

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

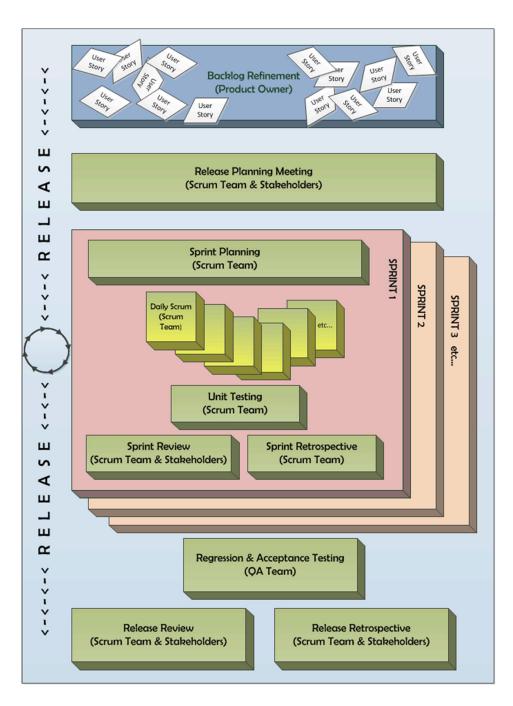
Please note that the testing procedures and artifacts, referenced below, are written to satisfy requirements of validation by a software development company. While Dataworks strives to include the most extensive variety of test cases and data ranges in our systems, they are in no way intended to replace 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.

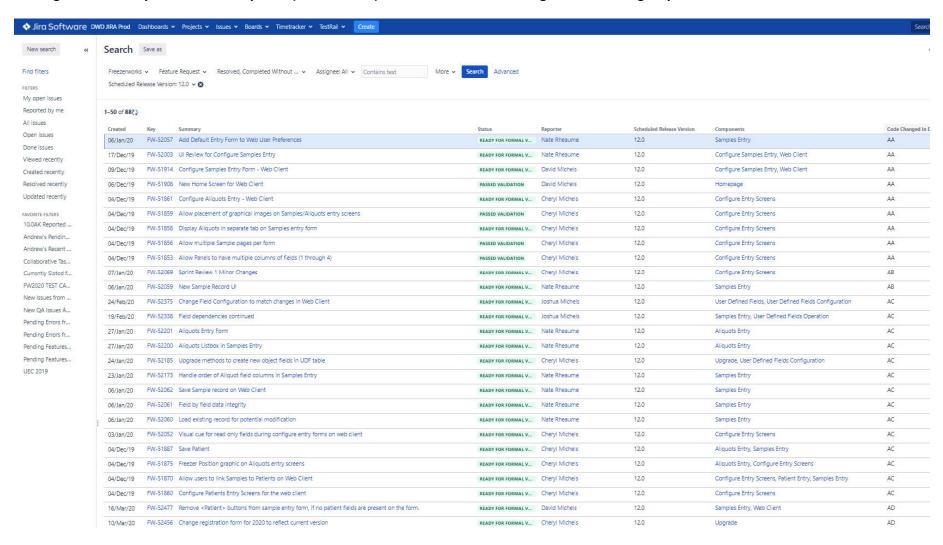
Release Retrospective

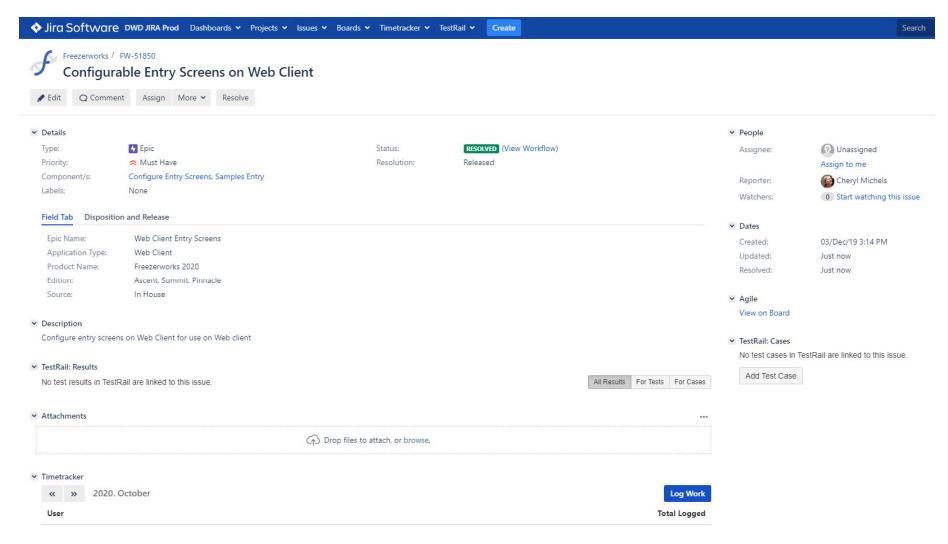
After the Release Review, internal stakeholders will meet with the Agile Development Team to discuss what went well during the Release cycle, what went poorly, and what changes need to be made to the process.

