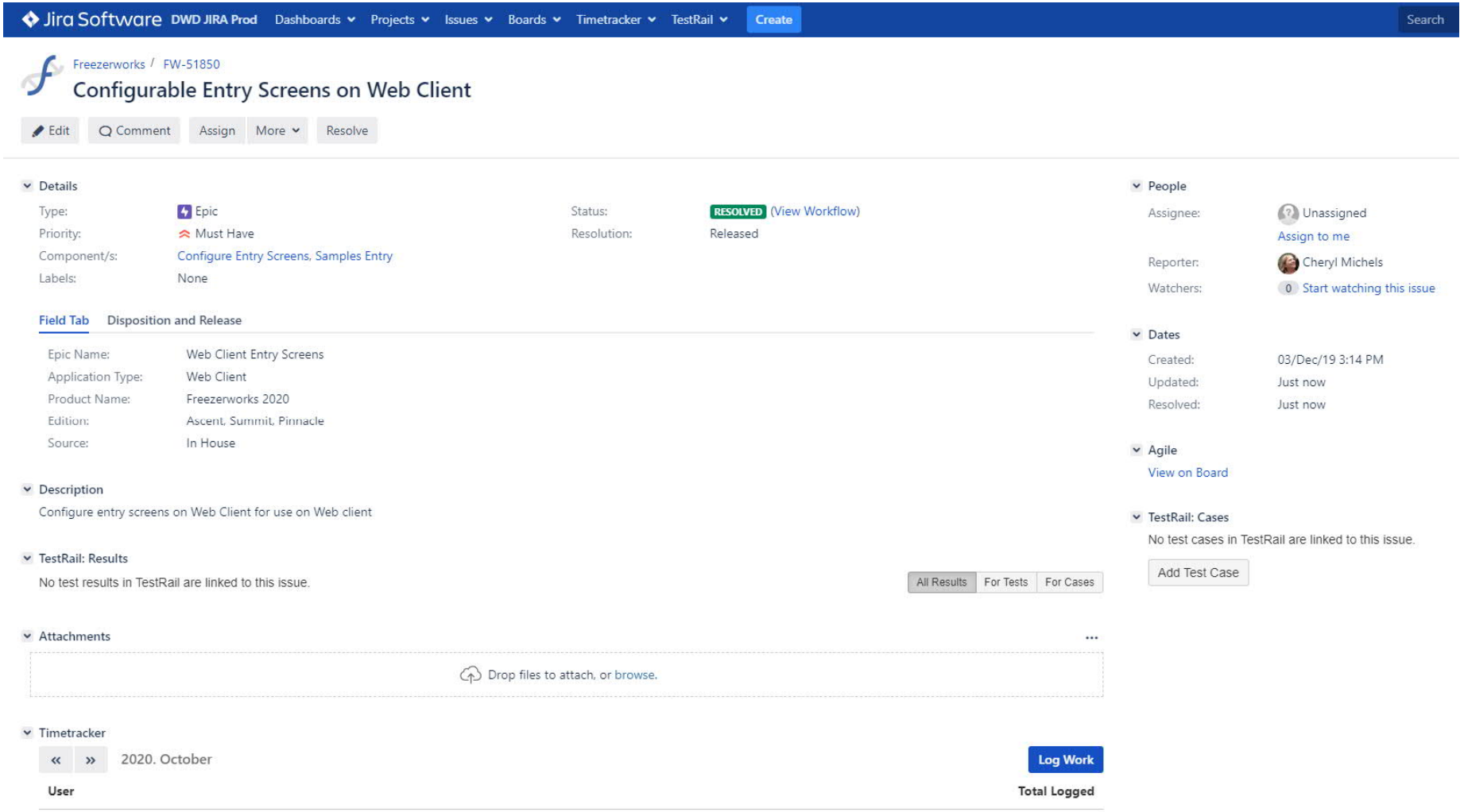
Release Publication

The Quality Assurance Department will oversee the release process. “General” releases consist of upgrades, maintenance updates, or hot fixes. Each release follows the SDLC procedure. Upgrades are released every 4-6 months; maintenance updates (including hot fixes) will follow an expedited schedule as needed. Customers are informed of upgrades and updates via e-mail and website notifications. “Limited” releases are sometimes made available to customers who have been affected by very specific error fixes within the release that does not affect the common use of the program. The Customer Support Department will distribute upgrades to existing customers. Following a release, any new feature requests and error reports will be added to the product backlog in Jira, as the SDLC continues on.

Testing Artifact Sample: Feature Requests (User Stories) from the Product Backlog tracked during a Sprint



Testing Artifact Sample: Detailed view of an Epic (Grouping of Feature Requests) in the Jira database



Testing Artifact Sample: Detailed view of an Epic (Grouping of Feature Requests) in the Jira database (continued)

