Hotspot Clinical Pipeline

**Performance Qualification (PQ)**

**PQP-HPS-0001**

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# PROTOCOL PRE-APPROVAL

Signing this protocol indicates that the contents of this document have been reviewed, all test procedures are accurate and the acceptance criteria are applicable for the intended purpose of this performance qualification. The following responsible functional areas have approved this testing plan:

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Business Owner/Designee Date

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dir of Bioinformatics/Designee Date

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Quality Assurance Date

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Clinical Lab Director/Designee Date

# PURPOSE

The purpose of this Performance Qualification Protocol (PQ) is to provide documented evidence that all modifications to the Hotspot Clinical Pipeline system function, according to the Software Requirements Specification (SRS) found in the Validation Project Plan and the User Requirements Specification (URS). The PQ will demonstrate that the configured system conforms to the agreed business process and functional design. The configured system is to be validated during PQ, which will be performed according to this pre-approved protocol.

All functions will have at least one test case associated to them to test the precise functionality listed in the SRS and URS. Test Cases will also test downstream impact with regression testing when needed. The requirements and test cases are linked to the Traceability Matrix included in Traceability Matrix section. Test Cases are included in [Test Cases](#_TEST_CASES) section.

During PQ testing, the Hotspot Clinical Pipeline capabilities and functionality will be tested in order to confirm that the system performs as intended. All testing follows a plan and any supporting screenshots or documentation will be labeled with the number corresponding to the associated test case.

# SCOPE

This protocol outlines and documents system and software requirements for the Hotspot Clinical Pipeline for SEMA4-Connecticut. Successful completion and execution of the below test cases validate that Hotspot Clinical Pipeline meets the system requirements for the Performance Qualification portion of the overall validation package.

Requirements for this protocol are outlined in the Software Requirements Specification found in the Validation Project Plan document and the User Requirements Specification included in the validation package folder.

# IDENTIFICATION

|  |  |
| --- | --- |
| **Test Environment:** | Hotspot Clinical Pipeline |
| **Configuration Version Number:** | 3.0 |

# Traceability Matrix

All functions will have at least one test case associated to them to test the precise functionality listed in the SRS. Test Cases will also test downstream impact and regression testing when needed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Requirement** | **Description** | **# Linked Cases** | **Test Cases** |
| HPS-47 | Add a "Director Override (DO)" tier to the variant quality control page. Variants that are assigned to this tier will be included in the "Significant Genomic Alterations" section in the report. In addition a new section titled "Other Significant Findings" will be placed after the tier 2 section and before the VUS section and will include all variants in the DO tier. |  |  |
| HPS-49 | Remove the "Special Considerations" label from above report level comment. This means the report level comment should now directly follow the header "Interpretation" |  |  |
| HPS-50 | Change Variant calling pipeline wrapper to Bpipe from Perl. |  |  |
| HPS-51 | Modify loader to deal with Torrent 5.4 Database Changes. |  |  |
| HPS-52 | Change variant calling pipeline to use Torrent Variant Caller (TVC) 5.4. |  |  |
| HPS-53 | Change value of filter\_unusal\_predictions parameter for TVC in variant calling pipeline. The setting for the filter\_unusual\_predictions parameter will be set to 0.3. |  |  |
| HPS-54 | Modify the hotspot data loader so that the variant allele frequency cutoff threshold for non-control samples is greater than or equal to 1%. |  |  |
| HPS-55 | Add an allele frequency filter text entry box to the Variant QC page in the dashboard. Entering a number into the text box will result in all variants for that sample with allele frequency below that number being hidden from view. The default for this filter will be empty, however the default should be able to be changed in future versions of the dashboard. All variants for a sample, even if they are hidden, must still have a status set besides pending for the sample to be able to move on to the next step in the workflow. |  |  |
| QI-001 | Fluidigm results shall be uploaded to the QCAR database on a per chip basis | 1 | TC-1 |
| QI-002 | NGS sequencing data for each sample shall be processed resulting in a final VCF file | 1 | TC-2 |
| QI-003 | NGS sequencing quality matrix data shall be uploaded to the QCAR database | 1 | TC-2 |
| QI-004 | Sample level QC (sequence QC, Identity QC) and plate level QC (Control QC) shall be performed for all NGS sequencing data after all related data are available in the QCAR database | 1 | TC-2 |
| CD-001 | All sequencing samples need to pass sequencing QC, control run QC and identity QC using pre-set QC matrix and manual check prior to the Variant QC step | 1 | TC-3 |
| CD-002 | Any sample failing any step of QC could be sent back to a re-queue list which can be entered into LIMS for re-sequencing in the lab | 2 | TC-3, TC-4 |
| CD-003 | Clinical Directors can withdraw samples during Sample QC and Variant QC steps for quality or other reasons | 1 | TC-5 |
| CD-004 | Any samples that pass sequencing QC, control QC and identity QC shall be subject to variant QC during which time, each variant shall be checked for quality which sets a status for the sample to move into variant annotation | 1 | TC-6 |
| CD-005 | Any variants identified by the Clinical Director requiring confirmation by Sanger technology shall be queued in a list where the confirmation results can later be uploaded to the Clinical Dashboard for evaluation | 1 | TC-7 |
| CD-006 | Any variants identified by the Clinical Director requiring confirmation by qPCR technology shall be queued in a list where the confirmation results can later be uploaded to the Clinical Dashboard for evaluation | 2 | TC-6, TC-8 |
| CD-007 | Any clinical patient samples shall have their variants annotated using the combined sources of commercial databases (e.g., iCMDB) and any other public database and information sources that the Clinical Director deems necessary | 1 | TC-9 |
| CD-008 | Any annotated samples can be configured to report any or all of the annotated variants | 2 | TC-9, TC-10 |
| CD-009 | The Clinical Director can digitally sign the final report | 1 | TC-10 |
| CD-010 | Administrator of the system can assign users to different roles: | 1 | TC-11 |