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





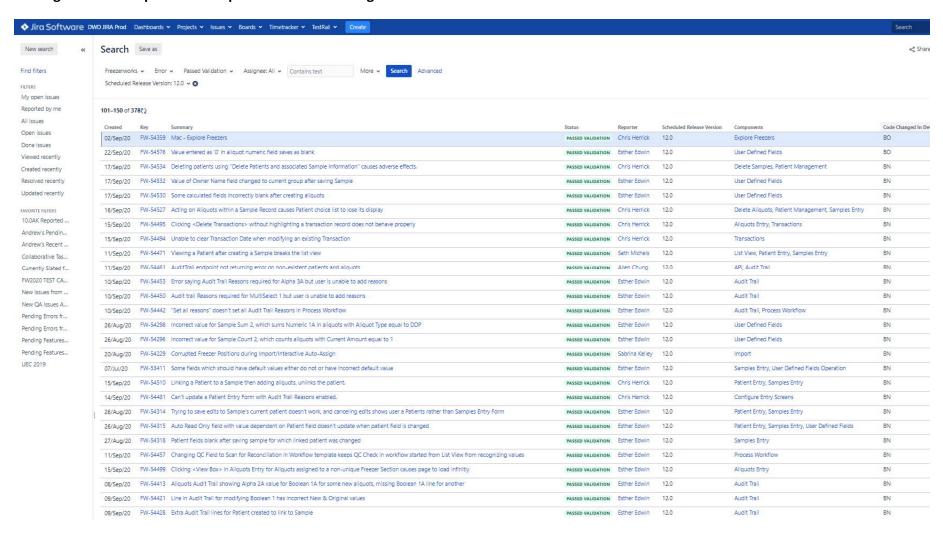
ssues in Epic					
FW-51886	Save new Sample, new Aliquot		RESOLVED	Unassigned	
FW-51890	Update calculated fields		RESOLVED	Unassigned	
FW-51889	Populate default values		RESOLVED	Unassigned	
FW-52300	Number of Aliquots needs to be required on Aliquot Forms		READY FOR FORMAL V	Cheryl Michels	
FW-52304	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	8	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	E
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	8	READY FOR FORMAL V	Cheryl Michels	
FW-52123	Give Confirmation Message when leaving Sample Record		READY FOR FORMAL V	Cheryl Michels	
W-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	_

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

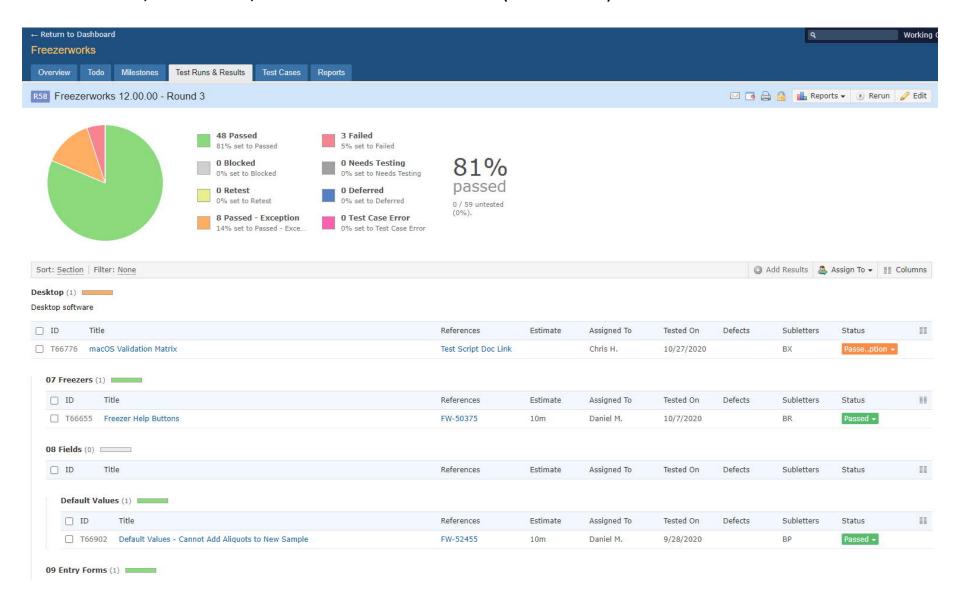
FW-51995	API Endpoint for Saving new or modified Samples		IN TEST CASE REVIEW	Cheryl Michels	
FW-52052	Visual cue for read only fields during configure entry forms on web client		READY FOR FORMAL V	Cheryl Michels	
FW-52057	Add Default Entry Form to Web User Preferences	T.	READY FOR FORMAL V	Cheryl Michels	
> 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	ξ <u>ή</u> ς -
FW-52063	UI for selecting available entry forms	A	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	R	READY FOR FORMAL V	Cheryl Michels	
FW-52067	Add API Endpoint for retrieving the locked status of a Sample	A	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	R	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	T.	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	
EM 54070	Allow users to link Samples to Patients on Web Client		READY FOR FORMAL V	Cheryl Michels	