Issues in Epic

FW-51886	Save new Sample, new Aliquot	RESOLVED	*Unassigned*
FW-51890	Update calculated fields	RESOLVED	*Unassigned*
FW-51889	Populate default values	RESOLVED	*Unassigned*
FW-52300	Number of Aliquots needs to be required on Aliquot Forms	READY FOR FORMAL V...	Cheryl Michels
FW-52304	Double-clicking an Aliquot on the Inventory List View	READY FOR FORMAL V...	Cheryl Michels
FW-51961	Search Audit Trail in desktop client for changes made to Web Entry forms	READY FOR FORMAL V...	Cheryl Michels
FW-52628	Display Samples on Patients Entry Form	READY FOR FORMAL V...	Cheryl Michels
FW-52305	Change label on all Cancel buttons for Patients/Samples/Aliquots entry	READY FOR FORMAL V...	Cheryl Michels
FW-52420	No error if no default Samples entry form is set	READY FOR FORMAL V...	Cheryl Michels
FW-52421	Enter multiple unique values on Aliquots entry screen in Web client	READY FOR FORMAL V...	Cheryl Michels
FW-51863	Print labels from selected Aliquots on a single Samples entry form	READY FOR FORMAL V...	Cheryl Michels
FW-51939	View detail screen for Tests from Web Client Inventory List View	READY FOR FORMAL V...	Cheryl Michels
FW-51892	Audit Trail reasons on Web Client	READY FOR FORMAL V...	Cheryl Michels
FW-52379	Review Audit Trail Entries for saving data on Web Client	APPROVED	Cheryl Michels
FW-52449	Error when attempting to verify action on Unavailable Aliquot	READY FOR FORMAL V...	Cheryl Michels
FW-52123	Give Confirmation Message when leaving Sample Record	READY FOR FORMAL V...	Cheryl Michels
FW-51884	Create another checkbox	RESOLVED	*Unassigned*
FW-51862	Load Sample record Read Only on the Web Client	RESOLVED	*Unassigned*
FW-51891	Modify existing Samples, Aliquots, Patients	RESOLVED	*Unassigned*
FW-51859	Allow placement of graphical images on Samples/Aliquots entry screens	PASSED VALIDATION	Daniel Michels
FW-51931	Include current Notes field on Samples Entry Form	RESOLVED	*Unassigned*
FW-51881	Warning on any PHI field added to an entry screen	READY FOR FORMAL V...	Cheryl Michels

Testing Artifact Sample: Detailed view of an Epic (Grouping of Feature Requests) in the Jira database (continued)

	FW-51683	Configure Samples Entry Form - API - Retrieve Forms Data	IN TEST CASE DEVELOP...	*Unassigned*
	FW-51914	Configure Samples Entry Form - Web Client	READY FOR FORMAL V...	Cheryl Michels
	FW-51925	Configure Aliquots Entry - API	IN TEST CASE DEVELOP...	*Unassigned*
	FW-51858	Display Aliquots in separate tab on Samples entry form	READY FOR FORMAL V...	Cheryl Michels
	FW-51853	Allow Panels to have multiple columns of fields (1 through 4)	PASSED VALIDATION	Daniel Michels
	FW-51857	Display Aliquots in collapsible Section on entry form	REVIEWED	*Unassigned*
	FW-51888	Display color formatting during data entry	REVIEWED	*Unassigned*
	FW-51854	Allow Panels to be grouped into collapsible Sections	REVIEWED	*Unassigned*
	FW-51865	Lineage tab on web client	APPROVED	*Unassigned*
	FW-51866	Workflow History on Web Client	APPROVED	*Unassigned*
	FW-51869	Add charts to Patient and Sample entry screens	REVIEWED	David Michels
	FW-51882	Next and previous buttons	REVIEWED	*Unassigned*
✓	FW-51851	Upgrade existing entry forms to web version	RESOLVED	*Unassigned*
	FW-51864	Create form templates with guidance text to help admins configure forms	REVIEWED	*Unassigned*
	FW-51868	Display dial for Count fields	REVIEWED	*Unassigned*
	FW-51871	Link Samples to Study and Visit	REVIEWED	*Unassigned*
	FW-51872	Add and open Attachments	REVIEWED	*Unassigned*
	FW-51873	Eliminate Notes tab	REVIEWED	*Unassigned*
	FW-51876	Delete Aliquots	REVIEWED	*Unassigned*
	FW-51943	View editable Tests tab on Sample Entry Screen	REVIEWED	*Unassigned*
	FW-51928	Configure Samples Entry API - Save Forms Data	IN TEST CASE DEVELOP...	*Unassigned*
	FW-51856	Allow multiple Sample pages per form	PASSED VALIDATION	Daniel Michels
✓	FW-51993	Audit Trail Reasons	RESOLVED	David Michels

