TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	3/25/2021
Department:	Core Lab	**Due Date:**	4/25/2021

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Respiratory Panel with SARS CoV2 using QIAstat-Dx Analyzer SGMC.M1010 v9

Description of change(s):

Section	Reason
8.2	Added statement about archiving
19	Added add. 4 with archive instructions

This revised SOP will be implemented on April 6, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Respiratory Panel with SARS CoV2 using QIAstat-Dx Analyzer**
Prepared by	Leslie Barrett, Robert SanLuis Date: 3/29/2020
Owner	Ron Master Date: 3/29/2020

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Respiratory Pathogen Panel with SARS CoV2	QIAstat-Dx Analyzer	RVPNLS

Synonyms/Abbreviations
Respiratory panel, SARS CoV2

Department
Core Lab

2. ANALYTICAL PRINCIPLE

The QIAstat-Dx® Respiratory Panel is a multiplexed nucleic acid test intended for use with QIAstat-Dx system for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) eluted in universal transport media (UTM) obtained from individuals suspected of respiratory tract infections.
The following organism types and subtypes are identified using the QIAstat-Dx RP SARS-CoV-2: SARS-CoV-2, Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus A+B, Influenza A, Influenza A H1, Influenza A H3, Influenza A H1N1/pdm09, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus A+B, *Bordetella pertussis*, *Chlamydophila pneumoniae* and *Mycoplasma pneumoniae*.

The extraction, amplification, and detection of nucleic acids in the sample are performed automatically by the QIAstat-Dx Analyzer 1.0.

1. The liquid sample is homogenized and cells are lysed in the lysis chamber of the QIAstat-Dx RP SARS-CoV-2 Cartridge, which includes a rotor that turns at high speed.
2. Nucleic acids are purified from the lysed sample via binding to a silica membrane in the purification chamber of the QIAstat-Dx RP SARS-CoV-2 Cartridge in the presence of chaotropic salts and alcohol.
3. The purified nucleic acids are eluted from the membrane in the purification chamber and are mixed with the lyophilized PCR chemistry in the dried-chemistry chamber of the Respiratory Panel Cartridge.
4. The mixture of sample and PCR reagents is dispensed into the Respiratory Panel Cartridge PCR chambers, which contain lyophilized, assay-specific primers and probes.
5. The QIAstat-Dx Analyzer creates the optimal temperature profiles to carry out effective multiplex real-time RT-PCR and performs real-time fluorescence measurements to generate amplification curves.
6. The QIAstat-Dx Analyzer Software interprets the resulting data and process controls, and delivers a test report.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	Collect nasopharyngeal swab samples according to the swab manufacturer's recommended procedures and place the swab into Universal Transport Medium (UTM) or Viral Culture Medium (VCM).
Special Collection Procedures	None
Other	None

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Nasopharyngeal swab in transport medium None
Collection Container	Swab in transport medium
Volume - Optimum **- Minimum**	NP swab in transport medium N/A
Transport Container and Temperature	NP swab in transport medium (UTM or VCM) at room temperature
Stability & Storage Requirements	Room Temperature: 4 hours
	Refrigerated: 3 days
	Frozen: 30 days
Timing Considerations	Not applicable
Unacceptable Specimens & Actions to Take	• Any specimen, which does not meet the above criteria • Follow specimen rejection process
Compromising Physical Characteristics	Not applicable
Other Considerations	None

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
QIAstat-Dx RP SARS-CoV-2 (6 cartridges and 6 transfer pipettes)	QIAGEN, Cat. No. 691223

4.2 Reagent Preparation and Storage

Reagent	QIAstat-Dx RP SARS-CoV-2
Container	Individually wrapped cartridges and pipettes
Storage	15-25C
Stability	Until expiration date on package
Preparation	None Do not remove the Cartridges or transfer pipettes from their individual packaging until actual use.

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Internal Control	Cartridge component
QIAstat-Dx RP SARS-CoV-2 Control Panel, contains: • QIAstat-Dx RP Positive A QIAstat-Dx RP Positive B1 • QIAstat-Dx RP Negative	Maine Molecular Quality Controls, Inc., M360

6.2 Control Preparation and Storage

External Controls	**QIAstat-Dx RP SARS-CoV-2 Control Panel** **Note**: Only the vials of Positive A and B1 are used. These contain a mixture that yields positive and negative results for each of the target organisms. The RP Negative control is discarded.
Preparation	Allow to come completely to room temperature (18-25°C) Use the control as provided. **DO NOT DILUTE**. Immediately before use, mix the control thoroughly by inverting several times and tap the tube several times on the bench to remove any control caught in the cap before opening the tube.

Storage/Stability	Frozen at -20°C or colder Unopened material is stable through the expiration date when stored frozen. Each control vial is single use, discard after use. Positive A and B1 controls are slightly cloudy.

6.3 Frequency

Internal positive control performed with each test.

External controls are performed with each new kit lot number or shipment or every 31 days, whichever is more frequent.

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits
The QIAstat-Dx RP SARS-CoV-2 Cartridge includes a full process Internal Control which is titered MS2 bacteriophage. The MS2 bacteriophage is a single-stranded RNA virus that is included in the cartridge in dried form and is rehydrated upon sample loading. This Internal Control material verifies all steps of the analysis process, including sample resuspension/homogenization, lysis, nucleic acid purification, reverse transcription and PCR.

B. Criteria for Acceptable QC
- The internal control must produce a result of 'passed'.
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

C. Corrective Action
- Failed control = negative signal of the Internal Control does not negate any positive results for detected and identified targets, but it does invalidate all negative results in the analysis. Repeat the testing using a new QIAstat-Dx RP SARS-CoV-2 Cartridge.
- All rejected runs must be effectively addressed and include the following documentation:
    - Actions taken
    - Statement of what was done with the patient samples from the affected run/batch,
    - Date and initials of the person recording the information.
- Patient samples in failed analytical runs must be reanalyzed.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

- Record all Quality Control results (failed and successful) manually or electronically. Refer to Related Documents for manual QC forms.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

QIAstat-Dx Analyzer with software

7.2 Equipment

- Computer, monitor, printer, and required application software
- Biological Safety Cabinet

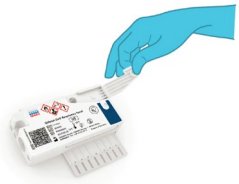
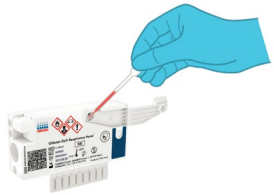
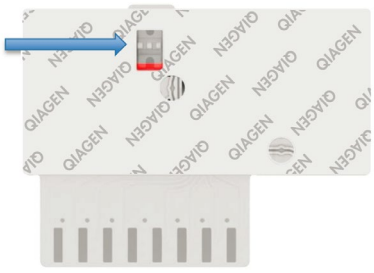
7.3 Supplies

QIAstat-Dx Respiratory SARS-CoV-2 Panel **Catalog no.** **Number of tests**	 **691223** **6**
QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge*	6
Transfer pipettes†	6

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Preparation of Cartridge
1.	Remove the Respiratory Panel Cartridge from the packaging and position it so that the QR code on the label faces you.

8.1	Preparation of Cartridge
	Note: After the package is open, sample should be added to the cartridge and loaded into the Analyzer within 2 hours.
2.	Place an LIS label or manually write patient identifiers on the top of the cartridge. Make sure that the label is properly positioned and does not block the lid opening. 
3.	Open the sample lid of the main port on the front of the cartridge. 
4.	Mix the sample by inverting 5-6 times. Using the supplied transfer pipette, draw up sample to the third fill line on the pipette (i.e., 300 µL). Transfer sample into the main port of the cartridge. **Note**: do not aspirate any air or beads (if Copan UTM tube) 
5.	Close the cartridge lid until it clicks.
6.	**Visually confirm that the sample has been loaded by checking the sample inspection window of the cartridge. Gently tap the cartridge while observing for bubbles**. **Note**: cartridge must be loaded onto analyzer within 90 min. 

