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COVID19 Antigen Rapid Test Using QuickVue by Quidel

Purpose This procedure provides instructions for using the QuickVue At-Home OTC COVID-19 Test. The QuickVue At-Home OTC COVID-19 Test is intended for the qualitative detection of the nucleocapsid protein antigen of SARS-CoV-2 from individuals with or without symptoms of COVID-19 or at risk of COVID-19 due to epidemiological factors.

Scope This procedure may be performed by personnel who are trained and approved to perform point-of-care test (POCT) as defined in Chapter 510 of the California Business and Professions Code (CBPC) or per departmental policy, whichever is more restrictive.

This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA) for use in a waived, moderate complexity or high complexity setting certified under CLIA, or at home. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The QuickVue At-Home OTC COVID-19 Test is a home use kit that is being performed by a healthcare provider. Per CMS guidelines, since the OTC test is being performed in a waived (or higher) setting, the instructions for use in a waived setting are followed.

Principle The QuickVue At-Home OTC COVID-19 Test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal specimens during the acute phase of infection.

Specimen Source Nasal Swab (NS) Sample

- Specimen must be collected using the provided nasal swabs in the test kit.
- Samples must be tested as soon as possible after collection and read within 5 minutes after the 10-minute incubation period.

Specimen Rejection

- Improperly collected and submitted specimen will be rejected per laboratory policy.

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Reagent Kit

The following reagent kit is used for testing.

Description	Vendor	Storage
QuickVue At-Home OTC COVID-19 Test	Quidel	Store the kit at room temperature (15°C-30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box.

Reagents and Materials Supplied

Each 25-Test Kit contains the following:

- 25 Individually Packaged Test Strips: Monoclonal anti-SARS antibodies
 - 25 Tubes
 - 25 Sterile Nasal Swabs (Kit #20387)
 - User Instructions in English
 - User Instructions in Spanish
 - Quidel QuickVue At-Home OTC COVID-19 Test Fact Sheet for Individuals
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Reagents and Materials Not Supplied

The following list of reagents and materials are not supplied with the test kit:

- Timer or watch
 - External Quality Control materials
-

Safety Precautions

- Wear suitable protective clothing, gloves (nitrile or latex), and eye/face protection when handling patient samples or used kit components.
 - Wear appropriate personal protective equipment (PPE) when swabbing others.
 - Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube. The solution in the tube contains hazardous ingredients. If the solution contacts the skin or eye, flush with plenty of water.
 - Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
 - Wash hands thoroughly after handling samples and testing materials.
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Quality Control

There are two primary types of Quality Control (QC) for this assay: the built-in control and the external controls.

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Built-in Control Features

The QuickVue SARS Antigen test contains built-in procedural control features. The manufacturer's recommendation for daily control is to document these built-in procedural controls for the first sample tested each day.

The two-color result format provides a simple interpretation for positive and negative results. The appearance of a blue procedural control line provides positive control by demonstrating sufficient flow has occurred and the functional integrity of the test strip was maintained. If a blue procedural control line does not develop within 10 minutes on the test strip, then the test result is invalid.

A built-in negative control is provided by the clearing of red background color, verifying that the test has been performed correctly. Within 10 minutes, the result area should be white to light pink and allow the clear interpretation of the test result. If background color remains and interferes with interpretation of the test result, then the test result is invalid. Should this occur, review the procedure and repeat the test with a new patient sample and a new test strip. If retesting is required, it is necessary to collect another patient specimen; patient swabs or reagents cannot be reused.

External Quality Control

External Controls are used to demonstrate that the reagents and assay procedure perform properly. Positive and negative controls are to be run once for each untrained operator, once for each new shipment of kits, and each new kit lot.

The Test Procedure should be used when testing the external controls.


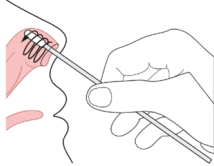
If the external controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens. Additional Control Swabs may be obtained separately by contacting Quidel's Customer Support Services.

Collection Procedure

Below are the steps for sample collection.


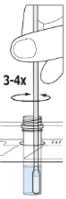
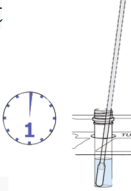
Step	Action
1	Identify the patient using two identifiers prior to nasal swab collection.

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2	Prior to collecting the nasal swab, the patient should be instructed to blow their nose. Remove the swab from its wrapper, being careful not to touch the swab head.	
3	Gently insert the swab ½ to ¾ of an inch (1 to 1.5 cm) into the nostril, depending on the size of the person’s nose. Firmly rub the swab in a circular motion around the inside wall of each nostril at least 4 times. Be sure to rub both nostrils with the same swab.	
Note: Failure to swab properly may cause false negative results.		
4	Submit specimen to lab immediately.	