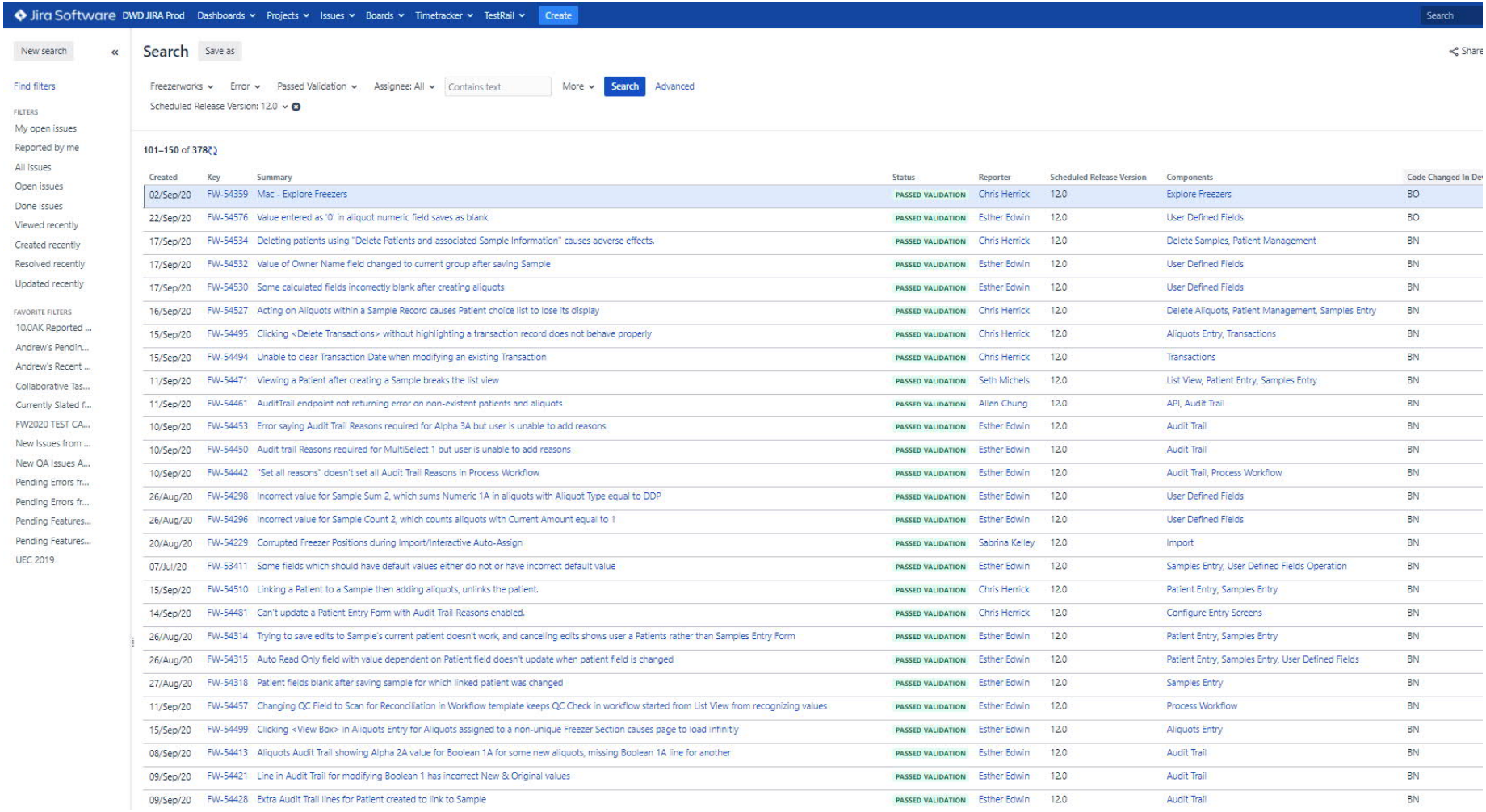
Testing Artifact Sample: Detailed view of an Epic (Grouping of Feature Requests) in the Jira database (continued)

FW-51995	API Endpoint for Saving new or modified Samples	IN TEST CASE REVIEW	Cheryl Michels	
FW-52052	Visual cue for read only fields during configure entry forms on web client	READY FOR FORMAL V...	Cheryl Michels	
FW-52057	Add Default Entry Form to Web User Preferences	READY FOR FORMAL V...	Cheryl Michels	
FW-52058	Display Form to add record	RESOLVED	Nate Rheaume	
FW-52059	New Sample Record UI	READY FOR FORMAL V...	Cheryl Michels	
FW-52060	Load existing record for potential modification	READY FOR FORMAL V...	Cheryl Michels	
FW-52062	Save Sample record on Web Client	READY FOR FORMAL V...	Cheryl Michels	
FW-52063	UI for selecting available entry forms	RESOLVED	*Unassigned*	
FW-52065	API for getting auto incrementing field data for new records	IN TEST CASE REVIEW	Cheryl Michels	
FW-52066	Add fields to UDF table to store dependency definitions	RESOLVED	Cheryl Michels	
FW-51861	Configure Aliquots Entry - Web Client	READY FOR FORMAL V...	Cheryl Michels	
FW-52067	Add API Endpoint for retrieving the locked status of a Sample	RESOLVED	David Michels	
FW-52068	Add API Endpoint for loading a Sample for view or potential modification	IN TEST CASE DEVELOP...	Allen Chung	
FW-52069	Sprint Review 1 Minor Changes	READY FOR FORMAL V...	Cheryl Michels	
FW-52072	Modify API to include Default Entry Form User Preference	DONE	Joshua Michels	
FW-52126	Implement Double-Data Entry	APPROVED	*Unassigned*	
FW-52128	Date and Time Validation on leaving field.	IN TEST CASE REVIEW	Cheryl Michels	
FW-52301	Allow Aliquot listbox columns to be resize-able	REVIEWED	*Unassigned*	
FW-52166	Better Messaging when a Sample is saved	APPROVED	*Unassigned*	
FW-51860	Configure Patients Entry Screens for the web client	READY FOR FORMAL V...	Cheryl Michels	
FW-51887	Save Patient	READY FOR FORMAL V...	Cheryl Michels	
FW-52061	Field by field data integrity	READY FOR FORMAL V...	Cheryl Michels	
FW-52202	API for Aliquots Entry	IN TEST CASE DEVELOP...	Allen Chung	
FW-52173	Handle order of Aliquot field columns in Samples Entry	READY FOR FORMAL V...	Cheryl Michels	
FW-51867	Audit Trail	READY FOR FORMAL V...	Cheryl Michels	
FW-51870	Allow users to link Samples to Patients on Web Client	READY FOR FORMAL V...	Cheryl Michels	

Testing Artifact Sample: Detailed view of an Epic (Grouping of Feature Requests) in the Jira database (continued)

