

Sofia[®]

by **QUIDEL[®]**



simple
sensible
sophisticate

Sofia is easy to use.

4 simple steps . . .



Step 1.
Enter or scan patient ID



Step 2.
Pipette sample



Step 3.
Place cassette into drawer and close



Step 4.
Review result

. . . leading to objective results within **minutes**.

So simple

Sofia places you in control.

Flexible workflow options, security features and digital/LIS capabilities . . .

Choice in workflow option gives you the flexibility to change the mode to fit your specific workload.



Pipette sample



Walk Away Mode – 1 Sample

Place cassette in drawer and close. Sofia will time development, scan and display the test result, allowing you to record the result at your convenience.

OR



Read Now Mode – Multiple Samples

Time the sample on the benchtop, then place cassette drawer and close. Sofia will scan the cassette and display the test result in less than 1 minute, allowing you to batch and run multiple samples at a time.

SO sensible

LIS, Middleware, EMR

Digital connectivity capabilities

Barcode Scan

Effortlessly links patient, operator, instrument, time/day/date and results

Data Management

Stores, updates, installs and prints data

Guided User Interface

Easy, intuitive, effective



. . . giving you the freedom of choice.

Sofia is a comprehensive solution.

	Traditional Visual Tests	Basic Reflection Readers	Sofia Analyzer
Simple	•	•	•
Fast	•	•	•
CLIA-Waived Influenza Test	•	•	•
Objective Results		•	•
Fluorescent Technology			•
Walk-Away Automation			•
User/Patient ID Barcode			•
Results Print Out			•
Data Storage/Management			•
Digital/Connectivity Capabilities			•
QC Data Management			•
User Security Features			•

Sofia Platforms For Growth

Upper Respiratory | Infectious Diseases | Women's Health | Endocrine | General Health



For more information on Sofia, visit our website or call 800.874.1517 | quidel.com | sofiastupport.com

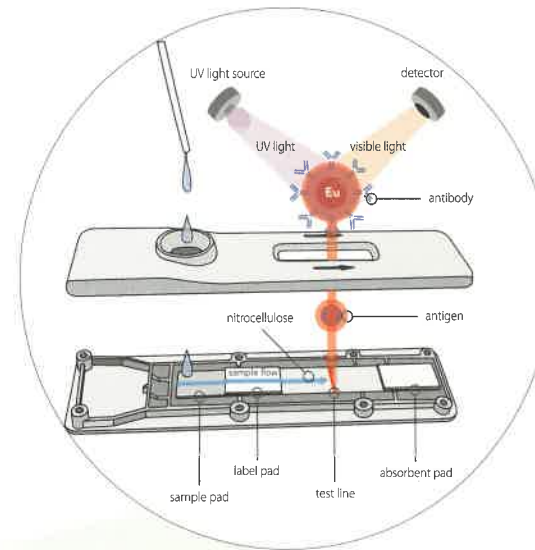
Quidel Corporation | Worldwide Headquarters | 10165 McKellar Court | San Diego | CA 92121 | USA

Sofia provides greater stability and improved sensitivity

Sophisticated approach with lateral flow simplicity . . .

- Europium-based fluorescent chemistry
- Concentrated fluorescent signal
- Optical sensors and proprietary algorithms interpret signals and analyze data

S O sophisticated



. . . providing results you can **trust**.



Confidence in your rapid test results

You no longer have to choose between accurate results and fast turnaround time.

Quidel's Sofia Legionella FIA takes lateral flow to a whole new level, utilizing advanced immunofluorescence technology intended for the rapid qualitative detection of *Legionella pneumophila* Serogroup 1, directly from urine specimens.

This test, used with the Sofia Analyzer, allows you to rapidly diagnose and treat.

The Sofia Legionella FIA is highly accurate, giving you confidence in the results so you can provide the right care now.