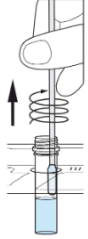
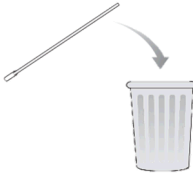
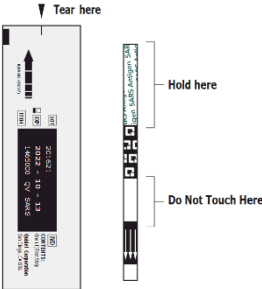
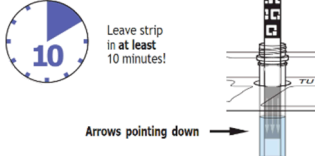

Test Procedure

Follow the steps below to perform testing.

Step	Action		
1	Identify the patient specimen using two identifiers. Ensure that order is for SARS-COV-2 (Covid-19) Antigen, Qualitative, Rapid Immunoassay by checking that test on specimen label is COVID19 AG.		
2		Remove cap from one pre-filled tube and place in the tube holder.	
3	Place the swab into the pre-filled tube, and ensure the swab is touching the bottom of the tube. Stir 3-4 times.		
4	Leave the swab in the solution for one (1) minute. Do not remove the swab prior to one minute.		
Note: If the swab is in the solution for more than 10 minutes it should not be used. Incorrect or invalid results may occur if the incubation time is too short or too long.			


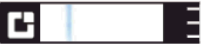
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5	<p>After one minute, remove the swab from the tube by rubbing the swab head against the inside wall of the tube to squeeze out as much liquid as possible.</p>	
6	<p>Dispose of swab in the biohazard waste bin.</p>	
7	<p>Open the test strip pouch carefully at the slit and hold the test strip as indicated (only hold the top portion of the strip).</p> <p>Note: If the test strip is open for an hour or longer, invalid test results may occur.</p>	
8	<p>Place the test strip into the pre-filled tube with the arrows pointing down. Leave the strip in the tube for a full 10 minutes. Do not handle or remove during this time.</p>	
9	<p>At 10 minutes, remove the test strip from the tube and read result according to the Interpretation of Results section. Ensure the test strip is on a flat surface and in good lighting.</p> <p>Note: The test is intended to be read at 10 minutes. If the test is read before this or is read more than 5 minutes after the indicated read time, results may be inaccurate (false negative, false positive, or invalid) and the test should be repeated.</p>	
10	<p>Document test result in- Cerner ARE.</p>	


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Interpretation of Results Use the table below to read and interpret results.

Result	Interpretation	Visual Guide
Positive	<p>At 10 minutes, ANY shade of a pink-to-red Test Line AND the appearance of a blue procedural Control Line indicates a positive result for the presence of SARS antigen. Results will remain stable for five (5) minutes after the recommended read time. Do not read the result more than fifteen minutes after placing into the pre-filled tube.</p> <p>Note: A very faint, pink Test Line and a blue Control Line is a Positive result.</p> <p>Additional confirmatory testing with a molecular test for positive results may be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.</p>	 <p style="text-align: center;">C T</p> <p>C = Control Line T = Test Line</p>
Negative	<p>At 10 minutes, the appearance of ONLY the blue procedural Control Line indicates SARS antigen was not detected. Results will remain stable for five (5) minutes after the recommended read time. Do not read the result more than fifteen minutes after placing into the pre-filled tube.</p> <p>Note: Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such as for individuals in close contact or suspected exposure to a person with</p>	 <p style="text-align: center;">C T</p> <p>C = Control Line T = Test Line</p>

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	COVID-19 or in communities with high prevalence of infection.	
Invalid	<p>If at 10 minutes, the blue procedural Control Line does not appear, even if any shade of a pink-to-red Test Line appears, the result is invalid.</p> <p>If at 10 minutes, the background color does not clear and it interferes with the reading of the test, the result is also invalid.</p> <p>If the result is invalid, a new test should be performed with a new patient sample and a new Test Strip.</p>	 <p style="text-align: center;">C T</p> <p>C = Control Line T = Test Line</p>

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such as for individuals in close contact or suspected exposure to a person with COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

