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.

For *in vitro* diagnostic use only

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.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 is generally detectable 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 are required to report all positive 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 trained clinical laboratory personnel proficient in performing tests using the Solana instrument.

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 frozen Master Mix vial contains RT-HDA reagents, dNTPs, primers and probes. The thawed Master Mix is transferred to empty reaction tubes. The processed sample is then transferred to a Reaction Tube containing Master Mix. Once the Master Mix and the processed sample are mixed, the Reaction Tube is placed in Solana for amplification and detection of SARS-CoV-2 specific target sequences. In Solana, the target sequences are amplified by SARS-CoV-2 specific primers and detected by SARS-CoV-2 specific fluorescence probes, respectively. A competitive process control (PRC) is included in the Master Mix 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. In addition, the target probe and PRC probe have one or more bases that are comprised of ribonucleic acid. Upon annealing to SARS-CoV-2 or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and 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. #M313
96 Tests per Kit

Component	Quantity	Storage
Box A		
Master Mix Tubes	8 tubes/kit 0.300 mL, amber tube	≤ -70°C
Box B		
Process Buffer	96 tubes/kit 0.75 mL	2°C to 8°C
Empty Reaction Tubes	96 tubes/kit	2°C to 30°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)
- Transport Media (BD/Copan UTM Quidel Transport Media (QTM))
- Ultra-low temperature freezer -70°C or below

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use under Emergency Use Authorization only.
- 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.
- Transport media not listed above must be validated by the user prior to use with the Solana SARS-CoV-2 Assay.
- All tubes should be capped tightly prior to vortexing.
- Proper sample collection, storage and transport are essential for correct results.
- Master Mix should remain frozen until use. Do not refreeze. Once thawed, Master Mix is stable for up to 24-hours when stored at 2° to 8°C.
- 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

Store the Master Mix at -70°C or below. Once thawed, the Master Mix is stable for up to 24-hours when stored at 2° to 8°C. The remaining 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 or Quidel QTM are stable at room temperature (RT), 2°C to 8°C or -70°C or below for up to 4 days.

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. Remove the required number of Empty Reaction Tubes from the bag and place in the Workflow tray. Label the Reaction Tubes on the cap.
4. Mix the specimen received in viral transport media by vortexing the tubes for 5 seconds.
5. 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.
6. 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 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.
7. Thaw one (1) Master Mix vial for every 12 tests you wish to perform for 13-15 minutes before proceeding to the next step. This may also be performed at beginning of test procedure if user intends to perform sample testing through amplification.
   NOTE: Only thaw the volume of Master Mix required to complete testing.
   NOTE: Master Mix is stable with one freeze/thaw cycle when stored for up to 8 hours between refreezing at 2° to 8°C.
8. Mix thawed Master Mix for 5 seconds.
9. Add 25 µL of Master Mix to each empty reaction tube.
10. Add 25 µL of each heat lysed Process Buffer specimen to the corresponding Reaction Tube directly into the liquid Master Mix and mix by vigorously pipetting up and down 5 times. Firmly close the Reaction Tubes.
11. 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

12. 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.
13. Enter User ID, press ↵ (ENTER) and enter Password and press ↵ (ENTER).
14. Select "NEW TEST." If Solana displays a different screen, go to the home screen.
15. Select the tube positions to use.
16. 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 "▶."
17. Select sample type (patient or QC) from the drop-down menu and enter Sample IDs (optional; see 2nd Note in next step).
18. 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.
19. 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 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 device has not been assessed in a population vaccinated against COVID-19.

CLINICAL PERFORMANCE

A study was performed comparing the Solana SARS-CoV-2 Assay to an authorized EUA RT-PCR assay. 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 Swabs	Number Tested	True Positive	False Positive	True Negative	False Negative	PPA%	NPA%	PPA 95% CI	NPA 95% CI
Nasal	240	69	0	169	2	97.2	100	90.3% - 99.2%	97.8% - 100%
Nasopharyngeal	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%

ANALYTICAL PERFORMANCE

Limit of Detection

The Limit of detection (LoD) was established with BEI NR-52286, SARS-Related Coronavirus 2, Isolate USA-WA1/2020, Heat Inactivated in three (3) separate studies using dilutions in negative nasal matrix collected into UTM.

Study 1 – LoD Screen

Ten-fold dilutions of the heat-inactivated 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.