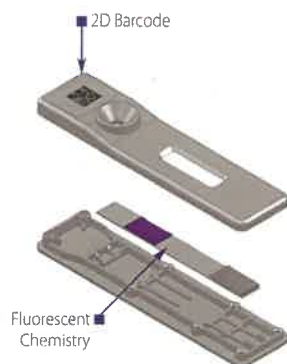


Sofia: A Next Generation Rapid Immunoassay

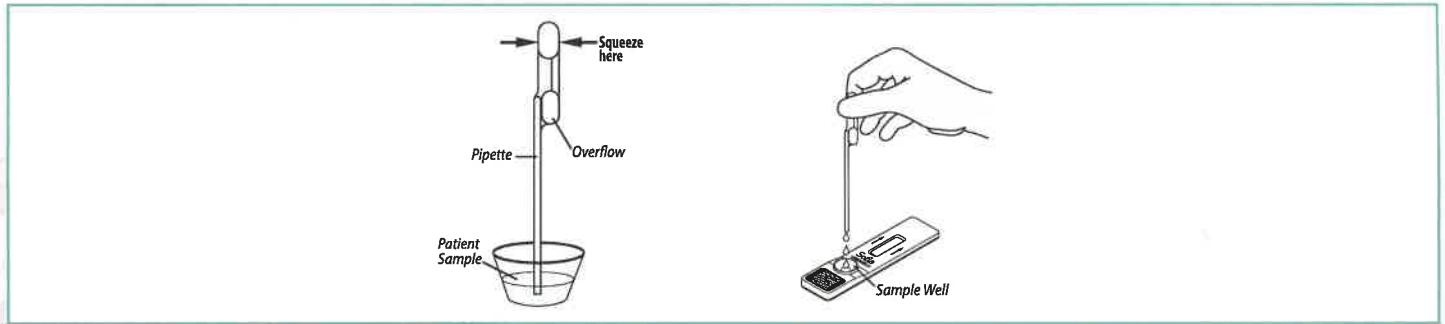
- Excellent performance as demonstrated by a competitive comparator study using 149 clinical specimens
- Simple, 3-step procedure
- Accurate detection with urine samples
- Highly accurate results in 10 minutes
- Available in 25-test kit
- Room temperature storage

The Sofia Analyzer

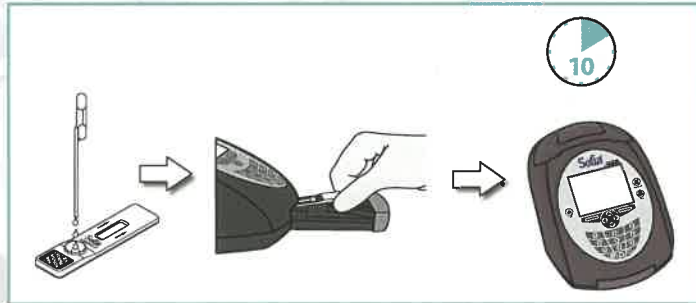
- Advanced fluorescence detector with ultraviolet LED energy source
- Optical sensor scans and collects hundreds of data points on the test strip
- Proprietary algorithms analyze data, interpret signals and determine results
- Easy to use interface, customizable settings, bar code technology and LIS connectivity
- Automated results eliminate the interpretation subjectivity and variability from operator to operator
- Results can be stored in the analyzer, on the provided SD card, displayed on the screen and sent to the LIS
- Flexible work flow options



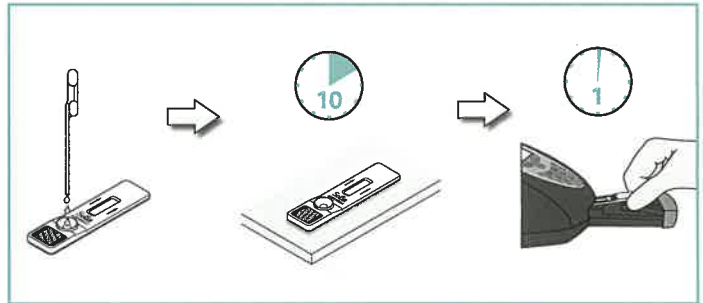
Urine Sample Procedure



Walk Away Mode – Walk away and multitask



Read Now Mode – Batch several samples per hour



Analytical Sensitivity Comparison

Dilutions of Knoxville Legionella Strain (cfu/mL)	Sofia Legionella (10 minutes)	BinaxNOW (15 minutes)	BinaxNOW (60 minutes*)
60,000	10/10	6/6	6/6
30,000	10/10	1/6	5/6
10,000	10/10	1/6	2/6
5,000	10/10	n/a	n/a
2,500	10/10	n/a	n/a

In a comparison LoD study to Binax NOW, dilutions of bacteria were made from a negative urine matrix spiked with Knoxville-1 strain at 6×10^4 , 3×10^4 , 1×10^4 , 5×10^3 , 2.5×10^3 , and 1×10^3 cfu/mL. For Binax NOW, the suspensions at 6×10^4 , 5×10^4 , 3×10^4 , and 1×10^4 were tested with 6 replicates and read at 15 minutes. Ten (10) replicates were tested at 6×10^4 , 3×10^4 , 1×10^4 , 5×10^3 , 2.5×10^3 , and 1×10^3 cfu/mL were tested on Sofia cassettes from the same suspensions. Sofia called 10 out of 10 replicates positive down to a bacterial suspension containing 2.5×10^3 cfu/mL.