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
O FW-52295	Aliquot Field names are saved with the Entry Form configuration		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



Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run (Rounds 3 and 4)



Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run continued (pg. 2 of 9)

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□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T67907	Filter Entry Form Selection	FW-54669	15m	Chris H.	10/12/2020		BU	Passed →	
24 Import (1									
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T67851	Import with Non-consecutive Freezer Sections	FW-54229	10m	Esther E.	10/2/2020		BR	Passed →	
46 Scheduled	d Search Email (1)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66612	46 Scheduled Search Email	Test Script Doc Link	1h 30m	Chris H.	10/2/2020		BP	Passeptic	on 🕶
☐ ID ☐ T67858	Title 54.4 Client Licenses Upgrade Server Data in Standalone	References FW-54323	Estimate 30m	Assigned To	Tested On 10/5/2020	Defects	Subletters BR	Status Passed •	
105 Workflow	ws (5)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66058	105 - Configure Workflows UI	Test Script Doc Link	3h	Daniel M.	9/17/2020		BM	Passed ▼	
☐ T66659	105.1 Process Workflows	Test Script Doc Link	4h	Daniel M.	9/21/2020		BM	Passed •	
☐ T67802	QC Recon results remembered between workflows - should not be	FW-54156	15m	Daniel M.	9/16/2020		BM	Passed ▼	
☐ T67837	Order Tests OFF but Modifiable during Processing ON	FW-54009	10m	Esther E.	10/2/2020		BQ	Passed ▼	
☐ T67879	Null Values stay Null when incremented/decremented during Workflow	FW-53131	15m	Esther E.	10/2/2020		BQ	Passed +	
Study Manag	pement (1)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	1
☐ T67991	Print Patient data on Visit Label	FW-54055	20m	Esther E.	10/14/2020	FW-54055	BV	Failed →	

Web Client (17)

Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run continued (pg. 3 of 9)

☐ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	II
☐ T66149	WS14 Web Client Requisitions	Test Script Doc Link	1h	Esther E.	9/21/2020		ВМ	Passed ▼	
☐ T66151	WS16 Processing Workflows	Test Script Doc Link	4h 30m	Esther E.	9/28/2020		BP	Passeption →	
☐ T66154	WS19 Audit Trail	Test Script Doc Link	1h	Chris H.	10/6/2020		BS	Passed -	
☐ T66903	WS25.1 Transactions	FW-51874	1h	Chris H.	9/25/2020		BP	Passed +	
☐ T66904	WS33 Aliquot Status	FW-52540	45m	Daniel M.	9/25/2020		BP	Passed →	
☐ T66909	WSB1 Base Edition Testing	FW-52378	45m	Daniel M.	9/29/2020		BQ	Passed ▼	
☐ T66912	WS19.1 Audit Trail with Reasons	FW-52675	2h 30m	Esther E.	10/7/2020		BS	Passed →	
☐ T66921	WS26 Deleting Patients, Samples, Aliquots	FW-52573	1h	Chris H.	10/13/2020	FW-54765	BU	Failed →	
☐ T66925	WS31 Field Security	FW-52980	45m	Esther E.	10/1/2020		BQ	Passed ▼	
☐ T66926	WS32 Locked Records	FW-52067	45m	Daniel M.	9/30/2020		BQ	Passed -	>
☐ T66929	WS16.1 Processing Sub-Aliquot Workflows	N/A	5h	Esther E.	10/1/2020		BQ	Passed ▼	
☐ T66936	WS8 Login and Homepage	FW-53152	2h	Daniel M.	9/18/2020		ВМ	Passed ▼	
☐ T67795	Edit Freezer Position Twice on Aliquot Page (FW-54135)	FW-54135	10m	Daniel M.	9/17/2020		ВМ	Passed ▼	
☐ T67809	Logging in with Different Date Formats	FW-53046	10m	Esther E.	9/18/2020		вм	Passed -	
☐ T67823	Creating Samples and Patients while using the List View	FW-54471	15m	Esther E.	10/2/2020		BQ	Passed ▼	
☐ T67914	Admin user has no access to Web Client	FW-54695	10m	Chris H.	10/9/2020		BT	Passed -	
☐ T67984	Aliquots with "Can Requisition" checked OFF are prevented from being a part of new requisiti	FW-54749, FW-44070	15m	Daniel M.	10/13/2020		BU	Passed →	
Web Clie	Aliquots with "Can Requisition" checked OFF are prevented from being a part of new requisit nt Search (4) search in Web Client							Name of the last o	
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T661	143 WS9 Search and List View	Test Script Doc Link	4h 30m	Esther E.	10/14/2020		BV	Passed -	