8.2	Test Run
1.	Turn on the analyzer. Status indicators will turn blue

8.2	Test Run
2.	Wait until the Main screen appears and the status indicators turn green and stop blinking. Log in with user name and password.
3.	Press the Run Test button in the top right corner of the touchscreen
4.	When prompted, scan the LIS bar code located on the top of the cartridge, using the integrated front bar code reader of the QIAstat-Dx Analyzer.  **Notes**: • Sample ID can be manually entered using the virtual keyboard of the touchscreen by selecting the Sample ID field. • Instructions from the analyzer appear in the Instructions Bar at the bottom of the touchscreen.
5.	When prompted, scan the bar code of the cartridge. The analyzer automatically recognizes the assay to be run based on the cartridge bar code. **Note**: the analyzer will not accept expired or previously used cartridges. An error message will display.
6.	The Confirm screen will appear. Review the entered data and make any necessary changes by selecting the relevant fields on the touchscreen and editing the information. Press Confirm when all the displayed data are correct. If needed, select the appropriate field to edit its content, or press Cancel to cancel the test
7.	Verify the swab port and main port lids of the cartridge are firmly closed. When the cartridge entrance port on the top of the analyzer automatically opens, insert the cartridge with the bar code facing to the left and the reaction chambers facing down.  **Note:** There is no need to push the Cartridge into the analyzer. Position it correctly into the cartridge entrance port and the analyzer will automatically move the cartridge into the Analytical Module.

8.2	Test Run
8.	Once the analyzer detects the cartridge, it will automatically close the lid of the cartridge entrance port and start the test run. **Notes:** • The analyzer will not accept a cartridge other than the one used and scanned during the test setup. If another cartridge inserted, an error will be generated and the cartridge will be automatically ejected. • Up to this point, it is possible to cancel the test run by pressing the Cancel button in the bottom right corner of the touchscreen. • Depending on the system configuration, the operator may be required to re-enter their user password to start the test run. • The lid of the cartridge entrance port will close automatically after 30 seconds if a cartridge is not positioned in the port. If this occurs, repeat from step 6.
9.	While the test is running, the remaining run time is displayed on the touchscreen.
10.	After the test run is completed, the Eject screen will appear and the Module status bar will display the test result as one of the following options: TEST COMPLETED: The test was completed successfully TEST FAILED: An error occurred during the test TEST CANCELED: The user canceled the test
11.	Press Eject on the touchscreen to remove the cartridge and dispose into biohazardous waste. **Note:** If a cartridge gets stuck in the instrument, use these steps to free if – • turn the instrument off in the back using the toggle switch  • leave instrument off for 1 full minute • toggle the switch to turn it on in the back • turn the computer back on in the front
12.	The results Summary screen will appear. Refer to section 10 for further details. To begin the process for running another test, press Run Test.
13.	If the analyzer is slow to respond to prompts, archiving should be performed. Refer to addendum 4 for detailed process.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

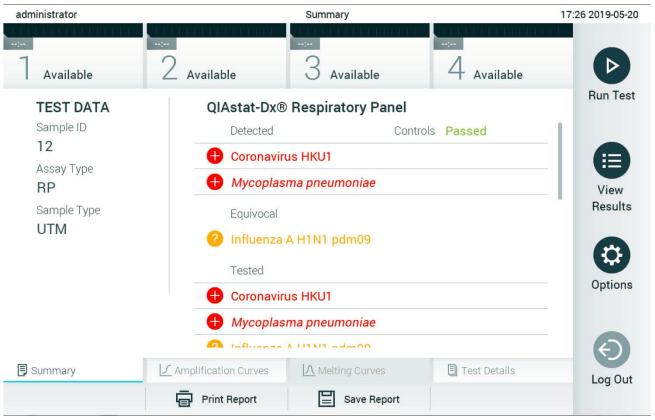
9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The QIAstat-Dx Analyzer 1.0 automatically interprets and saves test results. After ejecting theCartridge, the results Summary screen is automatically displayed.



The main part of the screen provides the following three lists and uses color-coding and symbols to indicate the results:

1. The first list includes all pathogens detected and identified in the sample, preceded by a + **(plus)** sign and are colored red.
2. The second list includes all equivocal pathogens, preceded by a yellow question mark ?, in the event any of the subtypes H1, H3 and/or H1N1 pdm09 are detected and identified in the sample, but Influenza A is not detected.
3. The third list includes all pathogens tested in the sample. Pathogens detected and identified in the sample are preceded by a red + sign. Pathogens that were tested but not detected are preceded by a green – (**minus**) sign. Equivocal pathogens are preceded by a yellow ? mark.

Outcome	Result	Description
Positive	pos	At least one pathogen is positive
Positive with warning	pos*	At least one pathogen is positive but the Internal Control failed
Negative	neg	No pathogens were detected
Failed	fail	The test failed because either an error occurred or the test was canceled by the user
Successful	suc	The test is either positive or negative, but the user does not have the access rights to view the test results

Notes:
Pathogens detected and identified in the sample are shown in all lists.

If the test failed to complete successfully, a message will indicate "Failed" followed by the specific Error Code.

Printing results:
No need to print the results when results are interfacing.

From the Instrument

- On the instrument select view result list.
- Select the result to view.
- Select Print Report.

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.6 Repeat Criteria and Resulting

IF the result is …	**THEN…**
Negative for any organism	Report as "Not Detected"
Positive	Report as "Detected"
Positive for *Bordetella pertussis*	Retest sample using the BioFire RP2.0 panel. If the BioFire *B. pertussis* target is positive, report *B. pertussis* as "Detected". If the BioFire *B. pertussis* target is negative, report *B. pertussis* as "Not Detected'.
If seasonal Influenza A H1 strain is detected, results will post for Influenza A and a second one for H1 strain (acceptable if only the H1 signal is obtained, which would be indicated as "equivocal")	Instrument Reports "Equivocal"

IF the result is …	THEN…
If seasonal Influenza A H3 strain is detected, results will post for Influenza A and a second one for H3 strain (acceptable if only the H3 signal is obtained, which would be indicated as "equivocal")	Instrument Reports "Equivocal"
If a pandemic Influenza A/H1N1/2009 strain is detected, results will post for Influenza A and a second one for H1N1/2009 (acceptable if only the H1N1/2009 signal is obtained, which would be indicated as "equivocal")	Instrument Reports "Equivocal"
If only the Influenza A signal is obtained, which would be indicated as "Influenza A (no subtype detected)".	Instrument Reports "Influenza A (no subtype detected)"
Positive with warning	Repeat testing with new cartridge
Failed	Repeat testing with new cartridge

***** The panel is designed to detect Influenza A as well as Influenza A subtype H1N1/2009, Influenza A subtype H1 or Influenza A subtype H3.

Note: If only an Influenza A signal is present and no additional signal for any of the subtypes is generated, it can be due to either low concentration or, in very rare cases, a new variant or any Influenza A strain other than H1 and H3 (e.g., H5N1, which can infect humans).

Message	Code
Detected	DET
Not Detected	NTD

If instrument is interfaced with Sunquest, use function **OEM** to view and release results.

Shift: Press Enter
Device: Type in **WOQDX** (White Oak) **or SQDX** (Shady Grove)
Refer to **Addendum 1 f**or additional information on interfaced results.