Sofia Provides Greater Sensitivity in Less Time Than the Leading Assay

	Sofia Legionella (10 minutes)	BinaxNOW (15 minutes)	BinaxNOW (1 hour*)
Positive	56	38	47
Negative	93	111	102**
Total	149	149	149

*Held J. et al. Increasing the sensitivity of the BinaxNOW Legionella urinary antigen immunochromatographic test by additional readings at later time points. *Med Microbiol* 2012 61 (Pt_6), p. 884.

**After one hour incubation, an additional 9 of the 111 samples originally declared negative by BinaxNOW at 15 minutes resolved positive. Of the remaining 9 discordant results between Sofia and BinaxNOW (102-93=9), 2 samples were resolved positive by Meridian TRU Legionella and 3 samples could not be tested.

Features	Instrumented Systems	Rapid Visual Assays
	Sofia	Binax NOW
Results Interpretation	Automatic and objective	Visual
Time to Result	10 minutes	15 minutes
Workflow	Two work modes: Walk away and batching	Manual
Auto Data Management	Barcode Scanning of Patient and User IDs/Controls	None
QC Data Management	Electronically entered, captured and stored	Manual
User Entry Requirements (optional)	Yes	No
LIS Compatible	Yes	No
Result Print Out	Yes	No

To order: Call your Quidel Account Manager or your local distributor.
Legionella FIA – 25/Kit: Catalog #20244



For more information on the Sofia Legionella FIA, contact your Quidel Account Manager at 858.552.1100 (outside the U.S.) or your local distributor.

Quidel Corporation Worldwide Headquarters 10165 McKellar Court, San Diego, CA 92121 USA quidel.com



QUIDEL®



Sofia®

Next Generation
Rapid Diagnostics

INTERNATIONAL

PRODUCT CATALOG



Quidel is a leading manufacturer of diagnostic healthcare solutions serving to enhance the health and well-being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system.

Our product base and technology platforms have continued to expand through internal development and acquisitions of other products and technologies allowing for a core competency that includes:

- Immuno and molecular assay development
- Automated manufacturing lateral flow (LF) technologies
- Direct fluorescent antibodies (DFA) production
- Monoclonal antibody characterization



With Sofia, you no longer have to choose between accurate results and fast turnaround time. Sofia 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 is a small, easy to use bench top analyzer offering a choice in workflow options that allows for greater flexibility based on workload.

Combined with a growing menu of fluorescent immunoassays, Sofia takes lateral flow to a whole new level.

Sofia[®]

Next Generation Rapid Diagnostics

You no longer have to choose between accurate results and fast turnaround time.

Next Generation Rapid Diagnostics

Advanced immunofluorescence technology.

Sofia Influenza A+B FIA

For the rapid qualitative detection and differentiation of influenza A and influenza B viral nucleoprotein antigens

- Accurate detection with nasal swab, nasopharyngeal swab and nasopharyngeal aspirate/wash samples
- Results in 15 minutes
- Positive and negative control swabs included
- Nasal collection swabs included
- Compatible with several brands of viral transport media
- Room temperature storage
- 21-month shelf life from date of manufacture
- CLIA waived



Catalog #	Qty	Description
20254	25 tests	Sofia Influenza A+B FIA

Sofia Strep A+ FIA

For the rapid qualitative detection of Group A Streptococcal antigens

- Accurate detection with throat swab samples
- Results in 5 minutes
- Positive and negative control swabs included
- Rayon throat collection swabs included
- Room temperature storage
- 24-month shelf life from date of manufacture
- CLIA waived



Catalog #	Qty	Description
20276	25 tests	Sofia Strep A+ FIA

Sofia RSV FIA

For the rapid qualitative detection of respiratory syncytial virus nucleoprotein antigens