# PROCEDURES AND TEST INSTRUCTIONS

The performance test case results will be reported through a result column along with the initials of the tester and date of the test. The results will be summarized in Section 5.0 – Conclusion. Any errors will be documented in the Validation Testing Error and Resolution form(s). Each test case includes predetermined acceptance criteria.

The following must be conducted as part of the procedure for each test case using the hardware and software identified, unless otherwise noted within the test case:

1. Before proceeding with a test case, verify any preconditions have been completed and passed.
2. Test cases are intended to be performed in sequential order when instructed to do so.
3. Test steps may have icons indicating screenshots or printout. Refer to Appendix 1 for details. Any screenshots or printouts should be saved with the naming format: Test Case #.Step # (i.e. Test Case 1, Step 1 should be named 1.1). There may be several screenshots/documents for one test case.
4. Verify at each step that the action indicated in the Expected Results column occurred. Indicate if each step passes or fails by entering ‘P’ or ‘F’ into the ‘Result (P/F)’ column.
5. Each test case step requires the tester’s initials and the date the test step was executed.
6. If Actual Results are not equal to the Expected Results, then that step fails. Note any discrepant results in the Conclusion section at the end of the protocol. Also, if the test case does not pass, follow Validation Testing Error and Resolution Instructions referenced in Appendix 1 of the VPP. Complete a single report for each error found.
7. If the actual results were captured in a separate document, print out the results using the labeling scheme described and include as documentation along with results.
8. Objective Evidence is documented by any screen prints, reports or other data generated as part of the protocol.
9. After execution of each test step is completed, determine a PASS/FAIL status for the entire protocol and indicate this in the Conclusion section. Add additional comments and any reported issues if appropriate and enter them in the area indicated.
10. The use of N/A or shading means no data is required in this block. (If the Expected Results column is N/A, then Comment(s)/Attachment columns will be blank)

