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Nov 23, 2021

# LIS-001 INSPECT CLIA User Manual

## version 1.0 V.1

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protocol .

Shashank Sathe

Document Title: INSPECT CLIA User Manual

Document No. LIS-001

Document version: 1.0

User guide for the INSPECT (Instant Service Platform for Emergency COVIDTests) CLIA LIS application for use by EXCITE (Expedited COVID IdenTification Environment) Lab.

INSPECT is a companion LIS to testing performed with Thermo Fisher or Perkin Elmer testing testing kits. Workflows and procedures differ for each kit. Please refer to the corresponding test kit lab documents when using INSPECT and this guide.

Sections are divided into end user application use and admin setup and maintenance. Please refer to lab documents for details on lab testing processes. Only trained users will be given access to the INSPECT system. Please contact an Admin user and lab supervisor to set up a login and user training.

Admin use is restricted to users granted access to administer the INSPECT application and access to AWS services. Please contact an Admin and AWS support staff as applicable for access to admin functions. Use is restricted to individuals trained on admin functions.

Adam N Baer, Shashank Sathe 2021. LIS-001 INSPECT CLIA User Manual version 1.0. **protocols.io**

<https://protocols.io/view/lis-001-inspect-clia-user-manual-version-1-0-bvy6n7ze>

INSPECT, EXCITE, UCSD, Covid 19, qPCR, LIMS

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Jun 21, 2021

Nov 23, 2021

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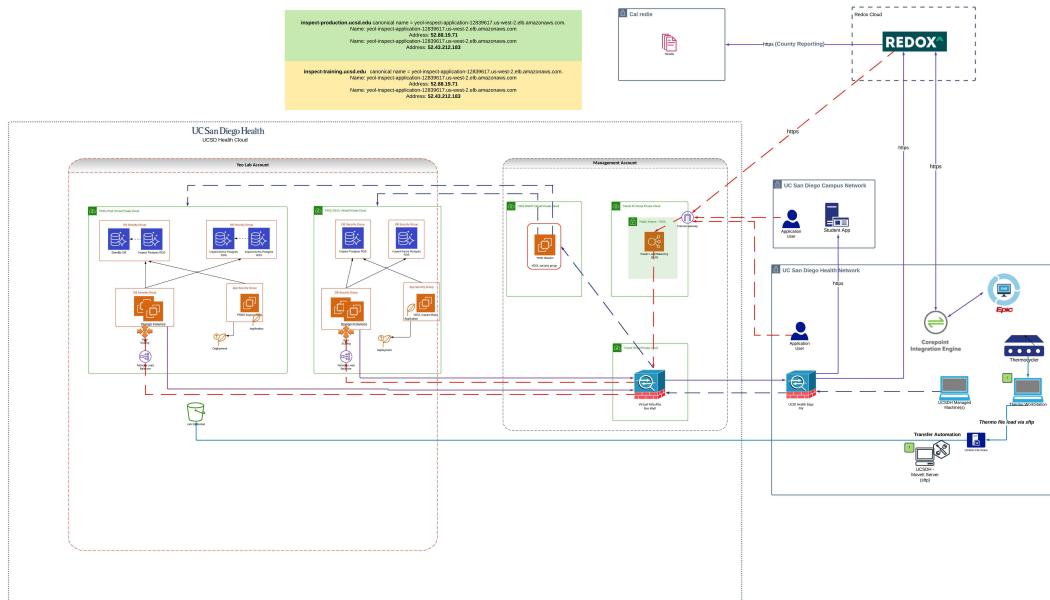
NA

NA

NA

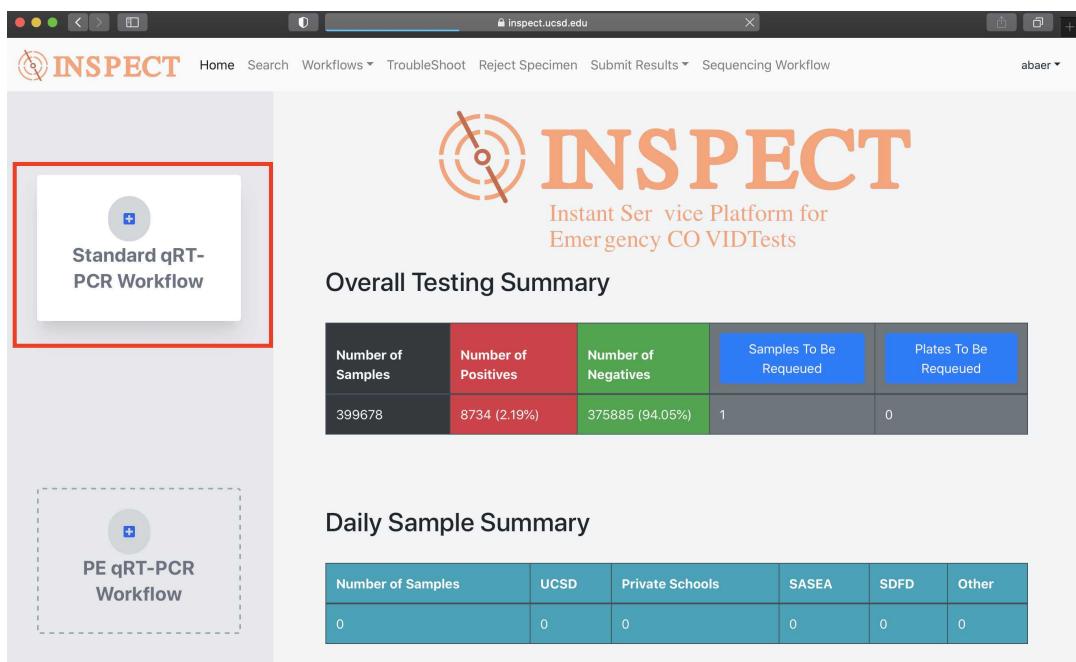
## INSPECT CLIA System Architecture

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## 2 Selecting a Workflow:

Select the workflow from the left side navigation bar, this will link to the menu displayed in the following step where each workflow step may be selected.



The screenshot shows the INSPECT home page. At the top, there is a navigation bar with links: Home, Search, Workflows ▾, TroubleShoot, Reject Specimen, Submit Results ▾, Sequencing Workflow, and a user account dropdown. Below the navigation bar is the INSPECT logo with the tagline "Instant Service Platform for Emergency COVIDTests". On the left side, there are two workflow options: "Standard qRT-PCR Workflow" (selected) and "PE qRT-PCR Workflow". The "Standard qRT-PCR Workflow" section contains an overall testing summary table:

Number of Samples	Number of Positives	Number of Negatives	Samples To Be Rqueued	Plates To Be Rqueued
399678	8734 (2.19%)	375885 (94.05%)	1	0

Below the summary is a "Daily Sample Summary" table:

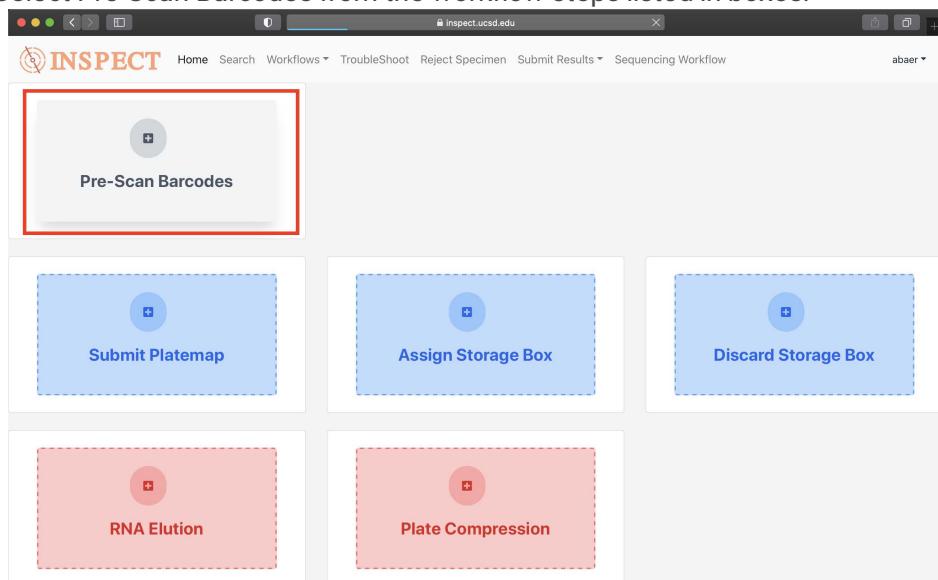
Number of Samples	UCSD	Private Schools	SASEA	SDFD	Other
0	0	0	0	0	0

The top navigation bar also has a Workflow drop down that is linked to the two selectable workflows.

### Standard (Thermo) Workflow

#### 3 Pre-Scan Barcodes.

##### 3.1 Select Pre-Scan Barcodes from the workflow steps listed in boxes:



The screenshot shows the workflow selection interface. A red box highlights the "Pre-Scan Barcodes" step. Below it are four other steps: "Submit Platemap", "Assign Storage Box", "Discard Storage Box", "RNA Elution", and "Plate Compression". The "RNA Elution" and "Plate Compression" steps are highlighted with a dashed red box.

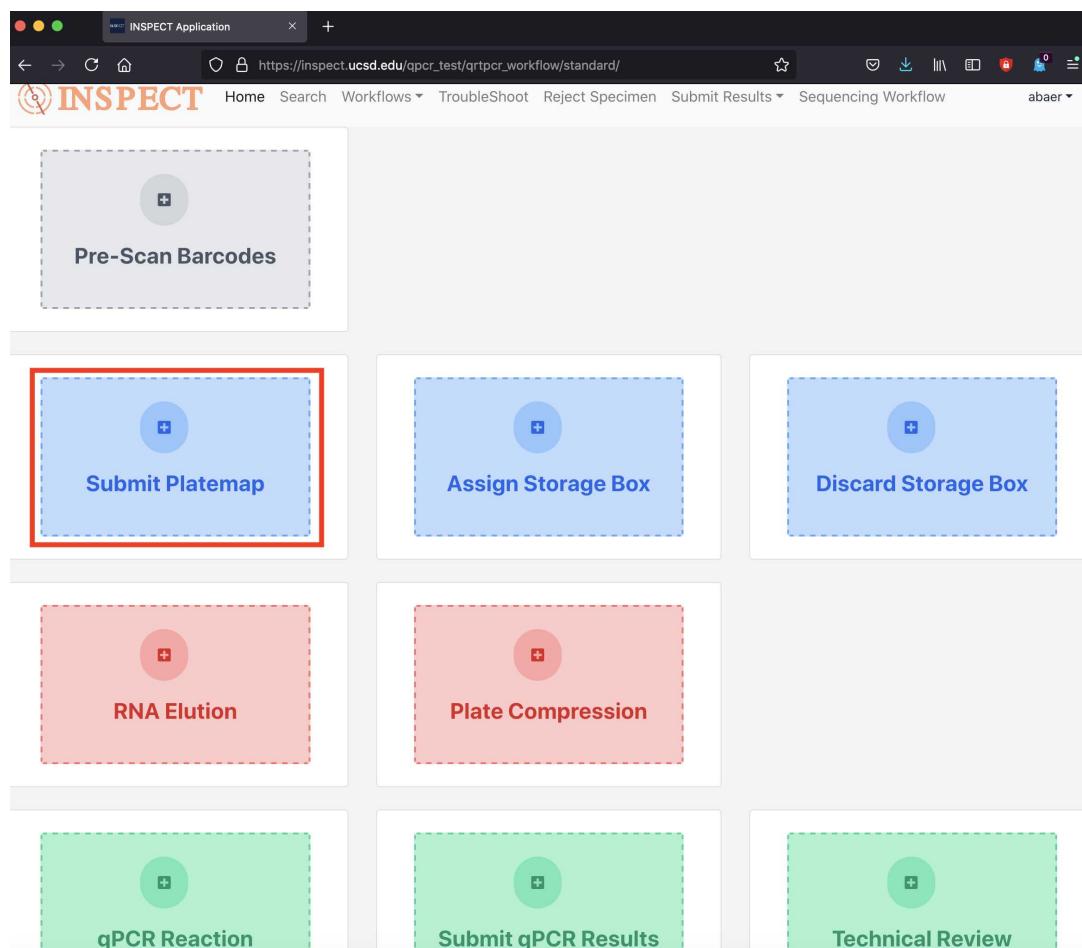
##### 3.2 Follow the instructions on the page to enter or scan in barcodes. Turn on the newline setting on the barcode scanner. This will automatically enter a new

barcode on a new line. Select the source of the samples entered from the drop down menu. All samples scanned will be assigned to the same source. Once all samples for the source are entered, click the submit button and you will be redirected to the home page with a message showing the number of samples that were pre-scanned into the INSPECT database. Repeat this process for each set of samples for each source.

The screenshot shows a web browser window with the URL [inspect.ucsd.edu](https://inspect.ucsd.edu) in the address bar. The page title is "Pre-Scan Barcodes InTo Inspect". Below the title, a sub-instruction says "Select the source of samples and scan barcodes in the text area one at a time." A section titled "Recommendation." suggests turning on the newline setting on the barcode scanner. The main form area has a label "Barcodes\*" above a text input field containing three entries: "EXC\_TEST\_000001", "EXC\_TEST\_000002", and "EXC\_TEST\_000003". Below the input field is a placeholder text "Scan barcodes one at a time". Underneath the input field is a label "Source\*" followed by a dropdown menu set to "Nuevo East". At the bottom of the form is a blue "Submit" button.

#### 4 Upload platemap file.

##### 4.1 Select the "Submit Platemap" button from the menu:



- 4.2 Click the "Choose File" button to add the platemap file. Enter the ID for the Hamilton machine used. Enter your name. If the platemap contains sequencing or environmental samples, select the appropriate source from the drop down menu, otherwise, do not select a source. If the sample plate contains only ANX samples, click the checkbox before submitting the plate. INSPECT will look for any MAWI barcodes on the plate and error if any are found, since mixed plates are not allowed.

 **INSPECT** Home Search ▾ Workflows ▾ TroubleShoot Reject Specimen Submit Results ▾ Sequencing Workflow

**Reminder:** Upload the platemap for the Hamilton run and enter the corresponding hamilton ID .

Hamilton Platemap File To Upload\*

example\_platemap.csv

Enter ID of Hamilton machine used\*

Name of Person Uploading Platemap\*

Select for ANX Workflow

**Optional: Applicable only to sequencing and environmental samples. Leave blank for clinical samples**  
Select the source of samples. If any samples are found in the Student-App or Inspect-Forms, that source will overwrite the source selected here.

Source

- 4.3** If using the Visionmate barcode reader, upload all the associated Visionmate platemap files using the "Choose Files" button. Enter the ID of the Visionmate machine used.

**Reminder:** Upload the platemap for the Hamilton run and enter the corresponding hamilton ID .

Hamilton Platemap File To Upload\*

example\_platemap.csv

Enter ID of Hamilton machine used\*

Name of Person Uploading Platemap\*

Select for ANX Workflow

**Optional: Applicable only to sequencing and environmental samples. Leave blank for clinical samples**  
Select the source of samples. If any samples are found in the Student-App or Inspect-Forms, that source will overwrite the source selected here.

Source

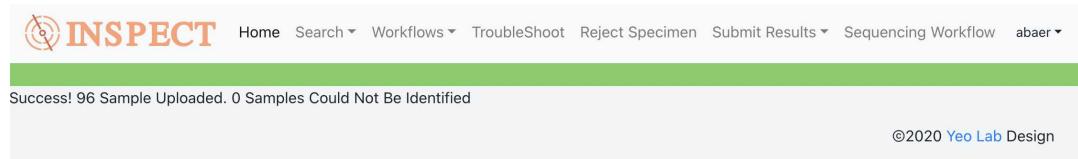
**Optional:** Upload the associated visionmate platemaps and the visionmate ID. Leave empty if not applicable.

Visionmate Files To Upload

2 files selected.

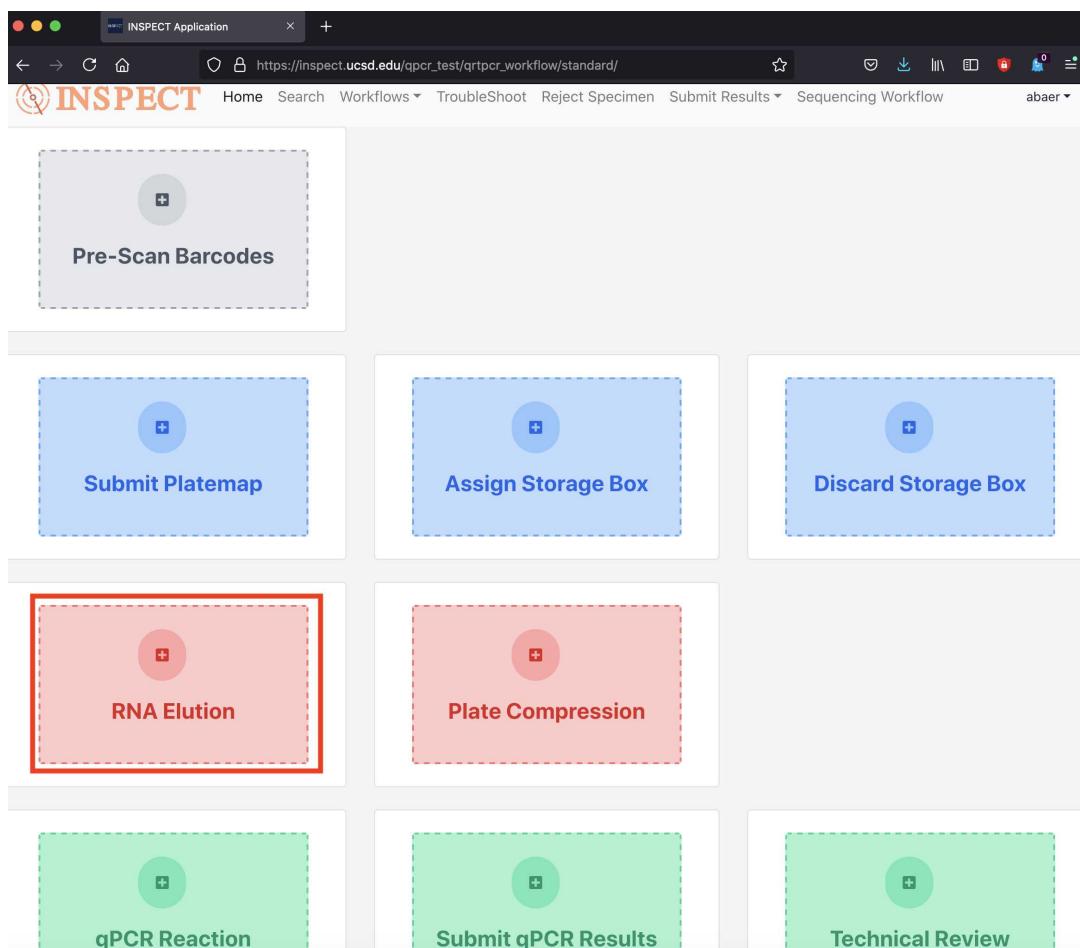
Enter ID of Visionmate machine used

- 4.4** Click "Assign Plates" and the sample barcodes in the platemap will be assigned sample information from the UCSD student app, INSPECT Forms database, REDCap, or other associated databases. The page will redirect to a progress bar and a success message will be displayed showing the number of samples that were successfully associated and if any samples were not assigned sample information. Contact an admin if any error messages are displayed. There is a set 15 minute time limit for this step in INSPECT, so if the assignment and database lookups take longer than 15 minutes a timeout error will show. If a platemap times out please troubleshoot the SEP IDs listed on the platemap file and please separate all SEPs listed into separate platemap files and upload the files.



