For use under the Emergency Use Authorization (EUA) only
For in vitro diagnostic use

℞ ONLY

QUIDEL | Solana® SARS-CoV-2 ASSAY

FOR USE WITH SOLANA
For the qualitative detection of SARS-CoV-2 viral RNA in nasal and nasopharyngeal swabs in viral transport medium from individuals suspected of COVID-19 by their healthcare provider.

A symbols glossary can be found at quidel.com/glossary.

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INTENDED USE

The Solana SARS -CoV-2 Assay is an isothermal Reverse Transcriptase - Helicase-Dependent Amplification (RT-HDA) assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient 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 do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Solana SARS-CoV-2 Assay is intended for use by laboratory personnel who have received specific training on the use of the Solana SARS-CoV-2 Assay and/or the Solana Instrument. The Solana SARS -CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

SARS-CoV-2, also known as the COVID-19 virus, was first identified in Wuhan, Hubei Province, China December 2019. This virus, as with the novel coronavirus SARS-1 and MERS, is thought to have originated in bats, however the SARS-CoV-2 may have had an intermediary host such as pangolins, pigs or civets.[1] On March 11, the WHO had declared the SARS-CoV-2 as a global pandemic. As of 13 December 2020, the number of new COVID-19 cases and deaths continued to rise with 70 million cumulative cases and 1.6 million deaths globally since the start of the pandemic. The Regions of the Americas and Europe continue to shoulder the burden of the pandemic, accounting for 85% of new cases and 86% of new deaths globally.[1]

The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.[2] The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.[3]

The Solana SARS -CoV-2 Assay has been designed to specifically detect SARS-CoV-2 RNA.

PRINCIPLE OF THE TEST

The Solana SARS-CoV-2 Assay amplifies and detects viral RNA present in nasopharyngeal or nasal swab specimens collected and placed into viral transport media.

The assay consists of two major steps: (1) specimen preparation, and (2) amplification and detection of target sequences specific to SARS-CoV-2 using isothermal Reverse Transcriptase – Helicase-Dependent Amplification (RT-HDA) in the presence of target-specific fluorescence probes.

A patient nasal or nasopharyngeal swab specimen in viral transport media is transferred to a Process Buffer Tube, mixed, and subjected to heat treatment at 95°C for 5 minutes. The processed sample is then transferred to a Reaction Tube containing lyophilized RT-HDA reagents, dNTPs, primers and probes. Reaction Tube once rehydrated with the processed sample, the Reaction Tube is placed in Solana for amplification and detection of SARS-CoV-2 specific target sequences. A

competitive process control (PRC) is included in the Reaction Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure.

The target and PRC probes are labeled with a quencher on one end and a fluorophore on the other end. Upon annealing to target or PRC amplicons, the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana then reports the test results to the user on its display screen, and it can print out the results via an integrated printer.

MATERIALS PROVIDED

Cat. #M312
48 Tests per Kit

Component	Quantity	Storage
Process Buffer	48 tubes/kit 1.55 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C
Negative Control	1 tube/kit 2.0 mL	2°C to 8°C
Positive Control	1 tube /kit 1.0 mL	2°C to 8°C

MATERIALS REQUIRED BUT NOT PROVIDED

- Sterile DNAse-free filter-blocked positive displacement micropipettor tips
- Micropipettor
- Stopwatch or timer
- Vortex Mixer
- Scissors or a blade
- Workflow tray
- Transfer Rack
- Heat block capable of 95°C ± 2°C temperature
- Thermometer
- Solana instrument (firmware version 2.0.11 or higher)
- Transport Media (BD/Copan UTM®, CDC Viral Transport Media, Remel M4RT®, Quidel Transport Media (QTM))

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- For use under Emergency Use Authorization only.
- Prescription Use Only.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- All reagents are for *in vitro* diagnostic use only.
- Refer to the Solana Operator's Manual for further information regarding instrument installation and operation.
- Only use the protocol described in this package insert. Deviations from the protocol may give erroneous results.
- Treat all specimen/samples as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- All tubes should be capped tightly prior to vortexing.
- Proper sample collection, storage and transport are essential for correct results.
- Store assay reagents as indicated on their individual labels.
- Reagents are not interchangeable between lots.