During interface downtime:

- Record results on QIAstat Dx RP SARS-CoV-2 Panel Patient Result Form.
- Use Sunquest GUI Result Entry to report patient results – See **Addendum 2**.

11. EXPECTED VALUES

11.1 Reference Ranges

Not Detected

11.2 **Critical Values** (infectious disease purposes)

SARS-CoV-2 (COVID 19) Detected *(inpatients and WOMC ED only)*

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

The detection and identification of specific viral and bacterial nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information.
The results of this test should not be used as the sole basis for diagnosis, treatment or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by the test or lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. Positive results do not rule out coinfection with other organisms: the agent(s) detected by the QIAstat-Dx RP SARS-CoV-2 may not be the definite cause of disease. Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

13. PROCEDURE NOTES

- **FDA Status: For Use Under an Emergency Use Authorization (EUA) Only**
- **Validated Test Modifications: None**

- Results from the QIAstat-Dx RP SARS-CoV-2 are not intended to be used as the sole basis for diagnosis, treatment or other patient management decisions.
- The performance of this test has not been established for immunocompromised individuals.
- The performance of this test has not been established for patients without signs and symptoms of respiratory infection.
- Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx RP SARS-CoV-2. The agent detected may not be the definitive cause of the disease.
- Negative results do not preclude infection of the upper respiratory tract. Not all agents of acute respiratory infection are detected by this assay and sensitivity in some clinical settings may differ from that described in the package insert.
- A negative result with the QIAstat-Dx RP SARS-CoV-2 does not exclude the infectious nature of the syndrome. Negative assay results may originate from several factors and their combinations, including sample handling mistakes, variation in the nucleic acid sequences targeted by the assay, infection by organisms not included in the assay, organism levels of included organisms that are below the limit of detection for the assay and use of certain medications, therapies or agents.
- The QIAstat-Dx RP SARS-CoV-2 is not intended for testing of samples other than those described in these Instructions for Use. Test performance characteristics have been established only with nasopharyngeal swab samples collected in universal transport media (UTM), from individuals with acute respiratory symptoms.
- The QIAstat-Dx RP SARS-CoV-2 is intended to be used in conjunction with standard of care culture for organism recovery, serotyping and/or antimicrobial susceptibility testing where applicable.
- The results from the QIAstat-Dx RP SARS-CoV-2 must be interpreted by a trained healthcare professional within the context of all relevant clinical, laboratory and epidemiological findings.

- The QIAstat-Dx RP SARS-CoV-2 can be used only with the QIAstat-Dx Analyzer 1.0.
- The QIAstat-Dx RP SARS-CoV-2 is a qualitative assay and does not provide a quantitative value for detected organisms.
- Viral and bacterial nucleic acids may persist in vivo, even if the organism is not viable or infectious. Detection of a target marker does not imply that the corresponding organism is the causative agent of the infection or the clinical symptoms.
- Detection of viral and bacterial nucleic acids depends on proper sample collection, handling, transportation, storage and loading into the QIAstat-Dx RP SARS-CoV-2 Cartridge. Improper operations for any of the aforementioned processes can cause incorrect results, including false-positive or false-negative results.
- The performance of this test has not been established for screening of blood or blood products.
- The performance of this test has not been established in individuals who received influenza vaccine. Recent administration of a nasal influenza vaccine may cause false positive results for Influenza A and/or Influenza B.
- The QIAstat-Dx RP SARS-CoV-2 may not be able to distinguish between existing viral strains and new variants as they emerge. For example, the QIAstat-Dx RP SARS-CoV-2 can detect seasonal H3N2 Influenza but may not be able to distinguish seasonal H3N2 from H3N2 variant (H3N2v).
- The QIAstat-Dx RP SARS-CoV-2 detects the multi-copy IS481 insertion sequence present in multiple Bordetella species. False positive B. pertussis results are possible if the specimen is contaminated with non-pertussis Bordetella species.
- The assay sensitivity and specificity, for the specific organisms and for all organisms combined, are intrinsic performance parameters of a given assay and do not vary depending on prevalence. In contrast, both the negative and positive predictive values of a test result are dependent on the disease/organism prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence is moderate or low.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

None of the substances tested showed inhibition, except for the nasal influenza vaccines. This was due to the fact that the selection of substances concentration was higher than the concentrations expected to be present in a sample. In addition, nasal influenza vaccines (Fluenz Tetra and FluMist®) were predicted to be reactive with the QIAstat-Dx RP SARS-CoV-2 Influenza A (subtype) and Influenza B assays. Final dilution without observable interfering effect was 0.000001% v/v for both vaccines.

Refer to QIAstat RP SARS-CoV-2 Panel Instructions for Use (Handbook) 3/2020 for a complete list of substances tested.

14.4 Clinical Sensitivity/Specificity/Predictive Values

- The Analytical Sensitivity, or Limit of Detection (LoD), is defined as the lowest concentration at which ≥95% of the tested samples generate a positive call.
- The LoD for each QIAstat-Dx RP SARS-CoV-2 pathogen was assessed by analyzing serial dilutions of analytical samples prepared from high-titer stocks obtained from commercial suppliers (ZeptoMetrix® and ATCC®) or artificial samples for commercially unavailable target analytes.
- The LoD concentration was determined for a total of 51 pathogen strains. The LoD of the QIAstat-Dx RP SARS-CoV-2 was determined per analyte using selected strains representing individual pathogens that are possible to detect with the QIAstat-Dx RP SARS-CoV-2. To confirm the established LoD concentration, the detection rate of all replicates must be ≥95% (at least 19/20 replicates must generate a positive signal).
- At least three different cartridge lots and at least three different QIAstat-Dx Analyzers were used for LoD determination for every pathogen.

15. SAFETY

Refer to the safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

Cartridge contains: ethanol; guanidine hydrochloride; guanidine thiocyanate; isopropanol; proteinase K; t-Octylphenoxypolyethoxyethanol. Highly flammable liquid and vapor; harmful if swallowed or if inhaled. Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Contact with acids liberates very toxic gas. Corrosive to the respiratory tract. Keep away from heat/sparks/open flames/hot surfaces. Avoid breathing fumes.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor/ physician. Remove person to fresh air and keep comfortable for breathing.

16. RELATED DOCUMENTS

- Laboratory Quality Control Program
- Laboratory Safety Manual
- Safety Data Sheets (SDS)
- Specimen Acceptability Requirements (Lab policy)
- QIAstat Dx RP SARS-CoV-2 Control Panel Log (AG.F534)
- QIAstat Dx RP SARS-CoV-2 Panel Patient Result Form (AG.F506)
- QIAstat Dx RP SARS-CoV-2 Panel Internal QC Log (AG.F521)
- Qiagen QIAstat Dx Respirator SARS-CoV-2 Panel Individual Quality Control Plans (VC 667.2, VC 668.2)

17. REFERENCES

- QIAstat-Dx® Respiratory SARS-CoV-2 Panel, Instructions for Use (Handbook), QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden, 3/2020.
- Guidelines for Laboratory Verification of Performance of the QIAstat-Dx® Respiratory SARS-CoV-2 Panel, 3/2020.
- Package insert for QIAstat-Dx RP SARS-CoV-2 Control Panel, M360v1.1, Maine Molecular Quality Controls, Inc., May 2020