# TEST CASES

### Test Case 01: Import Fluidigm and Identity QC

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test Case # | TC-1 | | | | |
| Title | **Import Fluidigm and Identity QC** | | | | |
| Requirement # | CI-001 | | | | |
| Test Type | Regression | | | | |
| Description | Import Fluidigm results in CSV format, run store procedure to check Identity for the samples | | | | |
| Precondition(s) | Fluidigm results are available and sequencing results have been imported | | | | |
| Acceptance Criteria | Fluidigm data is successfully loaded into the database and identity QC is calculated | | | | |
| Test Step Number | Instructions/Description | Expected Results | Result  (P/F) | Tester Initial & Date | Tester  Comments |
| 1 | Log into variant caller Server (10.93.132.63) with designated username such as “ctpipeline” | Successfully logged into Linux server |  |  |  |
| 2 | Ensure that the ‘PIPELINE\_SCRIPT\_DIR’ variable has been defined and the defined PATH variable has ‘PIPELINE\_SCRIPT\_DIR’ path. Run command line ‘upload\_fluidigm.pl’ with no argument to confirm that. | ‘ PIPELINE\_SCRIPT\_DIR’ variable is defined clearly and should not be empty. Command line ‘upload\_fluidigm.pl’ can be run directly under Home Directory. |  |  |  |
| 3 | Transfer all of the fluidigm csv files into the linux server folder “/data/ctpipeline/fluidigm”. Using winscp or equivalent transfer software; login username “ctpipeline” should be used in order to obtain proper username file permission. | One or more fluidigm csv files will show up in /data/ctpipeline/fluidigm folder of bigiron with writable permission. |  |  |  |
| 4 | Copy file “1382222353\_Hotspot\_Validation\_07192016\_MBP.csv” to /data/ctpipeline/fluidigm folder, Execute the following command line in variant calling linux server:  **upload\_fluidigm.pl –fludir /data/ctpipeline/fluidigm --overwrite\_old 1** | Identity QC will be calculated and recorded in Mysql database “fluidigm” table. “fluidigm” table should have 7200 rows of records. A log file will be generated at bigiron in the filename like /data/ctpipeline/fluidigm/upload\_fluidigm\_20169221623\_nohup.out.  The original fluidigm csv file will be moved into folder /data/ctpipeline/fluidigm/done |  |  |  |
| 5 | Confirm the “upload\_fluidigm.pl” overwrite\_old option with a modified subset of original fluidigm csv file. Run below commands to obtain such file “RSM28495.csv”:  $prompt: head -n 16 1382222353\_Hotspot\_Validation\_07192016\_MBP.csv > RSM28495.csv  $prompt: grep RSM28495 1382222353\_Hotspot\_Validation\_07192016\_MBP.csv >> RSM28495.csv  Modify the “RSM28495.csv”, convert text “No Call” into “XX”, then re-run below:  $prompt: upload\_fluidigm.pl –fludir /data/ctpipeline/fluidigm --overwrite\_old 1 | The QCAR Database fluidigm table should have same number of rows (7200). Out of 75 rows for RSM28495, one row with “No Call” should be changed to “XX”. |  |  |  |
| 6 | Move file “RSM28495.csv” back to folder /data/ctpipeline/fluidigm , run below command to ensure “--clear\_old” option is functioning properly:  $prompt: upload\_fluidigm.pl –fludir /data/ctpipeline/fluidigm --overwrite\_old 1 --clear\_old 1 | The QCAR Database fluidigm table should have 75 rows total. Out of 75 rows RSM28495, one row with “No Call” should be changed to “XX”. |  |  |  |
| 7 | Move the file “1382222353\_Hotspot\_Validation\_07192016\_MBP.csv” into /data/ctpipeline/fluidigm folder, run below command to re-ensure the overall upload operation works with “—overwrite\_old” option enabled:  $prompt: upload\_fluidigm.pl –fludir /data/ctpipeline/fluidigm --overwrite\_old 1 | QCAR Database “fluidigm” table should have 7200 rows of records. For the sampleName “RSM28495”, there should be 75 rows with one “No Call” row. |  |  |  |
| End of Test | | | | | |