- Never pool reagents from different tubes even if they are from the same lot.
- Do not use the reagents after their expiration date.
- Do not interchange caps among reagents as contamination may occur and compromise test results.
- Only open the tubes when adding aliquots into tubes or removing aliquots from tubes. Keep the tubes closed at any other time to avoid contamination.
- For accurate results, pipette carefully using only calibrated equipment. Use of inaccurate volumes may give erroneous results.
- To avoid contamination of the environment with SARS-CoV-2 amplicons, do not open the Reaction Tubes post-amplification.
- Avoid microbial and ribonuclease (RNAse) contamination of reagents when removing aliquots from tubes.
- Performing the assay outside of the recommended time ranges can produce invalid results. Assays not completed within specified time ranges should be repeated.
- Additional controls may be tested according to guidelines or requirements of local, state, provincial and/or federal regulations or accrediting organizations.
- Do not pipette by mouth.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Maintenance and decontamination of workspace and equipment should follow and be performed according to established laboratory protocols and schedules. Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STORAGE AND HANDLING OF KIT REAGENTS

The Assay Kit should be stored at 2°C to 8°C until the expiration date listed on the outer kit box.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Nasal and nasopharyngeal specimens should be collected, transported, stored, and processed according to CLSI M41-A[4]. Specimens collected in BD/Copan UTM, Remel M4RT, or Quidel QTM are stable at room temperature (RT), 2°C to 8°C or –70°C or below for up to 4 days. Specimens collected in the CDC Viral Transport Medium should be stored at 2-8°C for up to 72 hours after collection or at –70°C or below if a delay in testing or shipping is expected.

TEST PROCEDURE

1. Turn on Solana by pressing the power button and wait until it completes self-testing.
   NOTE: Do not open the lid during the self-testing.
2. Place the required number of Process Buffer Tubes in the Workflow tray. Label the Process Buffer Tubes on the cap and/or side of the tube.
   NOTE: One (1) Process Buffer Tube is required for each specimen or control to be tested.
   NOTE: A maximum of 12 tests can be performed per test run in a single Solana instrument.
3. Mix the specimen received in viral transport media by vortexing the tubes for 5 seconds.
4. Remove 50 µL of the mixed specimen or External control and add to labeled Process Buffer Tubes and then vortex the Tubes for 5 seconds.
5. Heat the Process Buffer Tubes at 95 ±2°C for 5 minutes and then vortex the Tubes for 5 seconds.
   NOTE: Begin 5-minute lysis procedure after placing tubes in block and waiting until block returns to 95°C.
   NOTE: Allow the heated Process Buffer Tubes to return to Room Temperature prior to addition to the Reaction Tubes Master Mix.
   NOTE: Samples are stable in process buffer up to 6-days at 2°C to 8°C, –20°C, and –70°C after the heat step.
6. Remove the required number of Reaction Tubes from the protective container and close cap immediately after removal.
7. Transfer 50 µl of the processed sample to the labeled Reaction Tube, mix the solution by pipetting up and down a minimum of 5 times and close the cap. The solution should be clear, free of solid material.
   Note: Use a new pipette tip for each processed sample.

Note: Proceed immediately to the next step. Do not allow reconstituted Reaction Tubes to sit for longer than 15 minutes.

