



QUIDEL

Sofia<sup>®</sup>  
hCG FIA

# QUICK REFERENCE INSTRUCTIONS

For use with Sofia only.

CLIA Complexity: MODERATE

This test is for urine specimens only.



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

## Test Procedure

DO NOT open the foil pouch containing the test Cassette until ready to test the specimen.

Urine specimens must be at room temperature before beginning the assay.

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

Refer to the Sofia User Manual for operating instructions.

### Part 1: Set Up Sofia

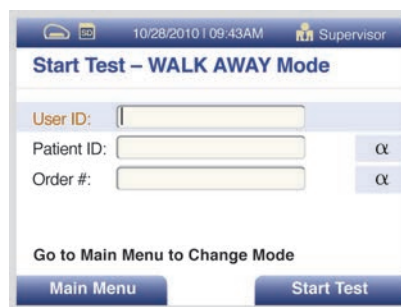
1

Select "Run Test" from the main menu on Sofia.

2

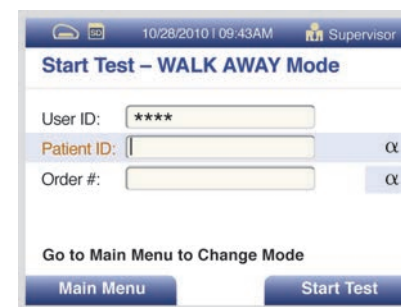
If necessary, input the User ID using the barcode scanner or manually enter the data using the key pad.

**NOTE:** If you mistakenly scan the incorrect barcode, use the Arrow Buttons on the Sofia key pad to re-highlight the field. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.



3

If necessary, input Patient ID or Order # using the barcode scanner or manually enter the data using the key pad.



4

Press Start Test and the Sofia drawer will automatically open.



**NOTE:** Regardless of the current selected Mode, the Sofia hCG FIA will automatically be forced into the WALK AWAY Mode once the test Cassette is inserted and the drawer is closed.

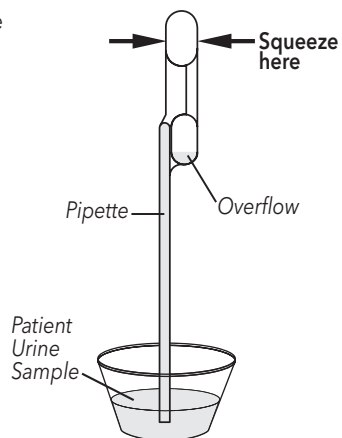
## Part 2: Prepare the Test Cassette

5

Fill the provided fixed volume Pipette with the patient sample from the specimen collection container.

**To fill the fixed volume Pipette with the patient sample:**

- FIRMLY squeeze the top bulb.
- Still squeezing, place the Pipette tip into the patient sample.
- With the Pipette tip still in the patient sample, release pressure on bulb to fill the Pipette.

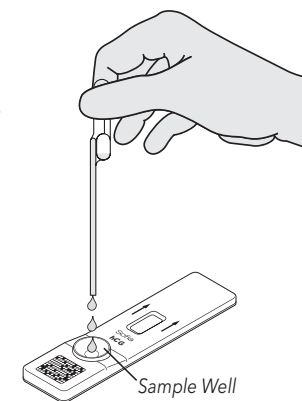


6

Firmly squeeze the top bulb to empty the contents of the fixed volume Pipette into the Cassette sample well. Extra liquid in the overflow bulb is OK. Do not attempt to dispense it too.

**NOTE:** The fixed volume Pipette is designed to collect and dispense the correct amount of liquid sample. Discard the Pipette in your biohazard waste.

**Note:** Proceed promptly to the next step.



## Part 3: Insert the Cassette into Sofia

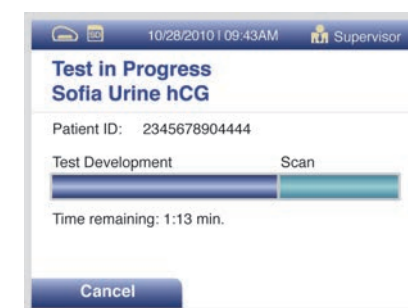
7

Carefully lift the test Cassette and insert the Cassette into Sofia. **Gently** close the drawer.



8

Sofia will start automatically in WALK AWAY Mode and display the progress, as shown in the example below. The test results will be displayed on the screen in approximately 3 minutes. See Interpretation of Results section.



