

Sofia[®] 2

Revolutionizing
Rapid Diagnostics



Sofia[®] 2

Innovating diagnostics, enabling unlimited insights

Sofia 2 uses **advanced immunofluorescence technology** that combines intuitive software, fluorescent chemistry and lateral flow technology to automatically deliver accurate results in minutes without the need for visual interpretation.

Sofia 2 is a **portable, easy-to-use benchtop** analyzer that offers **enhanced workflow flexibility** based on your unique testing demands. Combined with a growing menu of fluorescent immunoassays on the system, Sofia 2 takes lateral flow testing to a whole new level.

Highly accurate and reliable results ideal for both point-of-care and laboratory test settings

Fluorescence-based chemistry combined with rapid results

- Offers you confidence in your rapid test results
- Within minutes, patients can be quickly and properly managed without the need to manually interpret test results

Flexible, dual-mode testing

- WALK AWAY Mode facilitates laboratory multitasking by eliminating manual timekeeping
- READ NOW Mode allows batch processing of dozens of samples per hour by utilizing rapid, successive Test Cassette reads following a simple benchtop incubation step

Automated results generation

- Removes the variability from operator to operator caused by interpreting visually read test results
- Advanced Result Technology (ART) available on Sofia 2 can provide results in as few as 3 minutes for certain assays
- Results are displayed on screen, printed and can be transmitted to the LIS effortlessly

Barcode technology

- Provides full traceability of individual Test Cassettes, individual test results, as well as test operator profiles
- An internal barcode scanner reads each Test Cassette to record test- and lot-specific data. The external barcode reader is used to scan Patient and Operator IDs

LIS connectivity

- Reduces your staff's burden of manually recording test results
- Sofia 2 connects to the majority of existing information systems using the ASTM or POCT1-A protocols

External and internal memory storage

- Internal memory stores patient results
 - External SD Cards on Sofia and external USB Drives on Sofia 2 are capable of storing thousands of test results
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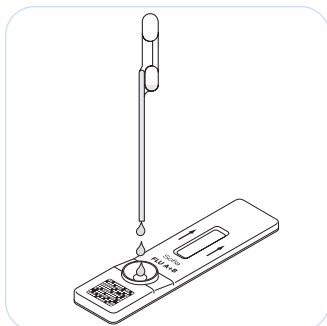
QuidelOrtho's industry-leading expertise in immunoassays, molecular testing, clinical chemistry and transfusion medicine delivers fast, accurate and reliable diagnostics to diverse healthcare settings. Partnering globally, we pioneer innovations, forging seamless connections and illuminating paths to informed decisions.

Rapid, objective Sofia 2 results delivered by trusted technology

Flexible dual-mode testing

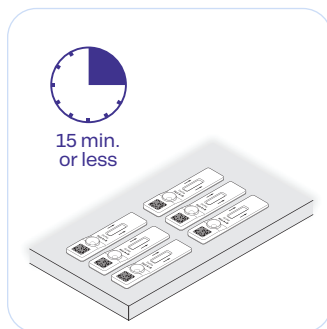
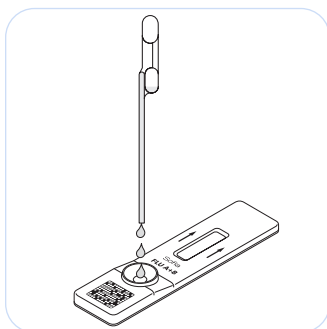
WALK AWAY Mode

Facilitates laboratory multitasking by eliminating manual timekeeping. Load and go for automated processing and results.



READ NOW Mode

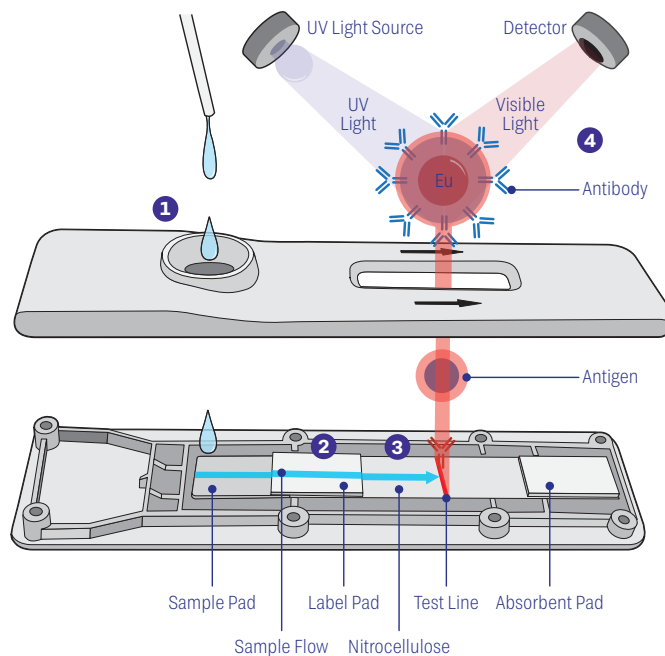
Allows batch processing of up to dozens of samples per hour by utilizing rapid, successive Test Cassette reads following a simple benchtop incubation step.