FW-52173	Handle order of Aliquot field columns in Samples Entry		READY FOR FORMAL V...	Cheryl Michels
FW-51867	Audit Trail		READY FOR FORMAL V...	Cheryl Michels
FW-51870	Allow users to link Samples to Patients on Web Client		READY FOR FORMAL V...	Cheryl Michels
FW-52257	Newly created fields do not show up in Entity Selections		READY FOR FORMAL V...	Cheryl Michels
FW-52255	Fix how the API returns time values		READY FOR TESTING	Andrew Michels
FW-52295	Aliquot Field names are saved with the Entry Form configuration		RESOLVED	*Unassigned*
FW-52296	Aliquots Listbox in Samples Entry can't sort with Nulls		READY FOR FORMAL V...	Cheryl Michels
FW-52302	Allow multiple pages/tabs of the Web Client to be opened		REVIEWED	*Unassigned*
FW-52303	Add a ribbon of Sample fields to the top of the Aliquots page		APPROVED	*Unassigned*
FW-52325	API for Configure Patient Entry Screen		IN TEST CASE DEVELOP...	*Unassigned*
FW-52326	API for Saving Patient Data		CODE REVIEW COMPLE...	Cheryl Michels
FW-52327	API for Retrieving Audit Trail		IN TEST CASE REVIEW	Cheryl Michels
FW-52329	API for Add, Modify, Delete Transactions		READY FOR CODE REVI...	Cheryl Michels
FW-52330	API for linking Samples to Patients		READY FOR CODE REVI...	Cheryl Michels
FW-52331	API to check uniqueness of multiple fields returned with new Aliquots		READY FOR CODE REVI...	Cheryl Michels
FW-51875	Freezer Position graphic on Aliquots entry screens		READY FOR FORMAL V...	Cheryl Michels
FW-52350	Description field is empty for web Entry Forms		READY FOR FORMAL V...	Cheryl Michels
FW-52338	Field dependencies continued		READY FOR FORMAL V...	Cheryl Michels
FW-52431	Allow adding/editing of Patients from the Samples Entry Screen		READY FOR FORMAL V...	Cheryl Michels
FW-51877	Process workflow from Samples entry screen		READY FOR FORMAL V...	Cheryl Michels
FW-51874	Add, modify, and delete Transactions on individual Aliquot		READY FOR FORMAL V...	Cheryl Michels
FW-51878	SubAliquot Workflow		READY FOR FORMAL V...	Cheryl Michels
FW-52627	Unable to edit existing Transaction		RESOLVED	*Unassigned*

Testing Artifact Sample: Error Reports corrected throughout the Release



Jira Software DWD JIRA Prod Dashboards Projects Issues Boards Timetracker TestRail Create Search

New search

Find filters

FILTERS
My open issues
Reported by me
All issues
Open issues
Done issues
Viewed recently
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Resolved recently
Updated recently

FAVORITE FILTERS
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UEC 2019

Search Save as Share

Freezerworks Error Passed Validation Assignee: All Contains text More Search Advanced
Scheduled Release Version: 12.0