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1	4/3/20	6.1	Delete UTM as negative QC	R SanLuis	R SanLuis
		6.2	Revise preparation of external QC	R SanLuis	
		11	Change Neg/Pos to Not detected/Detected	R SanLuis	
		10.5, 16	Add patient result form	L Barrett	
		Add 1	Update worklist process, add call documentation	M Sabonis	
2	4/30/20	3	Add VCM	L Barrett	R Master
		6.2	Revise prep & stability for external QC	R SanLuis	
		10.5	Add interface result entry	L Barrett	
		19	Add addendum 2	L Barrett	
3	5/7/20	11.2, 19	Specify only applies to inpatients	L Barrett	R Master
4	5/19/20	6.5	Added reference to related documents	L Barrett	R Master
		8.2	Added steps to free a cartridge		
		10.6	Specified interface downtime process		
		16	Added Internal QC form		
5	8/18/20	6.1,6.2	Changed QC product	L Barrett	R Master
		10.6	Added *B. pertussis* confirmation and reporting; updated addenda numbers	R Master	
		16	Updated Control Panel log	L Barrett	
		17	Added QC insert	L Barrett	
		19	Reversed order of addenda	M Sabonis	
		Add. 1	Updated to hold results for any positives	M Sabonis	
		Add. 2	Added note for default results	M Sabonis	
6	9/10/20	6.3	Changed external QC frequency to match IQCP	L Barrett	R Master
		16	Added IQCP info	L Barrett	
		19	Added addendum 3	M Sabonis	
7	10/9/20	11.2, Add. 1	Added WOMC ED location for calling positive SARS-CoV-2 results	L Barrett	R Master

Version	Date	Section	Reason	Reviser	Approval
8	3/18/21	8.2	Added statement about archiving	L Barrett	R Master
8	3/18/21	19	Added add. 4 with archive instructions	L Barrett	R Master

19. ADDENDA

Addendum	Title
1	Sunquest Interfaced Result Entry
2	Sunquest GUI Result Entry - Respiratory Pathogen Panel
3	Replacing Ink Cartridges
4	QIAstat-Dx Analyzer Archive with Results Removal

Addendum 1

Sunquest Interfaced Result Entry

General information:

- The QIAstat is interfaced with Sunquest. It does NOT go through DI-Instrument Manager.
- Upon completion of testing, the results transmit to Sunquest. If needed you can print the results from the instrument.
- If ALL results are negative then the results will autofile into Sunquest and transmit to Cerner.
- If any of the tests are Positive, then ALL the tests for that accession number are held in Sunquest. (**Refer to section 10.6 if multiple results are positive and retest as needed**)
- Review results in Sunquest OEM as described below.

Reviewing and releasing results using Sunquest SmarTerm:

1. Access OEM
2. At DEVICE: prompt, type in Method code **WOQDX** (WOMC) or **SQDX** (SGMC).
3. Results will display cup by cup.
   - If ALL are negative, then those results auto-filed and require no action. Proceed to next cup.
   - For positive results that were held, continue with step 4 below.
   - Refer to *OEM - On Line Result Entry Method* procedure (LIS SOP) for additional information about review and release of results.

4. Positive (Detected) Results
   a. For all organisms except COVID, review and release results.
   b. For positive SARS CoV2 (COVID):
      - Results are **NOT** called to the SGMC ED (release without call documentation)
      - **Results are called for inpatients and WOMC ED**
      - Results will be tagged with CALL in Sunquest to indicate the result must be called and documented using proper format.
        Append CBACK documentation to results including who you called, date, time and tech code; then click Accept to release. Required format is:

        -CBACK-;full name of person called DATE TIME Tech code
        Example -CBACK-;Sue Smith 032420 1420 4568

5. Perform an OFC (Online File Cleanup) at least once per shift. This process cleans up the online data that was sent to Sunquest.
   a. In Sunquest (SmarTerm) access function OFC
   b. Type in the method code (WOQDX or SQDX).
   c. At the Start at Cup Number prompt, type in 1 and then press ENTER.
   d. At the Stop at Cup Number prompt, press ENTER.

Notes:

Fort Washington Medical Center (MR# starts with FWMC-)

- Call all results and document call in Sunquest.
- Fax results to FWMC (see FWMC requisition for specific details)

Howard University Hospital (MR# starts with HUH-)

- Call all results and document call in Sunquest.
- Fax results to HUH (see HUH requisition for specifics)

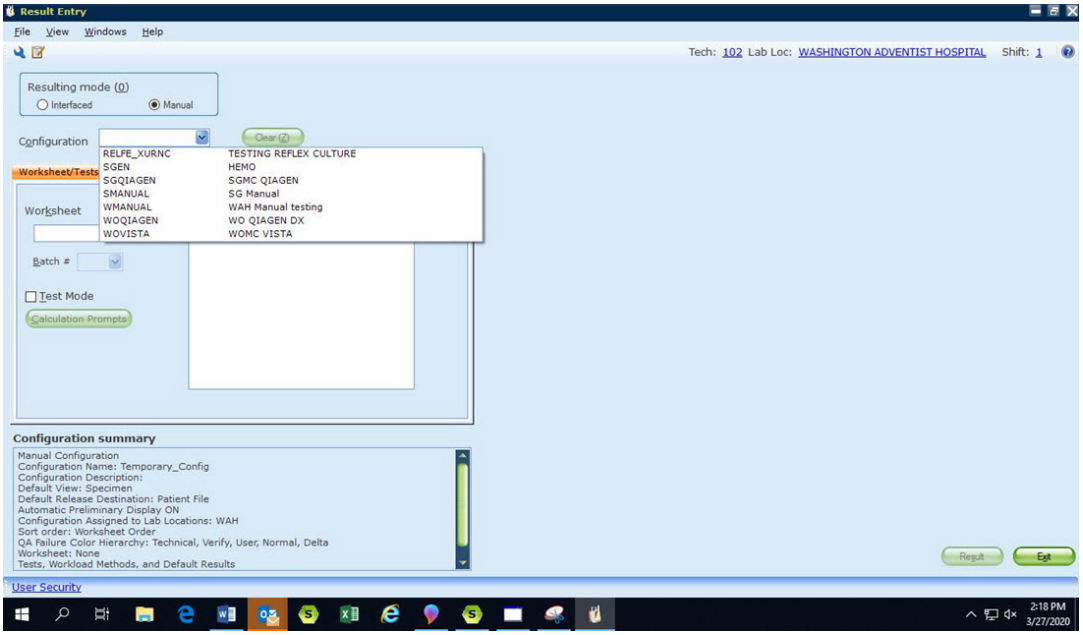
Addendum 2

Sunquest GUI Result Entry - Respiratory Pathogen Panel

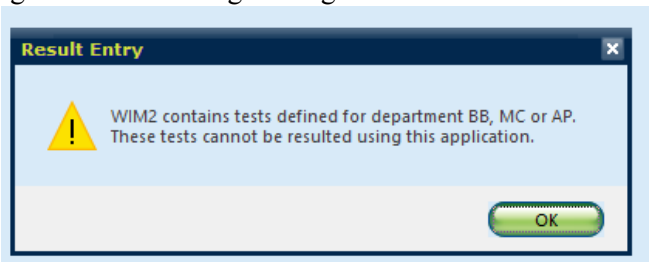
Note: The test profile is defined in the LIS with the default result of "Not Detected" for all the tests.