8. Using the Solana Transfer Rack to hold Reaction Tubes at eye-level, visually inspect each Reaction Tube to ensure there are no air bubbles present at the bottom of the tube and liquid levels are equivalent. Flick tube lightly to remove any air bubbles observed.
   NOTE: Only touch Reaction Tubes with gloved hands.
9. Open the lid of the Solana instrument and place the Reaction Tubes in Solana via the Transfer Rack. Close the lid.
   NOTE: Be sure that all tubes are in tight contact with heat block.
10. Enter User ID, press ↵ (ENTER) and enter Password and press ↵ (ENTER).
11. Select "NEW TEST." If Solana displays a different screen, go to the home screen.
12. Select the tube positions to use.
13. Scan the assay barcode or manually enter Lot ID/Exp Date, then select "SARS-CoV-2 Assay" from the Select Test drop-down menu and press "▶."
14. Select sample type (patient or QC) from the drop-down menu and enter Sample IDs (optional; see 2nd Note in next step).
15. Press "Start" to initiate the Solana SARS -CoV-2 Assay. Solana will display the progress and the count-down to assay completion. Test results will be displayed on the screen in approximately 25 minutes.
    NOTE: To avoid laboratory contamination, once the tube has been closed and the amplification reaction started, **DO NOT** open the Reaction Tube.
    NOTE: While the test is running, sample ID can be entered or edited by pressing the pencil icon.
16. After the run is completed the results can be printed by selecting the print button.
    NOTE: Do not navigate away from this screen before printing results. Once the screen is gone, it cannot be revisited. If this occurs, the results can be viewed individually by going to Home and then selecting Review Results. To determine if sample is positive for SARS-CoV-2, press the tube sample number.

INTERPRETATION OF RESULTS

The Solana software automatically determines the specimen results for SARS-CoV-2 virus. A positive result indicates that the viral RNA for the SARS-CoV-2 virus was detected. A negative result indicates that SARS-CoV-2 virus RNA was not detected, and the process control was detected. Solana reports a specimen result as invalid when both SARS-CoV-2 virus was not detected, and the process control was undetected. The process control (PRC) is used to monitor sample processing, to detect HDA inhibitory specimens, and to confirm the integrity of assay reagents and the operation of the Solana instrument.

Single Sample Results Screen	
Assay Result	**Interpretation**
SARS-CoV-2 POSITIVE	SARS-CoV-2 RNA detected
SARS-CoV-2 NEGATIVE	No SARS-CoV-2 RNA detected/PRC detected
SARS-CoV-2 INVALID	No SARS-CoV-2 RNA and No PRC detected; for invalid test results, re-process another aliquot of the same sample or obtain a new sample and re-test.

QUALITY CONTROL

The Solana SARS-CoV-2 Assay incorporates several controls to monitor assay performance.

- A positive control (such as a positive patient sample) should be processed and tested with each batch of specimens.
- The process control (PRC) consists of single stranded RNA and is used to monitor HDA inhibitory specimens, and to confirm the integrity of assay reagents and the operation of the Solana instrument. The process control is included in the Reaction Tube.
- The external positive control (containing SARS-CoV-2 Synthetic RNA) may be treated as a patient specimen. The control should be sampled and tested as if it were a patient specimen and processed as described above in the Assay Procedure. The external positive control is intended to monitor substantial reagent and instrument failure.

- The external negative control may be treated as a patient specimen. The control should be sampled and tested as if it were a patient specimen and processed as described above in the Assay Procedure. The external negative control is used to detect reagent or environmental contamination (or carry-over) by SARS-CoV-2 RNA or amplicon.

It is recommended that the reactivity of each new lot and each new shipment of the Solana SARS-CoV-2 Assay be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines. The Solana SARS-CoV-2 Assay should not be used in patient testing if the controls do not produce the correct results.