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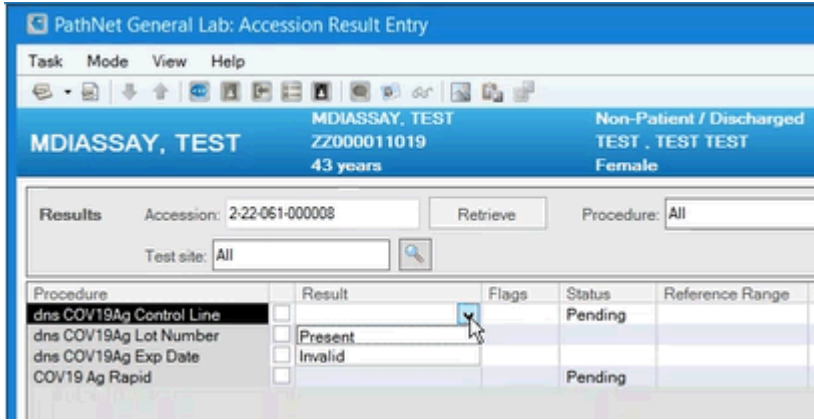
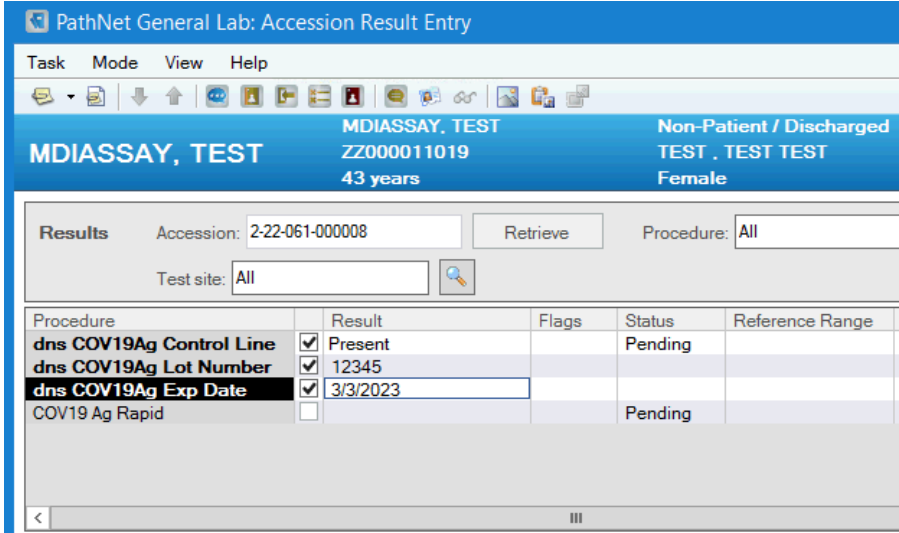
Limitations

- The test is intended for direct anterior nasal swab specimens only. Using another sample collection device or with transport medium such as viral transport medium (VTM) or saline should not be used with this test as it may cause false results.
 - The contents of this kit are to be used only for the qualitative detection of SARS antigens from anterior nares nasal swab specimens. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
 - The QuickVue At-Home OTC COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2.
 - Failure to follow the test procedure and interpretation of results may adversely affect test performance and/or invalidate the test results.
 - Test results must be evaluated in conjunction with other clinical data available to the physician.
 - Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
 - Positive test results do not rule out co-infections with other pathogens.
 - Negative results should be treated as presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed.
 - If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
 - The performance of this test for SARS-CoV-2 was established based on the evaluation of a limited number of clinical specimens collected between August 2020 and December 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
 - The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.
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Result Reporting

To result a test performed for the COVID19 antigen:

Step	Action
1	<p>Document the Internal Control line by choosing from the drop-down option for dns COV19Ag Control Line.</p> 
2	<p>Enter the kit lot number and expiration date on the corresponding fields.</p> 

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- 3 Choose your reading from the drop down of the COV19Ag Rapid field.

The screenshot shows the 'PathNet General Lab: Accession Result Entry' interface. At the top, it displays patient information: MDIASSAY, TEST, ZZ000011019, 43 years, Non-Patient / Discharged, TEST, TEST TEST, Female. Below this is a 'Results' section with 'Accession: 2-22-061-000008' and 'Test site: All'. A table lists test procedures with columns for Procedure, Result, Flags, Status, and Reference Range. The 'COV19 Ag Rapid' row is selected, and a dropdown menu is open showing options: Negative, Positive, and Invalid. The 'Result' column for this row currently shows 'Present'.