1. Click on **Result Entry** 

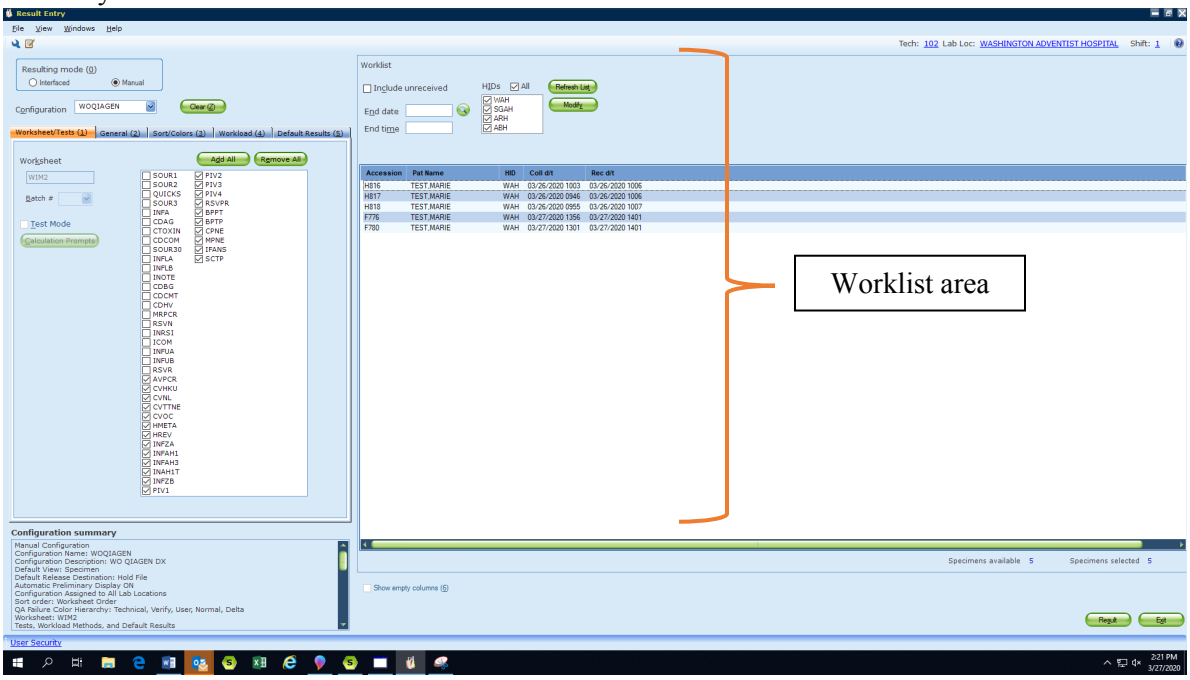
2. Select **Manual Resulting Mode**.
3. Select the configuration based on SITE and Instrument



4. Ignore the following message



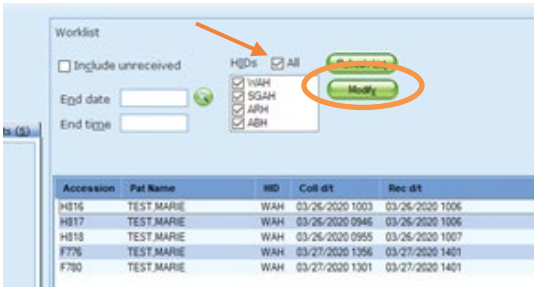
5. Anatomy of the screen



6. The Worklist area displays all the orders that have been received in the lab.

7. MODIFY the HID by Unclicking ALL. Next check the HIDs you want to result and then click on Refresh List.

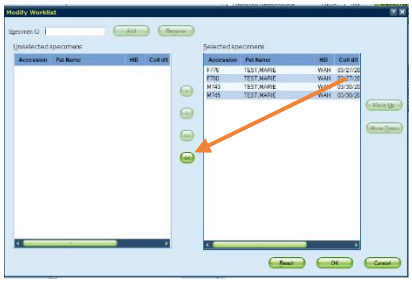
   SGMC - Click on SGAH and ARH
   WOMC - Click on WAH and ARH
   Note: ARH includes Rockville and Takoma Park
   ABH can be excluded since it is included in SGMC (SGAH)



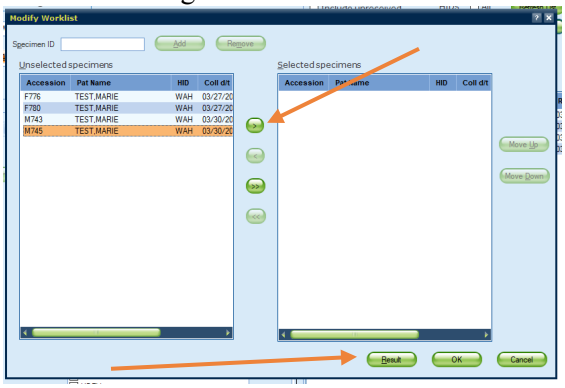
8. Modify Worklist to select the accession number that you are resulting.

   a. Click on Modify (see circle in above screen shot)

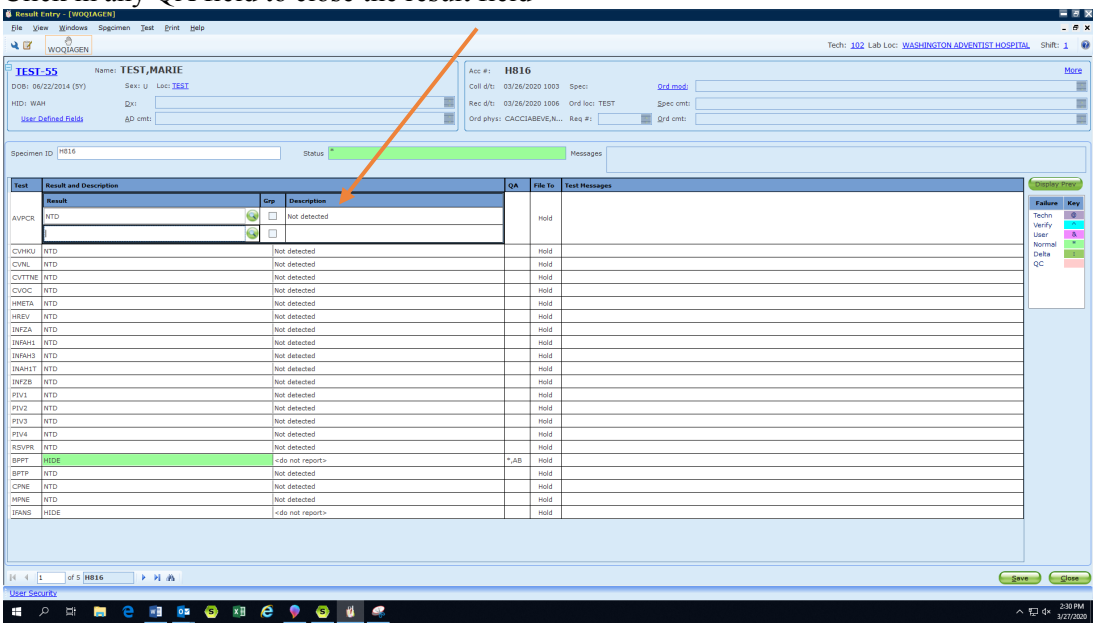
b. Move all the accession numbers over to the left pane by clicking on the double arrow << button



c. Highlight the Accession number that you want to result then click on arrow > button to move it back to the right side.