- Accurate detection with nasopharyngeal swab and nasopharyngeal aspirate/wash specimens
- Results in 15 minutes
- Positive and negative control swabs included
- Nasopharyngeal collection swabs included
- Room temperature storage
- 24-month shelf life from date of manufacture
- CLIA waived



Catalog #	Qty	Description
20242	25 tests	Sofia RSV FIA

Sofia hCG FIA

For the rapid qualitative detection of human Chorionic Gonadotropin (hCG) in urine specimens

- Accurate detection with urine specimens
- Results in 3 minutes
- 20 mIU/mL sensitivity in urine
- > 99% positive and negative agreement
- Room temperature storage
- 18-month shelf life from date of manufacture



Catalog #	Qty	Description
20266	50 tests	Sofia hCG FIA

Sofia Legionella FIA

NOT AVAILABLE FOR SALE IN THE USA.

For the rapid qualitative detection of Legionella pneumophila serogroup I from urine specimens

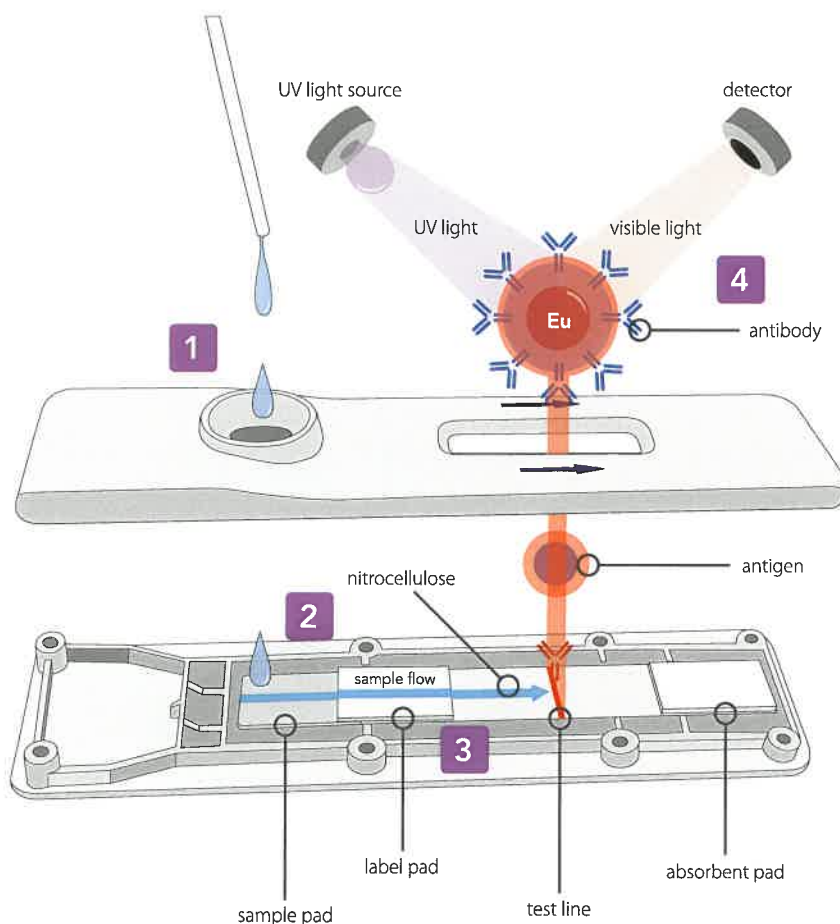
- Simple 2 part protocol
- Accurate detection with urine specimens
- Results in 10 minutes
- Positive and negative liquid controls included
- Room temperature storage
- 24-month shelf life from date of manufacture



Catalog #	Qty	Description
20244	25 tests	Sofia Legionella FIA

Confidence in Your Rapid Test Results

Feature	Benefit
Fluorescence-based chemistry combined with rapid results	<ul style="list-style-type: none"> Sofia offers you confidence in your rapid test results. Within minutes, patients can be quickly and properly managed.
Automated results generation	<ul style="list-style-type: none"> Sofia removes the variability from operator to operator caused by interpreting visually read test results. Results can be stored in Sofia on an external SD card (slot located on back of Sofia). Results are displayed on screen, printed, and can be sent to the LIS effortlessly.
LIS connectivity	<ul style="list-style-type: none"> Reduce your lab's time manually recording test results. Using the ASTM protocol, Sofia connects to the majority of existing information systems.
Barcode technology	<ul style="list-style-type: none"> Sofia provides traceability of test results, operators and individual Cassettes. 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.
External and internal memory storage	<ul style="list-style-type: none"> Internal memory stores 500 patient results. External (SD Card) memory stores thousands.



