1. REVISION HISTORY

Revision #	Change Description	Changed by	Change Date
0	Initial Release	Manmeet Chadha	2024/03/04

2. APPROVALS

Signature Meaning	Name	Title	Date	Signature
Author	Manmeet Chadha	SW Test		
Approved By	Søren Therkelsen	COO		

3. PURPOSE

This document describes the links from software requirements (SR-nnn) to software test cases (TC-nnn) and in some cases from software requirements upstream to product requirements (PR-nnn) and risks (RISK-nnn).

4. SCOPE

This trace matrix covers all the software associated with the Qvin Sample Management Software, including the following:
- Qvin Mobile App
- Qvin Backend

5. REFERENCES

- SOP-Q009 Design Controls
- SOP-Q038 Software Development
- DOC-329 Software Development Plan R6
- DOC-16 Product Requirements
- DOC-17 Software Requirements, Sample Management Software

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6. DEFINITIONS

- SR - Software Requirement
- TC - Test Case
- PR - Product Requirement
- RISK - Risk item (row) from a hazard analysis table

7. SUMMARY

All software requirements are covered by one or more test case.

8. REQUIREMENTS DOWN TRACE

Item	Downlinks
SR-29 Health Screen	**TC-216 Verify the user will see a message in the top widget, prompting to get started in case the user is not currently using any kit or waiting for any results** **TC-217 Verify the user will see a message in the top widget, prompting that results are ready, after results have been released to her** **TC-2523 Verify the user will see a message in the top widget, prompting to start using the QPad, in case the user has registered the kit, but not yet started using the pad.** **TC-2524 Verify the user will see a message in the top widget, prompting to start second pad, if first pad usage was complete** **TC-2525 Verify the user will see a message in the top widget, prompting to ship the QPad, in case the user has completed with both QPasds of the kit, but not yet shipped the kit.** **TC-2526 Verify the user will see a message in the top widget, prompting about the results being awaited after kit is received ny the lab**
SR-45 Used Kit Cards	**TC-399 Verify the no reports message, if user has not yet completed using any kit.** **TC-2145 Verify different cards for every kit usage completed by the user.** **TC-355 Verify the order of appearance of kit result cards**
SR-226 Kit Details	**TC-347 Verify the kit details and assay details are visible when user taps on healthcard 'We're analysing your QPad'** **TC-2069 Verify results for a kit with multiple tests and A1c having**

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Item	Downlinks
	critical result
	TC-342 Verify the status 'We received your Q-pad.' on Kit Details screen of a used kit which has multiple assays, when it reaches the lab
	TC-344 To verify the status 'Some results are ready' on Kit Details screen of a used kit , after it is returned from lab to Qvin, but all results not yet released to customer.
	TC-345 Verify the status on Kit Details screen of a used kit , after it is returned from lab to Qvin, and all results are marked as released to customer.
	TC-352 Verify for a user who already has results of old kits, the color of assay tiles for a kit which has some assays released and some not yet.
	TC-349 Verify for a Comprehensive successfully analysed kit that the assay result range and color is appearing correctly for each assay on the assay card without opening it..
	TC-2146 On the kit details screen of any analyzed kit, verify sorting based on assay results
	TC-2210 Verify the kit details screen on mobile app, while an amendment is in process.
	TC-2212 Verify the kit details screen on mobile app, when an amendment is complete and assay results are released thru medical dashboard.
	TC-2214 Verify the kit details screen on mobile app, when an assay is marked 'Rejected' during amendment on the Dendi side and all results released to customer.
	TC-2311 Verify the PDF report on the kit details screen shows the amended results along with status 'AMENDED'
	TC-2349 Verify for FDA test panels , the user will always see the option for viewing PDF lab report from Dendi.
	**TC-2074 For FDA test panel, verify results for kits in which use time was added thru Accessioning dashboard after marking them Confirmed_By_Carrier. **
	TC-2049 For kit with multiple assays, verify failure on mobile_app if all assays in analysis_request marked 'Rejected for analysis'(P_PhysRejectedAnalysis), for a Dendi kit.
SR-9 Report Details	**TC-347 Verify the kit details and assay details are visible when user taps on healthcard 'We're analysing your QPad'**
	TC-2069 Verify results for a kit with multiple tests and A1c having critical result
	TC-352 Verify for a user who already has results of old kits, the color of assay tiles for a kit which has some assays released and some