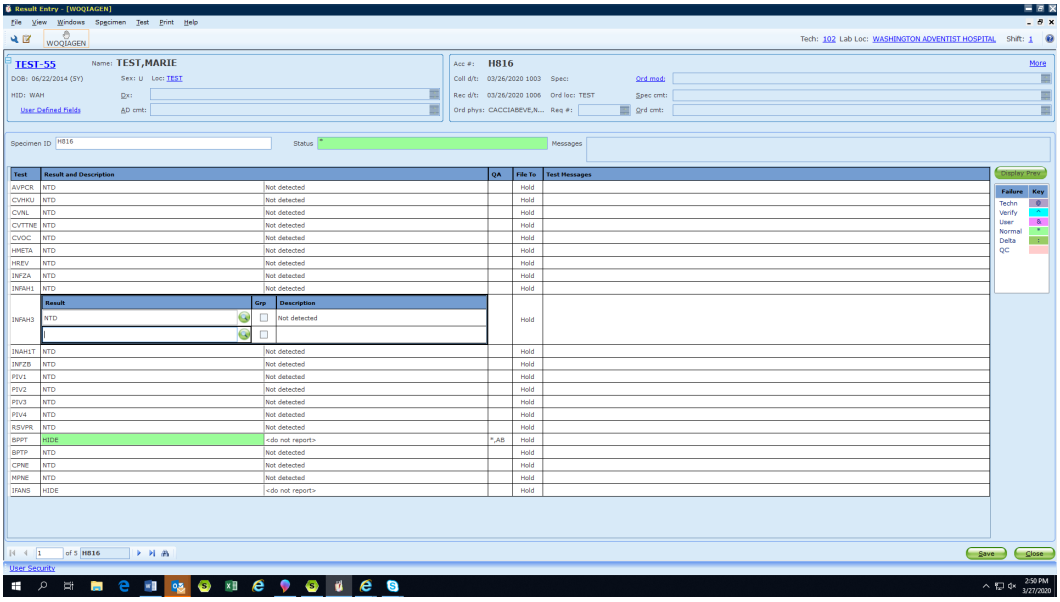


9. Click on ***RESULT*** at bottom right to proceed to resulting
10. Click in any QA field to close the result field



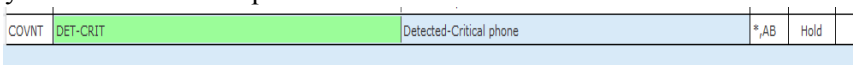
11. Note:
    a. The results of "NTD" are defaulted in.
    b. The "File To" column for all the tests displays "HOLD"
12. You can hover over the Test code and the description of the test displays

13. If you need to change a result. Click on the result for the test that you need to change.



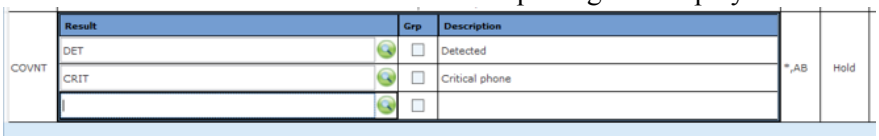
A. With your cursor in the result field., either use the backspace **or** highlight then press the Delete key to remove the result.
   a. Type in the result and then **TAB.**
   b. Cursor will then move to the next field below. If you don't have anything else to add for this test, click in any QA field.

B. If COVNT (SARS CoV2 PCR) is DETECTED on an inpatient, then the results must be called and documented in Sunquest. Once you change result to DET and press TAB, Sunquest will display comment "Critical phone"



COVNT	DET-CRIT	Detected-Critical phone	*,AB	Hold	

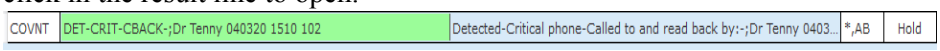
   a. Double click in result area and additional reporting line display.



	Result	Grp	Description		
COVNT	DET	☐	Detected	*,AB	Hold
	CRIT	☐	Critical phone		
		☐			

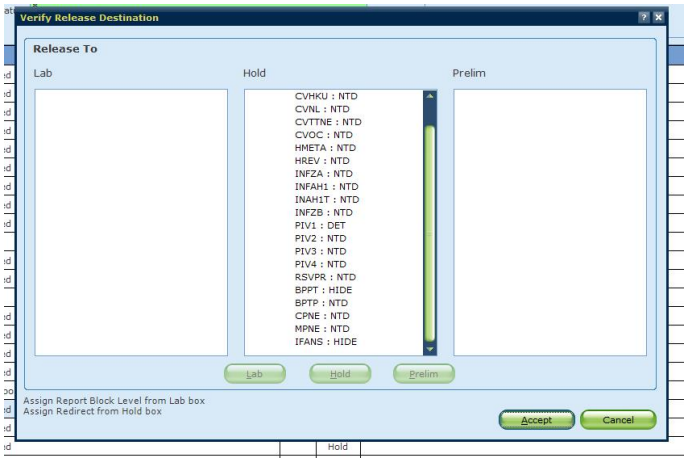
   b. In the field below CRIT, type in **CBACK** and then press the **TAB** key
   c. Another result line will display below CBACK. In this line, type the name of person who you spoke with, the date/time and your tech code using the format ;Name of person called date/time tech code. Press the TAB key when done.
      Note: CBACK and your documentation MUST be on two separate result lines. If they are on the same line, you will get an error message.

      Example: ;Dr Tenney 040320 1510 102
   d. Another result line displays. Press TAB to complete reporting. Review the screen to ensure that your documentation is present AND correct. If you have to correct it, double click in the result line to open.

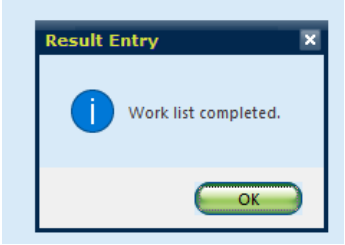


COVNT	DET-CRIT-CBACK-;Dr Tenny 040320 1510 102	Detected-Critical phone-Called to and read back by:-;Dr Tenny 0403...	*,AB	Hold

C. If there are no further changes, click on **SAVE**. "Verify Release Destination" appears to let you know where the results relased to. They should go to HOLD. Click **Accept** to move to next Accession number.