Inside Sofia

For enhanced sensitivity, sample detection and data compilation is achieved in a matter of seconds as Sofia excites and scans hundreds of data points per strip.

- 1 Sample is added to the Test Cassette and capillary action draws the fluid through the strip.
- 2 On the label pad, complexes are formed when analyte (e.g., viral or bacterial antigen) in the patient sample is captured by the antibody coated to fluorescent europium beads.
- 3 These complexes travel through the nitrocellulose membrane until reaching a group of capture antibodies at the test line.
- 4 An ultraviolet light source excites the Europium molecules of the beads in the complex trapped at the test line, and the emission energy is released as visible light that is read by the detector.

Next Generation Rapid Testing

Sofia, a small bench top analyzer, offers rapid, highly accurate and reliable results for centralized testing locations by integrating a unique fluorescent chemistry, quality control and fail-safe measures, and connectivity to your lab electronic medical records.

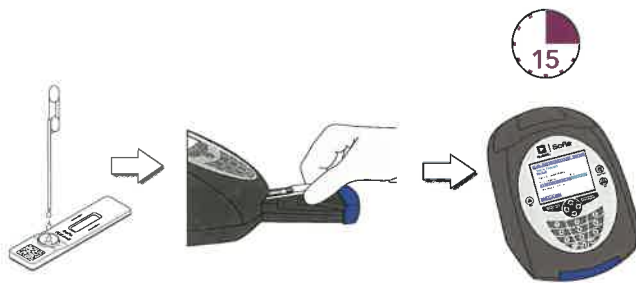
- Fluorescence-based chemistry combined with rapid results
- Automated results generation
- LIS connectivity
- Barcode technology
- External and internal memory storage



Catalog #	Qty	Description
20221	1	Sofia Analyzer
<i>Kit Includes:</i>		
N/A	1	Paper Roll
N/A	1	4 AAA Batteries
N/A	1	AC Power Cord
N/A	1	DC Power Cord
20230	1	Sofia Install Pack
<i>Kit Includes:</i>		
N/A	1	Barcode Scanner
N/A	1	SD Card(s)
N/A	1	Calibration Cassette
N/A	1	User Manual
N/A	1	QuickStart Guide

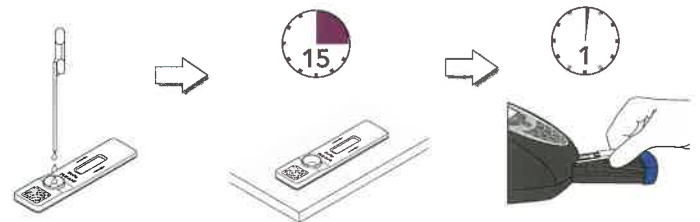
WALK AWAY Mode

Facilitates laboratory multitasking by eliminating manual timekeeping.



READ NOW Mode

Allows batch processing up to 60+ samples/hour through rapid, successive Cassette reads following a benchtop incubation step.



Virena

Sofia is compatible with Virena, Quidel's proprietary, global wireless data management system that provides near real-time de-identified patient results to assist in disease mapping and surveillance. With Virena, clinicians can trend and report on positivity rates and other metrics in patient populations. For more information visit quidel.com/immunoassays/virena.