### 

### Test Case 02: Variant calling, QCAR Import, Calculation of SequenceQC, ControlQC and IdentityQC

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test Case # | TC-2 | | | | |
| Title | **Variant Calling, QCAR Import, Calculation of SequenceQC, ControlQC and IdentityQC** | | | | |
| Requirement # | CI-002, CI-003, CI-004 | | | | |
| Test Type | Regression | | | | |
| Description | Variants will be called by Somatic Combo Variant Caller; Data from one S5 sequence run will be imported into QCAR Database; SequenceQC, ControlQC and IdentityQC will be calculated in QCAR Database; | | | | |
| Precondition(s) | Run has been completed and analysis information is stored on Ion Torrent Cluster  MySQL QCAR Database is Operating  CORE LIMS is Operating and License Seat Available  IdentityQC Fluidigm csv file has been Uploaded | | | | |
| Acceptance Criteria | All samples have imported variant calls, sequence QC metrics, and control QC/Identity QC has been calculated | | | | |
| Test Step Number | Instructions/Description | Expected Results | Result  (P/F) | Tester Initial & Date | Tester  Comments |
| 1 | Log into Variant Calling Server (10.93.132.63) with designated User such as “ctpipeline” | Brought to the User Home Directory |  |  |  |
| 2 | Ensure that the ‘QCAR\_ROOT\_DIR’ variable has been defined and the defined PATH variable has ‘QCAR\_ROOT\_DIR’ path. Run command line ‘ccg\_load\_analysis.pl’ with no argument to confirm that. | ‘QCAR\_ROOT\_DIR’ variable is defined clearly and should not be empty. Command line ‘ccg\_load\_analysis.pl’ can be run directly under Home Directory. |  |  |  |
| 3 | Ensure that the ‘COMBO\_ROOT\_DIR’ variable has been defined and the defined PATH variable has ‘COMBO\_ROOT\_DIR’ path. Run command line ‘Combo\_vcf.pl’ with no argument to confirm that. | ‘COMBO\_ROOT\_DIR’ variable is defined clearly and should not be empty. Command line ‘Combo\_vcf.pl’ can be run directly under Home Directory. |  |  |  |
| 4 | Use the URLID of the S5 Run to Obtain Runname and ReportName from Torrent Cluster with command ‘urlid2runmetrics.pl’. Ensure that the connection with Torrent Cluster is Operating Normally | Command ‘urlid2runmetrics.pl’ should run promptly with Run Name and Report Name displayed as Results. The Run Name and Report Name should match those in Torrent Browser. |  |  |  |
| 5 | Run variant calling and data uploading in one command line “ccg\_autoVariantCaller.pl” with cluster script “submit\_job.pl” and with upload option enabled as below for URLID run 4613:  $prompt: submit\_job.pl 1 ccg\_autoVariantCaller.pl --urlid 4613 --upload 1 | Command ‘ccg\_autoVariantCaller.pl’ should run without errors with log file written into local disk. Use the command line “qstat” to ensure that the SGE jobs are running properly in SGE cluster. |  |  |  |
| 6 | After the variant calling cluster jobs are completed, run command line “grep -vc '^#' temp\*/R\_\*Combo/\*/\*.vcf” to ensure that the variants are generated properly. | Variants should be generated by the variant caller for both the “fluidigm.vcf” or the “Combo\_samplename\_leftaligned.vcf” file. |  |  |  |
| 7 | Login to Torrent Cluster web browser, look up the run QC metrics of the run, check against QCAR Database RUN table values. | URLID, RUN\_NAME, ANALYSIS\_NAME, TOTAL\_READS, MEAN\_READ\_LENGTH, chipType values of the RUN table for the run in the QCAR Database should match those in Torrent Browser. |  |  |  |
| 8 | Login to Torrent Cluster web browser, look up all samples IonXpress barcode and sample names for the loaded run. Check against QCAR Database corresponding fields. | BARCODE, SAMPLE\_NAME, SAMPLELOT\_NAME fields of the loaded run in QCAR Database should match ‘Barcode Name’ and ‘Sample’ in Torrent Browser. |  |  |  |