## 5 RNA Elution

- 5.1** Select the RNA Elution button from the menu:



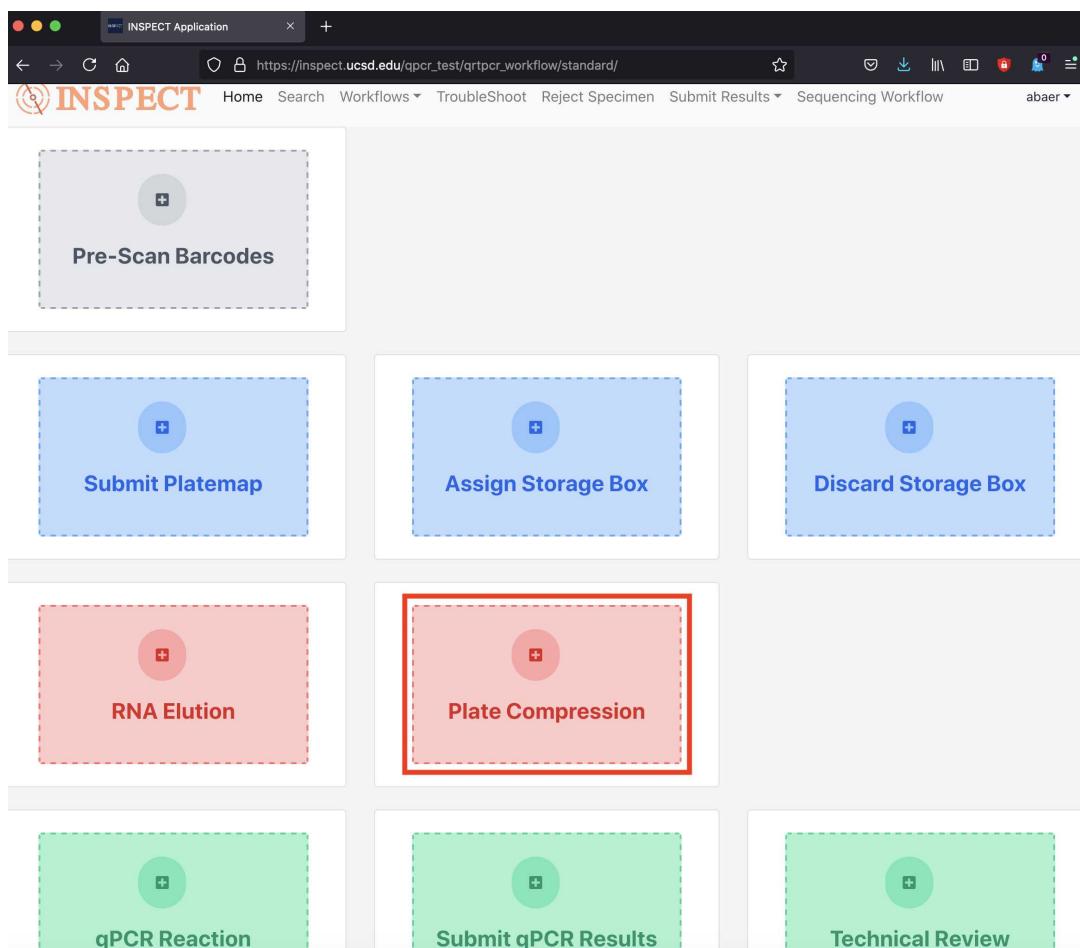
- 5.2 Enter the appropriate lot numbers or "N/A" used for the MS2 Phage, Wash buffer, Binding Solution, Binding Bead, EtOH (used in the second wash plate), and nuclease-free water (used in the elution plate). Scan or enter in the Sample Extraction Plate Barcode and RNA Elution Plate Barcode in the appropriate boxes and click the "Assign Plates" button. This will link the SEP and REP in the INSPECT database. Click the Assign Plates button on the bottom of the form to link the plates. A message will display giving success or failure confirmation, and reason for failure, if applicable.

The screenshot shows the INSPECT software interface on a Mac OS X desktop. The window title is 'inspect.ucsd.edu'. The main content area displays a form for sample setup. It includes fields for 'MS2 Phage Lot #' (N/A), 'MagMAX Viral/Pathogen Wash Solution\*' (966544), 'MagMAX Viral/Pathogen Binding Solution\*' (2009096), 'MagMAX Viral/Pathogen Elution Solution\*' (RNBJ6144), 'Sigma 100% EtOH\*' (SHBM5942), 'Sigma Water\*' (RNBJ6144), 'KingFisher ID\*' (EXC\_KFF\_004), and 'Proteinase K\*' (2009050). A reminder message at the top says 'Reminder: Add MS2 PHAGE.' Below the form, another reminder says 'Reminder: RNA Elution Plate ID will be linked with the Sample Extraction Plate ID. Make sure you have the correct RNA Elution and Sample Extraction Plates.' At the bottom left is a blue 'Assign Plates' button, and at the bottom right is the copyright notice '©2020 Yeo Lab Design'.

 Warning! Please be sure to wait at least 5 minutes for the INSPECT database to update sample information before proceeding to the compression step. This is critical, since the database updates can take a few minutes and if the samples are not associated with the correct plate they will not be able to be reported and the entire plate must be troubleshooted and re uploaded to fix the issue.

## 6 Plate Compression

### 6.1 Select the Plate Compression button from the menu:



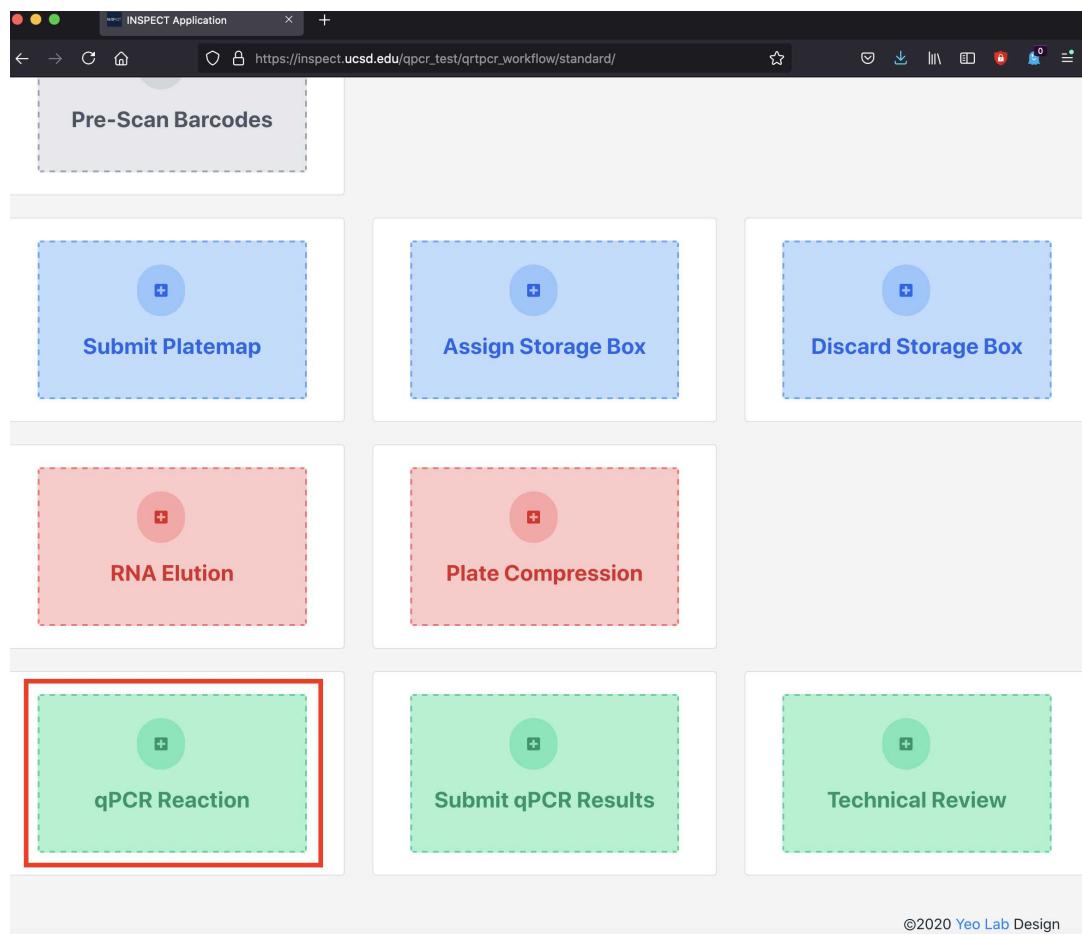
- 6.2 Enter the EpMotion ID to determine which compression program is used, if EXC\_JNS\_004, EpMotion1a, EXC\_EPM\_001, EXC\_EPM\_002 is entered INSPECT will use the EpMotion compression procedure. If anything else is entered, INSPECT will use the Bravo compression protocol. Enter the REP plate IDs in the correct order since the order of the plates entered and well positions on the 384 well plate are dependent on the order of the REP plates entered. Enter or scan in the RWP ID in the RNA Working Plate Barcode field. Click the Assign Plates button on the bottom of the form to link the plates. A message will display giving success or failure confirmation, and reason for failure, if applicable.

The screenshot shows the INSPECT Application interface for RNA Elution Plates. At the top, there's a navigation bar with links for Home, Search, Workflows (with dropdowns for Troubleshoot, Reject Specimen, Submit Results, and Sequencing Workflow), and a user account (abaer). Below the navigation is a reminder message: "Reminder: All RNA Elution Plates will be linked with the RNA Working Plate ID. Make sure you have the correct RNA Elution and RNA Working Plates". A field for "EpMotion ID\*" contains "EXC\_JNS\_004". A placeholder text "Enter EpMotion ID" is visible below it. Another reminder box says "Reminder: Make sure that the RNA Elution Plate IDs are entered in the corresponding EpMotion Arraying Positions only". There are four input fields for plate IDs: "First 96-Well Plate in Array Position B2\*" (REP\_000001), "Second 96-Well Plate in Array Position B3" (REP\_000002), "Third 96-Well Plate in Array Position B4" (REP\_000003), and "Fourth 96-Well Plate in Array Position B5" (REP\_000004). A "RNA Working Plate Barcode\*" field contains "E0000000" with a placeholder "Scan or Enter Barcode of RNA Working Plate (RWP)". A blue "Assign Plates" button is at the bottom left. In the bottom right corner, there's a copyright notice: "©2020 Yeo Lab Design".

 **Warning!** Please be sure to wait at least 5 minutes for the INSPECT database to update sample information before proceeding to the qPCR Reaction step. This is critical, since the database updates can take a few minutes and if the samples are not associated with the correct plate they will not be able to be reported and the entire plate must be troubleshooted and re uploaded to fix the issue.

## 7 qPCR Reaction

### 7.1 Select the qPCR Reaction button from the menu:



- 7.2 Enter the Probe Mix Lot #, Enzyme Type, Enzyme Mix Lot #, Mosquito ID, and Tip Spool Serial # in the appropriate boxes. Make sure the qRT-PCR Plate Barcode is correct and is linked to the correct RWP Barcode. Click the Assign Plates button on the bottom of the form to link the plates. A message will display giving success or failure confirmation, and reason for failure, if applicable.

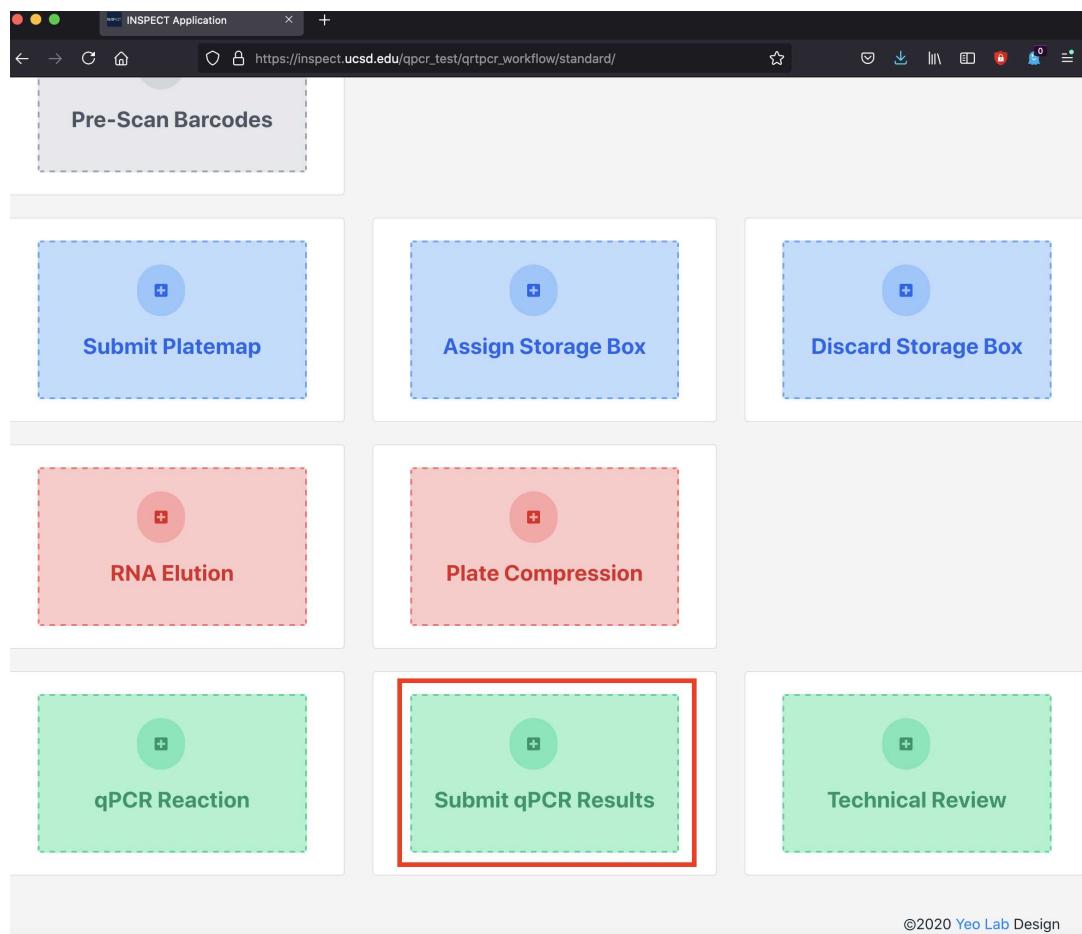
The screenshot shows the 'INSPECT Application' interface with the URL [https://inspect.ucsd.edu/qpcr\\_test/qpcr\\_plate\\_capture/standard/](https://inspect.ucsd.edu/qpcr_test/qpcr_plate_capture/standard/). The page title is 'qPCR Test'. The main content area contains several input fields:

- Probe Mix Lot #\*: 2102241
- Enzyme Type\*: TaqPath
- Enzyme Mix Lot #\*: 2264682
- Mosquito ID\*: EXC-MHV-001
- Tip Spool Serial #\*: TVW40HI
- RNA Working Plate Barcode\*: E0000000
- qRT-PCR Plate Barcode\*: EXMPL1BC

At the top of the form, there is a reminder: "Reminder: RNA Working Plate will be linked to entered qRT-PCR Reaction Plate". At the bottom, there is another reminder: "Reminder: Make sure you have the correct RNA Working and qRT-PCR Reaction plates". A blue button labeled "Assign Plates" is located at the bottom left. In the top right corner, the user 'abaer' is logged in.