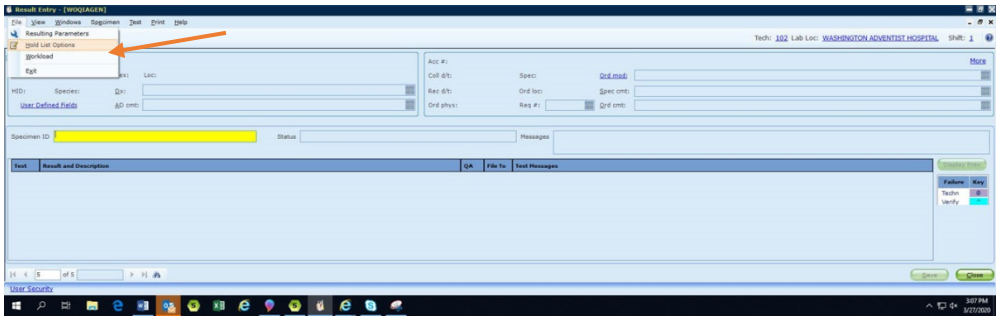


D. When complete, a Message displays that worklist is completed.

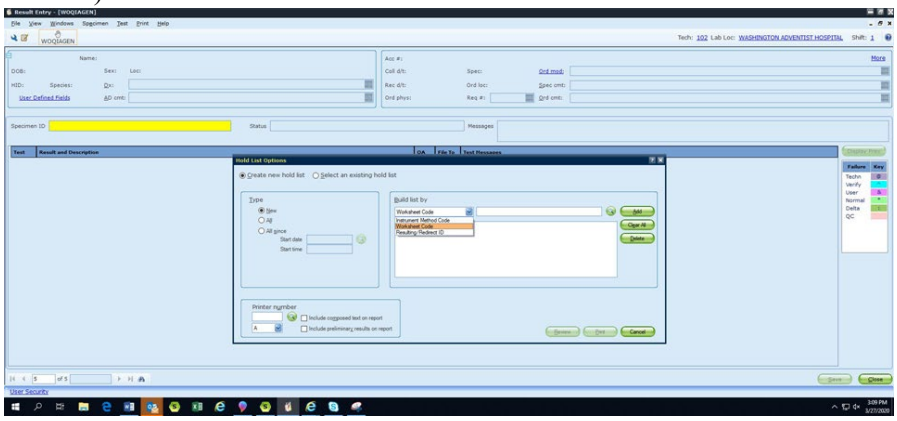


14. Releasing results from HOLD. This is used for second tech review of results prior to releasing them.

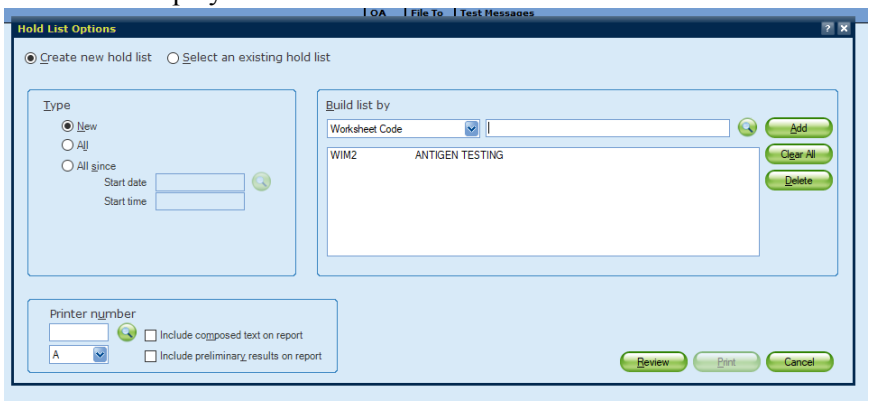
A. From the same Result Entry screen, click on **File** (upper ledt corner) and then select **HOLD LIST OPTION**



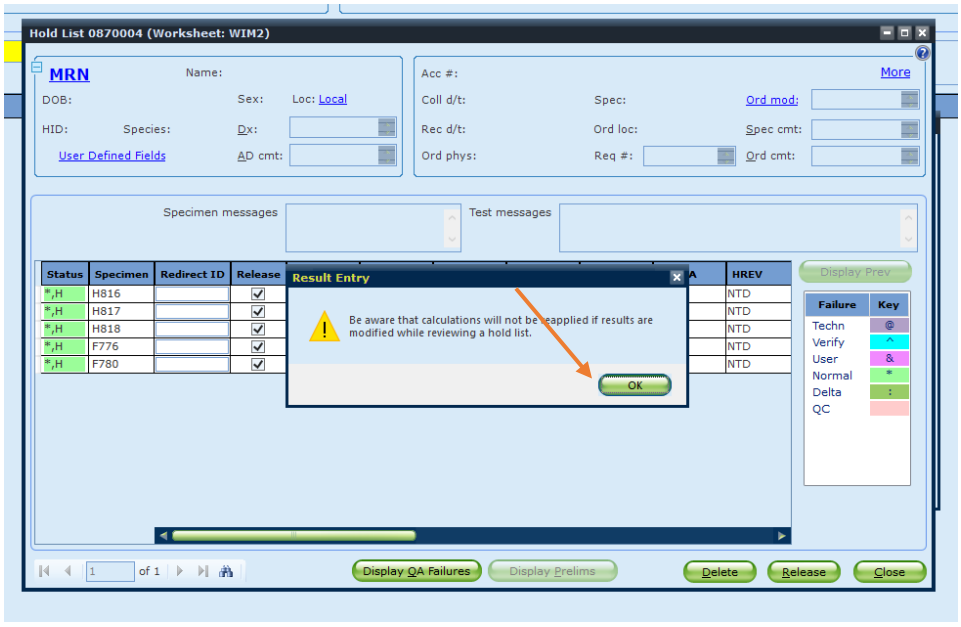
B. Build list by changing drop down to Worksheet Code and enter appropriate code (SIM2 or WOM2). Then click on **ADD**



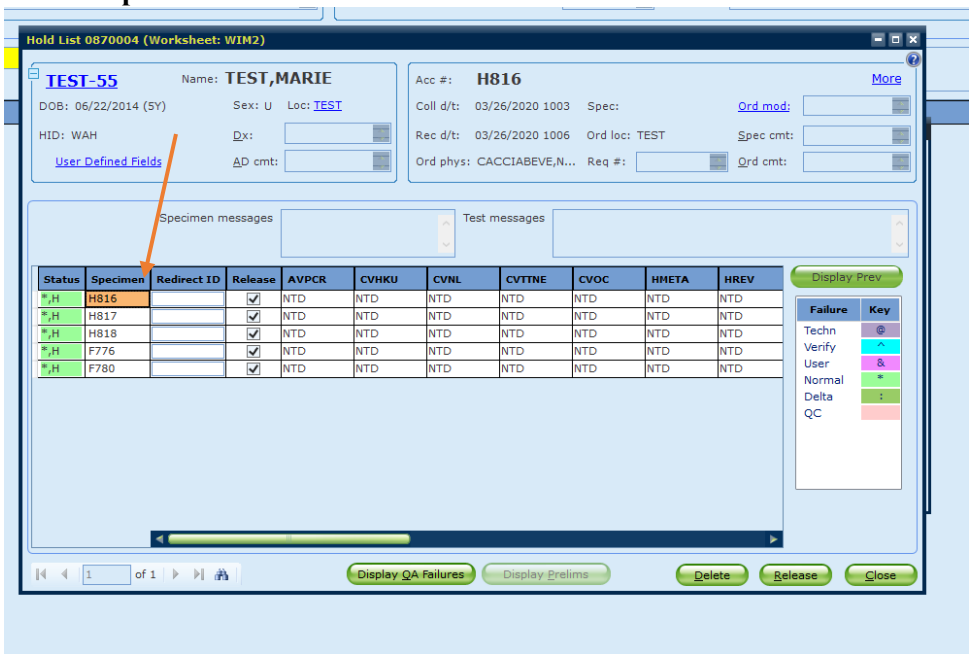
C. Worksheet displays. Click on **Review**.



E. Click on **Ok**



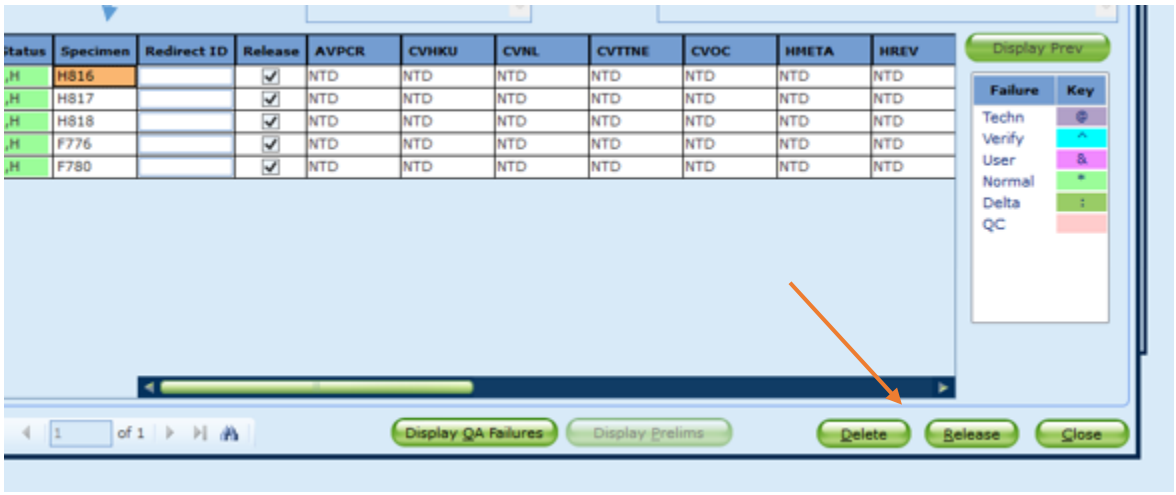
F. Click in **Specimen ID** field to close a result window.