Item	Downlinks
	not yet.
	TC-349 **Verify for a Comprehensive successfully analysed kit that the assay result range and color is appearing correctly for each assay on the assay card without opening it..**
	TC-361 **To Verify the Result Details Screen show right HbA1c value if it falls under 'Diabetic Range' range**
	TC-360 **To Verify the Result Details Screen show right HbA1c value if it falls under 'Elevated' range**
	TC-359 **To Verify if the Result Details Screen show right HbA1c value if it falls under 'Normal' range**
	TC-356 **Verify tapping the 'Learn More" link on Assay Details screen**
	TC-353 **Verify assay result screens having the right assay value, range, slider value and range specific color when assay result status value is 'Released'**
	TC-1695 **Verify all range colors for any assay are available on the Y axis of the chart .**
	TC-1696 **Verify the months of the year are plotted on the X axis of the assay trends chart and trends can be seen for 6M and 12M periods on the mobile app.**
	TC-2033 **Verify trends for an assay which has had prior values, but still results not released for the current kit**
	TC-2123 **Verify that the test result screen opens up on tapping the link received by SMS after results are ready.**
	TC-2211 **Verify the assay details screen on mobile app, while an amendment is in process.**
	TC-2213 **Verify the assay details screen on mobile app, when an amendment is complete and assay results are released thru medical dashboard.**
	TC-2215 **Verify the assay details screen on mobile app, when an assay is marked 'Rejected' during amendment on the Dendi side and all results released to customer.**
	TC-2269 **Verify for Qualitative assays the trends are shown in a tabular form**
	TC-2355 **Verify if assay result value is below the Y axis minm scale value, the Y axis maximum plot will be equal to the Y axis scaling value.**
	TC-2356 **Verify the last results on trends charts are anchored to 1 month before "graph length"**
	TC-355 **Verify the order of appearance of kit result cards**
	TC-559 **Verify pad kit status is changed to ISSUE and Analysis_Request is 'Failed', during accessioning, if the kit expiry date has approached.**

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Item	Downlinks
SR-221 Assay result notification	**TC-2123 Verify that the test result screen opens up on tapping the link received by SMS after results are ready.**
SR-246 Customer Tests	**TC-2046 For LDT test panel, verify results for kits in which use time was added thru Accessioning dashboard after marking them Delivered_To_Lab** **TC-2074 For FDA test panel, verify results for kits in which use time was added thru Accessioning dashboard after marking them Confirmed_By_Carrier. ** **TC-2434 Verify that assays result visibility on mobile app does not change if in the test panel, the assay's customer test value changes from true to false. after result release.** **TC-2435 Verify that assays result visibility on mobile app does not change if in the test panel, the assay's customer test value changes from false to true. after result release.**
SR-266 Kit Rejections	**TC-2483 Verify resolving rejection thru mobile by ordering a replacement kit, against a shopify 'Shipped_By_Customer' kit that was marked missing via the logistics dashboard.** **TC-2485 Verify resolution of rejected orders and kits associated to those orders** **TC-2486 Verify resolving rejection thru mobile by pressing 'Understood', against a rejected shopify A1c kit that was rejected during accessioning, due to 'k_mismatchdevices', but no new kit was offered against it.** **TC-2487 Verify resolving rejection thru mobile by pressing 'Understood', against a rejected shopify kit that was rejected during accessioning, due to 'k_NoStripsRSC', but no new kit was offered against it.** **TC-2488 Verify resolving rejection thru mobile by pressing 'Understood', against a rejected shopify kit that was rejected during accessioning, due to 'k_Empty', but no new kit was offered against it.** **TC-2489 Verify resolving rejection thru mobile by ordering a replacement kit, against a shopify Comprehensive kit which was originally part of an order with multiple kits and then was rejected during accessioning, due to 'k_Damaged'** **TC-2490 Verify resolving rejection thru mobile by refunding the amount, against a shopify kit which was originally part of an order with single kit and kit was rejected during accessioning, due to 'k_Norsc'** **TC-2491 Verify resolving rejection thru mobile by refunding the amount, against a shopify kit which was originally part of an order with multiple kits and then the kit was rejected in Dendi due to**