## 8 Submit qPCR Results

### 8.1 Select the Submit qPCR Results button from the menu:

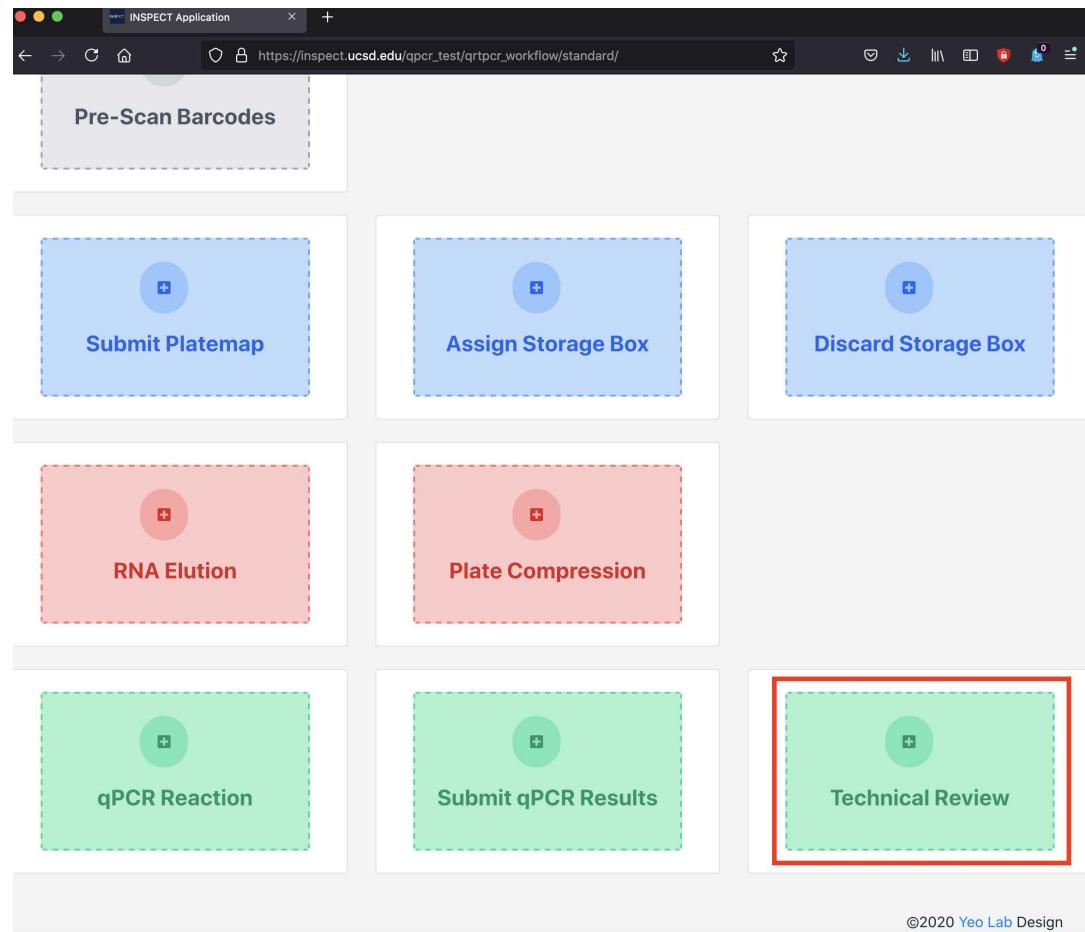


- 8.2 Upload the qPCR results file. Make sure that the RT-qPCR plate ID in the file matches an existing RT-qPCR plate in INSPECT and that the results have not yet been uploaded, or the file will not be able to be uploaded. If any samples matching the QRP ID have results in INSPECT the file cannot be uploaded since results will not be over-written.

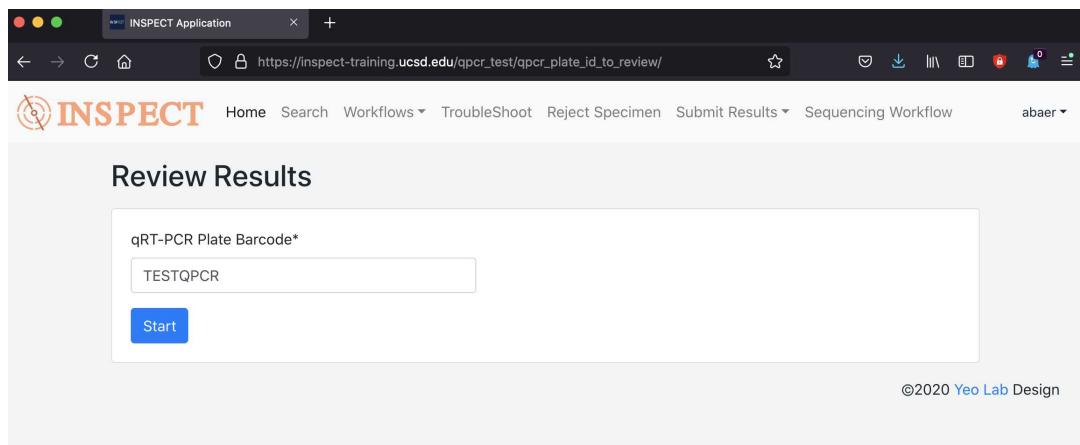
The image shows a screenshot of the 'Upload qPCR Results' form. At the top, there's a header bar with the title 'INSPECT Application' and a URL 'https://inspect.ucsd.edu/qpcr\_test/upload\_qpcr\_results/standard/'. Below the header, the page title is 'Upload qPCR Results'. A blue banner at the top contains the text 'Reminder: Make sure that the RT-qPCR plate ID matches an existing RT-qPCR plate in Inspect.'. Below the banner, there's a file input field labeled 'Qpcr results file\*' with a 'Browse...' button. The button has the text 'No file selected.' underneath it. At the bottom of the form is a blue 'Upload' button. In the bottom right corner, there's a copyright notice '©2020 Yeo Lab Design'.

## 9 Technical Review

### 9.1 Select the Technical Review button from the menu:



### 9.2 Input the qRT-PCR Plate Barcode ID into the box and click the Start button to begin the review process:



Note: The screenshots for the Technical Review process contain only test data from a development INSPECT server.

- 9.3** Review the results following POA-007 Data Analysis and Interpretation for SARS-CoV-2 Assay, including Data Delivery Review. The SOP contains the latest tables and diagrams outlining results thresholds and decision tree assessment calls.

Each result has a drop down menu allowing the user to select the corrected result for each sample. If any changes are made, comments must be added explaining the change. All original results from the QRP result file will be stored in the database for reference (INSPECT Decision field). Select the Confirm button once all samples are reviewed and any comments are added.

Tube Barcode	SEP	QRP	QRP Well	RP Ct value	Ms2 Ct value	N Ct value	Orf1ab Ct value	S Ct value	Inspect Decision	Final result	Add Comments
EXC-TEST-anamika1232	EXC_SEP_100001	TESTQPCR	A1	27.499	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detec	
EXC_TEST-CHARLES-1223-06	EXC_SEP_100001	TESTQPCR	A2	30.571	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detec	
EXC_TEST_UFDIH7J	EXC_SEP_100001	TESTQPCR	A3	25.405	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detec	
EXC_TEST-CHARLES-1209-03	EXC_SEP_100001	TESTQPCR	A4	30.952	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detec	
EXC_TEST-CHARLES-1123-4	EXC_SEP_100001	TESTQPCR	A5	30.136	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detec	
EXC_TEST_EauvRv6	EXC_SEP_100001	TESTQPCR	A6	26.84	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detec	
EXC_TEST-CHARLES-0114-01	EXC_SEP_100001	TESTQPCR	B1	27.708	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detec	
Pos_000001	EXC_SEP_100001	TESTQPCR	B2	-1.0	-1.0	28.322	28.427	27.737	Detected	Detected	

Note: The screenshots for the Technical Review process contain only test data from a development INSPECT server. More samples are listed for review than are displayed in the screenshot, during review, make sure the positive and negative control for each plate are listed and have the expected result. If any controls are missing or have unexpected data, please contact an Admin for troubleshooting.

- 9.4 You can change the final result by clicking on the drop down arrow in the box, for example, if a sample is actually Invalid (due to RP Ct value > 35). If you change a result, add a comment to say why.



- 9.5 Verify that the correct amount of samples are displayed, that all the controls have the correct calls, and that the Inspect calls are correct.

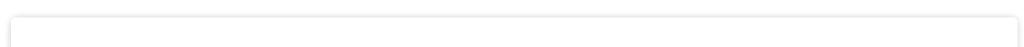
*Red= Detected (shown below for a Positive control sample)*

*Green= Not Detected (shown below)*

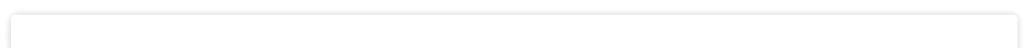
*Grey= Invalid (shown below)*

*Yellow= Inconclusive*

Positive (Control) Example:



Invalid Example:



Samples with "Undetermined" results highlighted in white are samples that failed to upload any results or have a bug preventing results from updating correctly. If any samples in review have "Undetermined" results please contact an Admin user immediately and do not continue to review the plate.



If detected samples are next to each other in the SEP, and the difference between the Cq values are >8, then the high Cq value samples need to be re-run to rule out any kind of contamination for the low Cq samples.

- 9.6 Verify that all samples meet criteria and that Inspect is making the correct calls. See below charts for gene calls. Cq Confidence is not listed in INSPECT, however, these cutoffs are automatically applied when the qpcr results are uploaded. If Cq Confidence needs to be reviewed, refer to the qpcr results file for the values.

A	B	C
<b>ORF, N, S Gene</b>		
<b>Cq Cutoff</b>	<b>Cq Confidence</b>	<b>Target Call</b>
< 37	> 0.7	<b>Detected</b>
< 37	< 0.7	<b>Not Detected</b>
> 37	< 0.7	<b>Not Detected</b>
> 37	> 0.7	<b>Not Detected</b>
<b>MS2 Gene</b>		
<b>Cq Cutoff</b>	<b>Cq Confidence</b>	<b>Target Call</b>
< 37	> 0.3	<b>Detected</b>
< 37	< 0.3	<b>Not Detected</b>
> 37	< 0.3	<b>Not Detected</b>
> 37	> 0.3	<b>Not Detected</b>

A	B	C
RNAse P Gene		
<b>Cq Cutoff</b>	<b>Cq Confidence</b>	<b>Target Call</b>
< 35	> 0.7	<b>Detected</b>
< 35	< 0.7	<b>Not Detected</b>
> 35	< 0.7	<b>Not Detected</b>
> 35	> 0.7	<b>Not Detected</b>

A	B	C	D	E	F
Control Sample	Orf	N	S	MS2 or RP	Target Call
<b>Negative Control</b>	Negative	Negative	Negative	Positive	<b>Not Detected</b>
<b>Positive Control</b>	Positive	Positive	Positive	Negative	<b>Detected</b>
<b>Negative Control</b>	Negative	Negative	Negative	Negative	<b>Invalid</b>
<b>Positive Control</b>	Positive	Positive	Positive	Positive	<b>Invalid</b>

A	B	C	D	E	F
Clinical Sample	Orf	N	S	MS2 or RP	Target Call
1	Positive	Positive	Negative	Positive	<b>Detected</b>
2	Negative	Negative	Negative	Positive	<b>Not Detected</b>
3	Negative	Negative	Negative	Negative	<b>Invalid</b>
4	Positive	Negative	Negative	Positive	<b>Inconclusive</b>
5	Positive	Positive	Positive	Negative	<b>Detected</b>

## Shared Workflow

### 10 Receiving Test Orders (ELR)

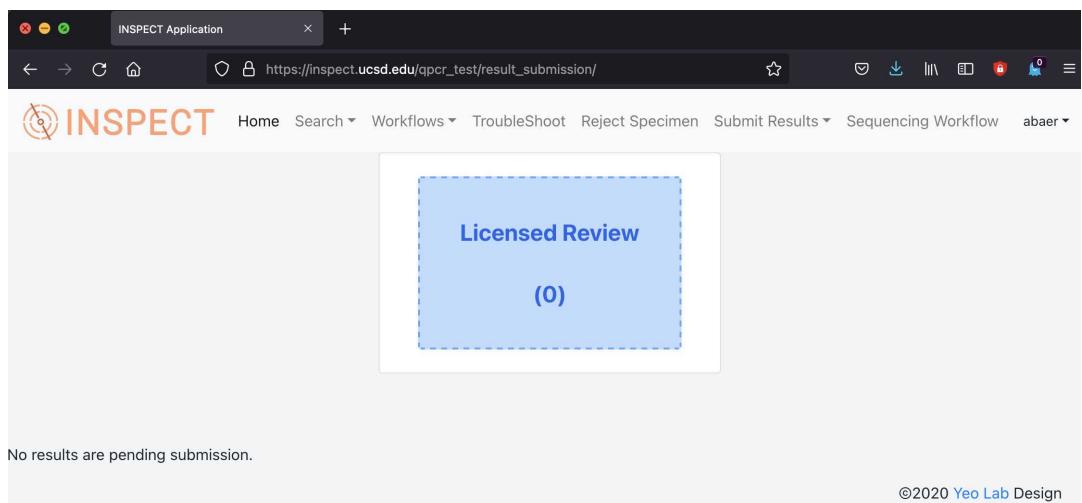
**10.1** EHR messages are received from Redox and are parsed by INSPECT using an automated process. The messages are received in json format and information is taken from the message fields and added to the test\_order and PI tables in the INSPECT database.

If we have more unidentified samples from an ELR partner than expected, check Redox for errors in the log files. If no errors are present on the INSPECT side, please contact the partner and have them check their messages. If both sides do not have error messages, please contact Redox support for more information.

Troubleshooting any issues with ELR or EHR messages must be handled through Redox, since they control encrypting/decrypting and sending messages. Contact an Admin for any issues with Redox or messaging.

## 11 Licensed Review

- 11.1 Licensed review is performed by a CLS according to POA-007 Data Analysis and Interpretation for SARS-CoV-2 Assay including Data Delivery Review.
- 11.2 Click on "Submit Results" on the top menu bar to see pending results submissions and tubes ready for licensed review. If no samples are pending submission or licensed review the page will look like the following screen shot below. If there are samples pending licensed review the number will be listed in the licensed review box. If there are samples pending submission they will be listed by source.



- 11.3 Click the licensed review box to list each set of samples for review by SEP plate. The control samples and results will be listed, if the control sample results are not as expected the plate may be rejected by clicking the red "Reject" button. Click the green "Continue" button to review sample results from the SEP listed.

EXC_SEP_003605												
Tube Barcode	SEP ID	SEP Well	QRP ID	QRP Well	RP Ct Value	MS2 Ct Value	N Ct Value	Orf1ab Ct Value	S Ct Value	INSPECT Decision	Technician Result	
Neg_002536	EXC_SEP_003605	H3	H3N00Z8K	P6	28.82	-1.0	-1.0	-1.0	-1.0	Not Detected	ND	
Pos_002533	EXC_SEP_003605	A4	H3N00Z8K	B8	-1.0	-1.0	29.092	28.631	28.222	Detected	D	

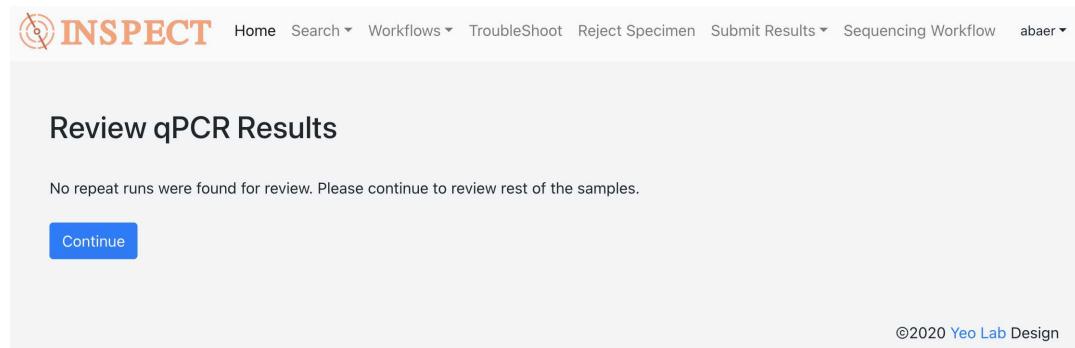
Reject Continue

PE_SEP_V031921B												
Tube Barcode	SEP ID	SEP Well	QRP ID	QRP Well	RP Ct Value	MS2 Ct Value	N Ct Value	Orf1ab Ct Value	S Ct Value	INSPECT Decision	Technician Result	
Negative	PE_SEP_V031921B	E6	E0000572	I11	-1.0	26.02	-1.0	-1.0	-1.0	Not Detected	Not Detected	
Positive	PE_SEP_V031921B	D6	E0000572	G11	-1.0	25.67	30.22	29.19	-1.0	Detected	Detected	

Reject Continue

- 11.4 If there are any duplicate samples on the SEP plate they must be resolved before continuing. Please add comments to help keep track of duplicates when applicable. If there are none, click "Continue" to review the the rest of the samples.



The screenshot shows the INSPECT software interface. At the top, there's a navigation bar with links like Home, Search, Workflows, TroubleShoot, Reject Specimen, Submit Results, Sequencing Workflow, and a user account dropdown. Below the navigation bar, the title "Review qPCR Results" is displayed. A message states "No repeat runs were found for review. Please continue to review rest of the samples." There is a blue "Continue" button at the bottom left. At the bottom right, there's a copyright notice: "©2020 Yeo Lab Design".

- 11.5 Review results for each sample. Detected samples' results will be highlighted in red, not detected in green, invalid in grey, and inconclusive in yellow, including control samples. Samples with "Undetermined" results highlighted in white are samples that failed to upload any results or have a bug preventing results from updating correctly. If any samples in review have "Undetermined" results please contact an Admin user immediately and do not continue to review the plate. The Licensed Result column drop down may be changed for any sample if the results are inconsistent with the ct values noted. Please add comments if any results

are changed for tracking purposes. Once review for all results is complete, click the "Confirm" button.

Review qPCR Results																		
Tube Barcode		SEP		Sampling Date/Time		QRP		QRP Well	RP Ct value	Ms2 Ct value	N Ct value	Orf1ab Ct value	S Ct value	Inspect Decision	Final result	Technical Review Comments	Licensed result	Add Comments
EXC_MW4_099947	EXC_SEP_003605	March 4, 2021, 3:06 p.m.		H3N00Z8K		B2	28.96	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not I ✓				
EXC_MW4_107832	EXC_SEP_003605	March 4, 2021, 3:06 p.m.		H3N00Z8K		B20	23.67	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not I ✓				
EXC_MW4_094527	EXC_SEP_003605	March 4, 2021, 3:06 p.m.		H3N00Z8K		B22	26.794	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not I ✓				
EXC_MW4_119212	EXC_SEP_003605	March 4, 2021, 3:06 p.m.		H3N00Z8K		B24	25.453	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not I ✓				
EXC_MW4_094625	EXC_SEP_003605	March 4, 2021, 3:06 p.m.		H3N00Z8K		B4	29.435	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not I ✓				
EXC_MW4_085853	EXC_SEP_003605	March 4, 2021, 3:06 p.m.		H3N00Z8K		B6	26.924	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not I ✓				
Pos_002533	EXC_SEP_003605	March 4, 2021, 3:06 p.m.		H3N00Z8K		B8	-1.0	-1.0	29.092	28.631	28.222	Detected	Detected	Detected ✓				

## 12 Results Submission:

12.1 Results Submission is performed by a CLS according to POA-007 Data Analysis and Interpretation for SARS-CoV-2 Assay including Data Delivery Review.