	earch (4) ch in Web Client								
☐ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66143	WS9 Search and List View	Test Script Doc Link	4h 30m	Esther E.	10/14/2020		BV	Passed -	
☐ T66144	WS9.1 Search by ID	Test Script Doc Link	40m	Daniel M.	9/24/2020		ВО	Passeption ▼	
T67781	Attempt to modify someone else's Saved Search on Web Client	FW-54238	10m	Daniel M.	9/16/2020		BL	Passed ▼	
☐ T67956	FW-54681: Transaction ID should not be included in search fields list	fw-54681	10m	Esther E.	10/9/2020		ВТ	Passed -	

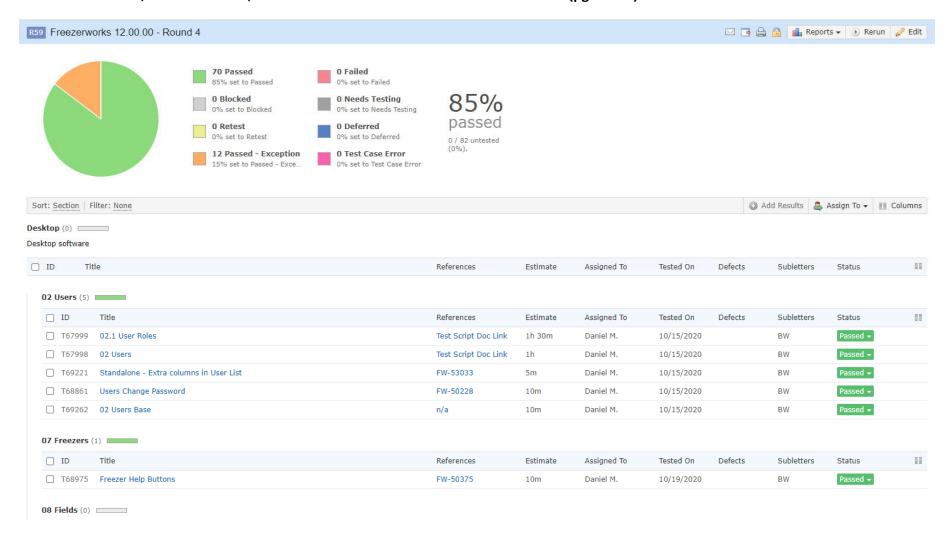
Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run continued (pg. 4 of 9)

☐ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	1
☐ T65759	Assign to Groups	FW-47084		Chris H.	9/22/2020	FW-53730	BN	Passeption →	
☐ T66090	Column Charts - Data Integrity	FW-47085, FW-47763		Chris H.	9/22/2020		BN	Passed ▼	
☐ T66092	Misc. Chart Testing	FW-47085, FW-47763		Chris H.	9/22/2020	FW-53741	BN	Passed ▼	
☐ T66130	Charts with Show Null Values checked ON	FW-48204		Chris H.	9/22/2020		BN	Passed ▼	
☐ T66111	Column Chart with Single Select Choice Lists for XAxis and GroupBy Field	FW-48158		Chris H.	9/22/2020		BN	Passed →	
☐ T65950	Freezer Fields are available in xAxis and GroupBy on Charts	FW-47799		Esther E.	10/9/2020		BT	Passed ▼	
☐ T67732	Searching from a Dashboard	FW-54353, FW54454		Esther E.	10/5/2020	FW-54680	BR	Passeption →	
☐ ID ☐ T66147	Title WS12 Web Client Import	References Test Script Doc Link	Estimate 3h	Assigned To Daniel M.	Tested On 10/8/2020	Defects	Subletters	Status Passeption •	
	mport (2)								
☐ T66147	WS12 Web Client Import	Test Script Doc Link	3h	Daniel M.	10/8/2020		BS	Passeption →	
☐ T67900	Web Client Import Boolean fields	FW-53203	20m	Esther E.	10/5/2020		BR	Passed →	
Web Client S	amples Entry (8)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66916	WS23.2 Samples Entry Data Integrity	FW-46030	3h 30m	Daniel M.	10/9/2020	FW-54737	BT	Failed 🕶	
☐ T66917	WS23.3 Freezer Position Assignment	FW-46030	1h	Daniel M.	10/8/2020		BS	Passed →	
☐ T66918	WS23.4 Linking Samples to Patients	FW-46030	1h	Daniel M.	10/8/2020		BT	Passed -	>
☐ T66915	WS23.1 Samples Entry UI	FW-46030	1h 30m	Esther E.	10/9/2020		BT	Passed -	
☐ T67830	Default Time Fields with Different Time Formats	FW-52427	20m	Esther E.	10/5/2020		BR	Passed ▼	
☐ T67921	Required Fields remain required after value being cleared	FW-52711	20m	Chris H.	10/12/2020		BU	Passed →	
☐ T 67949	Deletion of MultiSelect field values using X saves correctly	FW-54713	10m	Esther E.	10/12/2020		BU	Passed -	
☐ T67977	Multiselect fields sometimes become BLANK and don't allow you to save the sample.	FW-54711	10m	Esther E.	10/12/2020		BU	Passed -	

Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run continued (pg. 5 of 9)

: Section Fi	ilter: None					(Add Results 🚨	Assign To ▼	≣≣ Colu
☐ T67949	Deletion of MultiSelect field values using X saves correctly	FW-54713	10m	Esther E.	10/12/2020		BU	Passed ▼	
☐ T67977	Multiselect fields sometimes become BLANK and don't allow you to save the sample.	FW-54711	10m	Esther E.	10/12/2020		BU	Passed ▼	
Veb Client Co	configure Samples Entry (1)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66913	WS21 Configure Samples Entry	FW-51914	3h 20m	Daniel M.	9/24/2020		ВО	Passed ▼	
Veb Client Co	onfigure Patients Entry (1)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66914	WS22 Configure Patients Entry	FW-51860	1h 15m	Chris H.	9/29/2020		ВР	Passed -	
/eb Client Pa	atients Entry (2)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66920	WS24.2 Patients Entry Data Integrity	FW-52431	1h 30m	Chris H.	10/14/2020	FW-54505	BV	Passeptic	n 🕶
	WS28 Patient Alias	FW-47716	1h	Daniel M.	9/17/2020		ВМ	Passed ▼	
3)									
ID Tit	tle	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
Γ65700 4D	D License - ODBC Login	FW-47373	30m	Beth M.	10/8/2020		BS	Passed ▼	
T65705 4D	D License - Multiple Clients	FW-47373	10m	Beth M.	10/7/2020		BS	Passed ▼	
T65706 4D	D License - SQL Views	FW-47373	20m	Beth M.	10/8/2020		BS	Passed ▼	
llation (0)									
ID Tit	tle	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
pgrade (1)									
_ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T66935	FW2020 Upgrade	FW-52805	1h	Daniel M.	9/16/2020		BL	Passed ▼	

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Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run continued (pg. 7 of 9)