LIMITATIONS

- Negative results do not preclude infection with SARS-CoV-2 and should not be the sole basis of a patient treatment decision.
- The performance of this test was assessed using nasal and nasopharyngeal swab specimens in viral transport medium.
- Improper collection, storage or transport of specimens may lead to false negative results.
- Inhibitors present in the sample and/or errors in following the assay procedure may lead to false negative results.
- A trained health care professional should interpret assay results in conjunction with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests.
- Analyte targets (viral sequences) may persist *in vivo*, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or that they are the causative agents for clinical symptoms.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay.
- Based on the *in-silico* analysis, SARS-CoV and other SARS-like coronaviruses in the same subgenus (Sarbecovirus) as SARS-CoV-2 may cross-react with the Solana SARS-CoV-2 Assay. SARS-CoV is not known to be currently circulating in the human population, therefore is highly unlikely to be present in patient specimens.
- There is a risk of false negative values due to the presence of sequence variants in the viral targets of the assay.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. 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.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The Solana SARS-CoV-2 Assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

However, to assist clinical laboratories using the Solana SARS -CoV-2 Assay, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using the Solana SARS-CoV-2 Assay will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the Solana SARS-CoV-2 Assay will use the Solana SARS-CoV-2 Assay as outlined in the "Solana SARS-CoV-2 Assay" Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Solana SARS-CoV-2 Assay are not permitted.
- Authorized laboratories that receive the Solana SARS-CoV-2 Assay will notify the relevant public health authorities of their intent to run the Solana SARS-CoV-2 Assay prior to initiating testing.
- Authorized laboratories using the Solana SARS-CoV-2 Assay will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

- Authorized laboratories will collect information on the performance of the Solana SARS-CoV-2 Assay and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Quidel (via email: QDL.COV2.test.event.report@quidel.com, or via phone by contacting Quidel Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the Solana SARS-CoV-2 Assay of which they become aware.
- All operators using the Solana SARS-CoV-2 Assay must be appropriately trained in performing and interpreting the results of the Solana SARS-CoV-2 Assay, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Quidel Corporation, authorized distributors, and authorized laboratories using the Solana SARS-CoV-2 Assay will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] For ease of reference, the letter of authorization refers to "authorized laboratories" as follows: laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high or moderate complexity tests.

CLINICAL PERFORMANCE

A study was performed comparing the Solana SARS-CoV-2 Assay to an authorized EUA RT-PCR assay. This study used a frozen version of the MasterMix and was part of the original Emergency Use Authorization. Two hundred forty (240) nasal swab samples and fifty-one (51) nasopharyngeal swabs in viral transport media were tested with both devices according to the respective package inserts. Two hundred four (204) samples were tested with the Solana assay after storage of the viral transport media at -70°C. Eighty-seven (87) were tested with the Solana assay after storage of the viral transport media at 2°C to 8°C.

Comparison of Solana SARS-CoV-2 Assay and an authorized EUA comparator assay									
Specimen Type	Number Tested	True Positive	False Positive	True Negative	False Negative	PPA%	NPA%	PPA 95% CI	NPA 95% CI
Nasal Swabs	240	69	0	169	2	97.2	100	90.3% - 99.2%	97.8% - 100%
Nasopharyngeal Swabs	51	19	1	31	0	100	96.9	83.2% - 100%	84.3% - 99.5%
Combined Swabs	291	88	1	200	2	97.8	99.5	92.3% - 99.4%	97.2% - 99.9%

A bridging validation with frozen clinical samples was performed to compare frozen version of the MasterMix with a lyophilized version of the MasterMix in the Solana SARS-CoV-2 Assay. One-hundred and fifty-seven (157) nasal samples in viral transport media were tested with both versions of the assay. The PPA was 100% (83/83), 95% CI: 95.6% - 100%. The NPA was 100% (74/74), 95% CI: 95.1% - 100%.

In addition, a study was performed comparing the Solana SARS-CoV-2 Assay to a FDA cleared molecular assay. This study used a lyophilized version of the MasterMix and is the currently marketed version of the assay. One hundred fifty-seven (157) nasal swab samples in viral transport media were tested with both devices according to the respective package inserts.