12.2 Click on "Submit Results" on the top menu bar to see pending results submissions and tubes ready for licensed review. If there are samples pending submission they will be listed by source. This will also include ELR submissions and manual submissions. ELR submissions will send automatically on a set schedule. Manual results will generate a csv file that needs to be emailed securely to the partner. Click a source to continue to results submission.

Licensed Review  
(169)

Partner	Pending Results	Recipients
UCSD	19	ELR
County (ELR)	24	ELR
County (Manual)	24	County (epi-cdreporting.hhsa@sdcounty.ca.gov), Marjorie Richardson (marjorie.richardson@sdcounty.ca.gov), Estrella Gaytan (estrella.gaytan1@sdcounty.ca.gov)

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- 12.3** For each source, each plate will be listed separately for submission. Click the Continue button to view and check the results before submitting.

E0000437

Total	Positives	Negatives	Invalids	Inconclusives
2	0	0	0	0

Reject Continue

E0000439

Total	Positives	Negatives	Invalids	Inconclusives
2	0	0	0	0

Reject Continue

- 12.4** Review the results and select the tubes to submit using the check boxes on the left side. Click the "Submit" button on the bottom to generate a csv file for manual submission or to send the results via ELR. The color scheme is the same as Licensed Review, Detected samples' results will be highlighted in red, Not Detected in green, Invalid in grey, and Inconclusive in yellow, including control samples. Samples with "Undetermined" results highlighted in white are samples that failed to upload any results or have a bug preventing results from updating correctly. If any samples in review have "Undetermined" results please contact an Admin user immediately and do not continue to submit results for the plate.

 **INSPECT** Home Search ▾ Workflows ▾ TroubleShoot Reject Specimen Submit Results ▾ Sequencing Workflow abaeer ▾

### Select Records To Submit To Epic

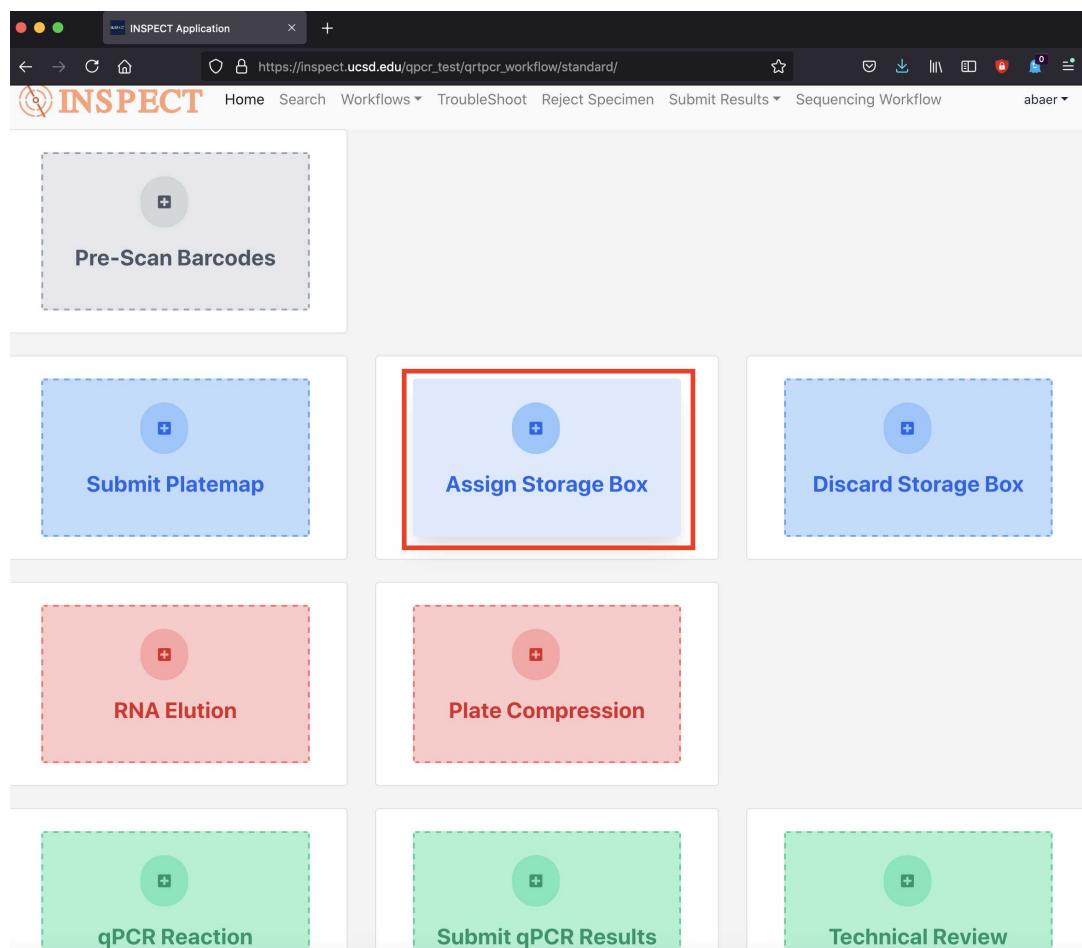
<input type="checkbox"/>	Tube Barcode	Test Completion Date	RP Ct Value	MS2 Ct Value	N Ct Value	Orf1ab Ct Value	S Ct Value	INSPECT Decision	Technical Result	Licensed Result	Submitted To Epic
<input type="checkbox"/>	EXC_MW4_119732	March 3, 2021, 5 p.m.	25.606	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Detected	
<input type="checkbox"/>	EXC_MW4_081601	March 3, 2021, 5 p.m.	26.822	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Detected	
<input type="checkbox"/>	EXC_MW4_120470	March 3, 2021, 5 p.m.	-1.0	-1.0	-1.0	-1.0	-1.0	Invalid	Invalid	Invalid	
<input type="checkbox"/>	EXC_MW4_119347	March 3, 2021, 5 p.m.	27.217	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not Detected	
<input type="checkbox"/>	EXC_MW4_094630	March 3, 2021, 5 p.m.	30.951	-1.0	-1.0	-1.0	-1.0	Not Detected	Not Detected	Detected	

[Submit to Epic](#)

Note: results can be changed during Licensed Review, like the first two results listed for this plate. Changed results will show only the highlight for the color for the Licensed Result.

## 13 Assign Storage Box

### 13.1 Select the Assign Storage Box button from the menu:



## 13.2 Enter the SEP and SSB plate IDs in the fields provided and click "Submit"

The screenshot shows the 'Assign Storage Box to an Sample Extraction Plate' form. It includes a reminder message, input fields for the Sample Extraction Plate Barcode and Sample Storage Box ID, and a 'Submit' button.

**Reminder:** Only 1 storage box can be assigned per sample extraction plate.  
Only 1 sample extraction can be assigned per sample storage box.

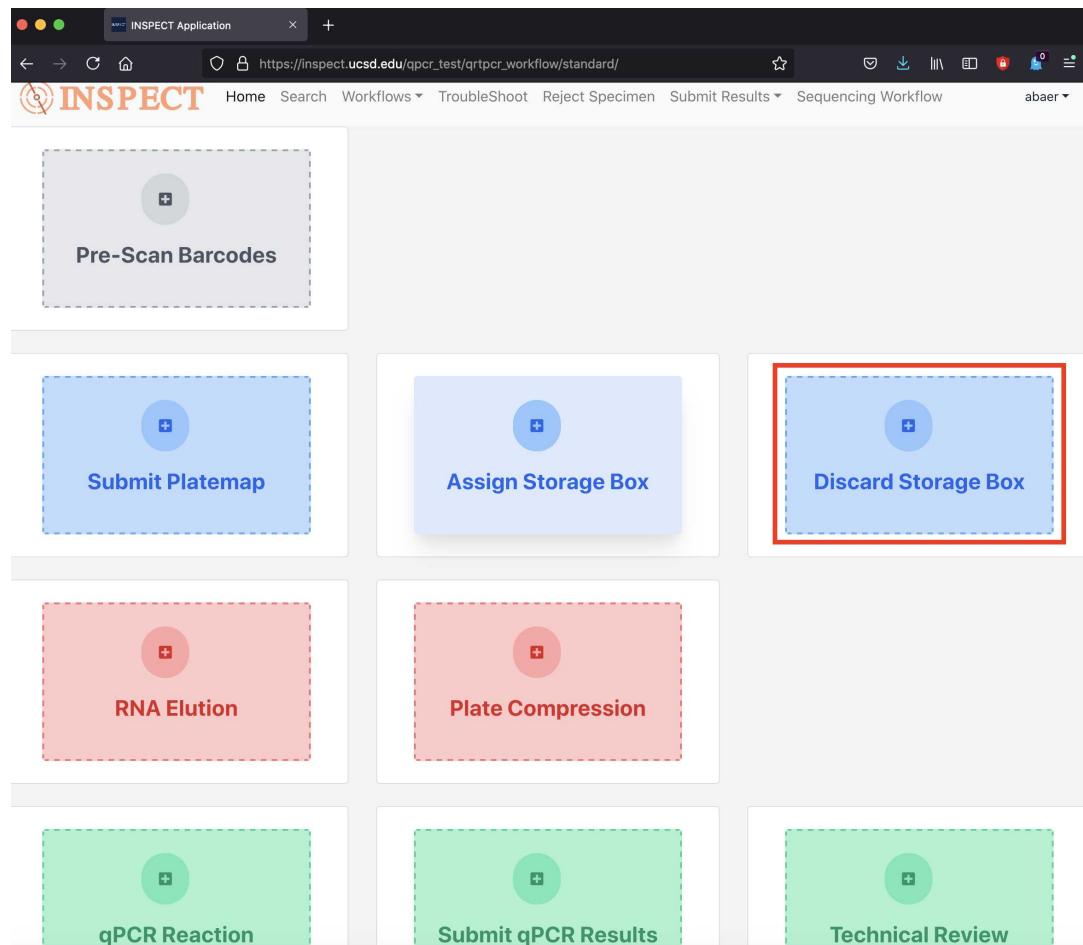
Sample Extraction Plate Barcode\*

Sample Storage Box ID\*

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## 14 Discard Storage Box

**14.1** Select the Discard Storage Box button from the menu:



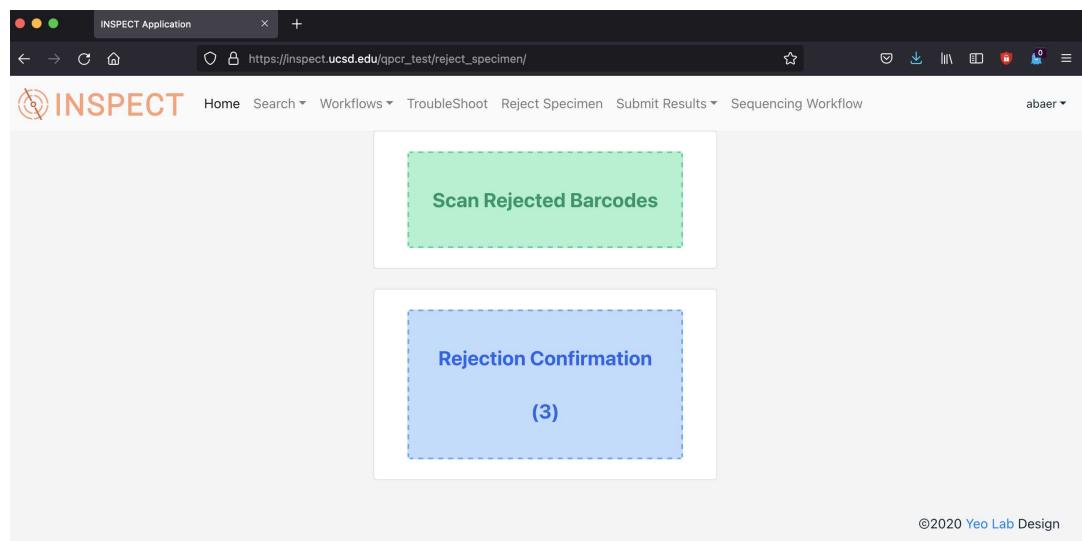
**14.2** Enter the SSB ID for the box being discarded and click "Submit"

A screenshot of the INSPECT Application 'Enter ID of Storage Box to Discard' page. The URL is https://inspect-training.ucsd.edu/qpcr\_test/discard\_storage\_box\_selection/. The page title is 'Enter ID of Storage Box to Discard'. It contains instructions: 'Enter or scan the barcode of the storage box to discard. All samples in the storage box will be marked as discarded. If you want to store positive samples (if any) in a new box, please keep the new storage box ready. You may enter the new storage box ID in the next page.' A 'Sample Storage Box ID\*' label is followed by a text input field containing 'EXC\_SSB\_000001'. A blue 'Submit' button is at the bottom. The bottom right corner of the page footer says '©2020 Yeo Lab Design'.

- 14.3** Once discarded, the flag "is\_destroyed" is set to True for all samples associated with the plate. A record is created in the qpcr\_troubleshoot table with the information from the original entry.

## 15 Sample Rejection

- 15.1** Navigate to the Reject Specimen workflow page by using the top navigation bar. The following page will be displayed showing a link box to scan rejected tubes (LAs) and another to confirm specimen rejection (CLSs only). Click the appropriate link box.



### 15.2 Scan Rejected Barcodes (LAs)

Enter or scan the rejected tube barcodes, multiple may be entered, and click the "Reject Listed Tubes" button to continue.

The screenshot shows a web browser window titled 'INSPECT Application'. The URL is 'https://inspect.ucsd.edu/qpcr\_test/reject\_specimen\_scan/'. The page has a header with the 'INSPECT' logo and navigation links: Home, Search, Workflows, TroubleShoot, Reject Specimen, Submit Results, and Sequencing Workflow. Below the header, the main title is 'Enter barcodes for rejected specimens'. A sub-instruction says 'Enter or scan barcodes in the text area one at a time or copy and paste a list.' A 'Recommendation:' section suggests turning on the newline setting on the barcode scanner. A text area labeled 'Barcodes\*' contains a list of four barcodes: EXC\_MW4\_000000, EXC\_MW4\_000001, EXC\_MW4\_000002, and EXC\_MW4\_000003. At the bottom of the text area is the instruction 'Enter or scan barcodes one at a time or copy and paste a list'. A blue button labeled 'Reject Listed Tubes' is at the bottom right.

- 15.3 Select the specimen disposition from the drop down menu. Enter the reason for rejection in the appropriate text box for each specimen and click the "Confirm" button. Once the samples are confirmed, database information, such as the employee ID will be added for each specimen. If the specimen is not present in the UCSD student application, INSPECT Forms, or test order database, the sample will not be displayed for the CLSS's reject confirmation list. Samples without database information cannot be rejected through this workflow. If any errors occur, please contact an admin user immediately and do not enter any tubes for rejection.

Tube Barcode	Sample Type	Specimen Disposition	Rejection Comments	Date and Time Rejected	User
EXC_MW4_000003	Nasal Swab	Discarded	No media	2021-08-04 18:03:57	Adam Baer
EXC_MW4_000000	Nasal Swab	Discarded	No media	2021-08-04 18:03:57	Adam Baer
EXC_MW4_000002	Nasal Swab	Discarded	No media	2021-08-04 18:03:57	Adam Baer
EXC_MW4_000001	Nasal Swab	Discarded	No media	2021-08-04 18:03:57	Adam Baer

**Confirm**

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## 15.4 Rejection Confirmation (CLSs)

Follow instruction to identify any duplicate tubes or multiple database entries. Add comments when applicable to help track duplicate tubes. If no duplicate tube barcodes are present, click "Continue" to proceed to the following page.

No duplicates were found for review. Please continue to review the rest of the rejected samples.

**Continue**

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## 15.5 Review the rejected specimen information and add comments as necessary.

Use the table and information provided to inform the partners about rejected specimen. Once the partners have been notified, check the boxes on the left for the entries in the table and click the "Submit Checked Tubes" button. A csv file will be generated listing all the rejected specimen information. Review the information in the csv and store it in the appropriate location. If any errors occur,

please inform a system admin immediately and do not confirm any rejected specimen.

	Tube Barcode	Source	Employee ID	Student ID	Full Name	Sample Type	Specimen Disposition	Reason for Rejection	Licensed Result	Date and Time Rejected	Rejecting Personnel	Comments
<input type="checkbox"/>	EXC_TEST_100450	SYHC	000450			Nasal Swab	Discarded	No media	Rejected	2021-08-16 20:15:22	Adam Baer	
<input type="checkbox"/>	EXC_TEST_100430	SYHC	000430			Nasal Swab	Discarded	No media	Rejected	2021-08-16 20:15:22	Adam Baer	
<input type="checkbox"/>	EXC_TEST_100440	SYHC	000440			Nasal Swab	Discarded	No media	Rejected	2021-08-16 20:15:22	Adam Baer	

[Submit Checked Tubes](#)

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## 16 Search Functions

INSPECT has 3 different search functions that can be accessed through the "Search" button in the top menu bar.