Procedure	Result	Flags	Status	Reference Range
dns COV19Ag Control Line	Present		Pending	
dns COV19Ag Lot Number	12345			
dns COV19Ag Exp Date	3/3/2023			
COV19 Ag Rapid	Present		Pending	

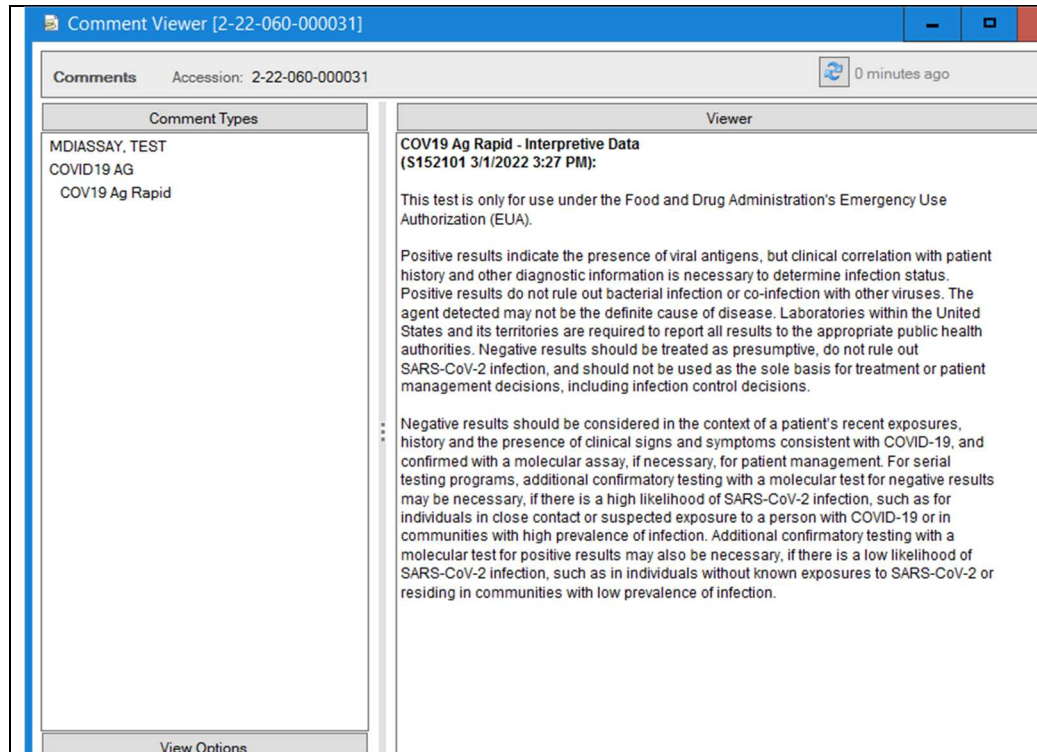
NOTE: An Invalid Control Line must be resultated as Invalid for COV19Ag Rapid.

This screenshot shows the same interface as above, but the 'COV19 Ag Rapid' result has been updated to 'Invalid'. The 'COV19 Ag Control Line' result is also updated to 'Invalid' with a '*' flag. The 'Status' for both rows is 'Pending'.

Procedure	Result	Flags	Status	Reference Range
dns COV19Ag Control Line	Invalid	*	Pending	
dns COV19Ag Lot Number	12345			
dns COV19Ag Exp Date	3/4/2023			
COV19 Ag Rapid	Invalid	*	Pending	

- 4 Once results are verified and test order is completed, an Interpretive Data will be part of the Comments for the test.

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Reference Range

Negative

Any Positive and Invalid results for COVID19 Ag Rapid will be flagged Abnormal in Cerner.

Non-Controlled Documents

The following non-controlled documents support this procedure.

- Quidel QuickVue At-Home OTC COVID-19 Test - Instructions for Use HCP
- Quidel QuickVue At-Home OTC COVID-19 Test – Healthcare Professional Fact Sheet
- Quidel QuickVue At-Home OTC COVID-19 Test User Instructions
- Centers for Medicare and Medicaid Services (CMS), Over the Counter (OTC) Home Testing and CLIA Applicability Frequently Asked Questions, November 22, 2021

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Technical Support Quidel’s QuickVue Technical Support: (800) 874-1517 or (858) 552-1100, Monday through Friday, from 7 AM to 5 PM, Pacific, or email technicalsupport@quidel.com.