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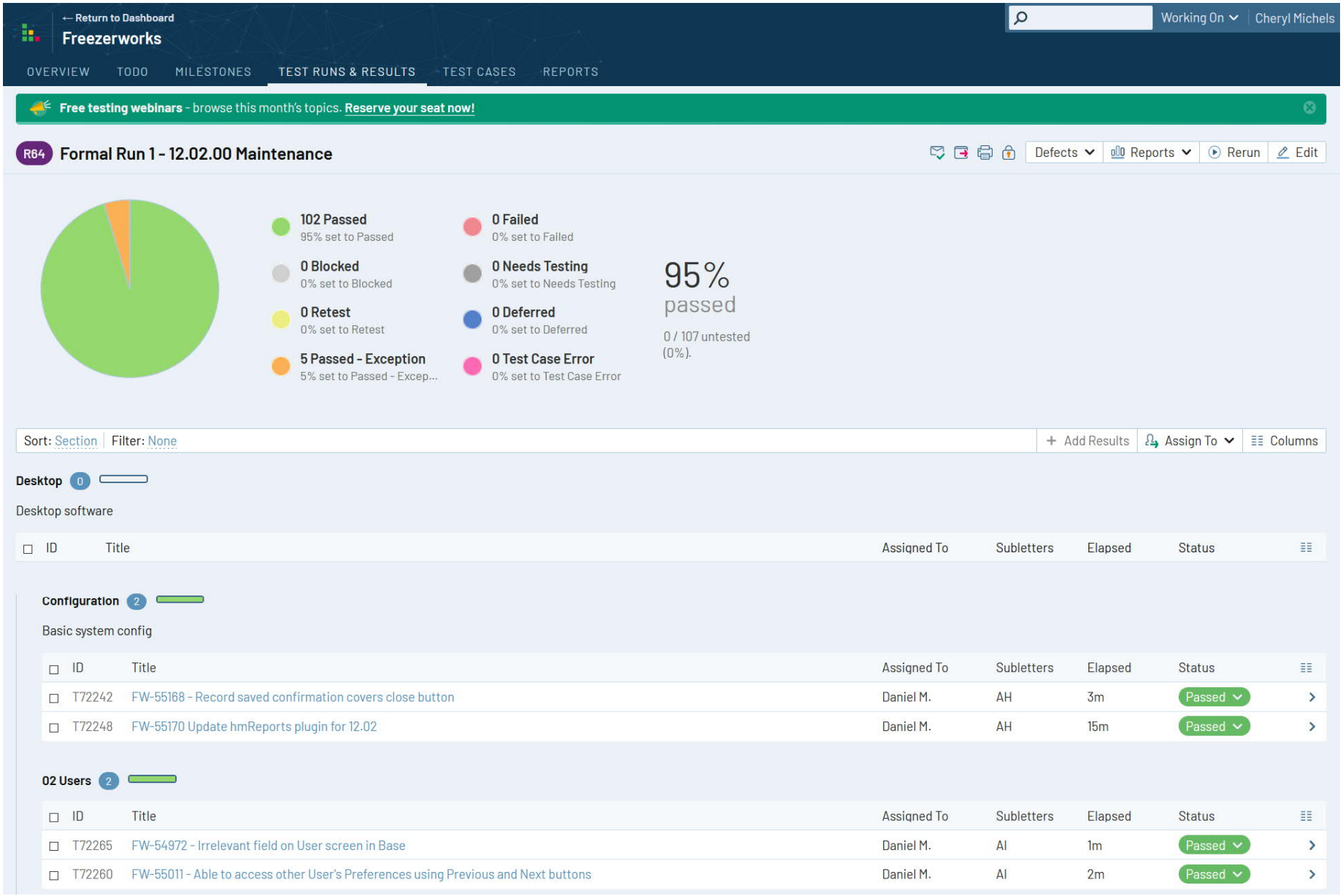
Created	Key	Summary	Status	Reporter	Scheduled Release Version	Components	Code Changed In De
02/Sep/20	FW-54359	Mac - Explore Freezers	PASSED VALIDATION	Chris Herrick	12.0	Explore Freezers	BO
22/Sep/20	FW-54576	Value entered as '0' in aliquot numeric field saves as blank	PASSED VALIDATION	Esther Edwin	12.0	User Defined Fields	BO
17/Sep/20	FW-54534	Deleting patients using "Delete Patients and associated Sample Information" causes adverse effects.	PASSED VALIDATION	Chris Herrick	12.0	Delete Samples, Patient Management	BN
17/Sep/20	FW-54532	Value of Owner Name field changed to current group after saving Sample	PASSED VALIDATION	Esther Edwin	12.0	User Defined Fields	BN
17/Sep/20	FW-54530	Some calculated fields incorrectly blank after creating aliquots	PASSED VALIDATION	Esther Edwin	12.0	User Defined Fields	BN
16/Sep/20	FW-54527	Acting on Aliquots within a Sample Record causes Patient choice list to lose its display	PASSED VALIDATION	Chris Herrick	12.0	Delete Aliquots, Patient Management, Samples Entry	BN
15/Sep/20	FW-54495	Clicking <Delete Transactions> without highlighting a transaction record does not behave properly	PASSED VALIDATION	Chris Herrick	12.0	Aliquots Entry, Transactions	BN
15/Sep/20	FW-54494	Unable to clear Transaction Date when modifying an existing Transaction	PASSED VALIDATION	Chris Herrick	12.0	Transactions	BN
11/Sep/20	FW-54471	Viewing a Patient after creating a Sample breaks the list view	PASSED VALIDATION	Seth Michels	12.0	List View, Patient Entry, Samples Entry	BN
11/Sep/20	FW-54461	AuditTrail endpoint not returning error on non-existent patients and aliquots	PASSED VALIDATION	Allen Chung	12.0	API, Audit Trail	BN
10/Sep/20	FW-54453	Error saying Audit Trail Reasons required for Alpha 3A but user is unable to add reasons	PASSED VALIDATION	Esther Edwin	12.0	Audit Trail	BN
10/Sep/20	FW-54450	Audit trail Reasons required for MultiSelect 1 but user is unable to add reasons	PASSED VALIDATION	Esther Edwin	12.0	Audit Trail	BN
10/Sep/20	FW-54442	"Set all reasons" doesn't set all Audit Trail Reasons in Process Workflow	PASSED VALIDATION	Esther Edwin	12.0	Audit Trail, Process Workflow	BN
26/Aug/20	FW-54298	Incorrect value for Sample Sum 2, which sums Numeric 1A in aliquots with Aliquot Type equal to DDP	PASSED VALIDATION	Esther Edwin	12.0	User Defined Fields	BN
26/Aug/20	FW-54296	Incorrect value for Sample Count 2, which counts aliquots with Current Amount equal to 1	PASSED VALIDATION	Esther Edwin	12.0	User Defined Fields	BN
20/Aug/20	FW-54229	Corrupted Freezer Positions during Import/Interactive Auto-Assign	PASSED VALIDATION	Sabrina Kelley	12.0	Import	BN
07/Jul/20	FW-53411	Some fields which should have default values either do not or have incorrect default value	PASSED VALIDATION	Esther Edwin	12.0	Samples Entry, User Defined Fields Operation	BN
15/Sep/20	FW-54510	Linking a Patient to a Sample then adding aliquots, unlinks the patient.	PASSED VALIDATION	Chris Herrick	12.0	Patient Entry, Samples Entry	BN
14/Sep/20	FW-54481	Can't update a Patient Entry Form with Audit Trail Reasons enabled.	PASSED VALIDATION	Chris Herrick	12.0	Configure Entry Screens	BN
26/Aug/20	FW-54314	Trying to save edits to Sample's current patient doesn't work, and canceling edits shows user a Patients rather than Samples Entry Form	PASSED VALIDATION	Esther Edwin	12.0	Patient Entry, Samples Entry	BN
26/Aug/20	FW-54315	Auto Read Only field with value dependent on Patient field doesn't update when patient field is changed	PASSED VALIDATION	Esther Edwin	12.0	Patient Entry, Samples Entry, User Defined Fields	BN
27/Aug/20	FW-54318	Patient fields blank after saving sample for which linked patient was changed	PASSED VALIDATION	Esther Edwin	12.0	Samples Entry	BN
11/Sep/20	FW-54457	Changing QC Field to Scan for Reconciliation in Workflow template keeps QC Check in workflow started from List View from recognizing values	PASSED VALIDATION	Esther Edwin	12.0	Process Workflow	BN
15/Sep/20	FW-54499	Clicking <View Box> in Aliquots Entry for Aliquots assigned to a non-unique Freezer Section causes page to load infinitly	PASSED VALIDATION	Esther Edwin	12.0	Aliquots Entry	BN
08/Sep/20	FW-54413	Aliquots Audit Trail showing Alpha 2A value for Boolean 1A for some new aliquots, missing Boolean 1A line for another	PASSED VALIDATION	Esther Edwin	12.0	Audit Trail	BN
09/Sep/20	FW-54421	Line in Audit Trail for modifying Boolean 1 has incorrect New & Original values	PASSED VALIDATION	Esther Edwin	12.0	Audit Trail	BN
09/Sep/20	FW-54428	Extra Audit Trail lines for Patient created to link to Sample	PASSED VALIDATION	Esther Edwin	12.0	Audit Trail	BN

