SARS-CoV-2 Assay

Frequently Asked Questions

Summary
Quidel received FDA Emergency Use Authorization for the Solana SARS-CoV-2 Assay to allow direct sample processing in nasal (NS) or nasopharyngeal (NP) direct swab specimens from individuals suspected of COVID-19 by their healthcare provider. Under the new EUA, hospital and reference laboratories no longer have to depend on an upfront sample extraction.

How does the assay work?
The Solana SARS-CoV-2 Assay amplifies and detects viral RNA present in viral transport media containing nasopharyngeal or nasal swab specimens obtained from symptomatic patients. 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.

In the Solana SARS-CoV-2 Assay, 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.

What equipment is needed to store the assay?
A –70°C or below Ultra-Low Temperature Freezer is required to store the master mix. Customers must have this freezer on-site **before** placing any orders so that the kit components can be stored properly. The Process Buffer is stored at 2°C to 8°C. Please follow storage requirements as stated in the PI for optimal performance and to prevent wastage.

Does the test come with everything needed to perform the assay?
As stated above, a –70°C or below Ultra-Low Temperature Freezer and a refrigerator are required. To perform the assay, controls are included in the kit and additional controls may be ordered separately by their individual part number. The assay kit is available as a standalone kit or with the ancillary materials such as swabs and transport media. The Solana Instrument, Accessory Packs, Refrigerators, and –70°C or below Ultra-Low Temperature Freezer are sold separately.

Where is the test performed?
Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests.

Can viral transport media (VTM) be used with this assay?
Yes. The assay is intended for use with specimens collected and transported in viral transport media. Currently, BD/Copan UTM and CDC Formulation VTM are authorized media types.

How fast is the test?
The upfront sample preparation of samples takes approximately 20 minutes and amplification and detection in the Solana Instrument takes 25 minutes.

Do you have a proficiency recommendation to validate the Solana SARS-CoV-2 Assay?
Check with your local and state regulation for proficiency requirements. All recommended surveys have been tested with this assay and performed satisfactorily.

If you are using the CAP proficiency program, we recommend using the SARS-CoV-2, Molecular – COV2 survey.

If you are using the API proficiency program, we recommend using the SARS-CoV-2 Liquid (molecular) package #385.

If you are using WSLH proficiency program, we recommend using the SARS-CoV-2 Molecular (5 samples) package, #PT06270.

What are the CMS suggested CPT codes and National Limit amounts for the Solana SARS-CoV-2 Assay?
Quidel has identified the following codes as relevant to report the Solana SARS-CoV-2 Assay. Please check with your payers to determine appropriate coding.

CPT CODE	DESCRIPTION
87635*	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
U0003*	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19], amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R.

For the Medicare Clinical Laboratory Fee Schedule, go to https://www.cms.gov. Please refer to your local Medicare Administrative Contractor (MAC) for the current reimbursement rate for this code. For reimbursement inquiries, please contact CodeMap® at quidel@codemap.com or 312.291.8408. You may also visit https://www.codemap.com/quidel.

Is the Solana SARS-CoV-2 Assay FDA cleared?
The Solana SARS-CoV-2 Assay has been authorized for use under the FDA Emergency Use Authorization Policy.

I would like to run Limits of Detection. Are your controls quantified?
No. The Solana SARS-CoV-2 Positive and Negative Controls are unassayed controls. Quantification of controls is the responsibility of the end user.

*This information is being provided as a reference, for informational purposed only, with no expressed or implied warranty and does not purport to provide legal or certified coding advice. Under Federal and State law, it is the individual providers responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their contracted payers to determine appropriate coding and charge or payment levels prior to submitting claims.

FQM313000EN00 (01/21)