Search Inspect database for records. Workflow searches can be made by all users. PII searches are restricted to CLSs, signing officers and admins

Sample Barcode

Sampling date (YYYY-MM-DD)

Sampling date end (Optional YYYY-MM-DD)

Plate id

Enter a Plate Barcode

Technician

Licensed Result

Search Term

Enter a tube barcode or student or employee ID to search

Search

App searches are restricted to CLSs, signing officers and admins

Tube Barcode

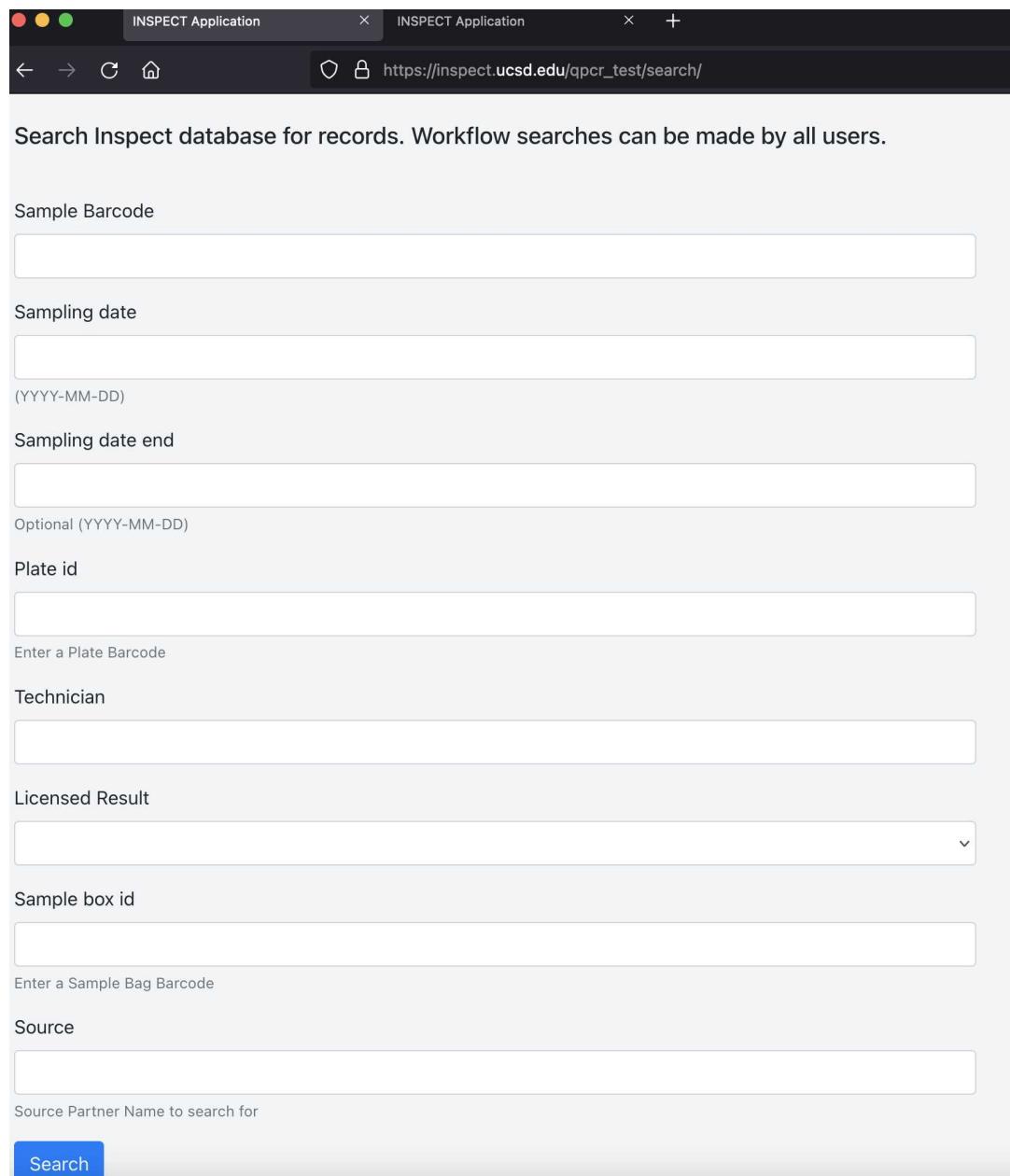
Enter a tube barcode to search whether the barcode was scanned in the UCSD Student or Inspect-Forms Apps.

Search

### 16.1 Searching the INSPECT database (all users)

Enter 1 or more search queries into the fields listed. Searches may be combined, i.e. searching for all "Detected" results across a date range. Rejected samples will search using the date time rejected (technical review datetime), all other searches will use the sampling datetime (plating). A maximum of 5000 results

may be returned. If any more results are returned an error message will be displayed.



The screenshot shows a web browser window titled "INSPECT Application" with two tabs open. The URL in the address bar is "https://inspect.ucsd.edu/qpcr\_test/search/". The page content is a search form for the INSPECT database. It includes fields for Sample Barcode, Sampling date (with a placeholder "(YYYY-MM-DD)"), Sampling date end (with a placeholder "Optional (YYYY-MM-DD)"), Plate id (with a placeholder "Enter a Plate Barcode"), Technician (with a placeholder "Enter a Sample Bag Barcode"), Licensed Result (a dropdown menu), Sample box id (with a placeholder "Enter a Sample Bag Barcode"), Source (with a placeholder "Source Partner Name to search for"), and a "Search" button at the bottom.

Search Inspect database for records. Workflow searches can be made by all users.

Sample Barcode

Sampling date

(YYYY-MM-DD)

Sampling date end

Optional (YYYY-MM-DD)

Plate id

Enter a Plate Barcode

Technician

Licensed Result

Sample box id

Enter a Sample Bag Barcode

Source

Source Partner Name to search for

Search

Error displayed when more than 5000 results are returned:

The search results will be displayed as a table on the results page:

The search results will be displayed as a table on the results page:

Sample Information												Result			Comments			Workflow		
Tube Barcode	PreScan Source	Source	RP Ct Value	MS2 Ct Value	N Ct Value	Orflab Ct Value	S Ct Value	INSPECT Decision	Technical Result	Licensed Result	Technical Review	Licensed Review	SEP ID	SEP Well	REP ID					
EXC_MW4_089801		Pacific Ridge School	-1.0	29.97	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not Detected			EXC_SEP_001894	A11	EXC REP_00189					
EXC_MW4_044425		Pacific Ridge School	-1.0	30.11	-1.0	-1.0	-1.0	Not Detected	Not Detected	Not Detected			EXC_SEP_001894	H6	EXC REP_00189					

## 16.2 PII Search (CLS only)

The PII search will query records in the PI table and the qpcr\_test table. Since PI is displayed, only CLSs and admins have access to the PI search. Enter a tube barcode or employee or student ID to search. The results will display 2 tables, the top table will display the PI information and the bottom table will display the qpcr\_test table information:

The screenshot shows the INSPECT Patient LookUp interface. At the top, there is a navigation bar with links to Home, Search, Workflows, TroubleShoot, Reject Specimen, Submit Results, and Sequencing Workflow. A reminder message "Reminder: This may page contain PII." is displayed. The main section is titled "Patient LookUp" and contains a table with columns: Student ID, MRN ID, Employee ID, First Name, Last Name, and Date of Birth. One row is populated with values: 123456, 123456, Example, Patient, and an empty Date of Birth field. Below this is a section titled "Associated Scan Information" with a table showing details like Tube Barcode, Student ID, Employee ID, Source, Licensed Result, Barcode Scan DateTime, Sampling DateTime, SEP ID, SEP Well, SSB ID, Licensed Review DateTime, and Resolved DateTime. The data in this table matches the previous row.

### 16.3 App Search (CLS only)

The app search will query additional databases, including the UCSD student app, and INSPECT Forms. Enter a tube barcode to search; this search only accepts tube barcodes, not employee or student IDs. The search results will include the information from the app and specify which app the record was found in.

The screenshot shows the INSPECT Tube Barcode LookUp interface. At the top, there is a navigation bar with links to Home, Search, Workflows, TroubleShoot, Reject Specimen, Submit Results, and Sequencing Workflow. A reminder message "Reminder: This may page contain PII." is displayed. The main section is titled "Tube Barcode LookUp In UCSD-Student or Inspect-Forms Apps" and displays the message "EXC\_TEST\_lx8J5gL found in the UCSD Student App.". Below this is a table with columns: Tube Barcode, Barcode Scan DateTime, Source, Full Name, Student ID, and Employee ID. One row is populated with values: EXC\_TEST\_lx8J5gL, 2021-01-14 10:49 AM, UCSD, Gupta, Mihir, A15956538, and 10405824.

## 17 CLS Dashboard

The CLS dashboard shows samples that have been submitted and are pending submission. It also shows Rejected samples, and all samples that have been tested but do not have assigned sources or demographics information and cannot be reported.

The dashboard displays the following data:

Nov. 9, 2021 Sample Count		Nov. 9, 2021 Results		Nov. 9, 2021 Submissions	
Total	1710	Total Results	1201	Total	0
PreScanned and Plated	1008	Undetermined	1201	Claimed Results	0
PreScanned Only	509			Unclaimed Results	0
Plated Only	193			Unidentified Samples	0

Unclaimed Results, Rejected Samples and Unidentified Samples Breakdown		
: Nov. 9, 2021		
<b>Unclaimed Results</b>	<b>Rejected Samples</b>	<b>Unidentified Sample</b>
SDSU 2	Rejected Samples 0	Unidentified Samples 28
UCSD 1		BRFII 1
		Francis Parker 3
		Muir 2
		Nuevo East 1

## 17.1

The Re-Sync Database button allows a user to check all pending samples that are missing demographics information against all connected databases (UCSD student app, INSPECT Forms, and REDCap (SASEA and SYHC Mobile Testing Sites)) to attach any updated demographics information. The re-sync will also update any samples in the qPCR\_test table with information from the test\_order table from messages received from partners' ELR systems, like Redox.

Click the button to begin the resync process. A progress bar will be displayed showing the number of samples being re-sync'd and the total sample to re-sync. Note that this process has a 15 minute timeout.

8 of 532 processed. 0 identified successfully. 8 samples not identified

## 17.2 Pending samples/submissions:

The dashboard will display a count of all samples for the current date (or a Sampling Date entered into the dashboard) and what step of the testing workflow they are in. A csv database dump can be output by clicking the Download Report link.

The screenshot shows the INSPECT dashboard at [https://inspect.ucsd.edu/qpcr\\_test/cls\\_dashboard/](https://inspect.ucsd.edu/qpcr_test/cls_dashboard/). On the left, there are two input fields for 'Sampling date\*' and 'Sampling date1\*', both set to '2021-11-09' (YYYY-MM-DD). Below them is a blue 'Search' button. To the right, there are two tables: 'Nov. 9, 2021 Sample Count' and 'Nov. 9, 2021 Results'. The 'Sample Count' table shows a total of 1936 samples, with breakdowns: PreScanned and Plated (1008), PreScanned Only (735), and Plated Only (193). The 'Results' table shows a total of 1201 results, with breakdowns: Total Results (1201) and Undetermined (1201). A modal dialog titled 'Opening table.csv' is displayed, asking what to do with the CSV file ('table.csv') from the URL. Options include 'Open with Microsoft Excel (default)', 'Save File', and 'Do this automatically for files like this from now on.' Buttons for 'Cancel' and 'OK' are at the bottom.

### 17.3 Unclaimed Results, Rejected Samples and Un-Identified Samples Breakdown:

The dashboard also displays counts for all samples for the last 48 hours or a given date range (enter on the left side, Sampling date1 and Sampling date2 then click search) that have been Rejected or have not been submitted. Unclaimed results will show a count of the samples that have a source associated but lack demographics; click the header to show a table of the sample information and results. Unidentified samples will show a count of all the samples that do not have a source associated listed by the pre-scan source; Click the header to show a table of the sample information and results for these samples.

The screenshot shows the INSPECT dashboard at [https://inspect.ucsd.edu/qpcr\\_test/cls\\_dashboard/](https://inspect.ucsd.edu/qpcr_test/cls_dashboard/). On the left, there are two input fields for 'Sampling date\*' and 'Sampling date2\*', both set to '2021-11-01' and '2021-11-09' (YYYY-MM-DD) respectively. Below them is a blue 'Search' button. To the right, there are three tables: 'Unclaimed Results', 'Rejected Samples', and 'Unidentified Sample'. The 'Unclaimed Results' table shows 5 samples from San Ysidro Health Clinic Mobile Sites, SDSU, and UCSD. The 'Rejected Samples' table shows 0 samples. The 'Unidentified Sample' table shows 26 samples from various locations: BRFII, Francis Parker, Muir, Nuevo East, One Miramar, Osler, Pepper Canyon, Price Center (Dropbox), Revelle, San Ysidro Health, Seventh, South Mesa, and UCSD. Each location has a count of 1.

Example table showing unclaimed results, may also be output as a .csv file:

The screenshot shows a web browser window for the INSPECT application at the URL [https://inspect.ucsd.edu/qpcr\\_test/unclaimed\\_results/](https://inspect.ucsd.edu/qpcr_test/unclaimed_results/). The page title is "Unclaimed Results" with the date range "2021-11-08 : 2021-11-09". Below the title is a "Download CSV" button. The main content is a table with the following columns:

Tube barcode	Student id	Employee id	Sample received datetime	Receiving source	Barcode scan datetime	Source	Sep id	Sep well	Sampling datetime	Rep id	Rep well	Rwp id	Rwp well	Rna extraction datetime	Qrp id
--------------	------------	-------------	--------------------------	------------------	-----------------------	--------	--------	----------	-------------------	--------	----------	--------	----------	-------------------------	--------

## PE Workflow

- 18 To start the PE workflow, click the "PE qRT-PCR Workflow" button. Follow steps outlined in PES-001 SARS-CoV-2 ASSAY USING THE PERKIN ELMER SYSTEM.

The screenshot shows the INSPECT application interface. On the left, there is a sidebar with two workflow options: "Standard qRT-PCR Workflow" and "PE qRT-PCR Workflow", with the latter being highlighted by a red box. The main content area displays the "Overall Testing Summary" and "Daily Sample Summary".

**Overall Testing Summary**

Number of Samples	Number of Positives	Number of Negatives	Samples To Be Requested	Plates To Be Requested
444206	13321 (3.0%)	413209 (93.02%)	15	1

**Daily Sample Summary**

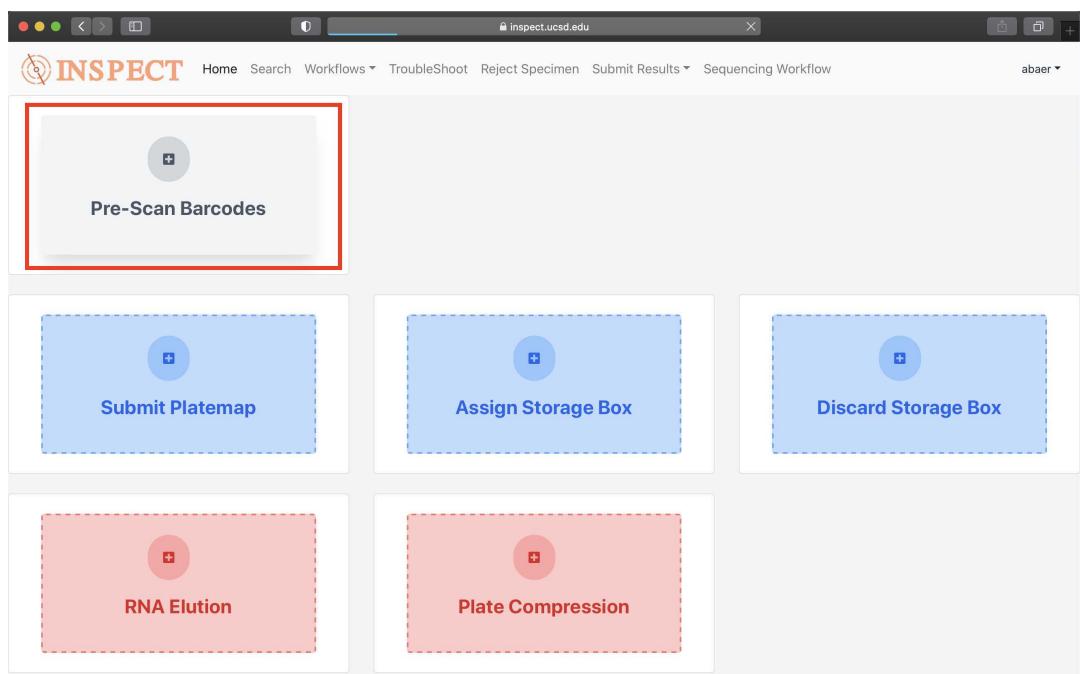
Number of Samples	UCSD	Private Schools	SASEA	SDFD	Other
0	0	0	0	0	0

**Plate Tracker**

Step Name	Number of Samples in Step	Number of Plates Already Evaluated	Evaluated Plate IDs
Sample Extraction Plate (SEP)	3542	39	EXC_SEP_005622, EXC_SEP_005642, EXC_SEP_005632, EXC_SEP_005646, EXC_SEP_005651, EXC_SEP_005623, EXC_SEP_005640, EXC_SEP_005631, EXC_SEP_005624, EXC_SEP_005653, EXC_SEP_005638, EXC_SEP_005643,

- 19 Pre-scan Barcodes

### 19.1 Select Pre-Scan Barcodes from the workflow steps listed in boxes:

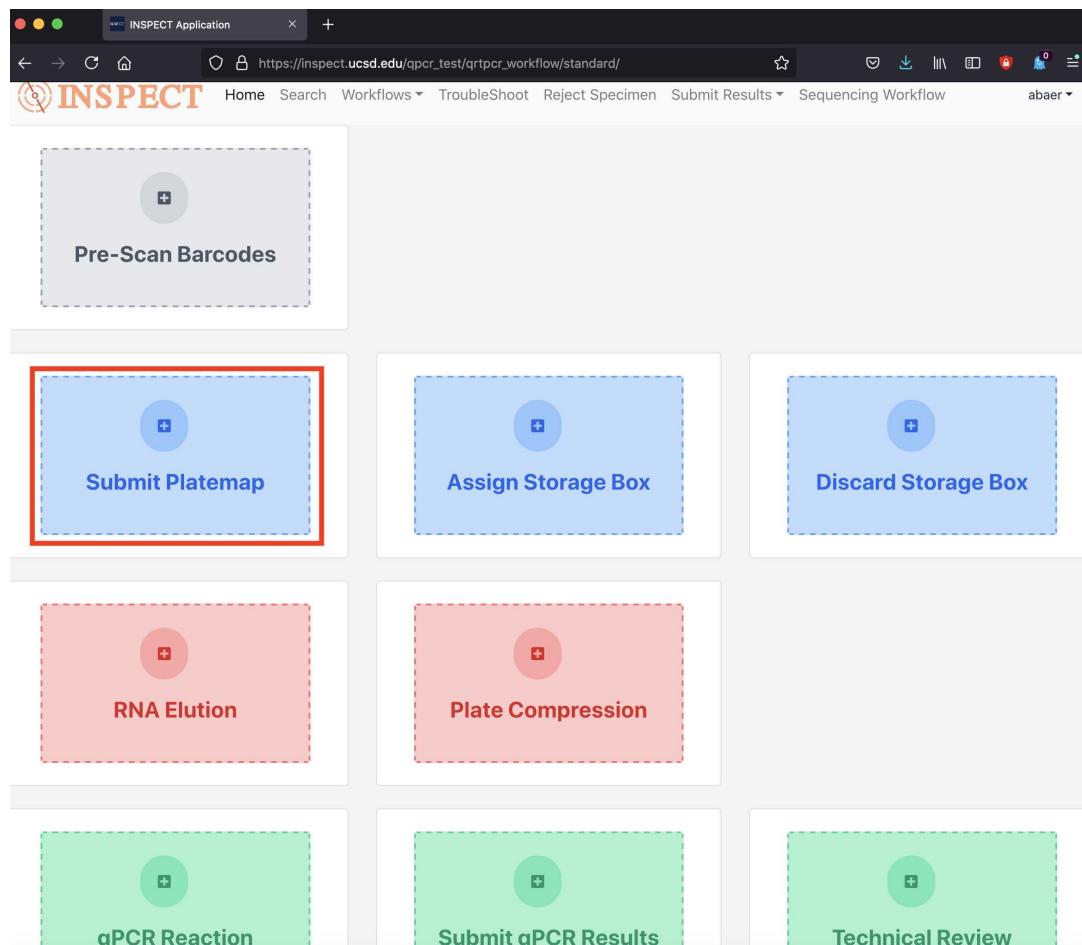


- 19.2** Follow the instructions on the page to enter or scan in barcodes. Turn on the newline setting on the barcode scanner. This will automatically enter a new barcode on a new line. Select the source of the samples entered from the drop down menu. All samples scanned will be assigned to the same source. Once all samples for the source are entered, click the submit button and you will be redirected to the home page with a message showing the number of samples that were pre-scanned in to the INSPECT database. Repeat this process for each set of samples for each source.