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Signature Manifest

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Change Request

Name/Signature	Title	Date	Meaning/Reason
Eleanor Callasan (C019388)	Practice Leader	04 Mar 2022, 03:24:22 PM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Eleanor Callasan (C019388)	Practice Leader	04 Mar 2022, 03:28:43 PM	Complete
Sienna Mendoza (Z344484)	Assistant Director	04 Mar 2022, 04:17:22 PM	Complete

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Tam Van (Y336579)	TECH DIR MICROBIOLOGY SVC	07 Mar 2022, 09:03:46 AM	Approved

Physician Director Approval

Name/Signature	Title	Date	Meaning/Reason
Jonathan Gullett (A278318)	Physician Dir, Microbiology	07 Mar 2022, 09:56:55 AM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
Steven McLaren (P158378)	Rgnl Mg Admn-PMG Executive	07 Mar 2022, 03:21:51 PM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Eleanor Callasan (C019388)	Practice Leader	07 Mar 2022, 04:06:13 PM	Approved

Notify Users

Name/Signature	Title	Date	Meaning/Reason
Henny Mason (Y469979)	Assistant Director	07 Mar 2022, 04:06:13 PM	Email Sent
Precious Joy D Cabasal (W413921)	Preanalytical Manager	07 Mar 2022, 04:06:13 PM	Email Sent
Armond Mehdkhani (A081527)	Laboratory Operations Director	07 Mar 2022, 04:06:13 PM	Email Sent
Mary Lou Beaumont (A335097)	Director Systems Administration	07 Mar 2022, 04:06:13 PM	Email Sent
Christine Chang (A674089)	ASST DIR OPER AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Michelle Perez (D103774)	Administrative Specialist	07 Mar 2022, 04:06:13 PM	Email Sent

Carlo Punu (F316195)	Assistant Director of Operations	07 Mar 2022, 04:06:13 PM	Email Sent
Edwin Espiritu (C264485)	Manager Operations Area Laboratory	07 Mar 2022, 04:06:13 PM	Email Sent
Marina Bonus (F234915)	ASST DIR OPER AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Matthew Jones (F754627)	Sr Systems Administrator	07 Mar 2022, 04:06:13 PM	Email Sent
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Ruchita Sukhadia (S346951)	ASST DIR OPER AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Desiree Palmera-Cohen (G022427)	ASST DIR OPER AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
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Laura Gabrys (G157770)	DIR OPER AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Timothy McSkane (W394565)	Exe Ldr, Lab Care Delivery	07 Mar 2022, 04:06:13 PM	Email Sent
Louie Farnacio (I575517)	RL OPERATIONS DIRECTOR	07 Mar 2022, 04:06:13 PM	Email Sent
Vincent Dizon (I713793)	Director of Lab Services, Chem	07 Mar 2022, 04:06:13 PM	Email Sent
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Keith Lawson (K059352)	LTS Director	07 Mar 2022, 04:06:13 PM	Email Sent
Stephanie Prien (K081422)	SCPMG Lab Informatics Director	07 Mar 2022, 04:06:13 PM	Email Sent
Julie Toti (K084521)	DIR AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Paulette Medina (K088673)	ASST DIR REGL LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Onie Bueno (K109914)	DIR OPER REGL LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Janice Wolf (K119893)	Director Operations Area Lab	07 Mar 2022, 04:06:13 PM	Email Sent
Diane Giles (K123520)	Director	07 Mar 2022, 04:06:13 PM	Email Sent
Chongbae Lee (K153165)	Director Core Lab	07 Mar 2022, 04:06:13 PM	Email Sent
Charles Park (K239415)	Director of Operations	07 Mar 2022, 04:06:13 PM	Email Sent
Dina Amirian (L788238)	Manager	07 Mar 2022, 04:06:13 PM	Email Sent
Aldie Garcia (D151456)	Assistant Department Adminstr	07 Mar 2022, 04:06:13 PM	Email Sent
Vahe Khanlian (O532803)	RRL DIR OF LAB SVCS, MIC	07 Mar 2022, 04:06:13 PM	Email Sent
Joanne Jocom (P170170)	MGR AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Hany Boutros (T193254)	OPS Director	07 Mar 2022, 04:06:13 PM	Email Sent
Jocelyn Javier (T684676)	Assist. ADA	07 Mar 2022, 04:06:13 PM	Email Sent
Karen Schellhardt (G586652)	Lab Ops Director	07 Mar 2022, 04:06:13 PM	Email Sent
Myra Wong (O028828)	Quality Systems Leader	07 Mar 2022, 04:06:13 PM	Email Sent
Trang Vo (I879089)	Director of Operations	07 Mar 2022, 04:06:13 PM	Email Sent
Charles Mabaquiao (W134322)	Lab/Path Director	07 Mar 2022, 04:06:13 PM	Email Sent
Mike Moradian (W555134)	DIR LAB SERVICES, Genetics	07 Mar 2022, 04:06:13 PM	Email Sent
Jecarl Viray (X358046)	MGR OPER REGIONAL LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Timothy Cotroneo (Y383647)	DIR OPER AREA LAB	07 Mar 2022, 04:06:13 PM	Email Sent
Sienna Mendoza (Z344484)	Assistant Director	07 Mar 2022, 04:06:13 PM	Email Sent