Freezerworks 2021, version 12.02.00, TestRail – Formal Validation Test Run (Round 1)



Freezerworks 2021, version 12.02.00, TestRail – Formal Validation Test Run continued (pg. 2 of 9)

Invoicing 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72229	FW-52215 - Editing an invoice jumps to another invoice	Daniel M.	AI	7m	Passed

03 Login 5

ID	Title	Assigned To	Subletters	Elapsed	Status
T72215	03 Login	Daniel M.	AT	58m	Passed
T72216	Saving System Properties	Esther E.	AM	32m 39s	Passed
T72247	FW-51679 - Can't paste into username password	Beth M.	AG	3m 25s	Passed
T72275	FW-55214 LDAP with Free Text names fails in web	Daniel M.	AT	8m	Passed
T72262	FW-55036 - VULNERABILITY - ctrl+"." can bypass login page and access patients/samples/aliquots	Daniel M.	AI	51s	Passed

04 Groups 3

ID	Title	Assigned To	Subletters	Elapsed	Status
T72259	FW-55140 Saved Searches in Groups includes BLANK lines	Daniel M.	AI	2m	Passed
T72246	FW-51981 - Wrong count on Freezers for Groups	Daniel M.	Ai	10m	Passed
T72427	FW-55272 - Web Client - groups with no list views have lots of problems	Esther E.	AN	16m 55s	Passed

07 Freezers 3

ID	Title	Assigned To	Subletters	Elapsed	Status
T72230	FW-55016 First freezer in FW2021 is a locked record (for config)	Daniel M.	Ai	2m	Passed
T72234	FW-55105 - Can configure Freezer that I have View Only access to	Daniel M.	Ai	6m	Passed
T72264	FW-55104 - Can delete a Freezer which has a Freezer Section for which your Group only has Modify access	Daniel M.	Ai	4m	Passed

Freezerworks 2021, version 12.02.00, TestRail – Formal Validation Test Run continued (pg. 3 of 9)

Freezer Configuration 3

ID	Title	Assigned To	Subletters	Elapsed	Status
T72268	FW-55212 - Can't use Next and Previous buttons in Freezer Sections	Daniel M.	Ai	2m	Passed
T72361	FW-55345 - Cannot alter new freezer configuration if created from duplicate or template sections	Daniel M.	Ai	4m	Passed
T72250	FW-52635 - Define Exceptions in Configure Freezers corrupts when you mix 9x9 and 10x10 boxes	Daniel M.	AQ	39m	Passed

08 Fields 9

ID	Title	Assigned To	Subletters	Elapsed	Status
T72236	FW-55137 - System Fields in Group definition that should not be	Daniel M.	Ai	7m	Passed
T72225	FW-52114 UDF Single-Select Dropdowns not being sorted alphabetically when restrictions are applied via Restricted Dropdown List	Esther E.	Ai	9m 33s	Passed
T72278	FW-53806 Count fields not updating when batch updating aliquot status or saving field configuration	Daniel M.	AJ	14m	Passed
T72290	FW-52311 Allow for more than 26 dependencies for Default Value field	Daniel M.	AP	20m	Passed
T72291	FW-53304 Checkboxes overlap when modifying a Summary Data field's configuration	Daniel M.	AJ	11m	Passed
T72288	FW-51115 - Update user defined count fields and Calc Fields in all records on Save	Beth M.	AG	15m 41s	Passed
T72285	FW-54936 - Calculated fields based on a sample date and patient date. Calculation does not trigger with exisitng sample date and NE...	Daniel M.	AJ	10m	Passed
T72342	FW-55142 - Restricted dropdowns lose blank top-most option	Daniel M.	AK	3m	Passed
T72397	FW-55363 - No fields in a Patient Sum Field configuration's dropdown when the Patient Table Alias is not "Patients"	Daniel M.	AK	2m	Passed

09 Entry Forms 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72271	FW-52409 Bad pointer error when opening aliquots	Esther E.	AJ	35m 48s	Passed
T72282	FW-55246 - Re-adding "Freezer Assignment Fields" on existing form causes syntax errors	Daniel M.	AK	2m	Passed

10 List Views 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72406	FW-55273 - Web Client - new user's default list view is System Default, but group doesn't have access, can't add samples in web	Daniel M.	AL	8m	Passed

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11 Samples 4

ID	Title	Assigned To	Subletters	Elapsed	Status
T72245	FW-52196 - Freezer Alias not displaying in Aliquots List View on Sample Entry Screen	Esther E.	Ai	7m 36s	Passed
T72253	FW-54931 Default values not triggered when tabbing through a choice list on sample entry form	Esther E.	Ai	3m 10s	Passed
T72293	Runtime error when creating a Sample after linking it to a Patient and selecting a Study	Esther E.	AM	3m 23s	Passed
T72436	FW-52968 - Linking Sample to Patient in 11.01.01 still loads aliquot for other sample (related to FW-52572)	Daniel M.	AM	8m	Passed