LoD Screen Results		
SARS-CoV-2 Concentration (cp/mL)	# Positive/Triplicate Test	% Positive
1.16×10^7	3/3	100%
1.16×10^6	3/3	100%

LoD Screen Results		
SARS-CoV-2 Concentration (cp/mL)	# Positive/Triplicate Test	% Positive
1.16×10^5	3/3	100%
1.16×10^4	3/3	100%
1.16×10^3	3/3	100%
1.16×10^2	0/3	0%

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: 0.75X LoD, 1X LoD, 3X LoD, 5X LoD and 10X LoD. Each dilution was tested in triplicate with the Solana SARS-CoV-2 Assay.

Pre-LoD Results		
SARS-CoV-2 Concentration (cp/mL)	# Positive/Triplicate Test	% Positive
1.16×10^4	3/3	100%
8.72×10^3	3/3	100%
3.48×10^3	1/3	33%
1.16×10^3	1/3	33%
8.72×10^2	1/3	33%

Study 3 – LoD Confirmation testing

Based on the Pre-LoD data, the dilution demonstrating ≥95% detection was used in the LoD confirmation study. A 1x LoD dilution was made in negative nasal matrix. This dilution was tested with twenty replicates with the Solana SARS-CoV-2 Assay.

LoD Confirmation		
SARS-CoV-2 Concentration (cp/mL)	# Positive/Triplicate Test	% Positive
8.72×10^3	16/20	80%

Based on this data, the next highest LoD dilution was made in negative nasal matrix (1.16×10^4). This dilution was tested with twenty replicates with the Solana SARS-CoV-2 Assay.

LoD Confirmation		
SARS-CoV-2 Concentration (cp/mL)	# Positive/Triplicate Test	% Positive
1.16×10^4	20/20	100%

The limit of detection (LoD) of the Solana SARS-CoV-2 Assay using limiting dilutions of heat-inactivated SARS-CoV-2 is 1.16×10^4 cp/mL. This LoD was confirmed by testing 20 replicates each of negative nasal matrix collected into the CDC Viral Transport Media spiked with heat-inactivated SARS-CoV-2 at 1.16×10^4 cp/mL.

The Solana SARS-CoV-2 Assay was evaluated using the FDA SARS-CoV-2 Reference Panel. 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 using 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 January 29, 2021, a total of 490,785 SARS-CoV-2 sequences were available from the GISAID and NCBI databases. Of these, 485,557 (98.93%) include the amplicon region (<5 undefined nucleotide bases in any oligonucleotide region) and are 88.46-100% conserved to the Solana SARS-CoV-2 oligonucleotides. 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	436,803	432,555	415,181	432,548
NCBI	53,982	53,002	41,040	53,002

Inclusivity of the Solana SARS-CoV-2 Assay with four (4) published variants (UK Variant (VUI202012/01), South Africa Variant (501Y.N2), Brazil Variant (484Y.V2), California Variant (L452R)) was established through an *in-silico* analysis of available sequences (35,882, 656, 250 and 980, respectively). All sequences are 88.46-100% 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	UK	36,122	35,882	35,786	35,881
	SA	667	656	653	656
	BZ	252	250	249	250
	CA	981	980	974	980

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

Cross-Reactivity/Microbial Interference Results					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
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
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

Homology Results of Solana SARS-COV-2 Primers Against Cross-Reactants	
Organism	**# Sequences ≥80% Conserved to both Primers**
SARS-1	227
Bacillus anthracis	0
Candida albicans	0
Chlamydia pneumoniae	0
Chlamydia psittaci	0
Corynebacterium diptheriae	0
Coxiella burnetii	0
Haemophilus influenzae	0
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

Cross-Reactivity/Interference Results				
Interfering Substance	**Active Ingredient**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5%	No Cross-Reactivity	No Interference

* Testing was performed in triplicate.

CUSTOMER AND TECHNICAL SUPPORT

If you have any questions regarding the use of this product or to report a product problem, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference quidel.com to see more options for Support.

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REF M313 – Solana SARS-CoV-2 Assay – 96-Test Kit

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Revision Changes:

- Initial release

GLOSSARY

REF Catalog number	LOT Batch code
EC REP Authorized representative in the European Community	CE CE mark of conformity
 Use-by date	 Manufacturer
 Temperature limitation	 Consult e-labeling instructions for use
IVD *In vitro* diagnostic medical device	 Contains sufficient for <n> tests

Revision Changes:
Updated with in silico inclusivity information, limitations, transport media, and testing location.