Comparison of Solana SARS-CoV-2 Assay and FDA cleared molecular comparator assay									
Specimen Type	Number Tested	True Positive	False Positive	True Negative	False Negative	PPA%	NPA%	PPA 95% CI	NPA 95% CI
Nasal Swabs	157	83	0	73	1	98.8	100	93.6% - 99.8%	95.0% - 100%

ANALYTICAL PERFORMANCE

LIMIT OF DETECTION

The Limit of detection (LoD) was established with BEI NR-52287, SARS-Related Coronavirus 2, Isolate USA-WA1/2020, gamma-irradiated in three (3) separate studies using dilutions in negative nasal matrix collected into UTM.

Study 1 – LoD Screen

Ten-fold dilutions of the gamma-irradiated SARS-CoV-2 were made in negative nasal matrix. Each dilution was tested in triplicate with the Solana SARS-CoV-2 Assay. The last dilution with detectable RNA was used for the Pre-LoD testing.

Summary of Qualitative Results for LoD Screen										
Concentration (cp/mL)	SARS-CoV-2									
	Lot 1					Lot 2				
	n	I	N	P	% Positivity	n	I	N	P	% Positivity
7.65E+07	3	0	0	3	100.0%	3	0	0	3	100.0%
7.65E+06	3	0	0	3	100.0%	3	0	0	3	100.0%
7.65E+05	3	0	0	3	100.0%	3	0	0	3	100.0%
7.65E+04	3	0	0	3	100.0%	3	0	0	3	100.0%
7.65E+03	3	0	0	3	100.0%	3	0	0	3	100.0%
7.65E+02	3	0	3	0	0.0%	3	0	1	2	66.7%
7.65E+01	3	0	3	0	0.0%	3	0	3	0	0.0%
n: # of replicates tested; I:# of invalid results; N:# of negative results; P:# of positive results										

Study 2 – Pre-LoD testing

Based on the LoD screen data, the following dilutions of the SARS-CoV-2 were made in negative nasal matrix: 10X LoD, 5X LoD, 1X LoD, 0.75X LoD, and 0.5X LoD. Each dilution was tested in triplicate with the Solana SARS-CoV-2 Assay.

Summary of Qualitative Results for Pre-LoD										
Concentration (cp/mL)	SARS-CoV-2									
	Lot 01					Lot 2				
	n	I	N	P	% Positivity	n	I	N	P	% Positivity
7.65E+04	3	0	0	3	100.0%	3	0	0	3	100.0%
3.83E+04	3	0	0	3	100.0%	3	0	0	3	100.0%
7.65E+03	3	0	0	3	100.0%	3	0	0	3	100.0%
5.74E+03	3	0	0	3	100.0%	3	0	0	3	100.0%
3.83E+03	3	0	1	2	66.7%	3	0	2	1	33.3%
n: # of replicates tested; I:# of invalid results; N:# of negative results; P:# of positive results										

Study 3 –LoD Confirmation testing

Based on the Pre-LoD data, the dilution demonstrating ≥95% detection was used in the LoD confirmation study. A concentration of 5.74×10^3 was made in negative nasal matrix. This concentration was tested with twenty replicates with the Solana SARS-CoV-2 Assay.

LoD Confirmation		
SARS-CoV-2 Concentration (cp/mL)	# Positive/Triplicate Test	% Positive
5.74×10^3	18/20	90%

Based on this data, two additional concentrations were in negative nasal matrix (7.65×10^3 and 3.83×10^4). Each dilution was tested with twenty replicates with the Solana SARS-CoV-2 Assay.

Summary of Qualitative Results for LoD Confirmation - Lot 2					
Concentration (cp/mL)	SARS-CoV-2				
	n	Invalid	Negative	Positive	% Positivity
3.83E+04	20	0	0	20	100.0%
7.65E+03	20	0	2	18	90.0%
5.74E+03	20	0	2	18	90.0%
n: # of replicates tested					

The limit of detection (LoD) of the Solana SARS-CoV-2 Assay using limiting dilutions of gamma-irradiated SARS-CoV-2 is 3.83×10^4 cp/mL.

The Solana SARS-CoV-2 Assay has previously been evaluated using the FDA SARS-CoV-2 Reference Panel using frozen MasterMix. The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to corroborate the LoD. The study was performed in the Solana instrument. The results are summarized in the Table below.