*For example: This display shows that the test has 1 minute, 13 seconds remaining.*

## Interpretation of Results

When the test is complete, the results will be displayed on the Sofia screen. The results can be automatically printed on the integrated printer if this option is selected. Test Lines, which are fluorescent, will never be visible to the naked eye.

**Results:** The Sofia screen will display results for the procedural control being "valid or invalid." If the control is "invalid," retest with a new patient sample and new test Cassette.

Reader Display	Interpretation
hCG: Positive	Positive for hCG
hCG: Negative	Negative for hCG
hCG: Invalid Procedural Control: Invalid	Result Invalid

## External Quality Control *(Consult the instructions for use provided with the external control set)*

1

From the main menu, select Run QC.



2

Following the prompt on the screen, scan the QC Card (located on the kit box).

3

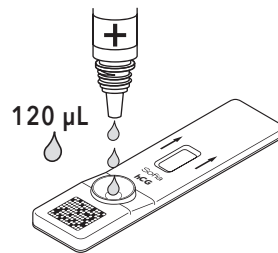
Sofia will prompt the user to select the desired mode (WALK AWAY) and then to run the External Controls.

**NOTE:** The Sofia hCG FIA will automatically be forced into WALK AWAY Mode when the test Cassette is inserted and the drawer is closed.

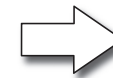
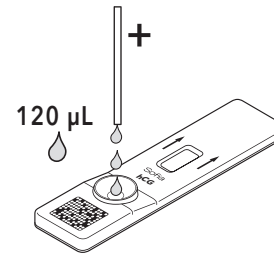
4

Use the following procedure to test each of the control solutions. **The Positive Control must be run first, followed by the Negative Control.** Do not allow the Cassette to develop on the bench prior to placing the Cassette into Sofia.

a) Prepare a *Positive Control Cassette* by adding **120 µL** of the Positive Control solution to a test Cassette sample well. Gently insert the Cassette into the Sofia drawer and gently close the drawer to start the Positive Control run.

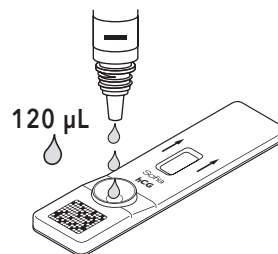


OR

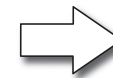
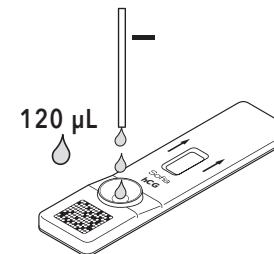


b)

When prompted by Sofia, prepare a *Negative Control Cassette* by adding **120 µL** of the Negative Control solution to a test Cassette sample well. Gently insert the Cassette into the Sofia drawer and gently close the drawer to start the Negative Control run.



OR



5

After both the Positive and Negative Controls have been run, the results will be displayed as "Passed" or "Failed."

## INTENDED USE

The Sofia hCG FIA is an immunofluorescence-based lateral flow assay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine specimens and is designed to aid early detection of pregnancy.

The test is intended for prescription use only, including use at point-of-care sites.

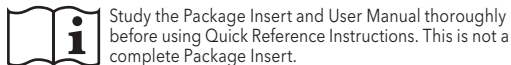
## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Use of Nitrile or Latex (or equivalent) gloves is recommended when handling patient samples.
- Dispose of containers and used contents in accordance with Federal, State and Local requirements.
- Do not reuse the used Cassette or Fixed Volume Pipettes.
- The user should never open the foil pouch of the test Cassette exposing it to the ambient environment until the Cassette is ready for immediate use.
- Discard and do not use any damaged Cassette.
- To obtain accurate results, the Package Insert instructions must be followed.
- The Sofia hCG FIA will automatically be forced into the WALK AWAY Mode when inserted into Sofia. DO NOT allow the test Cassette to develop on the bench or counter top prior to placing the Cassette into Sofia.
- The Calibration Cassette must be kept in the provided storage pouch between uses.
- Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
- Do not write on the barcode of the Cassette. This is used by Sofia to identify the type of test being run and to identify the individual Cassette so as to prevent a second read of the Cassette by the same Sofia.
- As the detection reagent is a fluorescent compound, no visible results will form on the test strip. Sofia must be used for result interpretation.

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

## ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please call Quidel's Technical Support Number 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S. contact your local distributor or [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com).



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