The screenshot shows the 'Pre-Scan Barcodes InTo Inspect' form. At the top, there's a header with the INSPECT logo and navigation links. Below the header is a section titled 'Pre-Scan Barcodes InTo Inspect' with the sub-instruction: 'Select the source of samples and scan barcodes in the text area one at a time.' A 'Recommendation' section suggests turning on the newline setting on the barcode scanner. The main form has a 'Barcodes\*' field containing three sample IDs: 'EXC\_TEST\_000001', 'EXC\_TEST\_000002', and 'EXC\_TEST\_000003'. Below this field is a note: 'Scan barcodes one at a time'. There's also a 'Source\*' dropdown menu set to 'Nuevo East' and a 'Submit' button.

## 20 Uploading Platemap(s)

### 20.1 Select the "Submit Platemap" button from the menu:



### 20.2 Click the "Browse..." button to add the platemap file. Enter the ID for the Janus machine used. Enter your initials. Enter the lot numbers for the qPCR kit and Chemagic kits. Click "Submit" to upload the platemap.

**Reminder:** Upload the Reformatter platemaps.

### Upload Janus Platemap Files

Platemap Files To Upload\*

example\_platemap.csv

Enter ID of Janus machine used\*

EXC\_JNS\_004

Name of Person Uploading Platemap\*

AB

Lot # of the qPCR Kit\*

Lot # of the Chemagic Kit\*

- 20.3** The sample barcodes in the platemap will be assigned sample information from the UCSD student app, INSPECT Forms database, REDCap, or other associated databases. The page will redirect to a progress bar and a success message will be displayed showing the number of samples that were successfully associated and if any samples were not assigned sample information. Contact an admin if any error messages are displayed. There is a set 15 minute time limit for this step in INSPECT, so if the assignment and database lookups take longer than 15 minutes a timeout error will show. If a platemap times out please troubleshoot the SEP IDs listed on the platemap file and please separate all SEPs listed into separate platemap files and upload the files.

INSPECT Home Search ▾ Workflows ▾ TroubleShoot Reject Specimen Submit Results ▾ Sequencing Workflow abaeer ▾

85 of 96 processed. 85 identified successfully. 0 samples not identified

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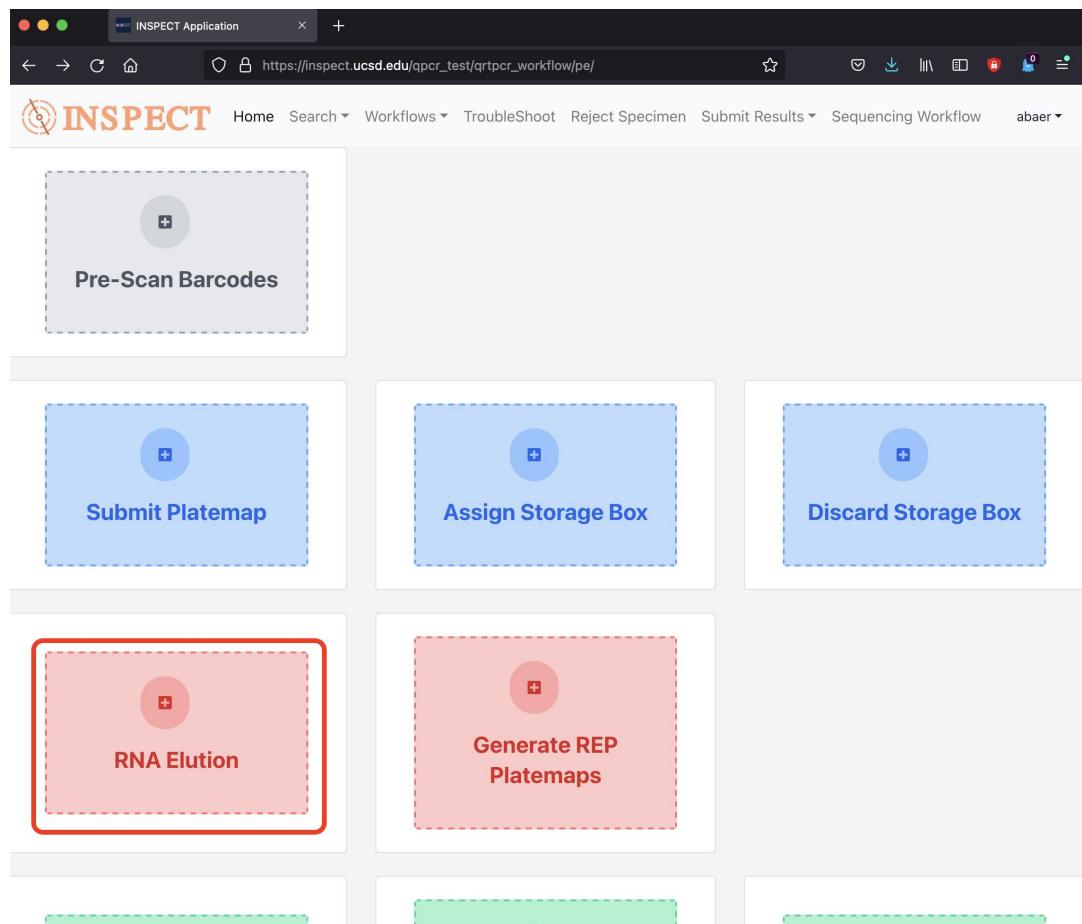
INSPECT Home Search ▾ Workflows ▾ TroubleShoot Reject Specimen Submit Results ▾ Sequencing Workflow abaeer ▾

Success! 96 Sample Uploaded. 0 Samples Could Not Be Identified

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## 21 RNA Elution

21.1 Click the RNA Elution box:

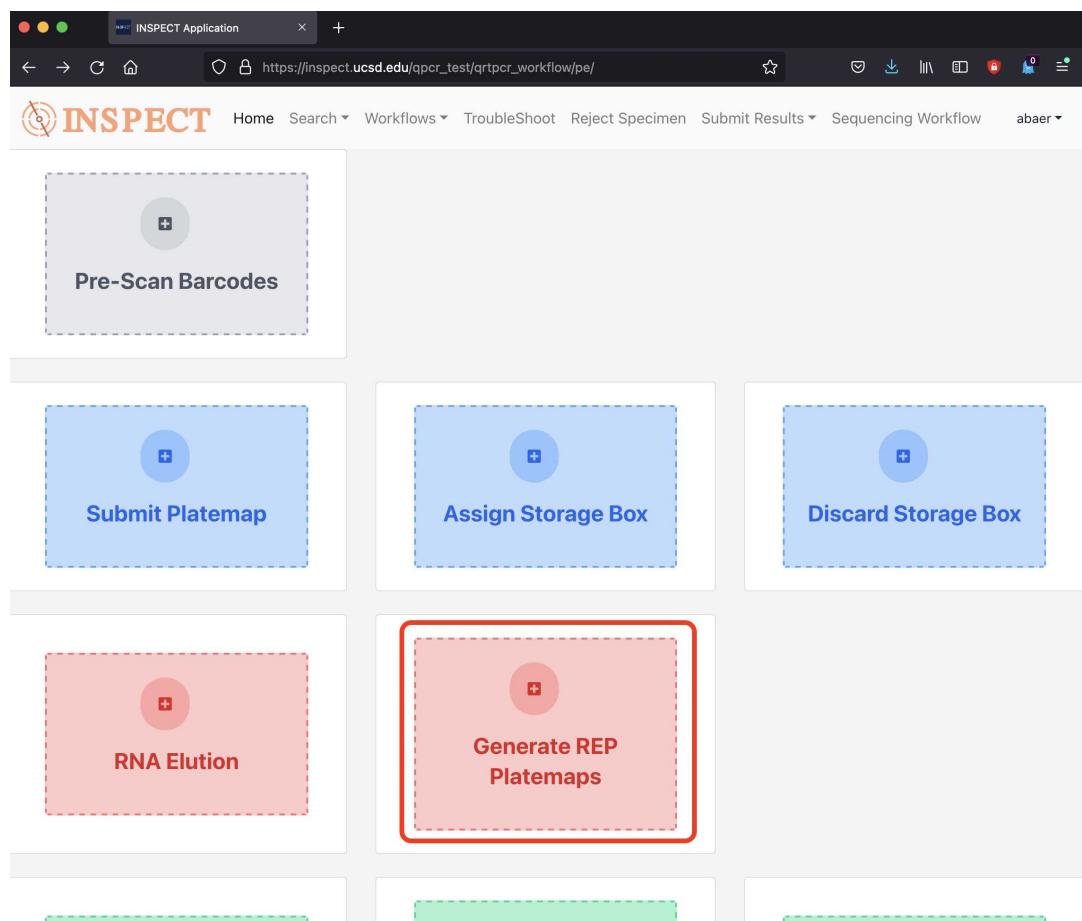


21.2 Enter the Chemagic ID, lot number for the Chemagic kit, and the sample extraction plate (SEP) barcode. Enter the RNA elution plate barcode to be assigned and click the "Assign Plates" button. A message will display giving success or failure confirmation, and reason for failure, if applicable.

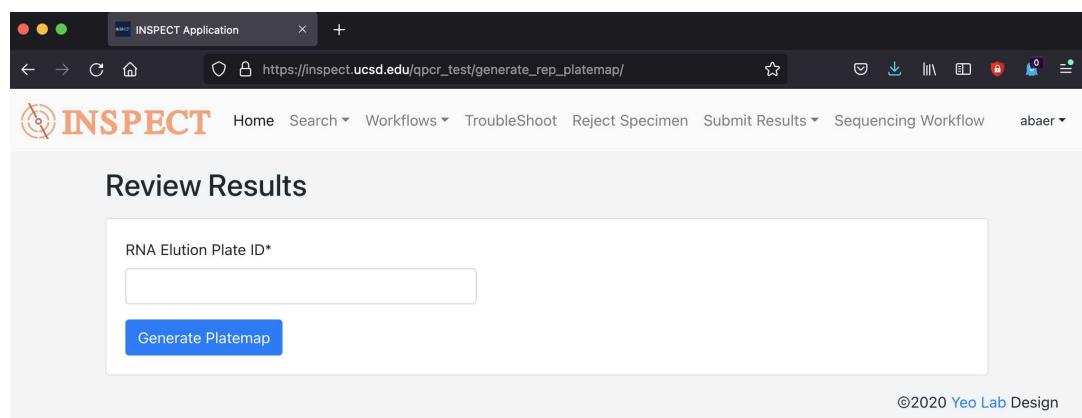
The screenshot shows a web browser window titled "INSPECT Application" with the URL [https://inspect.ucsd.edu/qpcr\\_test/rna\\_plate\\_capture/pe/](https://inspect.ucsd.edu/qpcr_test/rna_plate_capture/pe/). The page has a header with the INSPECT logo and navigation links: Home, Search, Workflows, TroubleShoot, Reject Specimen, Submit Results, Sequencing Workflow, and a user account dropdown for "abaer". Below the header are two input fields: "Chemagic ID\*" and "Lot # of the Chemagic Kit\*". A blue callout box contains the text: "Reminder: RNA Elution Plate ID will be linked with the Sample Extraction Plate ID. Make sure you have the correct RNA Elution and Sample Extraction Plates." Below these are two more input fields: "Sample Extraction Plate Barcode\*" containing "EXC\_SEP\_000000" and "RNA Elution Plate Barcode\*" containing "EXC REP\_000000". At the bottom is a blue "Assign Plates" button.

## 22 Generate REP Platemaps

22.1 Click on the "Generate REP Platemaps" box:



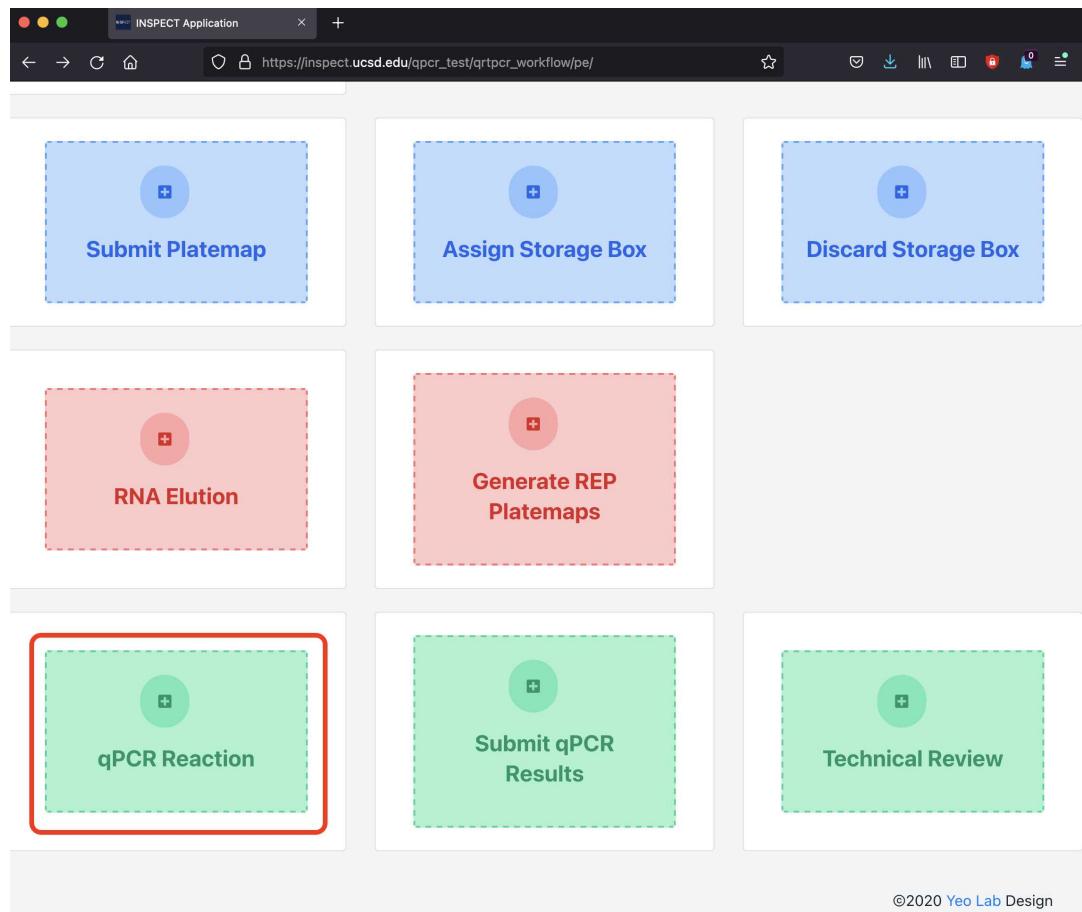
22.2 Enter the REP ID and click the "Generate Platemap" button to generate the platemap:



INSPECT will generate a platemap to input into the Janus machine for plate compression.

