



# Sofia<sup>®</sup>

## Quantitative Vitamin D FIA

### QUICK REFERENCE INSTRUCTIONS

For use with Sofia.



Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

**IMPORTANT!** Read instructions carefully before beginning. The test procedure below is unique to the Sofia Quantitative Vitamin D FIA and may differ from other Sofia FIA procedures.

### Test Procedure

DO NOT open the foil pouch containing the Test Cassette until ready to test the sample. Place the Test Cassette on a clean and level surface.

**Sofia Quantitative Vitamin D FIA testing must be performed between 65°F to 80°F (18°C to 27°C), and all samples must be at room temperature before beginning the assay.**

**Expiration Date:** Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

1

Fill a calibrated micropipette with **100 µL** of the patient serum sample.



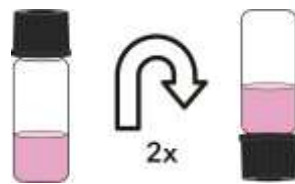
2

Add patient sample to the Reagent Vial.



3

Invert the Reagent Vial 2 times to mix. The Reagent Vial may also be vortexed to mix.



4

Let the sample stand in the Reagent Vial for 5 minutes.

While the patient sample is standing in the Reagent Vial, complete Steps 5 and 6. Continue with Step 7 immediately following the 5-minute incubation.



5

Select "Run Test" from the Main Menu on Sofia.



## Test Procedure (continued)

6

Input User ID and Patient ID or Order #.

- Input the User ID using the barcode scanner or manually enter the data using the key pad.
- Input the Patient ID or Order # using the barcode scanner or manually enter the data using the key pad.
- Press "Start Test" and the Sofia drawer will automatically open.

**NOTE:** If you mistakenly scan the wrong barcode, simply rescan using the correct barcode. The previous one will be overwritten with the new barcode.



7

Fill a calibrated micropipette with **120 µL** of the treated solution from the Reagent Vial.



8

Dispense the contents of the micropipette into the Test Cassette sample well.



9

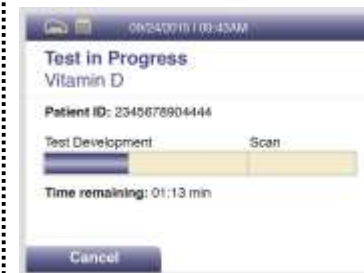
Insert the prepared Test Cassette into the drawer. Then gently close the drawer to start the timer.



10

Sofia will start automatically and display the progress. The test results will be displayed on the screen in approximately 5 minutes.

**NOTE:** Regardless of the currently selected mode, the Sofia Quantitative Vitamin D FIA will **automatically** be run in WALK AWAY mode once the Test Cassette is inserted and the drawer is closed.



## Interpretation of Results

When the test is complete, the results will be displayed on the Sofia screen. The results will be automatically printed on the integrated printer if this option is selected. Test Lines, which are fluorescent, cannot be seen with the naked eye.

The Sofia screen will display results for the procedural controls as being “valid” or “invalid” and will provide a quantitative result for the determination of the total 25-OH vitamin D level. If the procedural controls are “invalid,” retest the patient’s sample with a new Test Cassette.

Reader Display	Interpretation
25-OH: XX.X ng/mL Procedural Control: Valid	This is the amount of total 25-OH vitamin D in ng/mL in the patient’s blood.
25-OH: <10.0 ng/mL Procedural Control: Valid	The amount of total 25-OH vitamin D in the patient’s blood is less than the quantitative range of the assay.
25-OH: >100.0 ng/mL Procedural Control: Valid	The amount of total 25-OH vitamin D in the patient’s blood is greater than the quantitative range of the assay.
25-OH: [blank] Procedural Control: Invalid	Invalid result. Retest with a new Test Cassette.

## External Quality Control (Consult the Package Insert provided with the Control Set)

- 1 Begin testing with either Control 1 or Control 2.
- 2 Fill a calibrated micropipette with **100 µL** of the Control solution.
- 3 Add Control solution to the Reagent Vial.
- 4 Invert the Reagent Vial 2 times to mix.
- 5 Let the Control sample stand in the Reagent Vial for 5 minutes.
- 6 Select “Run QC” from the Main Menu on Sofia.
- 7 Scan the barcode on the QC Card (located on **assay** kit box).
- 8 Scan the barcode on the Control vial that you are testing.
- 9 Fill a calibrated micropipette with **120 µL** of the Control solution.
- 10 Dispense the contents of the micropipette into the Test Cassette sample well.
- 11 Insert the prepared Test Cassette and gently close the drawer.
- 12 Sofia will start automatically and display results in approximately 5 minutes.
- 13 Repeat the process from Step 2 with the second Control.

### INTENDED USE

The Sofia Quantitative Vitamin D FIA is an immunofluorescence-based lateral flow assay designed for the quantitative determination of total 25-OH vitamin D (25-hydroxy vitamin D) from serum samples. The Sofia Quantitative Vitamin D FIA is intended to be used as an aid in the assessment of vitamin D sufficiency.

**Reference the Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control.**

### ASSISTANCE

If Sofia or the assay do not perform as expected, contact Quidel Technical Support 858.552.1100, [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com), or your local distributor.



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