Item	Downlinks
	'K_Other' **TC-2492** **Verify resolving rejection as Resolved_By_System with 'No New Kit' , against a shopify 'CREATED' kit that was marked missing via the logistics dashboard.**
SR-267 **Panel Rejections**	**TC-2504** **Verify resolving panel rejection thru mobile by offering no kit when one assay is rejected due to p_stability, but other assay results released successfully and customer responding successfully to the rejection message received.** **TC-2505** **Verify resolving panel rejection thru mobile by offering a new kit when multiple panels are rejected during accessioning & others released with results and customer resolving rejection by placing the replacement order via the mobile** **TC-2506** **Verify resolving light sample prep rejection thru mobile by offering a kit refund from an order of multiple kits, when one prep is rejected with p_light during accessioning but other preps released successfully and customer resoving successfully for refund** **TC-2507** **Verify resolving NotIntact prep rejection thru mobile by offering a kit refund to an order of one kit when all preps are rejected with p_notintact, during accessioning and customer resoving successfully for refund.** **TC-2508** **Verify resolving panel rejection thru mobile, by offering a replacement kit, when one panel out of multiple panels is rejected for analysis ** **TC-2509** **Verify resolving panel rejection thru mobile, by offering no new kit, when the 'Reject All' button is pressed while analysis approval** **TC-2511** **Verify resolving light sample prep rejection thru mobile by offering a kit refund from an order of multiple kits, when the prep is rejected with p_light during accessioning and customer resoving successfully for refund** **TC-2512** **Verify resolving NotIntact prep rejection thru mobile by offering a kit refund to an order of one kit because its prep was rejected with p_notintact, during accessioning.** **TC-2513** **Verify resolving the P_Archived panel rejection caused by archiving the only available customer test while the kit was IN_Use** **TC-2514** **Verify resolving the P_Archived panel rejection caused by archiving the only available customer test after the kit was Shipped_By_Customer** **TC-2515** **Verify resolving the P_Archived panel rejection caused by archiving one of the available customer test while the kit was IN_Use**
SR-229 **Help & Support**	**TC-364** **Verify the various FAQ categories present on the Help &**

Item	Downlinks
	Support screen under Profile tab **TC-365** **Verify the section called 'Frequently asked questions' on the Help & Support' screen under Profile.** **TC-2209** **Verify the user can send an email to Qvin support from the 'Help & Support' page under PROFILE**
SR-64 **Kit and Analysis Request Details Screen**	**TC-1065** **Verify the widget 'Kit Details' on the screen showing kit and analysis request details** **TC-1066** **Verify the widget 'Order Details' on the screen showing kit and analysis request details** **TC-1067** **Verify the widget 'Turn around times' on the screen showing kit and analysis request details** **TC-1068** **Verify the widget 'Test results' on the screen showing kit and analysis request details** **TC-1069** **Verify the widget for 'Events' on the screen showing kit and analysis request details, when events are filtered by Customer Tests** **TC-1070** **For any Trial type kit, verify the Group under the Trial Management section** **TC-1071** **For any Trial type kit, verify the Collector Organization under the Trial Management section** **TC-1072** **For any Trial type kit, verify the Clinical Organization under the Trial Management section** **TC-1073** **For any Trial type kit, verify the Compensation amount under the Trial Management section** **TC-1074** **Verify the widget 'Rejections' for kit rejections, on the screen showing kit and analysis request details** **TC-1091** **Verify the widget for 'Events' on the screen showing kit and analysis request details, when events are not filtered by Customer Tests**
SR-84 **Device Details Screen**	**TC-1092** **Verify the widget 'Device Credentials' on the device details screen.** **TC-1093** **Verify the widget 'Collection Details' on the device details screen** **TC-1094** **Verify the widget 'Device encounter observations' on the device details screen** **TC-1095** **Verify the widget 'Device status' on the device details screen** **TC-1096** **Verify the widget 'Laboratory' on the device details screen** **TC-1111** **Verify if photos uploaded, if any, are appearing under the Photos section**
SR-235 **Lab reports for Quantitative test values**	**TC-2246** **Verify for tests with Customer Test as 'False' (On Qvin side) or having Hide Quantitative result as 'True' (Dendi side) the quantitative result values are not checked upon, while pulling**