| 9 | Login to Torrent Cluster web browser, click “Chef Summary” menu, look up “Chef Instrument Name”, “Chip Type”, ‘Solutions Lot’ , ‘Reagents Parts’ etc fields for the loaded run. Check against QCAR Database corresponding fields. | chefInstrumentName, chefReagentsLot, chefReagentsPart, chefSolutionsLot, chefSolutionsPart,chefKitType fields in QCAR Database should match those in Torrent Browser. |  |  |  |
| 10 | Login to Torrent Cluster web browser, look up the CoverageAnalysis QC metrics of all the samples. Compare the Coverage QC metrics to that of QCAR Database values | Torrent Browser CoverageAnalysis QC Metrics of Mapped Reads, On Target, Mean Depth, Uniformity Should be Equivalent to Corresponding Fields for each sample in QCAR Database |  |  |  |
| 11 | Login to CORE LIMS and use the “-1” version of the sample lot name to look up the patient ID and Collection Site. | The patient ID and Collection Site in CORE LIMS will be equivalent to the patient ID and Collection Site in the QCAR database. |  |  |  |
| 12 | Login to CORE LIMS and use Sample Name of PTC/NTC samples to look up the Name. | The name of PTC/NTC samples in CORE LIMS should match the SAMPLE\_TYPE in the QCAR Database |  |  |  |
| 13 | Login to CORE LIMS and use sample lot name of PTC/NTC samples to look up the library plate id. | The Library Plates Barcode in CORE LIMS shoud match the PLATE\_ID in the QCAR database. QCAR PLATE\_ID is LIMS plate id concatenated with URLID. |  |  |  |
| 14 | Login into QCAR database with phpmyadmin web interface or equivalent, check and ensure the status of Sequence QC, Control QC and Identity QC are correct for the passing runs. | For the passing runs and passing samples, QCAR Database “analysis” table field “sequenceQcStatus” should be “PENDING”, field “controlQcStatus” should be “PASSED”, “identityQcStatus” filed should be “PASSED”. |  |  |  |
| 15 | Login into QCAR database with phpmyadmin web interface or equivalent, check and ensure the status of SequenceQC are correct for the failed runs/samples due to SequenceQC failuure. | QCAR Database “analysis” table field “sequenceQcStatus” should be “FAILED” with reason provided in “SequenceQcComments” fields. Check and confirm with Torrent Browser information. |  |  |  |
| 16 | Login into QCAR database with phpmyadmin web interface or equivalent, check and ensure the status of Control QC are correct for the failed runs/samples due to ControlQC failuure. | QCAR Database “analysis” table field “sequenceQcStatus” should be “PENDING”, field “controlQcStatus” should be “FAILED”. Check and confirm with information from “ControlQcComments” field and “ControlCordance” field. |  |  |  |
| 17 | Login into QCAR database with phpmyadmin web interface or equivalent, check and ensure the status of Identity QC are correct for the failed runs/samples due to IdentityQC failure. | QCAR Database “analysis” table field “sequenceQcStatus” should be “PENDING” or “FAILED”. If “sequenceQCStatus” is “PENDING”, field “IdentityQcStatus” should be either “FAILED” or NULL. The NULL samples are those that either has no fluidigm csv content information, or require fluidigm re-queue due to > 10 NOCALL values. |  |  |  |
| 18 | After the same run was correctly run and uploaded to QCAR Database, rerun the same “ccg\_autoVariantCaller.pl” script on same run to ensure the pipeline can handle duplicate samples and duplicate runs properly. | The Sample Layout file in temp\* folder should be empty with no samplenames. The variant caller should run and exit quickly with no data uploaded to QCAR database. The log file should record that zero sample information was in the sample layout file. |  |  |  |
| End of Test | | | | | |