	Filter: None					O A	dd Results &	Assign To ▼	EE Column
8 Fields (0)									
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
Default V	/alues (1)								
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T692	222 Default Values - Cannot Add Aliquots to New Sample	FW-52455	10m	Daniel M.	10/15/2020		BW	Passed ▼	
)9 Entry For	ms (1)								
☐ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
☐ T69305	Filter Entry Form Selection	FW-54669	15m	Daniel M.	10/15/2020		BW	Passed •	
24 Import (1)									
□ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
				_ 32			DIM		
☐ T69297	Import with Non-consecutive Freezer Sections	FW-54229	10m	Esther E.	10/15/2020		BW	Passed ▼	
	Import with Non-consecutive Freezer Sections enses (5)	FW-54229	10m	Esther E.	10/15/2020		BW	Passed •	
		FW-54229 References	10m Estimate	Assigned To	10/15/2020 Tested On	Defects	Subletters	Passed •	
54 Client Lice	enses (5)					Defects		01024104	
54 Client Lice	enses (5) Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
54 Client Lice ID T68940	Title 54.1 Client Licenses (Client/Server Only)	References Test Script Doc Link	Estimate	Assigned To	Tested On 10/16/2020	Defects	Subletters BM	Status Passed •	
54 Client Lice ID T68940 T69227	Title 54.1 Client Licenses (Client/Server Only) 54.2 Client Licenses Standalone	References Test Script Doc Link FW-52377	Estimate 10m 30m	Assigned To Daniel M. Daniel M.	Tested On 10/16/2020 10/16/2020	Defects	Subletters BM BW	Status Passed • Passed •	
54 Client Lice ID T68940 T69227 T69228	Title 54.1 Client Licenses (Client/Server Only) 54.2 Client Licenses Standalone 54.3 Client Licenses Upgrade Server	References Test Script Doc Link FW-52377 FW-52377	Estimate 10m 30m 30m	Assigned To Daniel M. Daniel M. Daniel M.	Tested On 10/16/2020 10/16/2020 10/19/2020	Defects	Subletters BM BW BW	Status Passed ▼ Passed ▼	
54 Client Lice ID T68940 T69227 T69228 T69261 T69298	Title 54.1 Client Licenses (Client/Server Only) 54.2 Client Licenses Standalone 54.3 Client Licenses Upgrade Server 54.1 Client Licenses Server Base Edition	References Test Script Doc Link FW-52377 FW-52377 FW-53013	Estimate 10m 30m 30m 30m	Assigned To Daniel M. Daniel M. Daniel M. Daniel M.	Tested On 10/16/2020 10/16/2020 10/19/2020 10/19/2020	Defects	Subletters BM BW BW	Status Passed ▼ Passed ▼ Passed ▼	
54 Client Lice ID T68940 T69227 T69228 T69261 T69298	ritle 54.1 Client Licenses (Client/Server Only) 54.2 Client Licenses Standalone 54.3 Client Licenses Upgrade Server 54.1 Client Licenses Server Base Edition 54.4 Client Licenses Upgrade Server Data in Standalone	References Test Script Doc Link FW-52377 FW-52377 FW-53013	Estimate 10m 30m 30m 30m	Assigned To Daniel M. Daniel M. Daniel M. Daniel M.	Tested On 10/16/2020 10/16/2020 10/19/2020 10/19/2020	Defects Defects	Subletters BM BW BW	Status Passed ▼ Passed ▼ Passed ▼	
ID	Title 54.1 Client Licenses (Client/Server Only) 54.2 Client Licenses Standalone 54.3 Client Licenses Upgrade Server 54.1 Client Licenses Server Base Edition 54.4 Client Licenses Upgrade Server Data in Standalone	References Test Script Doc Link FW-52377 FW-52377 FW-53013 FW-54323	10m 30m 30m 30m 30m 30m	Assigned To Daniel M. Daniel M. Daniel M. Daniel M. Daniel M.	Tested On 10/16/2020 10/16/2020 10/19/2020 10/19/2020 10/19/2020		Subletters BM BW BW BW	Passed ▼ Passed ▼ Passed ▼ Passed ▼ Passed ▼	
ID	Title 54.1 Client Licenses (Client/Server Only) 54.2 Client Licenses Standalone 54.3 Client Licenses Upgrade Server 54.1 Client Licenses Server Base Edition 54.4 Client Licenses Upgrade Server Data in Standalone ws (5)	References Test Script Doc Link FW-52377 FW-52377 FW-53013 FW-54323	Estimate 10m 30m 30m 30m 30m	Assigned To Daniel M. Daniel M. Daniel M. Daniel M. Daniel M. Assigned To	Tested On 10/16/2020 10/16/2020 10/19/2020 10/19/2020 10/19/2020 Tested On		Subletters BM BW BW BW Subletters	Status Passed • Passed • Passed • Passed • Status	on v
ID	Title 54.1 Client Licenses (Client/Server Only) 54.2 Client Licenses Standalone 54.3 Client Licenses Upgrade Server 54.1 Client Licenses Server Base Edition 54.4 Client Licenses Upgrade Server Data in Standalone ws (5) Title 105 - Configure Workflows UI	References Test Script Doc Link FW-52377 FW-52377 FW-53013 FW-54323 References Test Script Doc Link	Estimate 10m 30m 30m 30m 30m 30m 30m	Assigned To Daniel M. Daniel M. Daniel M. Daniel M. Daniel M. Daniel M. Assigned To Daniel M.	Tested On 10/16/2020 10/16/2020 10/19/2020 10/19/2020 10/19/2020 Tested On 10/16/2020	Defects	Subletters BM BW BW BW Subletters	Passed • Passed • Passed • Passed • Passed • Passed •	on -

Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run continued (pg. 8 of 9)

ort: Section Filter: None					0	Add Results 👃	Assign To ▼	Column
	5.000	*****	Lucius Li	10/10/2020		mm.	10000	
☐ T69301 Null Values stay Null when incremented/decremented during Workflow	FW-53131	15m	Esther E.	10/16/2020		BW	Passed •	
Study Management (1)								
☐ ID Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	1
☐ T69317 Print Patient data on Visit Label	FW-54055	20m	Esther E.	10/15/2020		BW	Passed ▼	
b Client (27)								
ID Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	=
T68459 WS4 Audit Trail	Test Script Doc Link	30m	Daniel M.	10/16/2020		BV	Passed ▼	
T68469 WS14 Web Client Requisitions	Test Script Doc Link	1h	Daniel M.	10/16/2020		BV	Passed ▼	
T68471 WS16 Processing Workflows	Test Script Doc Link	4h 30m	Daniel M.	10/21/2020	FW-54163	BX	Passeption ·	
T68474 WS19 Audit Trail	Test Script Doc Link	1h	Daniel M.	10/19/2020	FW-54419	BW	Passeption ·	
T69223 WS25.1 Transactions	FW-51874	1h	Daniel M.	10/21/2020		BX	Passed ▼	
T69224 WS33 Aliquot Status	FW-52540	45m	Chris H.	10/16/2020		BW	Passed ▼	
T69225 WS27 Web Client Print Labels	FW-51863	30m	Daniel M.	10/19/2020		BW	Passed ▼	
T69229 WSB1 Base Edition Testing	FW-52378	45m	Daniel M.	10/20/2020		BW	Passed ▼	
T69230 WSA1 Ascent Edition Testing	FW-51914	20m	Daniel M.	10/20/2020		BW	Passed ▼	
T69231 WSP1 Pinnacle Edition Testing	FW-52807; FW-528	1h 30m	Daniel M.	10/21/2020		BW	Passeption -	
T69232 WS19.1 Audit Trail with Reasons	FW-52675	2h 30m	Daniel M.	10/21/2020		BX	Passeption -	
T69241 WS26 Deleting Patients, Samples, Aliquots	FW-52573	1h	Chris H.	10/15/2020		BW	Passed ▼	
T69243 WS29 Owner Security	FW-50200	30m	Chris H.	10/15/2020		BW	Passed ▼	
T69244 WS30 Freezer Security	FW-51861	1h	Chris H.	10/15/2020		BW	Passed ▼	
T69245 WS31 Field Security	FW-52980	45m	Chris H.	10/15/2020		BW	Passed ▼	
T69246 WS32 Locked Records	FW-52067	45m	Chris H.	10/15/2020		BW	Passed ▼	
T69247 WS34 Testing List View and Details	FW-51939	1h	Chris H.	10/19/2020		BW	Passed ▼	
T69249 WS16.1 Processing Sub-Aliquot Workflows	N/A	5h	Esther E.	10/15/2020		BW	Passed ▼	
T69256 WS8 Login and Homepage	FW-53152	2h	Chris H.	10/19/2020	FW-54818	BW	Passeption	
T69281 Single email workflow after multiple email workflow	FW-53989	10m	Esther E.	10/15/2020		BW	Passed ▼	

Freezerworks 2021, version 12.0.00, TestRail – Formal Validation Test Run continued (pg. 9 of 9)

