Technical Bulletin

Sofia® SARS Antigen FIA, Sofia 2 Flu + SARS Antigen FIA, and QuickVue® SARS Antigen Test Implementation Options

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The Sofia SARS Antigen FIA, Sofia 2 Flu + SARS Antigen FIA, and QuickVue SARS Antigen are authorized for use under FDA Emergency Use Authorization 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.

Clinical laboratories and POC facilities looking to implement Sofia SARS Antigen FIA, Sofia 2 Flu + SARS Antigen FIA, or QuickVue SARS Antigen Test should follow the guidance outlined by the CDC, CLIA (CMS), ASM and their accrediting agency to identify any specific implementation requirements. Each facility should review local, state, and federal guidance related to SARS-CoV-2 testing using methods authorized by the FDA under the Emergency Use Authorization process to determine the depth of verification needed to begin testing.

If you determine that a verification study or method comparison is necessary for Sofia SARS Antigen FIA, Sofia 2 Flu + SARS Antigen FIA, or QuickVue SARS Antigen Test implementation, please review the following recommendations to ensure optimal assay performance:

- **For best performance, please follow the Swab Test Procedure using direct nasal or nasopharyngeal (NP) swabs collected from a patient.**
- The use of viral transport media (VTM) is not supported for these products and this may result in decreased test sensitivity.
- Verifications should be performed using the same sample type as will be used for clinical testing.
- Only use acceptable swab types which include either the nasal swabs provided in the kit or nylon flocked nasopharyngeal swabs.
- If comparing a direct swab to an alternate method which requires use of VTM, a dual collection protocol should be used.
- The same sample type should be utilized for a method comparison. Comparing results from a direct nasal swab to an NP swab should not be done.
- Testing should be conducted using samples obtained from patients who are displaying symptoms associated with acute illness and within the first five days of the onset of symptoms.

If you have any questions regarding the use of this product, 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.

Country	Phone	E-Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
Austria	+43 316 231239	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Italy	+39 (800) 620 549	
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You may also visit our website at **quidel.com** for information on Quidel's line of Rapid Diagnostics, Molecular Diagnostics, Cell Culture and Specialty Products (Bone Health and Autoimmune & Complement). Other product information available on our website includes: CPT codes, CLSI procedure guides, SDS, and Package Inserts.

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https://www.cdc.gov/coronavirus/2019-ncov/downloads/OASH-COVID-19-guidance-testing-platforms.pdf

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/QSO18-19-CLIA

https://asm.org/Protocols/EUA-COVID-19-Testing-Protocol