Patients 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72297	FW-55277 - Participant ID can't be reused even if deleted	Daniel M.	AP	12m	Passed
T72545	FW-55059 - Patients can be enrolled in same study through import enrollment	Beth M.	AT	7m 39s	Passed

13 Aliquots 5

ID	Title	Assigned To	Subletters	Elapsed	Status
T72224	FW-52160 - Existing Box Map data in Add Aliquots displays incorrectly	Daniel M.	AK	5m	Passed
T72237	FW-49034 - Aliquots missing when sample form is in View Only	Beth M.	AG	3m 11s	Passed
T72263	FW-55045 - Modify Aliquots - can have positions missing subdivision when using 'assign alq to new position'	Daniel M.	AK	6m	Passed
T72415	Restricted Choice List on Aliquots Form	Daniel M.	AK	5m	Passed
T72508	FW-54809 - Runtime error when viewing an aliquot in a non-unique freezer	Daniel M.	AR	2m	Passed

15 Search 6

ID	Title	Assigned To	Subletters	Elapsed	Status
T72251	Patient field available for quick search	Esther E.	Ai	23m 37s	Passed
T72241	FW-55122 - Filter Current List not working as intended (Max number of aliquots per sample not honored)	Daniel M.	AK	10m	Passed
T72227	FW-48787 Program crashing whenever a scheduled search with email runs	Beth M.	AG	11m 52s	Passe..ption
T72286	FW-54841 - Patient/Testing Security Issue in Pinnacle	Beth M.	AM	1m	Passed
T72379	Test Results search Saved and Loaded Properly	Daniel M.	AK	5m	Passed
T72463	Search on Aliquots based on Study, Visit, and Patient data does not return results	Esther E.	AP	1m 34s	Passed

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16 View Listings 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72276	FW-52425 Print List does not always print patient data correctly	Daniel M.	AK	21m	Passed
T72298	FW-55341 - Runtime error on PHI field's column filter	Daniel M.	AK	2m	Passed

18 Explore Freezers 4

ID	Title	Assigned To	Subletters	Elapsed	Status
T72233	FW-55107 - Runtime Error after viewing Sample from Explore Freezers	Beth M.	AM	2m 45s	Passed
T72231	FW-52867 Box Map incorrectly displays aliquot position when order (direction of assignment) is reversed	Esther E.	AP	1h 20m	Passe..ption
T72292	FW-55321 - Exceptions & Non-Unique Freezer Capacities sometimes displayed as 0/0 or INF	Beth M.	AS	50m	Passed
T72351	FW-54105 - Freezer graphic not accurate for exceptions for % and heat map - Explore Freezers, no Exceptions	Beth M.	AO	22m 41s	Passed

19 Move Aliquots 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72244	FW-55038 - Move Aliquots - runtime error when moving same box aliquots	Esther E.	Ai	2m 28s	Passed
T72370	Move Aliquots - Different Sized Freezers - Non-Unique	Beth M.	AO	54m 23s	Passed

Move Aliquots Visual Freezer 5

ID	Title	Assigned To	Subletters	Elapsed	Status
T72416	Move Aliquots - Different Sized Freezers - Row/Column	Beth M.	AO	25m 34s	Passed
T72417	Move Aliquots - Different Sized Freezers - Position	Beth M.	AR	40m 57s	Passed
T72279	FW-55215 - Exceptions not created after moving subdivision with exceptions whose aliquots are defined by two subdivisions	Beth M.	AU	20m 17s	Passed
T72454	FW-55370 - More Aliquots than requested get added to Samples created in non-unique Freezers with each newly created Sample	Beth M.	AP	3m 13s	Passed
T72526	FW-55436 - Cannot return a box to its original location after successfully moving a different box	Daniel M.	AS	2m	Passed

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22 User Permissions 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72258	FW-55009 - User without Add/Modify Patients permission can Add New Patient	Daniel M.	AK	4m	Passed

24 Import 4

ID	Title	Assigned To	Subletters	Elapsed	Status
T72269	FW-54966 - 'Define Valid Ranges' for date field does not work in import when using 'Current Date' checkbox	Daniel M.	AK	10m	Passed
T72280	FW-55141 Import Creates duplicate aliquot level Unique IDs	Daniel M.	AL	4m	Passed
T72294	FW-55270 - Import Fields include Workflow fields and they should not	Daniel M.	AL	1m	Passed
T72481	FW-55433 - Import file locked on error during config	Daniel M.	AR	14m	Passed

25 Search Audit Trail 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72226	FW-49028 Error When Exporting Audit Trail	Beth M.	AG	9m 7s	Passed

26 System Properties 3

ID	Title	Assigned To	Subletters	Elapsed	Status
T72257	FW-55185 - Patient System Fields Don't Update When You Change The Patient Table's Alias	Daniel M.	AL	2m	Passed
T72261	FW-55052 - SSO can be turned on even when there are Users without LDAP UserNames	Beth M.	AM	6m 20s	Passed
T72273	FW-55063 Changing System Prop LDAP setting from Specified users to All users skips check on Users	Esther E.	AM	5m 44s	Passed

Audit Trail Reasons 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72238	FW-55150 - Audit Trail Reasons not sorted alphabetically	Daniel M.	AL	5m	Passed