NEW
PRODUCTS
INSIDE

Next Generation Rapid Diagnostics

International Product Catalog

Not For Use In The United States



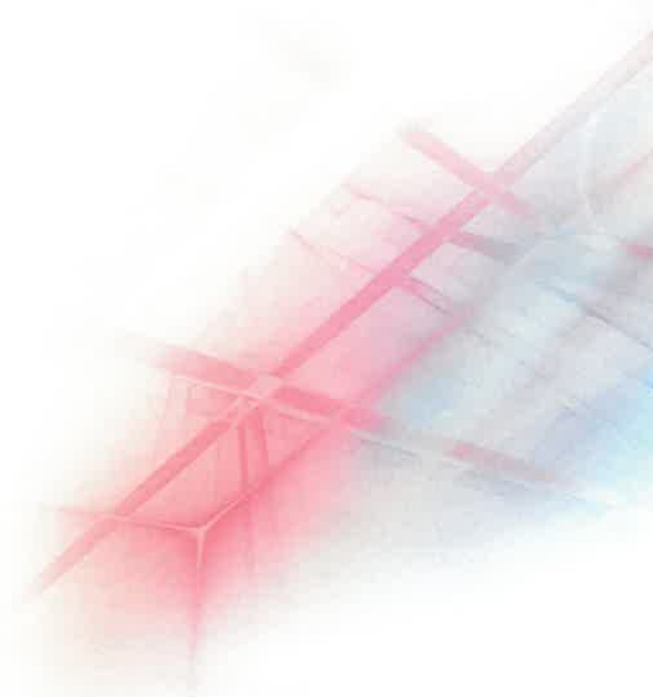
QUIDEL[®]

QUIDEL®

Quidel is a leading manufacturer of diagnostic healthcare solutions serving to enhance the health and well being of people around the globe with well-known and respected products that provide healthcare professionals with accurate and cost-effective diagnostic information.

Since 1979, Quidel has provided premium diagnostic products to professionals for use in physicians' offices, hospitals, clinical and reference laboratories, wellness centers, and retail clinics. Our product base and technology platforms have continued to expand through internal development and acquisitions of other products and technologies allowing for a core competency that includes:

- Immuno and molecular assay development
- Automated manufacturing Lateral flow (LF) technologies
- Direct Fluorescent Antibodies (DFA) production
- Monoclonal antibody characterization



Next Generation Rapid Testing

Quidel's newest platform, **Sofia**[®], takes lateral flow to a whole new level, utilizing 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 is a small, easy to use bench top analyzer offering a choice in workflow options that allows for greater flexibility based on workload. Combined with a growing menu of fluorescent immunoassays, Sofia takes lateral flow to a whole new level.

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Next Generation Rapid Testing

Confidence in Your Rapid Test Results

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Benefit

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Automated Results Generation

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LIS Connectivity

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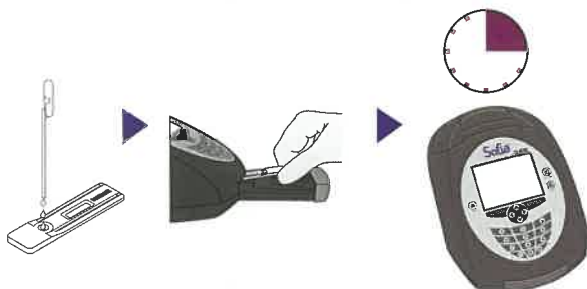
Barcode Technology

- Sofia provides traceability of test results, operators and individual cassettes.
- 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.

External and Internal Memory Storage

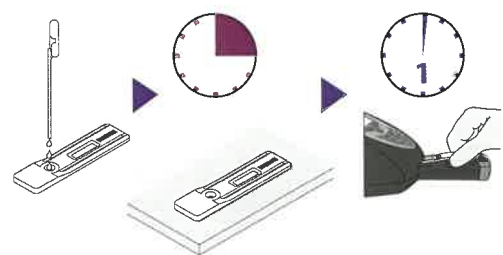
- Internal memory stores 500 patient results.
- External (SD Card) memory stores thousands.

Walk Away Mode



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Read Now Mode



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Sofia Analyzer

Sofia, a small bench top analyzer, offers rapid, highly accurate and reliable results for centralized testing locations by integrating a unique fluorescent chemistry, quality control and fail safe measures, and connectivity to your lab electronic medical records.



- Fluorescence-based chemistry combined with rapid results
- Automated results generation
- Lis connectivity
- Barcode technology
- External and internal memory storage

Catalog #	QTY	Description
20221	1	Sofia® Analyzer Kit Includes: Paper Roll, 4 AAA Batteries, AC Power Cord, DC Power Cord
20230	1	Sofia Install Pack Kit Includes: Barcode Scanner, SD Card(s), Multi-language CD-Rom, Calibration Cassette, User Manual, Quick Start Guide and Warranty Card



Next Generation Rapid Diagnostics

Quidel's Sofia takes lateral flow to a whole new level, utilizing advanced immunofluorescence technology.

Sofia Influenza A+B FIA

For the rapid qualitative detection of influenza A and influenza B viral nucleoprotein antigens.