## 23 qPCR Reaction

23.1 Click on the "qPCR Reaction" box:

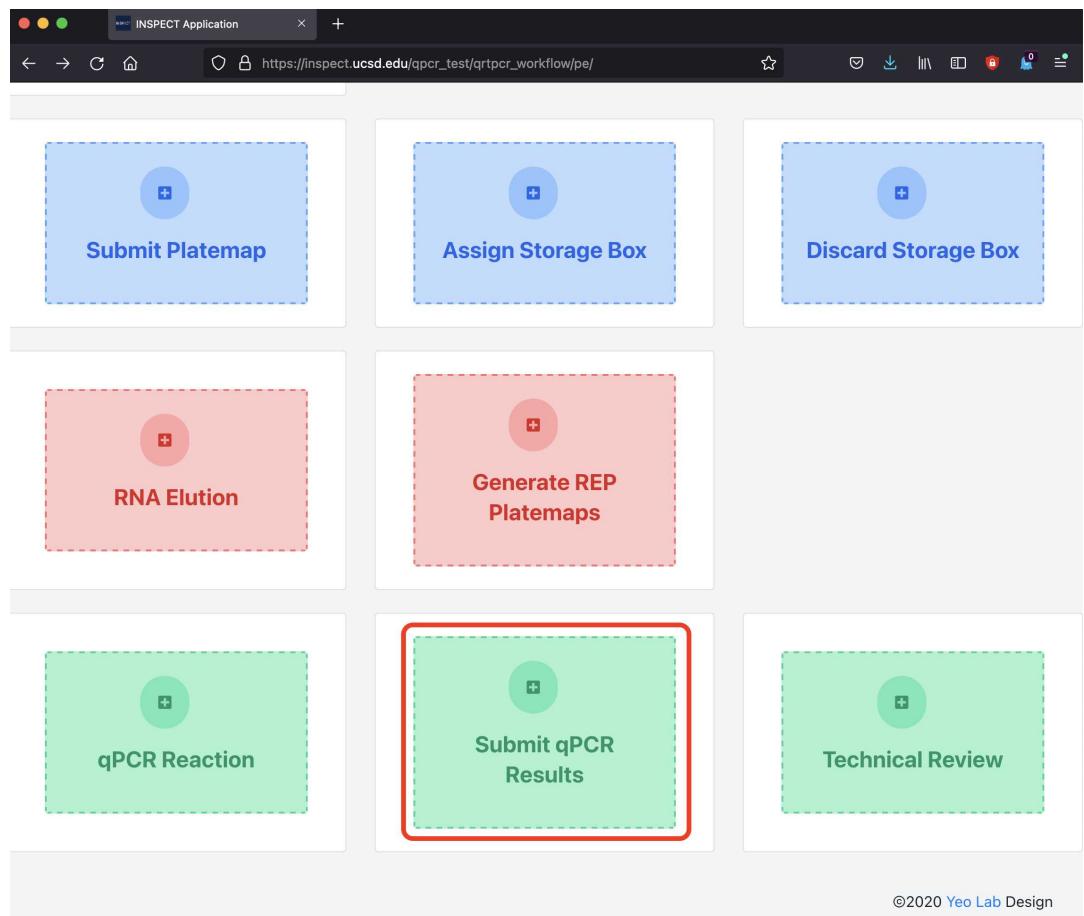


23.2 Click the "Browse..." button and upload the QRP platemap. Enter the ID of the Janus and the lot number of the qPCR kit and click "Submit" to link the RT-qPCR plate to the RNA Elution Plates listed in the RT-qPCR plate.

The screenshot shows the INSPECT Application interface. At the top, there's a navigation bar with links for Home, Search, Workflows, TroubleShoot, Reject Specimen, Submit Results, Sequencing Workflow, and a user account. Below the navigation is a reminder message: "Reminder: RT-qPCR Plate will be linked to the RNA Elution Plates in the Platemap". The main form has fields for "Platemap File To Upload\*" (with a "Browse..." button), "Enter ID of Janus machine used\*" (containing "JNS-004"), and "Lot # of the qPCR Kit\*". A "Submit" button is at the bottom. In the bottom right corner, it says "©2020 Yeo Lab Design".

## 24 Submit qPCR Results

### 24.1 Click the "Submit qPCR Results" box:

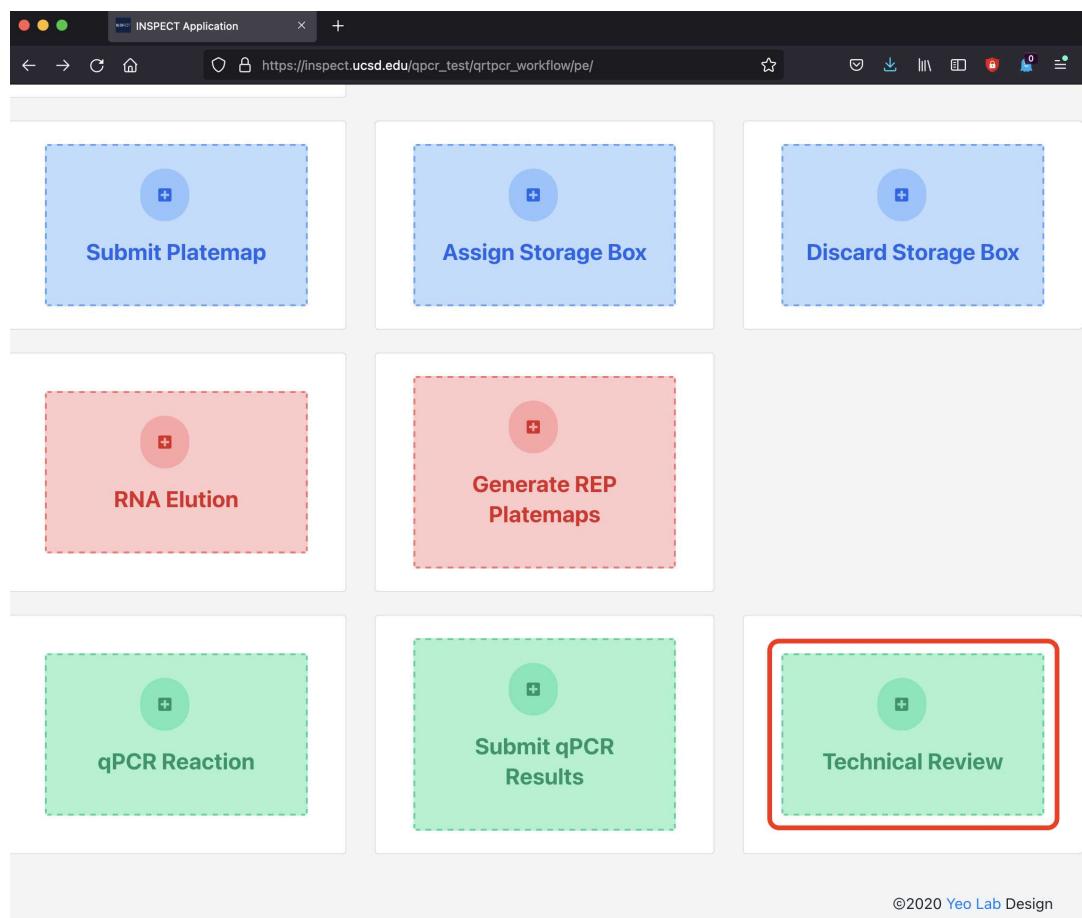


**24.2** Upload the qPCR results file. Make sure that the RT-qPCR plate ID matches an existing RT-qPCR plate in INSPECT and that the results have not yet been uploaded, or the file will not be able to be uploaded. If any samples matching the QRP ID have results in INSPECT the file cannot be uploaded since results will not be over-written. A message will display giving success or failure confirmation, and reason for failure, if applicable.

The screenshot shows a web browser window titled 'INSPECT Application'. The URL in the address bar is [https://inspect.ucsd.edu/qpcr\\_test/upload\\_qpcr\\_results/pe/](https://inspect.ucsd.edu/qpcr_test/upload_qpcr_results/pe/). The main content area is titled 'Upload qPCR Results'. A blue banner at the top contains the text: 'Reminder: Make sure that the RT-qPCR plate ID matches an existing RT-qPCR plate in Inspect.' Below this, there is a 'Qpcr results file\*' input field with a 'Browse...' button, which has 'example\_Results...9 095132.csv' selected. There is also an 'Enter ID of RT-qPCR Plate\*' input field with a placeholder 'Plate ID'. A blue 'Upload' button is located below the input fields. At the bottom right of the page, there is a copyright notice: '©2020 Yeo Lab Design'.

## 25 Technical Review

**25.1** Click the "Technical Review" box:



- 25.2** Input the qRT-PCR Plate Barcode ID into the box and click the Start button to begin the review process:

The screenshot shows the 'Review Results' page of the INSPECT Application. The URL is [https://inspect-training.ucsd.edu/qpcr\\_test/qpcr\\_plate\\_id\\_to\\_review/](https://inspect-training.ucsd.edu/qpcr_test/qpcr_plate_id_to_review/). The page features a search bar labeled 'qRT-PCR Plate Barcode\*' with the value 'TESTQPCR' and a blue 'Start' button below it. The top navigation bar includes links for Home, Search, Workflows, TroubleShoot, Reject Specimen, Submit Results, and Sequencing Workflow. The bottom right corner displays the copyright notice '©2020 Yeo Lab Design'.

Note: The screenshots for the Technical Review process contain only test data from a development INSPECT server.

- 25.3** Review the results following PES-006 Perkin Elmer System Data Analysis and Interpretation for SARS-CoV-2 Assay, including Data Delivery Review. The SOP contains the latest tables and diagrams outlining results thresholds and decision tree assessment calls.

Each result has a drop down menu allowing the user to select the corrected result for each sample. If any changes are made, comments must be added justifying the change. All original results from the QRP result file will be stored in the database for reference. Select the Confirm button once all samples are reviewed and any comments are added.

Verify that the correct amount of samples are displayed, that all the controls have the correct calls, and that the Inspect calls are correct.

*Red= Detected*

*Green= Not Detected (shown below)*

*Grey= Invalid (shown below)*

*Yellow= Inconclusive*

### Review qPCR Results

Review qPCR Results												
Confirm												
Tube Barcode	SEP	QRP	QRP Well	RP Ct value	Ms2 Ct value	N Ct value	Orf1ab Ct value	S Ct value	Inspect Decision	Final result	Add Comments	
EXC_TEST_AdamBaer001	EXC_SEP_002322	E0000277	A01	-1.0	31.3	-1.0	-1.0	-1.0	Not Detected	Not Det ▾		
EXC_TEST_AdamBaer009	EXC_SEP_002322	E0000277	A02	-1.0	30.34	-1.0	-1.0	-1.0	Not Detected	Not Det ▾		
EXC_TEST_AdamBaer017	EXC_SEP_002322	E0000277	A03	-1.0	-1.0	-1.0	-1.0	-1.0	Invalid	Invalid ▾		
EXC_TEST_AdamBaer025	EXC_SEP_002322	E0000277	A04	-1.0	28.28	-1.0	-1.0	-1.0	Not Detected	Not Det ▾		
EXC_TEST_AdamBaer033	EXC_SEP_002322	E0000277	A05	-1.0	30.15	-1.0	-1.0	-1.0	Not Detected	Not Det ▾		
EXC_TEST_AdamBaer041	EXC_SEP_002322	E0000277	A06	-1.0	27.48	-1.0	-1.0	-1.0	Not Detected	Not Det ▾		
EXC_TEST_AdamBaer049	EXC_SEP_002322	E0000277	A07	-1.0	-1.0	-1.0	-1.0	-1.0	Invalid	Invalid ▾		



The PE workflow does not utilize the S gene for viral signal. No values are expected for the "S Ct Value" field.

Additionally, the PE workflow does not utilize the RP gene for control signal. No values are expected for the "RP Ct Value" field.



Samples with "Undetermined" results highlighted in white are samples that failed to upload any results or have a bug preventing results from updating correctly. If any samples in review have "Undetermined" results please contact an Admin user immediately and do not continue to review the plate

Note: The screenshots for the Technical Review process contain only test data from a development INSPECT server. More samples are listed for review than are displayed in the screenshot, during review, make sure the positive and negative control for each plate are listed and have the expected result. If any controls are missing or have unexpected data, please contact an Admin for troubleshooting.

## 26

NOTE: If results are being submitted from the PE workflow, please follow the steps outlined in the shared workflow for submitting results.

### Troubleshooting

## 27 Troubleshooting (LAs and CLSs)

### 27.1 Access the TroubleShoot link via the top navigation bar.

Troubleshooting can be used to revert a plate of samples back to a specific step in the workflow, removing any downstream data. Never troubleshoot a plate that has ANY samples that have results submitted. Please contact an Admin to help troubleshoot a plate with samples that may have been submitted.

Troubleshooting is irreversible, once a plate has been troubleshooted it cannot be recovered. If a plate is accidentally troubleshooted or the original data from a plate needs to be recovered for any reason, please contact an Admin.

### 27.2 Some common reasons for troubleshooting a plate include but are not limited to:

- Incorrect assignment of plates (SEP to REP, etc).
- Issue generating platemaps at sampling step

- Problems during qPCR run (Regents, machines, etc). Needing to run the plate again.
- 

**27.3** Enter the plate ID to troubleshoot. A SEP or REP or RWP or QRP ID is may be used to start the process. Note that all samples on a plate will be affected by troubleshooting. Enter the reason for troubleshooting the plate, i.e. file upload issue, system down, entry error, etc. Select the step to troubleshoot the plate to, or select "Requeue" to requeue the plate. Once again, Troubleshooting is irreversible, once a plate has been troubleshooted it cannot be recovered. If a plate is accidentally troubleshooted, please contact an Admin.

The screenshot shows the 'INSPECT Application' interface with the URL [https://inspect.ucsd.edu/qpcr\\_test/workflow\\_troubleshoot/](https://inspect.ucsd.edu/qpcr_test/workflow_troubleshoot/). The page title is 'WorkFlow TroubleShoot'. It contains a form with a 'Plate ID\*' field containing 'EXC\_SEP\_000000', a 'Reason for Troubleshooting\*' field with the instruction 'Input reason for troubleshooting here, This box must be filled in in order to troubleshoot a plate.', and a dropdown menu titled 'Requeue Plate' with several options listed. The 'Requeue Plate' option is highlighted with a blue selection bar.

**27.4** Table showing each troubleshooting step and what the actions that will occur in INSPECT will be. Also shows common reasons for troubleshooting to each step, there may be additional reasons to troubleshoot plates to each step as well.

A	B	C
Troubleshooting Step	Actions	Reason
Requeue Plate	All samples associated with the plate will be labelled as "Requeue" for Technical and Licensed Result and will not be able to be reviewed or submitted.	Plate failure, control failure

Licensed Review	Licensed result is reset to the Technical Review result for all samples associated with the plate. Licensed Reviewed Datetime is set to "None".	Change any Licensed results BEFORE results are submitted
Technical Review	Licensed result is reset to the Technical Review result and Technical review result is reset to the Decision Tree result for all samples associated with the plate. Licensed Reviewed and Technical Review Datetime are set to "None".	Change any Technical Review results BEFORE results are submitted
RT-qPCR Results	Licensed result and Technical Review result is reset to "Undetermined" for all samples associated with the plate. All results values for all targets are reset to -1. Licensed Reviewed and Technical Review Datetime are set to "None". qpcr_file_received_datetime is set to "None".	Errors in results file, incorrect result file associated with QRP plate
RT-qPCR	QRP ID is removed and QPCR Datetime is set to "None". Licensed result and Technical Review result is reset to "Undetermined" for all samples associated with the plate. All results values for all targets are reset to -1. Licensed Reviewed and Technical Review Datetime are set to "None". qpcr_file_received_datetime is set to "None".	Remove QRP association from samples on a RWP
Plate Compression	The RWP ID is removed and the RWP and QRP wells are reset for all samples associated with the plate. QRP ID is removed and QPCR Datetime is set to "None". Licensed result and Technical Review result is reset to "Undetermined" for all samples associated with the plate. All results values for all targets are reset to -1. Licensed Reviewed and Technical Review Datetime are set to "None". qpcr_file_received_datetime is set to "None".	Reset plate compression for all REP associated with RWP, plates were incorrectly assigned at the compression step

RNA Elution	The REP ID and all lot numbers associated with samples on the plate are removed. RWP ID is removed and the RWP and QRP wells are reset for all samples associated with the plate. QRP ID is removed and QPCR Datetime is set to "None". Licensed result and Technical Review result is reset to "Undetermined" for all samples associated with the plate. All results values for all targets are reset to -1. Licensed Reviewed and Technical Review Datetime are set to "None". qpcr_file_received_datetime is set to "None".	REP was assigned to the incorrect SEP, incorrect lot numbers were entered or scanned
Sample Extraction	All data associated with the plate will be completely removed from INSPECT.  WARNING: This will also remove the pre-scan information, which cannot be restored except by a System Admin.	Incorrectly uploaded platemap, incorrect source or demographics, incorrect sample barcodes

- 27.5 Confirm troubleshooting on the following page, INSPECT will show information and counts for all samples and other possible associated plates. Note that all data displayed in this screenshot is testing data and not present in the INSPECT CLIA production database.

Selected Workflow Step and Plate ID

Workflow Step	Requeue Plate
Plate ID	EXC_SEP_000000
Plate Type	RT-qPCR Plate

Reason for Troubleshooting: Enter reason for troubleshooting here, this field must be filled in order to troubleshoot a plate.

Other Plates Associated With EXC\_SEP\_000000

Plate IDs	Total Sample Count
Sample Extraction Plates	0
RNA Elution Plates	0
RNA Compression Plates	0
RT-qPCR Plates	0

Review Selection

After reviewing the selected plate and associated sample information, confirm using the "Confirm" button at the bottom of the page.

**Selected Workflow Step and Plate ID**

Workflow Step	Requeue Plate
Plate ID	EXC_SEP_000000
Plate Type	RT-qPCR Plate
Reason for Troubleshooting	Enter reason for troubleshooting here, this field must be filled in order to troubleshoot a plate.

**Other Plates Associated With EXC\_SEP\_000000**

Plate IDs	Total Sample Count
Sample Extraction Plates	0
RNA Elution Plates	0
RNA Compression Plates	0
RT-qPCR Plates	0

**Review Selection**

You have selected to reset plate EXC\_SEP\_000000 to the Requeue Plate step. All data within plate EXC\_SEP\_000000 will remain unaffected and a copy of this plate will be maintained in Inspect. This plate will not be queued for Licensed Review and/or Result Submission (if already not queued). Refer the Plate Requeue tab on homepage to get the updated list of plates to be requeued. Do you want to proceed?

**Reset** **Confirm**

## 28 Troubleshooting (Admin troubleshooting and database management)

### 28.1 The Admin interface:

Admin sites are hidden and only accessible by Admin users. To access the admin site to display data tables, ask a staff user for the link to the admin interface. Users, groups, and data tables are accessible on the admin interface. The development instance (`inspect-training.ucsd.edu`) has the same data structures as the production database, but all users, groups, and data tables differ based on the database connection. Admin users may test any changes on the development server before applying them to the production server.

### 28.2 Restoring a plate that has been troubleshooted:

All plates that have been troubleshooted are stored in the `qpcr_test_troubleshoot` table. The entries may be restored by a staff user with access to the database back end only.