### Test Case 03: Sample QC

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test Case # | TC-3 | | | | |
| Title | **Sample QC** | | | | |
| Requirement # | CD-001 | | | | |
| Test Type | Regression | | | | |
| Description | Each sample will be checked for acceptable sequencing quality control metrics via web interface.  The user will have the option to requeue the sample or pass it for variant QC. | | | | |
| Precondition(s) | Runs/samples pre-loaded into QCAR database | | | | |
| Acceptance Criteria | All processed samples are requeued or passed to variant QC | | | | |
| Test Step Number | Instructions/Description | Expected Results | Result  (P/F) | Tester Initial & Date | Tester  Comments |
| 1 | Open Chrome browser and go to: <http://10.93.132.25:9090/login> | Web page opens with a login credential screen |  |  |  |
| 2 | Enter Mount Sinai user name and password.  Select Hotspot as the panel dashboard to load.  Click on Processing label to list samples at processing stage of queue.  Click on Sample QC label in pie chart key to list samples at Sample QC stage. | Log into the web site and Hotspot and Superpanel options are presented.  Hotspot dashboard loads initial interface.  Samples currently within Processing queue are displayed.  Samples pending at Sample QC stage are listed along with details. |  |  |  |
| 3 | Search for sample RSM28541 using the search box.  Search for samples with “Non-Small Cell Lung Cancer” as tumor type using the search box. | One sample (RSM28541) is shown.  Only four sample-runs with tumor type matching “Non-Small Cell Lung Cancer” are shown. |  |  |  |
| 4 | Click on “Non-Small Cell Lung Cancer” in key of tumor type pie chart at top right.  Click on “Melanoma” in key of tumor type pie chart at top right. | Thirteen sample-runs of eleven samples each with tumor type matching “Non-Small Cell Lung Cancer” are displayed. The data is read-only for review purposes.  Two samples with one sample-run each with tumor type matching “Melanoma” are displayed. The data is read-only for review purposes. |  |  |  |
| 5 | Click on “Link” under Image heading to open the Torrent Browser link to the run for sample RSM28516-5.  Click on sample name RSM28516-5 and enter the comment “Sample Fails Mapped Reads QC” in the text-box and click on “Submit” to save.  Click on checkboxes next to RSM28516-5 and RSM28525-5 twice so a X mark is displayed.  Click on Update at the bottom of the page to send samples to requeue list. | New window to Torrent Browser for run with sample RSM28516-5 will open. QC metrics should be identical to those shown in dashboard.  Comment will be permanently added to comment record for sample RSM28516-5.  Two samples will be added to the requeue sample list, showing as Failed in bar chart at top of page. |  |  |  |
| 6 | Click on the checkbox next to samples RSM28520-5, RSM28517-5, RSM28528-5, RSM28526-5 once so a ☑ is displayed.  Click on Update at the bottom of the page to send samples to Variant QC phase of review.  Click on Variant QC to show samples passed to Variant QC step. | Selected samples are moved from Sample QC page to Variant QC page.  Pie chart will change to reflect samples moved from Sample QC to Variant QC. |  |  |  |
| End of Test | | | | | |

### Test Case 04: Sample Requeue List Operations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test Case #** | **TC-4** | | | | |
| **Title** | **Sample Requeue List Operations** | | | | |
| **Requirement #** | **CD-002** | | | | |
| **Test Type** | **Regression** | | | | |
| **Description** | **Samples will be confirmed for wet-lab requeue. List of samples within Requeue List will be downloaded.** | | | | |
| **Precondition(s)** | **Runs/samples pre-loaded into QCAR database. Samples already sent to Requeue List.** | | | | |
| **Acceptance Criteria** | **All samples processed through requeue list are found on the downloaded requeue list.** | | | | |
| **Test Step Number** | **Instructions/Description** | **Expected Results** | **Result**  **(P/F)** | **Tester Initial & Date** | **Tester**  **Comment** |
| 1 | Open Chrome browser and go to: <http://10.93.132.25:9090/login> | Web page opens with a login credential screen |  |  |  |
| 2 | Enter Mount Sinai user name and password.  Select Hotspot as the panel dashboard to load. | Log into the web site and Hotspot and Superpanel options are presented.  Hotspot dashboard loads initial interface. |  |  |  |
| 3 | Click on Requeue Lists button at top of page.  Click on Requeue button in middle of page to display samples in Requeue list. | Sample Requeue and Withdraw buttons displayed.  Samples in Requeue List are displayed |  |  |  |
| 4 | Click on return arrow next to RSM28516-5 to send sample back to Sample QC step. | Sample RSM28516-5is removed from Requeue List and put back in Sample QC List. |  |  |  |
| 5 | Click on “requeueing” link under Status for RSM28525-5 to initiate wet-lab requeue of sample.  Click on green “Yes” button to complete wet-lab requeue of sample.  Repeat process for RSM28533-8 to confirm wet-lab requeue. | Dialog appears asking for confirmation of sample requeue.  Confirmation of requeue success displayed.  Sample status shows as complete. |  |  |  |
| 6 | Click on the blue “download” button to download the list of samples within the Requeue List. | CSV file of displayed table is downloaded. |  |  |  |
| **End of Test** | | | | | |