- Accurate detection with nasal swab, NP swab and NPA/Wash samples
- Results in 15 minutes
- Positive and negative control swabs included
- Nasal collection swabs included
- Compatible with several brands of viral transport media
- Room temperature storage
- 21-month shelf life from date of manufacture



Catalog #	QTY	Description
20218	25 Tests	Sofia Influenza A+B FIA

Sofia Legionella FIA

For the rapid qualitative detection of Legionella pneumophila serogroup 1 from urine specimens.

- Simple 2 part protocol
- Accurate detection with urine specimens
- Results in 10 minutes
- Positive and negative liquid controls included
- Room temperature storage
- 24-month shelf life from date of manufacture



Catalog #	QTY	Description
20244	25 Tests	Sofia Legionella FIA

Sofia Strep A FIA

For the rapid qualitative detection of Group A Streptococcal antigen from throat swabs.

- Accurate detection with throat swab samples
- Results in 5 minutes
- Positive and negative control swabs included
- Rayon throat collection swabs included
- Room temperature storage
- 24-month shelf life from date of manufacture



Catalog #	QTY	Description
20231	25 Tests	Sofia Strep A FIA

Sofia RSV FIA

For the rapid qualitative detection of respiratory syncytial virus nucleoprotein antigen from nasopharyngeal swab and nasopharyngeal aspirate wash specimens.

- Accurate detection with nasopharyngeal swab and nasopharyngeal aspirate wash specimens
- Results in 15 minutes
- Positive and negative control swabs included
- Nasopharyngeal collection swabs included
- Room temperature storage
- 24-month shelf life from date of manufacture

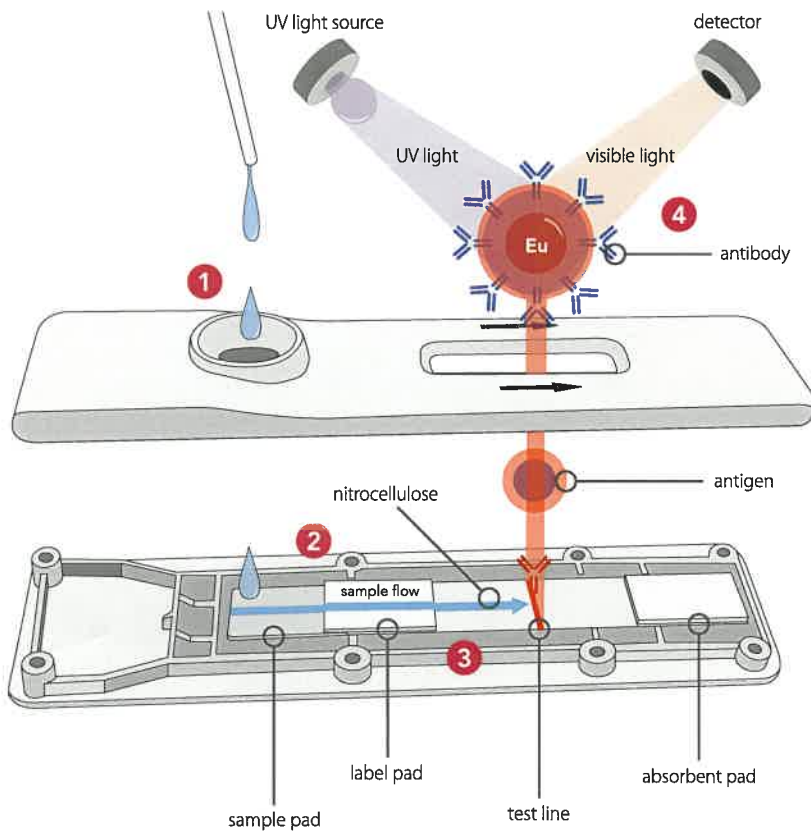


Catalog #	QTY	Description
20242	25 Tests	Sofia RSV FIA

Inside the Analyzer

For enhanced sensitivity, sample detection and data compilation is achieved in a matter of seconds as Sofia excites and scans hundreds of data points per strip.

- 1** Sample is added to the test cassette and capillary action draws the fluid through the strip.
- 2** On the label pad, complexes are formed when analyte (e.g., viral or bacterial antigen) in the patient sample is captured by the antibody coated to fluorescent europium beads.
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- 4** An ultraviolet light source excites the Europium molecules of the beads in the complex trapped at the test line, and the emission energy is released as visible light that is read by the detector.



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