



Sofia[®]

Technical Bulletin

Sofia S. pneumoniae FIA – AMF Update

This update on Assay Method File (AMF) provides the following features for Sofia S. pneumoniae FIA in Sofia 2 meter:

With Firmware (FW) 1.11 and above:

- Display signal over cutoff (S/CO) in result screen

with FW 1.14 and above:

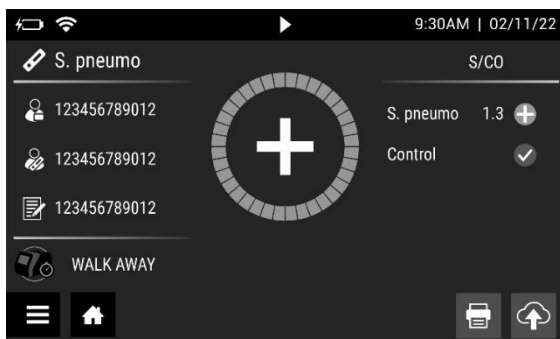
- Display S/CO in Patient Result Review
- Re-print result with S/CO value
- Transmit of S/CO via LIS

Note:

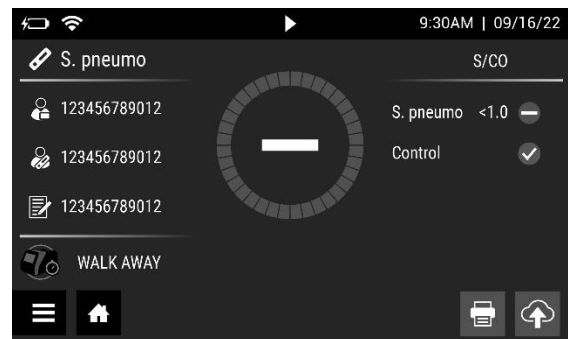
- This new AMF (EF1348003) for Sofia S. pneumoniae FIA is available for use outside U.S. The addition of this new feature has no impact on the assay performance.
- The S/CO value displayed is for information purposes only.
- There is no established correlation between the displayed S/CO value and the disease state:
 - The test result remains Qualitative not Quantitative - Please refer to the 'Interpretation of results' section detailed in the product Package Insert.

Example of result screen:

Positive results

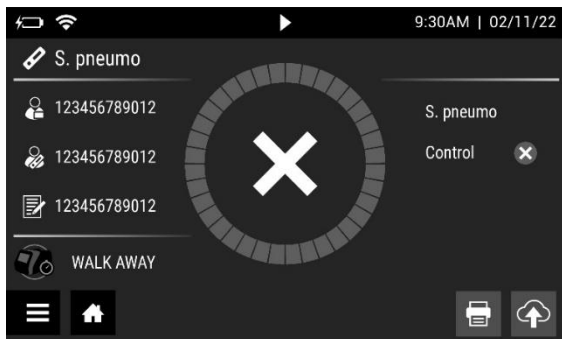


Negative results



Note: Qualitative result is *Negative* when S/CO is below the manufacturer defined assay specific cut-off.

Invalid



If you have any questions regarding the use of this product or to report a 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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