### 

### Test Case 05: QCAR Variant Checking

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test Case #** | **TC-5** | | | | |
| **Title** | **QCAR Variant Checking** | | | | |
| **Requirement #** | **BRCA-005** | | | | |
| **Test Type** | **Normal** | | | | |
| **Description** | **Each sample will be checked for the variants calling via web interface. The user will have options of fail the sample or pass it for export/report.** | | | | |
| **Precondition(s)** | **All reportable variants imported into QCAR** | | | | |
| **Acceptance Criteria** | **Selected samples have been failed or passed to sample export** | | | | |
| **Test Step Number** | **Instructions/Description** | **Expected Results** | **Result**  **(P/F)** | **Tester Initial & Date** | **Tester**  **Comment** |
| 1 | Open Chrome browser and go to:  <http://ctgroup-srv1.mssmcampus.mssm.edu> | Web page being open with a dialog box for login credential |  |  |  |
| 2 | Enter domain user name and password | Log into the web site and click on Variant in the menu bar |  |  |  |
| 3 | Select samples:  RSM11102  RSM11103  RSM11105  Enter a comment in the text-box and click on “Add to failed requeue list” | Three samples will be added to the failed requeue list |  |  |  |
| 4 | Select each of the remaining samples:  RSM11045  RSM11053  RSM11075  RSM11092  RSM11093  Enter a comment in the text-box and click on “Pass Variant QC” | The rest of samples will have Variant QC status set to “Pass”. Since this is the first run for these passed samples and all samples have at least 1 variant, they will be added to the confirmation requeue list automatically |  |  |  |
| **End of Test** | | | | | |

### Test Case 06: QCAR Re-queue list

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test Case #** | **TC-6** | | | | |
| **Title** | **QCAR Re-queue list** | | | | |
| **Requirement #** | **BRCA-006** | | | | |
| **Test Type** | **Normal** | | | | |
| **Description** | **Users can export the samples on the re-queue list to comma separated value (csv) files. These exported lists can be downloaded and marked as complete when all sample runs have been started.** | | | | |
| **Precondition(s)** | **Failed samples and confirmation of the positive samples available** | | | | |
| **Acceptance Criteria** | **A csv file of results for the selected samples is downloaded and the samples are marked as complete** | | | | |
| **Test Step Number** | **Instructions/Description** | **Expected Results** | **Result**  **(P/F)** | **Tester Initial & Date** | **Tester**  **Comment** |
| 1 | Open Chrome browser and go to:  <http://ctgroup-srv1.mssmcampus.mssm.edu> | Web page being open with a dialog box for login credential |  |  |  |
| 2 | Enter domain user name and password | Log into the web site and click on Re-queue List in the menu bar |  |  |  |
| 3 | Select samples:  RSM11102  RSM11103  RSM11105  Enter a reason for sample withdrawl/cancellation in the text box, and click on “Withdraw/Cancel Sample” | These three samples and all of their sample runs will be marked as withdrawn/canceled. |  |  |  |
| 4 | Click on the “Download Withdrawn/Canceled List” button | Thelist of samples that have been withdrawn and/or canceled will download and can be viewed in any text viewer or excel |  |  |  |
| 5 | Select the rest of the samples:  RSM11045  RSM11046  RSM11053  RSM11075  RSM11090  RSM11092  RSM11093  RSM11098  Click on “Generate Requeue List” | The remaining 8 samples will be added to requeue list 1 |  |  |  |
| 6 | Click the “Download” link next the generated Requeue List | Requeue list 1 with 8 samples will download and can be viewed in any text viewer or excel |  |  |  |
| 7 | Click the “Mark Completed” button next to the Requeue list | This indicates that all of the samples on the list have been succesfully re-loaded for another sequencing run. |  |  |  |
| **End of Test** | | | | | |