G. Review results on screen with instrument printout. You can hover over the test headers to see the description of the test. Results display horizontally. Use the scroll bar to scroll to see more test/results, if applicable.

H. To modify a result, click on the result cell and make the applicable changes. Once done click on the Specimen column.

I. Click on RELEASE to release the results



Addendum 3

Replacing Ink Cartridges

Ink levels on HP Officejet pro 6230

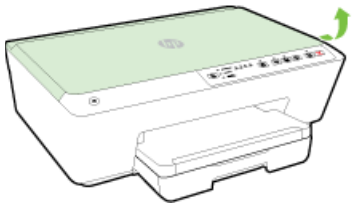
Front Panel:

Ink level alert indicators - lights up when ink is getting low or empty. Replace cartridge when print quality becomes unacceptable.

How to replace the ink cartridges

1. Make sure the printer is turned on.
2. Open the ink cartridge access door.

NOTE: Wait until the print carriage stops moving before proceeding.



3. Press the front of the ink cartridge to release it, and then remove it from the slot.

4. Remove the new ink cartridge from its packaging.


5. Using the color-coded letters for help, slide the ink cartridge into the empty slot until it clicks securely into the slot.



6. Make sure that you insert the ink cartridge into the slot that has the same colored letter as the color you are installing.

7. Repeat steps 3 through 5 for each ink cartridge you are replacing.

8. Close the ink cartridge access door.

Note:
Location of ink cartridges

- SGMC: Iron Mountain box below the Qiagen Instrument
- WOMC: Cabinet draw below printer

Addendum 4

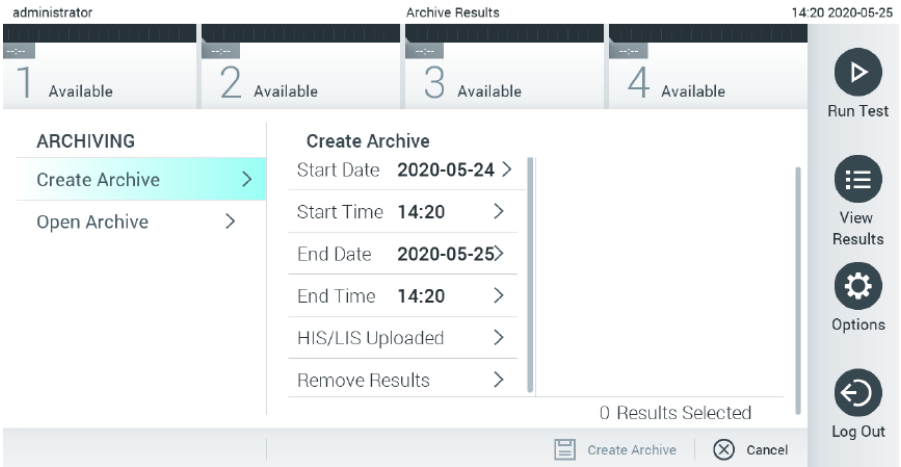
QIAstat-Dx Analyzer Archive with Result Removal

The QIAstat-Dx (Qiagen) instrument must be archived with result removal regularly to free up some memory space.
Note: Archiving can only be performed when there is no patient testing running on the Qiagen.

To Create an Archive with results removal:

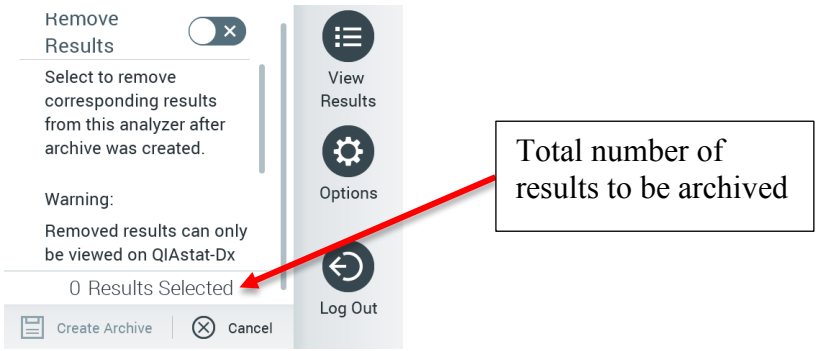
- Insert the USB Flash drive labeled "Archive" to the instrument's USB slot
- Select **Options** from the Main Menu Bar

- Select **Archive Results**
- Select **Create Archive**

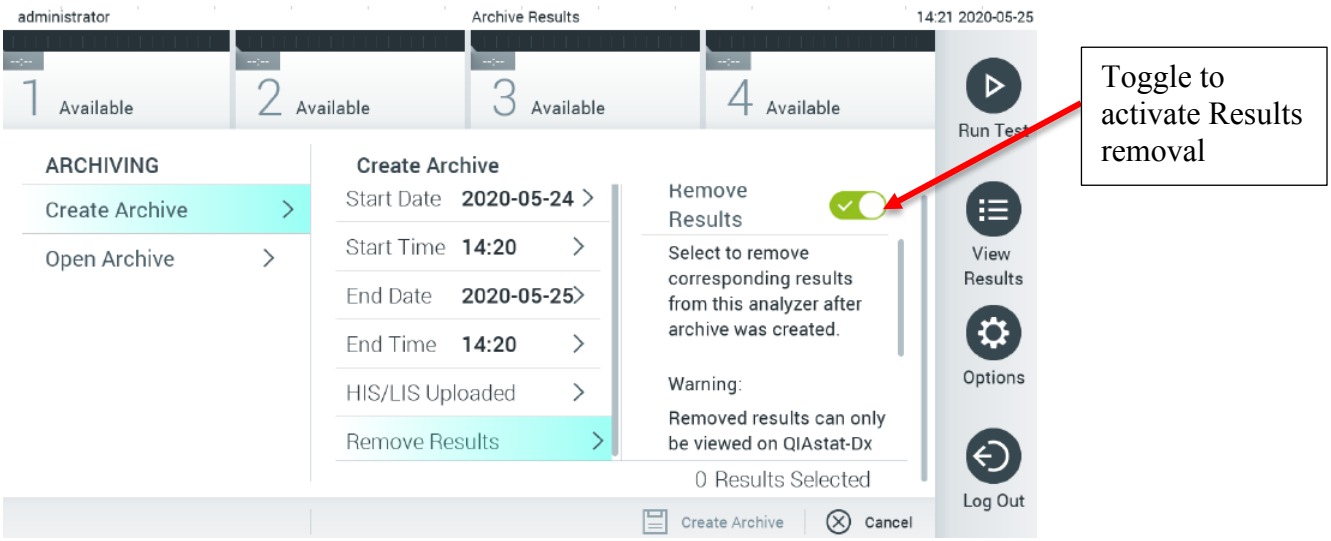


- Select the start and end dates

  Note: The bottom right corner of the screen will show the number of results selected. Limit to only 200 records at a time. Shorten the duration until the number of results selected is less than or equal to 200 results.



- Select Remove Results and activate the Remove Results option



- Select Create Archive.
  - If the archive file creation was successful, the selected results will be removed from the QIAstat-Dx Analyzer.
  - Since the removed results are no longer present in the QIAstat-Dx Analyzer, these results can no longer be printed or uploaded to LIS

Note: The screen saver functionality is inactive during the archive creation. It is recommended to not leave the QIAstat-Dx Analyzer unattended during archive creation