Table Summary of LoD Confirmation Result Using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	NPS	5.4×10^4 NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL: RNA NAAT detectable units/mL
N/A: Not Applicable
ND: Not Detected

ANALYTICAL REACTIVITY/INCLUSIVITY

Specific nucleic acid sequences used in the Solana SARS-CoV-2 Assay target the highly conserved regions of the SARS-CoV-2 virus non-structural Polyprotein (pp1ab).

The inclusivity of the Solana SARS-CoV-2 Assay was established through an *in-silico* analysis of available SARS-CoV-2 sequences. As of March 14, 2022 a total of 13,211,970 SARS-CoV-2 sequences were available from the GISAID and NCBI databases (9,279,826 and 3,932,144, respectively). Of these, 12,771,645 (98%) include the amplicon region (<5 undefined nucleotide bases in any oligonucleotide region). The number of sequences that are 100% and ≥95% conserved to the oligo set are summarized in the Table below.

Database	Sequences Available	Sequences Including Amplicon Region	Sequences with 100% Homology to Oligo Set	Sequences with ≥95% Homology to Oligo Set
GISAID	9,279,826	9,060,122	8,930,440	9,059,711
NCBI	3,932,144	3,899,817	3,841,205	3,899,738

Inclusivity of the Solana SARS-CoV-2 Assay with eight (8) published variants [Alpha (B.1.1.7+Q.x), Beta (B.1.351+B.1.351.x), Gamma (P.1+P.1.x), Delta (B.1.617.2+AY.x), Lambda (C.37+C.37.1), Mu (B.1.621+B.1.621.1+BB.2), Omicron (BA.x+BA.1.1), and VUM GH/490R (B.1.640.x)] was established through an *in-silico* analysis of available sequences (1,168,694, 41,945, 121,140, 4,280,840, 9,854, 15,599, 2,414,399, 794**,** respectively). All sequences are 53-100% conserved to the Solana SARS-CoV-2 oligonucleotides. The number of variant sequences that are 100% and ≥95% conserved to the oligo set are summarized in the Table below.

Database	Variant	Sequences Available	Sequences Including Amplicon Region	Sequences with 100% Homology to Oligo Set	Sequences with ≥95% Homology to Oligo Set
GISAID	Alpha (B.1.1.7+Q.x)	1,168,694	1,153,584 (98.71%)	1,142,665	1,153,552
	Beta (B.1.351+B.1.351.x)	41,945	41,230 (98.30%)	41,035	41,229
	Gamma (P.1+P.1.x)	121,140	119,782 (98.88%)	118,838	119,770
	Delta (B.1.617.2+AY.x)	4,280,840	4,250,102 (99.28%)	4,199,998	4,249,982
	Lambda (C.37+C.37.1)	9,854	9,779 (99.24%)	9,687	9,779
	Mu (B.1.621+B.1.621.1)	15,599	15,340 (98.34%)	13,702	15,338
	GISAID Omicron (BA.x+BA.1.1)	2,414,399	2,274,620 (94.21%)	2,245,624	2,274,481
	GISAID VUM GH/490R (B.1.640.x)	794	767 (96.60%)	762	767

CROSS-REACTIVITY (ANALYTICAL SPECIFICITY):

The Analytical Specificity of the assay was established by both direct testing of organisms in the assay ("wet" testing) and *in-silico* analysis.