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Shipping 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72266	FW-48211 - "Shipping Contact" check box should default on when adding person via shipping	Beth M.	AG	2m 17s	Passed

Testing 4

ID	Title	Assigned To	Subletters	Elapsed	Status
T72256	FW-55180 - User can Import Tests when System is set to order Tests on Both Samples and Aliquots	Daniel M.	AL	6m	Passed
T72272	FW-55181 - Import Tests Format doesn't save Import Type properly	Daniel M.	AL	5m	Passed
T72274	FW-51610 - Quantitative Results are stored in alphanumeric data, thereby making searching difficult	Esther E.	AR	21m 19s	Passed
T72296	FW-55290 - Searches for Quantitative Test Results Numeric (and maybe other fields?) do not work	Daniel M.	AM	18m	Passed

Study Management 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72232	FW-47199 - Sample is not shown in Patient Related Data when linking to non-enrolled Study	Beth M.	AM	2d 5h	Passed

27 Labels 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72243	FW-52438 - Sample Entry Screen - "Other Actions > Print Labels" causes labels to print out of order	Beth M.	AG	3m 42s	Passed
T72255	FW-54951 - Create Kits & Print - Site Name does not print in FW2021	Daniel M.	AM	4m	Passed

32 Reports 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72228	FW-52374 - "Principal Investigator" showing at as shipping field in reports in Summit	Beth M.	AG	1m 17s	Passed

36 Search by Location 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72284	FW-55236 - Quick Search breaks Search by Location	Daniel M.	AM	2m	Passed

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37 Empty Positions Report 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72299	FW-52197 - Empty Positions report not generating correct numbers	Daniel M.	AM	2m	Passed

38 Batch Entry 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72472	FW-55420 Runtime error when modifying a Date field in Batch Entry configuration	Esther E.	AR	9m	Passed

39 Batch Entry 4

ID	Title	Assigned To	Subletters	Elapsed	Status
T72223	FW-55044 Batch Entry - does not update 'Number of Aliquots' or 'Number of Aliquots with Positions'	Esther E.	Ai	10m 59s	Passe..ption
T72252	FW-52264 - runtime error when clicking ok on creating samples	Beth M.	AG	8m 31s	Passed
T72445	FW-55368 - Runtime error on Samples Fields 2 tab during Batch Entry	Esther E.	AM	5m 36s	Passed
T72536	CLIP NAP Calculation when saving multiple sessions	Daniel M.	BB	45m	Passed

45 Shipping 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72222	FW-54967 People - Second 'Address' line does not appear in "Ship To" in view shipments	Esther E.	Ai	6m 1s	Passed
T72221	FW-52696 Shipping - wrong aliquots display if you finish a shipping workflow, and then open another shipment	Esther E.	Ai	6m 40s	Passed

61 QC Check Freezer 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72277	FW-51906 QC Check Fails	Daniel M.	AM	7m	Passed

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105 Workflows 6

ID	Title	Assigned To	Subletters	Elapsed	Status
T72217	105 - Configure Workflows UI	Daniel M.	AM	1h 15m	Passed
T72219	105.1 Process Workflows	Esther E.	AP	2h 38m	Passe..ption
T72287	FW-54962 Manually entered position data doesn't get accepted in check in workflow	Esther E.	AM	3m 56s	Passed
T72267	FW-51684 - Process Workflow - Multiple issues with NAP while assigning positions	Esther E.	AJ	15m 3s	Passed
T72270	FW-55145 Inactivating or deleting a field used in a workflow or entry form makes the workflow/entry form unusable	Esther E.	Ai	11m 17s	Passed
T72283	FW-52530 Assign Position w/ Flatbed Scanner broken in FW2019	Esther E.	AM	43m 47s	Passed

106 User Preferences 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72281	FW-52911 Preference for field to display in visual freezers doesn't save	Esther E.	AM	8m 25s	Passed

Testing 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72239	FW-52088 - Test Results Missing from Audit Trail	Beth M.	AO	4m 56s	Passe..ption
T72295	FW-54998 - Trying to view an Aliquot while Viewing Sample from an Order Test causes Runtime Error and opens inaccessible window	Esther E.	AM	2m 43s	Passed

Study Management 1

ID	Title	Assigned To	Subletters	Elapsed	Status
T72240	FW-54846 - Study Enrollment within a Sample record creates aliquots for all Visits within that one sample	Beth M.	AM	2m 34s	Passed

Web Client 2

ID	Title	Assigned To	Subletters	Elapsed	Status
T72527	WS4 Audit Trail	Beth M.	AR	29m	Passed
T72490	FW-55391 - Prevent login to Web Client if SSO is enabled	Beth M.	AS	20m 58s	Passed

Certificate of Validation

Dataworks Development, Inc. hereby certifies that its latest product, Freezerworks® 2021 version 12.02.00, has been developed using the highest possible design and coding standards as set forth in the Dataworks Software Development Life Cycle.

Freezerworks® 2021 has undergone formal in-house validation testing in the Windows and Macintosh operating systems as well as Chrome, Edge, and Firefox for Web Client. The validation test cases and scripts are written to ensure that the software program performs in a manner consistent with the approved functional specifications for this version. They include new code tests as well as regression testing.

Dataworks will maintain validation documentation on-site at the main Dataworks offices in Mountlake Terrace, Washington. Access to the documentation will be available to customers (non-disclosure agreement required) and authorized governmental or regulatory agencies.

Freezerworks® 2021 has passed all Dataworks validation requirements and procedures and is hereby approved for release on May 3rd, 2021.

Andrew Michels
Dataworks Development, Inc.
Vice President, Head of Quality Assurance