Inside the Sofia Test Cassette

During a test run, Sofia excites and scans hundreds of data points originating from the test strip. Samples are processed, data analyzed and results reported with enhanced assay sensitivity in a matter of seconds.

- 1 The sample is added to the sample pad region of the Test Cassette, and capillary action then draws the fluid through the strip to initiate the test.
- 2 When the sample reaches the label pad, the intended analyte (e.g., a viral or bacterial antigen), if present in the sample, binds to antibody-coated fluorescent Europium beads.
- 3 These target analyte-Europium bead complexes then travel across a nitrocellulose membrane, until they reach a group of capture antibodies present on the test line of the device.
- 4 These complexes bind to the test line antibodies. Upon excitation of the Europium molecules by an ultraviolet light source, the analyzer detects the emission energy in form of visual light and determines the final test result.

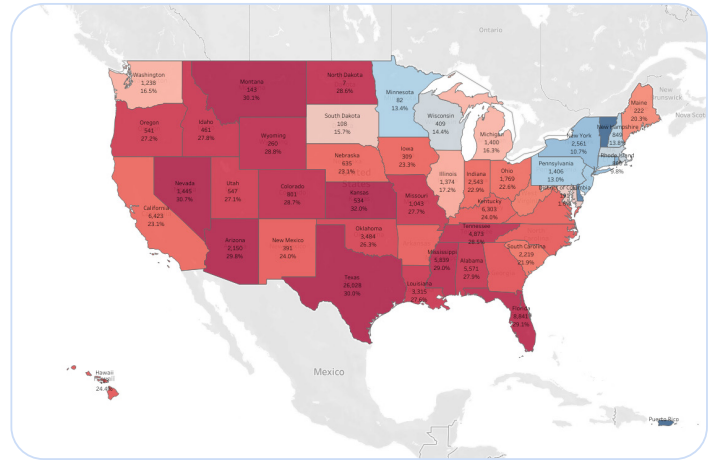


Virena[®]

Data analytics and surveillance

Virena is a wireless, cloud-based system that stores deidentified patient test results transmitted securely from Sofia and Sofia 2 in real time. Virena comes built-in with Sofia 2 via an internal cellular card, and allows clinicians to conveniently test and then track infectious diseases using interactive maps, monitor and adjust personnel and inventory based on real-time demands, cross-check test volumes versus billing and manage records and run reports across multiple locations.

For real-time disease tracking visit quidel.com/beinformed.



Sofia[®] 2 Analyzer



Catalog #	Quantity	Description
20299	1	Sofia 2 Analyzer
20300	1	Sofia 2 Analyzer (XUS)
20314	1	Sofia 2 Install Pack





Sofia and Sofia 2 menu of assays

Assay	Sofia	Sofia 2
Respiratory		
Sofia Influenza A+B FIA	✓	✓
Sofia 2 Flu+SARS Antigen FIA [†]		✓
Sofia Legionella FIA [†]	✓	✓
Sofia RSV FIA	✓	✓
Sofia S. pneumoniae FIA [†]	✓	✓
Sofia SARS Antigen FIA [*]	✓	✓
Sofia 2 SARS Antigen+ FIA [†]		✓
Sofia 2 SARS-CoV-2 IgG Antibody FIA [†]		✓
Sofia Strep A FIA	✓	
Sofia Strep A+ FIA	✓	✓
Gastrointestinal		
Sofia 2 C. difficile FIA [†]		✓
Sofia 2 Campylobacter FIA		✓
Vector-borne		
Sofia Lyme FIA	✓	✓
Sofia 2 Lyme FIA		✓
Sofia 2 Lyme+ FIA [†]		✓
Other conditions		
Sofia hCG FIA	✓	
Sofia Quantitative Vitamin D FIA [†]	✓	

***These tests are available for sale in the USA under emergency use authorization.**

These tests have not been FDA cleared or approved, but have been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. These assays are 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 authorization is terminated or revoked sooner.

†Not available for sale in the U.S.

***Not available outside of the U.S.**



New QuidelOrtho branding may not be available in all markets, subject to country-specific regulatory approval.
Please confirm with your local commercial team.



At QuidelOrtho, we transform diagnostic data into answers, understanding and action, illuminating the path forward for all. For more than 80 years, we've pursued the unknown with a passion and purpose to improve health. We will continue to transform the power of diagnostics into a healthier future for all.

9975 Summers Ridge Road
San Diego, CA 92121 USA

1-800-874-1517
quidelortho.com

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