The potential microbial interference or cross-reactivity of Solana SARS-CoV-2 Assay was evaluated by testing various microorganisms (13), viruses (16) that may potentially interfere or cross-react based on the reasonable likelihood that they may be present in upper respiratory tract specimens. Each organism and virus was tested in negative nasal clinical matrix at target concentrations in the absence (negative) and presence (positive) SARS-CoV-2. Each condition (negative or positive) was tested with three replicates per substance. The final concentrations of the organisms and viruses are documented in the table below:

Cross-Reactivity/Microbial Interference Results					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Adenovirus	Type 1	Isolate	$1 \times 10^{7.53}$ U/mL	No Cross-Reactivity	No Interference
Coronavirus	229e	Isolate	$1 \times 10^{6.10}$ U/mL	No Cross-Reactivity	No Interference
Coronavirus	OC43	Isolate	9.55×10^{6} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Coronavirus	NL63	Isolate	$5 \times 10^{4.67}$ U/mL	No Cross-Reactivity	No Interference
MERS-CoV (heat-inactivated)	Florida/USA-2_Saudi Arabia_2014	Isolate	1.17×10^{6} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Mycoplasma pneumoniae	M129	Isolate	3×10^{7} CCU/mL	No Cross-Reactivity	No Interference
Streptococcus pyogenes	Z018	Isolate	3.8×10^{9} cfu/mL	No Cross-Reactivity	No Interference
Influenza A H3N2	Brisbane/10/07	Isolate	$1 \times 10^{5.07}$ U/mL	No Cross-Reactivity	No Interference
Influenza A H1N1	New Caledonia/20/99	Isolate	$1 \times 10^{6.66}$ U/mL	No Cross-Reactivity	No Interference
Influenza B	Brisbane/33/08	Isolate	$1 \times 10^{5.15}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 1	Isolate	$1 \times 10^{8.01}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 2	Isolate	$1 \times 10^{6.34}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 3	Isolate	8.51×10^{7} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 4b	Isolate	$1 \times 10^{7.53}$ U/mL	No Cross-Reactivity	No Interference
Enterovirus	Type 68	Isolate	$1 \times 10^{6.5}$ U/mL	No Cross-Reactivity	No Interference

Cross-Reactivity/Microbial Interference Results					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Human Metapneumovirus	A1 (IA10-s003)	Isolate	$1 \times 10^{5.55}$ U/mL	No Cross-Reactivity	No Interference
Respiratory Syncytial Virus	Type A (3/2015 Isolate #3)	Isolate	$1 \times 10^{5.62}$ U/mL	No Cross-Reactivity	No Interference
Human Rhinovirus	N/A	Inactivated virus	Not available	No Cross-Reactivity	No Interference
Chlamydophila pneumoniae	AR-39	Isolate	2.9×10^{7} IFU/mL	No Cross-Reactivity	No Interference
Haemophilus influenzae	Type b; Eagan	Isolate	7.87×10^{8} cfu/mL	No Cross-Reactivity	No Interference
Legionella pneumophila	Philadelphia	Isolate	6.82×10^{9} cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	Z022; 19f	Isolate	2.26×10^{9} cfu/mL	No Cross-Reactivity	No Interference
Bordetella pertussis	A639	Isolate	6.37×10^{6} cfu/mL	No Cross-Reactivity	No Interference
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	1.56×10^{8} cfu/mL	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	H37Ra-1	Isolate	6.86×10^{7} cfu/mL	No Cross-Reactivity	No Interference
Streptococcus salivarius	Z127	Isolate	8.17×10^{8} cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	MRSE; RP62A	Isolate	1.21×10^{10} cfu/mL	No Cross-Reactivity	No Interference
Candida albicans	Z006	Isolate	6.27×10^{8} cfu/mL	No Cross-Reactivity	No Interference
Pseudomonas aeruginosa	Z139: VIM-1	Isolate	7.48×10^{8} cfu/mL	No Cross-Reactivity	No Interference

Coronavirus HKU1 was not tested for cross-reactivity due to lack of availability. 19 specimens containing Coronavirus HKU1 were tested and all resulted as negative, additional cross-reactivity wet testing was not required.
* Testing was performed in triplicate

The Solana SARS-CoV-2 Assay primers were analyzed against 32 organisms for *in silico* cross-reactivity. All organisms except SARS-1 were <80% conserved to both primers.