1.5	Filter: None					0	Aud Results	Assign To ▼	Joiuiiii
T69284 Au	udit Trail Reasons set to Change with New Record	FW-54445	20m	Daniel M.	10/19/2020		BW	Passed ▼	
T69289 Ed	dit Freezer Position Twice on Aliquot Page (FW-54135)	FW-54135	10m	Esther E.	10/16/2020		BW	Passed ▼	
T69291 Lo	ogging in with Different Date Formats	FW-53046	10m	Chris H.	10/16/2020		BW	Passed ▼	
T69293 Cr	reating Samples and Patients while using the List View	FW-54471	15m	Chris H.	10/16/2020		BW	Passed →	
T69306 Ad	dmin user has no access to Web Client	FW-54695	10m	Chris H.	10/16/2020		BW	Passed →	
T69316 Ali	liquots with "Can Requisition" checked OFF are prevented from being a part of new requisiti	FW-54749, FW-44070	15m	Esther E.	10/16/2020		BW	Passed →	
) T70102 Ad	dditional Transactions Testing	FW-54536		Esther E.	10/27/2020		BZ	Passed ▼	
API Tests (1)									
☐ ID	Title	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
T68562	WS18 Import Test (API Only) - Automated	WS18-Imports-Auto		Allen C.	10/21/2020		BX	Passed ▼	
Web Client So	Search (7) Creation with the control of the control							24000	
Web Client S	Search (7)	References	Estimate	Assigned To	Tested On	Defects	Subletters	Status	
Web Client So	Search (7) Creation with the control of the control	References Test Script Doc Link	Estimate 4h 30m	Assigned To Chris H.	Tested On 10/21/2020	Defects	Subletters BX	Status Passeption •	
Web Client So All things sear	Search (7) Tritle					Defects		V-0-0-000	
Web Client So All things sear ID T68463	Search (7) Title WS9 Search and List View	Test Script Doc Link	4h 30m	Chris H.	10/21/2020	Defects	ВХ	Passeption →	
Web Client So All things search ID T68463	Title WS9 Search and List View WS9.1 Search by ID	Test Script Doc Link Test Script Doc Link	4h 30m 40m	Chris H. Daniel M.	10/21/2020 10/20/2020	Defects	BX BW	Passed →	
Web Client So All things sear D ID T68463 T68464 T69287	Title WS9 Search and List View WS9.1 Search by ID Attempt to modify someone else's Saved Search on Web Client	Test Script Doc Link Test Script Doc Link FW-54238	4h 30m 40m 10m	Chris H. Daniel M. Chris H.	10/21/2020 10/20/2020 10/16/2020	Defects	BW BW	Passed ▼ Passed ▼	
web Client So All things search ID T68463 T69287 T69312	Title WS9 Search and List View WS9.1 Search by ID Attempt to modify someone else's Saved Search on Web Client FW-54681: Transaction ID should not be included in search fields list	Test Script Doc Link Test Script Doc Link FW-54238 fw-54681	4h 30m 40m 10m	Chris H. Daniel M. Chris H. Chris H.	10/21/2020 10/20/2020 10/16/2020 10/16/2020	Defects	BX BW BW	Passed → Passed → Passed →	
Web Client So All things sear ID ID T68463 T68464 T69287 T69312 T70078	Title WS9 Search and List View WS9.1 Search by ID Attempt to modify someone else's Saved Search on Web Client FW-54681: Transaction ID should not be included in search fields list Freezer Alias to Not Display on Web Client	Test Script Doc Link Test Script Doc Link FW-54238 fw-54681 FW-54878	4h 30m 40m 10m	Chris H. Daniel M. Chris H. Chris H. Daniel M.	10/21/2020 10/20/2020 10/16/2020 10/16/2020 10/26/2020	Defects	BX BW BW BW	Passed ▼ Passed ▼ Passed ▼ Passed ▼	
Web Client So All things sean	Title WS9 Search and List View WS9.1 Search by ID Attempt to modify someone else's Saved Search on Web Client FW-54681: Transaction ID should not be included in search fields list Freezer Alias to Not Display on Web Client Pinnacle list views that include Visits	Test Script Doc Link Test Script Doc Link FW-54238 fw-54681 FW-54878 FW-54858	4h 30m 40m 10m	Chris H. Daniel M. Chris H. Chris H. Daniel M. Chris H.	10/21/2020 10/20/2020 10/16/2020 10/16/2020 10/26/2020 10/27/2020	Defects	BX BW BW BW BX BZ	Passed ▼ Passed ▼ Passed ▼ Passed ▼ Passed ▼	
Web Client So All things sean	Title WS9 Search and List View WS9.1 Search by ID Attempt to modify someone else's Saved Search on Web Client FW-54681: Transaction ID should not be included in search fields list Freezer Alias to Not Display on Web Client Pinnacle list views that include Visits Only the relevant Participant Study IDs display on the Visit List View	Test Script Doc Link Test Script Doc Link FW-54238 fw-54681 FW-54878 FW-54858	4h 30m 40m 10m	Chris H. Daniel M. Chris H. Chris H. Daniel M. Chris H.	10/21/2020 10/20/2020 10/16/2020 10/16/2020 10/26/2020 10/27/2020	Defects Defects	BX BW BW BW BX BZ	Passed ▼ Passed ▼ Passed ▼ Passed ▼ Passed ▼	
Web Client So All things sear ID ID T68463 T68464 T69287 T69312 T70078 T70086 T70094 Web Client In	Title WS9 Search and List View WS9.1 Search by ID Attempt to modify someone else's Saved Search on Web Client FW-54681: Transaction ID should not be included in search fields list Freezer Alias to Not Display on Web Client Pinnacle list views that include Visits Only the relevant Participant Study IDs display on the Visit List View	Test Script Doc Link Test Script Doc Link FW-54238 fw-54681 FW-54878 FW-54858 FW-54858	4h 30m 40m 10m 10m	Chris H. Daniel M. Chris H. Chris H. Daniel M. Chris H. Chris H.	10/21/2020 10/20/2020 10/16/2020 10/16/2020 10/26/2020 10/27/2020 10/27/2020		BX BW BW BW BX BZ	Passed ▼ Passed ▼ Passed ▼ Passed ▼ Passed ▼ Passed ▼	



Certificate of Validation

Dataworks Development, Inc. hereby certifies that its latest product, Freezerworks® 2021 version 12.0.00, 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 November 2nd 2020.

Andrew Michels

Dataworks Development, Inc.

Vice President, Head of Quality Assurance