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Item	Downlinks
	results from Dendi,. **TC-2247** Verify for tests with Customer Test as 'True' (On Qvin side) or having Hide Quantitative result as 'False' (Dendi side), the quantitative result values are checked upon, while pulling results from Dendi.
SR-237 Lab reports based on Panel product regulatory status and CustomerTest value of biomarkers	**TC-2233** Verify assay result treated as pending and analysis_request treated as 'Analysis_Awaiting', if an out of expected range value is provided on the Dendi side. **TC-2242** Verify for tests with Customer Test 'False', the notifications for event 'Assay Result Failed ' are suppressed/cancelled **TC-2240** Verify for tests with Customer Test as 'False', the notifications for event 'Analysis Released to customer' are suppressed/cancelled **TC-2245** Verify for tests marked as Customer Test False, the assay will not be visible to the customer and also not visible on the analysis request screen of medical dashboard. **TC-2246** Verify for tests with Customer Test as 'False' (On Qvin side) or having Hide Quantitative result as 'True' (Dendi side) the quantitative result values are not checked upon, while pulling results from Dendi,. **TC-2247** Verify for tests with Customer Test as 'True' (On Qvin side) or having Hide Quantitative result as 'False' (Dendi side), the quantitative result values are checked upon, while pulling results from Dendi. **TC-2266** Verify in LDT panel products, biomarkers marked as Customer Test False will not be visible on the analysis_request screen but will be auto approved for analysis. **TC-2267** Verify in FDA panel products, biomarkers marked as Customer Test False will not be visible on the Analysis_Request screen and not visible to user at any time. **TC-2312** Verify in FDA panel products, biomarkers marked as Customer Test 'True' will not require Physician approval for analysis. **TC-2313** Verify in FDA panel products, biomarkers marked as Customer Test 'True' will not require Physician approval for release. **TC-2427** Verify the analysis_request for all trial kits ends in status 'Analysis_Partial' when there are no customer_tests associated to the kit. **TC-2445** Verify in LDT panel products, biomarkers marked as Customer Test 'True' will require Physician approval for analysis.

Item	Downlinks
	TC-2446 Verify in LDT panel products, biomarkers marked as Customer Test False will not be visible on the Analysis_Request screen and not visible to user at any time. **TC-2447** Verify in LDT panel products, biomarkers marked as Customer Test 'True' will require Physician approval for release.
SR-177 Physician Approval	**TC-1246** Verify only LDT kits appear under the Analysis Approval tab of doctor dashboard. **TC-1247** Verify only LDT kits appear under the Release Approval tab of doctor dashboard. **TC-1248** Verify Customer Details screen opens up on clicking the Customer Name on the LDT Results to Approve screen **TC-1249** On the Analysis Approval screen, for a kit, verify the scenario when all eligible LDT panels are approved. **TC-1250** On the Analysis Approval screen, for a kit, verify the scenario when all eligible LDT panels are rejected. **TC-2076** Verify that clinical physicians can not see any record for analysis approval and can not approve/reject **TC-2077** Verify that Patient Admins can see all record for Analysis approval and can approve/reject any record. **TC-2454** Verify that kits that have not gone thru 'IN_Use' state and 'Confirmed_By_Carrier' state, are not visible on the screen 'Analysis Approval' **TC-2455** On the Analysis Approval screen, for a kit, verify the scenario when some eligible LDT panels are approved and some rejected. **TC-2456** Verify kits that have not gone thru 'Confirmed_By_Carrier' state, are only visible on the screen 'Analysis Approval', after the accessioning has started for the kit and the notification 'Assay Analysis Approval Required' is sent to staff. **TC-2460** Verify 'Created' kits when directly accessioned and use time and customer info provided, are visible on the screen 'Analysis Approval', after the accessioning has started and kit quarantined due to assay analysis approval missing. **TC-1252** For LDT kit, verify the doctor can reject the release of some or all analysed results, to the customer

9. REQUIREMENTS UP TRACE

not applicable