Homology Results of Solana® SARS-COV-2 Primers Against Cross-Reactants

Organism	**# Sequences ≥80% Conserved to both Primers**
Adenovirus	0
Coronavirus (Seasonal)	0
Enterovirus	0
Influenza A Virus	0
Influenza B Virus	0
Influenza C Virus	0
Human Metapneumovirus	0
Human Parainfluenza Virus 1-4	0
Human Parechovirus	0
Human Respiratory Syncytial Virus	0
Rhinovirus	0
SARS-1	227
Bacillus anthracis	0
Candida albicans	0
Chlamydia pneumoniae	0
Chlamydia psittaci	0
Corynebacterium diptheriae	0
Coxiella burnetii	0
Haemophilus influenzae	0

Homology Results of Solana® SARS-COV-2 Primers Against Cross-Reactants

Organism	# Sequences ≥80% Conserved to both Primers
Legionella	0
Leptospira	0
Moraxella catarrhalis	0
Mycobacterium tuberculosis	0
Mycoplasma pneumoniae	0
Neisseria elongata & *N. meningitidis*	0
Pneumocystis jirovecii	0
Pseudomonas aeruginosa	0
Staphylococcus aureus	0
Staphylococcus epidermidis	0
Streptococcus pneumoniae	0
Streptococcus pyogenes	0
Streptococcus salivarius	0

INTERFERENCE SUBSTANCES STUDIES

A study was performed to demonstrate that potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the Solana SARS-CoV-2 Assay. Fourteen (14) potential interfering substances in the concentrations listed below were tested in the absence or presence of SARS-CoV-2. None of these substances demonstrated cross-reactivity or interference.

Cross-Reactivity/Interference Results				
Interfering Substance	**Active Ingredient**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Afrin – nasal spray	Oxymetazoline	5%	No Cross-Reactivity	No Interference
Blood (human)	Blood	5%	No Cross-Reactivity	No Interference
Chloraseptic, Cepacol	Benzocaine, Menthol	0.7 g/mL	No Cross-Reactivity	No Interference
Flonase	Fluticasone	5%	No Cross-Reactivity	No Interference
Halls Relief Cherry Flavor	Menthol	0.8 g/mL	No Cross-Reactivity	No Interference
Nasocort Allergy 24 hour	Triamcinolone	5%	No Cross-Reactivity	No Interference
Neo-Synephrine	Phenylephrine hydrochloride	5%	No Cross-Reactivity	No Interference
Oseltamivir	Oseltamivir	2.2 µg/mL	No Cross-Reactivity	No Interference
Purified mucin protein	Mucin protein	2.5 mg/mL	No Cross-Reactivity	No Interference
Rhinocort	Budesonide (Glucocorticoid)	5%	No Cross-Reactivity	No Interference
Saline nasal spray	Saline	15%	No Cross-Reactivity	No Interference
Tobramycin	Tobramycin	1.25 mg/mL	No Cross-Reactivity	No Interference
Zanamivir	Zanamivir	282.0 ng/mL	No Cross-Reactivity	No Interference
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5%	No Cross-Reactivity	No Interference

* Testing was performed in triplicate.

CUSTOMER AND TECHNICAL SUPPORT

To place an order or for technical support, please contact a Quidel Representative at 800.874.1517 (toll-free in the U.S.) or 858.552.1100 (outside of U.S.), Monday through Friday, between 8:00 a.m. and 5:00 p.m., Eastern Time. Orders may also be placed by fax at 740.592.9820. For e-mail support contact: customerservice@quidel.com or technicalsupport@quidel.com. For services outside the U.S., please contact your local distributor. Additional information about Quidel, our products, and our distributors can be found on our website quidel.com. Test system problems may also

be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; http://www.fda.gov/medwatch).

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REF M312 – Solana SARS-CoV-2 Assay – 48-Test Kit

IVD

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GLOSSARY

REF Catalog number	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx ONLY Prescription use only	 Consult e-labeling instructions for use
IVD For *In Vitro* diagnostic use	 Contains sufficient for 48 determinations
CONT Contents/Contains	