### Test Case 07: Clinical Report Generation

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| --- | --- | --- | --- | --- | --- |
| **Test Case #** | **TC-7** | | | | |
| **Title** | **Clinical Report Generation** | | | | |
| **Requirement #** | **BRCA-007** | | | | |
| **Test Type** | **Normal** | | | | |
| **Description** | **User can choose the samples ready for export and export them to excel file. The resulting excel file will be used to generate clinical report in Medgis** | | | | |
| **Precondition(s)** | **All the samples passed all the QC steps, including confirmation of the positive variant calling** | | | | |
| **Acceptance Criteria** | **A fully generated clinical report in Medgis** | | | | |
| **Test Step Number** | **Instructions/Description** | **Expected Results** | **Result**  **(P/F)** | **Tester Initial & Date** | **Tester**  **Comment** |
| 1 | Open Chrome browser and go to:  <http://ctgroup-srv1.mssmcampus.mssm.edu> | Web page being open with a dialog box for login credential |  |  |  |
| 2 | Enter domain user name and password | Log into the web site |  |  |  |
| 3 | Switch to export section by clicking on menu “Export” | Switch to “Export” section |  |  |  |
| 4 | Select all the samples:  RSM11046  RSM11092  RSM11093  RSM11098  RSM11102  RSM11103  RSM11105  And click on “Export” | One csv file exported |  |  |  |
| 5 | Open the exported csv file and save as excel file | Excel file saved |  |  |  |
| 6 | Log into Medgis by click on “Medgis MSCT” icon on the desktop and login using proper credential | Medgis open |  |  |  |
| 7 | Import the excel file by going to menu “Data” 🡪 “Import data” | “Import into Medgis” dialog open |  |  |  |
| 8 | Choose “DNA marker results (generic)” | “Import marker results” dialog open |  |  |  |
| 9 | Choose the excel file generated in step 5 and click on “OK” | “MarkerImport.txt” file open and records imported |  |  |  |
| 10 | Open patient record and check the final report | Clinical report generated |  |  |  |
| **End of Test** | | | | | |

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| **Test Case #** | **Overall Results (P/F)** | **Notes** (Please describe any incidents of failed tests) | **Resolution Report # Opened as a Result of Failed Test** |
| TC-1 |  |  |  |
| TC-2 |  |  |  |
| TC-3 |  |  |  |
| TC-4 |  |  |  |
| TC-5 |  |  |  |
| TC-6 |  |  |  |
| TC-7 |  |  |  |

# APPROVAL

The above test scripts have been successfully completed. Errors have been addressed and documented in the Validation Testing Error and Resolution Report form(s).

|  |  |
| --- | --- |
| **Performance Qualification Signatures:** | |
| **Performer**  **Performer**  **Performer**  **Performer** | I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Performer**  **Performer**  **Performer**  **Performer** | I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Performer**  **Performer**  **Performer**  **Performer** | I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have performed Performance testing for CoreLIMS according to the above test procedures and following our company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |
| --- | --- |
| **Performance Qualification Signatures:** | |
| **Approver**  **Quality Reviewer**  **Clinical Lab Director** | I indicate that I approve this Performance Testing for CoreLIMS and find it is appropriate for our business operations and find it reflects the procedure described.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have reviewed this Performance Testing for CoreLIMS and find that it meets all applicable quality requirements and company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have reviewed this Performance Testing for CoreLIMS and find that it meets all applicable clinical requirements and company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

# VERSION HISTORY:

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| --- | --- | --- | --- |
| **Date** | **Version** | **Description of Document Updates** | **Author** |
| 09/25/2017 | 1.0 | Initial Release | Jonathan Keeling |
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# APPENDIX 1: Information for Executing Test Cases

**Supporting Images and Documentation**

These icons can be found within the steps of the test cases when results are required for Supporting Images and Documentation.

|  |  |  |
| --- | --- | --- |
| **Name** | **Icon** | **Description** |
| **The Camera icon** |  | This icon indicates when a screenshot should be taken for documented evidence of a test step. |
| **The page icon** |  | This icon indicates when a printout is needed for documented evidence of a test step. |