### 28.3 Updating demographics:

If sample demographics are not entered into the database when a sample is plated and the platemap file is uploaded to INSPECT, the demographics must be updated manually before results may be released. Samples may be edited through the admin interface by admin users.

## 28.4 Pulling results for research or queries:

The most straightforward way to pull any information from INSPECT is by using the search function. If results from the search function are unable to satisfy a lab or research query, samples may be queried from the Admin interface. Each of the data tables in INSPECT may be searched by their primary key and additional fields listed in the admin.py file in the django project. Tables are listed under the QPCR\_TEST database. Additional databases are also listed as headers:

The screenshot shows the INSPECT Admin site with the following structure:

- INSPECT Admin** (header)
- Site administration**
- ACCOUNTS**
  - User profiles** (with Add and Change buttons)
- AUTH TOKEN**
  - Tokens** (with Add and Change buttons)
- AUTHENTICATION AND AUTHORIZATION**
  - Groups** (with Add and Change buttons)
  - Users** (with Add and Change buttons)
- CELERY RESULTS**
  - Task results** (with Add and Change buttons)
- QPCR\_TEST**
  - No\_student\_employee\_id\_orders** (with Add and Change buttons)
  - Pis** (with Add and Change buttons)
  - Qpcr\_test\_troubleshoots** (with Add and Change buttons)
  - Qpcr\_tests** (with Add and Change buttons)
  - Sequencing\_sampless** (with Add and Change buttons)
  - Submission\_logss** (with Add and Change buttons)
  - Test\_orders** (with Add and Change buttons)
  - Unidentified\_tube\_barcodeess** (with Add and Change buttons)

Example of searching for a tube barcode in the qpcr\_test table admin page:

INSPECT Admin

Home > QPCR\_Test > QPCR\_TESTS

**ACCOUNTS**

- User profiles [+ Add](#)

**AUTH TOKEN**

- Tokens [+ Add](#)

**AUTHENTICATION AND AUTHORIZATION**

- Groups [+ Add](#)
- Users [+ Add](#)

**CELERY RESULTS**

- Task results [+ Add](#)

Select qPCR\_TEST to change

Search: EXC\_TEST\_Ix8J5gL | Search 1 result (1560 total)

Action:	ID	STUDENT ID	EMPLOYEE ID	TUBE BARCODE	SAMPLE RECEIVED DATETIME
<input type="checkbox"/>	4818	A15956538	10405824	EXC_TEST_Ix8J5gL	-

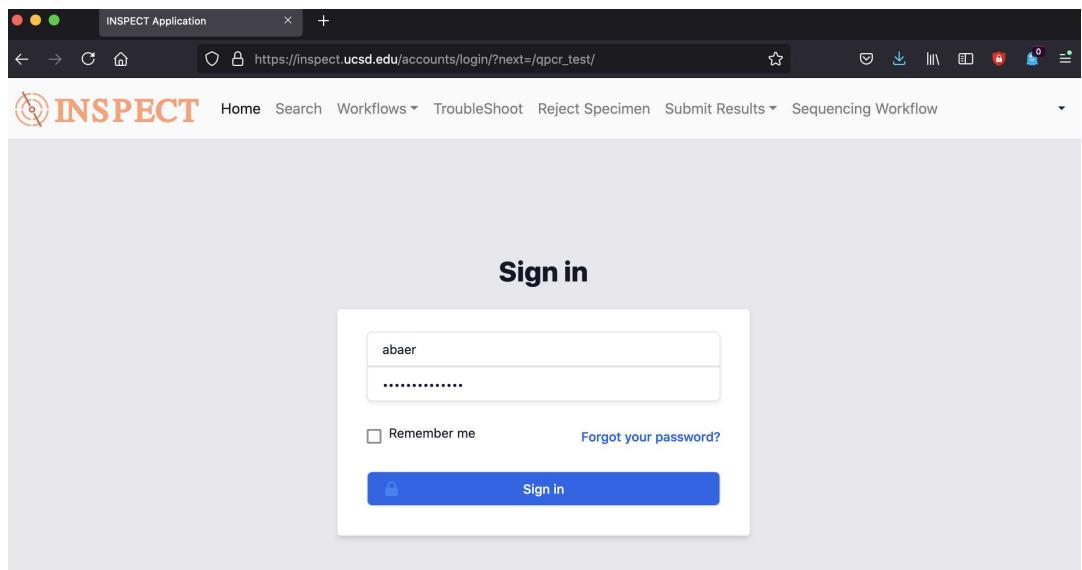
1 qPCR\_TEST

28.5

## User Login and Sample Tracking

### 29 User Login

- 29.1 All user activity requires a login and is recorded by the INSPECT system. Each user is tracked through their username for any action performed. Each individual user is tied to a trained member of the laboratory staff; shared logins are not allowed. Each user must be set up by an Admin after training has been completed. All logins are created by an Admin user. Only admin users can set or change passwords, so any password changes must be submitted to an Admin user. All login credential information must be sent via Secure email, please see the Admin section of this document for more details.
- 29.2 To log in, navigate to the index or home page for the INSPECT site [https://inspect.ucsd.edu/qPCR\\_test/](https://inspect.ucsd.edu/qPCR_test/) and enter your login credentials (note that the index page redirects to the login page as listed in the address bar below):



Note: The INSPECT system is only accessible on the UCSD protected network or via VPN connection. If you are unable to access INSPECT, please check your network status and contact an Admin user as needed.

### 30 Adding users to the database:

An Admin user can add additional users to the database. Generate a unique secure password for the user and input the user name and password in the fields and click "Save"

A screenshot of the 'DETECT Admin' application's 'Add user' form. The header shows 'WELCOME, ADAM. VIEW SITE / CHANGE PASSWORD / LOG OUT'. The breadcrumb navigation is 'Home > Authentication and Authorization > Users > Add user'. The form has a title 'Add user'. It contains fields for 'Username' (nbaer) and 'Password' (\*\*\*\*\*). Below the password field are validation messages: 'Your password can't be too similar to your other personal information.', 'Your password must contain at least 8 characters.', 'Your password can't be a commonly used password.', and 'Your password can't be entirely numeric.'. There is also a 'Password confirmation' field with a note: 'Enter the same password as before, for verification.' At the bottom right are three buttons: 'Save and add another', 'Save and continue editing', and a larger 'SAVE' button.

You will be prompted to add personal info, use a UCSD email for users whenever possible, and

can assign groups to the user as needed to access different parts of INSPECT. Do not assign a user superuser permissions. Staff users will only be assigned to trained system Admin users.

The screenshot shows the 'Personal Info' section with fields for First name (Adam), Last name (Baer), and Email address (nbaer@health.ucsd.edu). The 'Permissions' section includes a checked 'Active' checkbox (Designates whether this user should be treated as active. Unselect this instead of deleting accounts.), an unchecked 'Staff status' checkbox (Designates whether the user can log into this admin site.), and an unchecked 'Superuser status' checkbox (Designates that this user has all permissions without explicitly assigning them.). Below these are two lists for assigning groups: 'Available groups' (LabTechI, LabTechII, LabTechIII, LabTechV, LabTechVI) and 'Chosen groups' (empty). Buttons for 'Choose all' and 'Remove all' are at the bottom.

Groups are assigned to users needing the following functions:

A	B
LabTechI	LAs - Access all parts of the qPCR workflow up to technical review
LabTechII	LAs - Same as above, but access to troubleshoot plates, discard, and reassign storage boxes
LabTechIII	CLSS - Review and submit results
LabTechV	Sequencing users
LabTechVI	Pre-scan barcodes only

Do not assign any additional user permissions, access to INSPECT functions and admin functions are all controlled by groups and staff user designation. Click the "Save" button at the bottom of the form to add the information and group(s) to the user.

## 31 Sample Tracking (Index page)

- 31.1 After successful login, the index page loads displaying the navigation bar on the top, the workflow selections on the left bar and Sample Tracking and Summary information in the center. Your username will be displayed on the right top corner, clicking the arrow next to it will allow you to log out.

The screenshot shows the INSPECT Application interface. On the left, there are three workflow options: "Standard qRT-PCR Workflow", "PE qRT-PCR Workflow", and "CLS Dashboard", each represented by a circular icon with a plus sign. To the right, the main area displays the "INSPECT" logo with the tagline "Instant Service Platform for Emergency COVIDTests". Below the logo is the "Overall Testing Summary" table:

Number of Samples	Number of Positives	Number of Negatives	Samples To Be Requested	Plates To Be Requested
401605	8784 (2.19%)	377466 (93.99%)	3	0

Below the summary is the "Daily Sample Summary" table:

Number of Samples	UCSD	Private Schools	SASEA	SDFD	Other
218	216	2	0	0	11

At the bottom is the "Plate Tracker" table:

Step Name	Number of Samples in Step	Number of Plates Already Evaluated	Evaluated Plate IDs
Sample Extraction Plate (SEP)	389	5	EXC_SEP_005137, EXC_SEP_005138, EXC_SEP_005136, EXC_SEP_005140, EXC_SEP_005139
RNA Elution Plate (REP)	0	0	EXC REP_005140, EXC REP_005137, EXC REP_005138, EXC REP_005136, EXC REP_005139
RNA Working Plate (RWP)	389	3	E0000095, E0000096, E0000097

- 31.2 The Overall Testing Summary table shows all sample data from the INSPECT database. This includes the total number of samples run, the number of negative and positive samples, and the list of samples and plates to be requeued. Clicking on the Samples To Be Requeued or Plates To Be Requeued button will give a list of the samples or plates marked to be requeued.

Example of plates to be requeued:

## Plates To Be Requeued

X

SEP ID	Sampling DateTime
EXC_SEP_005357	Aug. 12, 2021, 6:07 p.m.
EXC_SEP_005360	Aug. 13, 2021, 7:29 p.m.
EXC_SEP_005364	Aug. 13, 2021, 5:48 p.m.

Close

Example of samples to be requeued:

## Samples To Be Requested

Tube Barcode	SSB	SEP ID	SEP Well	Sampling DateTime
EXC_MW4_447699	EXC_SEP_005405	EXC_SEP_005405	H8	Aug. 17, 2021, 6:48 p.m.
EXC_MW4_362905	EXC_SSB_005377	EXC_SEP_005377	E7	Aug. 14, 2021, 1:28 p.m.
EXC_MW4_447842	EXC_SEP_005405	EXC_SEP_005405	E11	Aug. 17, 2021, 6:48 p.m.
EXC_MW4_447360	EXC_SSB_005407	EXC_SEP_005407	C6	Aug. 17, 2021, 6:48 p.m.
EXC_MW4_365250	EXC_SSB_005377	EXC_SEP_005377	A1	Aug. 14, 2021, 1:28 p.m.
EXC_MW4_447228	EXC_SEP_005405	EXC_SEP_005405	C8	Aug. 17, 2021, 6:48 p.m.

- 31.3 The Daily Sample Summary displays the samples from today and what sources they have associated.

NOTE: The sample sources listed in this table are taken from the lab pre-scans, so the totals are meant to be a reference and may not encompass all samples processed by the lab on a given day.

## Daily Sample Summary

Number of Samples	UCSD	Private Schools	SASEA	SDFD	Other
0	0	0	0	0	0

- 31.4** The Plate Tracker table displays plates processed in the last 2 days. This tracker helps the lab keep track of which plates have been run for each step and track any plate failures or requeues.

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Plate Tracker			
Step Name	Number of Samples in Step	Number of Plates Already Evaluated	Evaluated Plate IDs
Sample Extraction Plate (SEP)	389	5	EXC_SEP_005137, EXC_SEP_005138, EXC_SEP_005136, EXC_SEP_005140, EXC_SEP_005139
RNA Elution Plate (REP)	0	0	EXC REP_005140, EXC REP_005137, EXC REP_005138, EXC REP_005136, EXC REP_005139
RNA Working Plate (RWP)	389	3	E0000095, E0000096, E0000097
RT-qPCR Plate (QRP)	389	3	H3U0A06F, H3U0A09J, H3U0A06H
Cleared Data	319	-	-

## Version Control

### 32 CodeCommit Version Control

- 32.1** All INSPECT code is stored on the AWS CodeCommit version control module. Please see the [CodeCommit User Guide](#) for more information about use and commands. Only Admin users will have AWS console access. To gain console access, contact an Admin user and include AWS application support staff as applicable.

- 32.2** Each INSPECT application is stored as a separate repository. The repositories will have branches for any changes made based on projects or updates. The latest version of the Master branch will store the code currently in on the production server. Other branches will be merged with the Master only after testing and approval.

- 32.3** All updates must be tested before deploying. Coding review is not required, but it is recommended that [best coding practices](#) for Django are followed.

### 32.4 Update procedure

- Proposed updates coded by the development team and applied tested on development servers only. Code is stored in the CodeCommit repository under a development branch while being developed.

2. A validation procedure will be created and written with test cases for testing the update and any components affected.
3. The validation procedure must be approved before testing by a CLS or the lab director.
4. Testing is performed according to the approved validation protocol by the designated tester.
5. Results and necessary supporting information is reviewed and must be signed off by a CLS or the lab director.
6. The code is updated on the production server by a designated admin user.

## INSPECT Updates

### 33 Procedure to Qualify Updates to the INSPECT system

- 33.1 Proposed updates coded by the development team and applied tested on development servers only. Code is stored in the CodeCommit repository under a development branch while being developed.
- 33.2 Once the code updates have been developed and tested on the development servers/systems, follow steps in INS-003 Clinical Laboratory Equipment for Performance Qualification. If applicable, forms INS-003-F2, F3, and F4 may be used to record the qualification procedure. All qualification or validation procedures must be approved and signed off by a CLS, Quality Assurance officer, or the Laboratory Director before qualification may begin.
- 33.3 Test cases for any added components must be created and performed to qualify any added components. If any existing components are modified, test cases must be created to ensure all connected components will function properly after the update is applied.

Note: components affecting the standard (thermo) workflow may or may not affect the PE workflow and vice versa. Please be sure to test the appropriate workflow or both workflows as necessary.

### 34 Testing system critical components

- 34.1 The following steps are a guide to testing the core or critical components of INSPECT. These steps may be taken to test end-to-end sample processing to ensure INSPECT functions correctly after an update.

These steps are NOT intended to be a full validation of the INSPECT system and all components, but can be used to qualify updates made to the production server or the core system of INSPECT. Additional components can include, but are not limited to, rejecting specimen, troubleshooting plates, and searching results.

Samples used for these steps can be the same samples for each step for end-to-end qualification. If testing on a development server, use only testing data to avoid any PHI or PII on the development servers.

Unless testing involves components that assign well positions or other updates that would require testing a whole plate or multiple plates, partial plates may be used for testing.



Expected results are listed after each test, be sure to include screenshots for evidence of execution and results for each step.

### 34.2 Pre-scan barcodes:

Add a list of barcodes to the database using the pre-scan function. Select a pre-scan source from the drop down.



Expected Results: Ensure all samples are recorded into the database by using the search function (can search by date). Check that the expected pre-scan source and the date and time were accurately added to the samples pre-scanned.

### 34.3 Upload platemap(s):

Generate a testing platemap csv file and enter your name and the Hamilton ID. Select a source from the drop down to assign a source to all samples on the plate not identified in the databases. Upload a Visionmate plate and enter the Visionmate ID, if applicable.

Be sure that all samples on the platemap are present in the UCSD student app or INSPECT Forms database, or the test order data table (orders from Redox partners). Any samples not identified in the databases will not have an associated source field and cannot proceed to result reporting steps (which may be preferred, depending on testing).



Expected Results: The samples from the platemap have been assigned the expected sources and have been assigned the SEP plate ID and

Equipment IDs and name entered.

Note: up to 4 platemaps can be compressed on to the 384 well plate in the RWP step.

#### 34.4 Assign the REP platemap(s):

Link a testing REP platemap to the testing SEP. Enter lot and ID information for all fields. Make sure all instrument IDs are valid equipment IDs.



Expected Results: The samples from the SEP have been assigned the expected REP plate ID and have been assigned the SEP plate ID and Equipment IDs and name entered.

#### 34.5 Assign REP plates to a compression plate:

Up to 4 REP plates can be compressed into 1 RWP. For testing, use as many testing REPs as are necessary. Make sure to enter a valid EpMotion ID.



Expected Results: All samples from all REP plates have been assigned the expected RWP and EpMotion ID.

Note: if the tested update involves changing the way the plates or wells are assigned, be sure to also check that the appropriate wells are assigned to each sample.

#### 34.6 Link the RWP to a qRT-PCR Reaction Plate:

Enter lot and ID information for all fields. Make sure all instrument IDs are valid equipment IDs. Enter the RWP plate ID and testing qRT-PCR plate ID.



Expected Results: The samples from the RWP have been assigned the expected qRT-PCR plate ID and have been assigned expected

equipment IDs and lot numbers.

### 34.7 Upload qPCR results:

Upload a testing qPCR results csv file. Make sure that the RT-qPCR plate ID in the file matches an existing RT-qPCR plate in INSPECT and that the results have not yet been uploaded, or the file will not be able to be uploaded.



Expected Results: The results from the results file are assigned to the correct samples by well position. This can be checked by comparing the results in the file to the technical review screen.

### 34.8 Technical Review:

Enter the barcode for the testing RT-qPCR plate.



Expected Results: The results for the samples from the RT-qPCR plate are displayed for review and the results match to the results file uploaded.

NOTE: Results files do not contain sample names so comparisons must be done by well position.

### 34.9 Additional components to INSPECT can be tested independently. All added components must be tested before being added to the production server and used for patient testing.

## INSPECT System Maintenance

### 35 System Backup and Recovery

#### 35.1 INSPECT system backup is handled by AWS. The system image is backed up

daily and can be restored from the AWS image. To restore an image of the INSPECT system from AMI contact a network admin and the AWS support team (currently Jit and team at ExperTech). Details on the AMI and recovery can be found here:

<https://docs.aws.amazon.com/AWSEC2/latest/UserGuide/AMIs.html> and here:  
<https://aws.amazon.com/backup-restore/>

- 35.2 If the INSPECT system is recovered from a backup or the codecommit repository, follow section 31, Testing system critical components to verify the system works as expected before processing any clinical samples.