

SC1/SCP1 Reference Viscosity Quality Control Kit

REF 900-1303 (V24)

INTENDED USE

The SC1/SCP1 Reference Viscosity QC test is a simple means of verifying proper operation of the Sonoclot Analyzer. These instructions are written for Sonoclot Analyzers Model SC1 and SCP1.

SUMMARY AND PRINCIPLES

This test consists of a two point verification of the electromechanical oscillator and also ensures that the heating control is operating accurately. The two verification points are: 1) Probe-In-Air, and 2) Probe-In-Oil.

The Probe-In-Air is the response of the electromechanical oscillator to air and should be between -3 and 3.

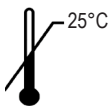
The Probe-In-Oil is the response of the electromechanical oscillator to a reference viscosity liquid and should be between 46 and 58. Since the viscosity of the reference viscosity fluid is significantly temperature dependent, the Probe-In-Oil test point also verifies the temperature regulation.

The SC1/SCP1 Reference Viscosity QC procedure is simple, easy to perform and requires little operator time. It takes less than a minute set-up, and results are available in about 4 minutes. The QC test should be run each day the Sonoclot Analyzer is used or as required by your institution.

CONTENTS

Each SC1/SCP1 Reference Viscosity Quality Control Kit contains 24 cuvettes, 24 probes, 1 vial of reference viscosity fluid with end cap, and these instructions. These supplies provide 24 QC tests for the analyzer.

STORAGE



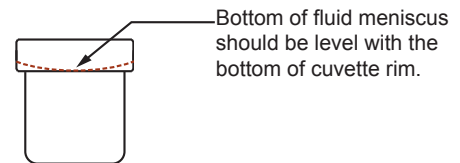
RUNNING A QC TEST

A SC1/SCP1 Reference Viscosity Oil QC test should be run DAILY on the Sonoclot Analyzer. Follow these instructions for both SC1 and SCP1.

- 1) Make sure that the Sonoclot Analyzer is turned on and warmed up with the head assembly in the down

position. The Sonoclot Analyzer should maintain the temperature at 37°C. Check that the analyzer is ready to run a test (see operator's manual).

- 2) Repeatedly press the SELECT TEST button until "ViscQC" appears on the LCD display.
- 3) Open the head assembly by tilting it backwards to its stop. With a slight twisting motion, insert a clean probe over the probe mount hub inside the head assembly. Make sure that the probe is fully seated on the probe mount hub for proper operation.
- 4) Holding the cuvette at eye level, fill an empty cuvette with the reference viscosity fluid so that the fluid level comes to the bottom of the rim of the cuvette. Accurate fill can be observed by verifying that the bottom of the meniscus is at the same level as the bottom of the cuvette rim. There should be no air bubbles in the liquid in the cuvette. Use the tip of the plastic pipette to remove any air bubbles.



- 5) Place the filled cuvette in a convenience well. Do not place in the cuvette holder.
- 6) Close the head assembly and press the START/STOP button. The cuvette holder will be empty.
- 7) After about 10 seconds, the LCD display will show the Probe-In-Air result.
- 8) After the Probe-In-Air result is displayed, open the head assembly and insert the filled cuvette from the convenience well into the cuvette holder. Close head assembly to lower the probe into the liquid. It is not necessary to restart the Sonoclot Analyzer to complete the test.
- 9) After 4 minutes, the Probe-In-Oil result will be displayed on the Sonoclot Analyzer LCD display.
- 10) The Probe-in-Air value should be between -3 and 3. The Probe-in-Oil value should be between 46 and 58. If results are outside these ranges see the Operational Precautions section of this insert.
- 11) The Sonoclot Analyzer will automatically stop the test after 4 minutes. Open the head assembly. Remove the cuvette and the probe using the probe extractor and discard. Keep the head assembly closed between samples to maintain thermal stability of the instrument.
- 12) Record results on the SC1/SCP1 Reference Viscosity QC Record. Results are displayed on the LCD

display. Results can also be retrieved with SonoView (SC1) or Signature Viewer (SCP1).

PLEASE REFER TO THE OPERATOR'S MANUAL FOR ADDITIONAL INSTRUMENT USE INFORMATION.

ACCEPTED VALUES

The Clot Signal value typically is above 60 at the beginning of the test and levels off at a value between 46 to 58 after 4 minutes.

SC1/SCP1 Reference Viscosity QC Test 900-1303	
Result	Acceptance Range
Probe-in-Air	-3 to 3
Probe-in-Oil	46 to 58

If the value is outside this range, see the Operational Precautions listed below. If the value continues to be outside this range for several tests in a row and the procedure has been followed exactly, contact Sienco, Inc. or your distributor.

OPERATIONAL PRECAUTIONS AND LIMITATIONS

The Sonoclot Analyzer is a sensitive instrument, even slight variation in procedural technique can produce noticeable differences during quality control tests. If the test results are outside of the stated values, check the following items:

- 1) Only properly trained lab personnel and health care professionals should operate the analyzer.
- 2) The reference viscosity sample must be accurately filled. Under or over-filling a cuvette will affect the results. Inaccurate filling is the most common error when running the SC1/SCP1 Reference Viscosity Oil QC test.
- 3) The Sonoclot Analyzer requires a warm-up time to thoroughly heat the head assembly. Not allowing the Sonoclot Analyzer to warm up to 37°C will vary the numerical reading. A low instrument temperature will yield a high numerical reading. This is one reason why we recommend leaving the Sonoclot Analyzer on continuously.
- 4) The probe must be fully seated on the probe mount hub. Always insert and remove the probe by moving it vertically over the probe mount hub. Never move the hub horizontally.
- 5) Do not overfill the cuvette. The proper fill level is slightly below the inner rim of the cuvette.
- 6) The cuvette must be fully seated in the cuvette holder.
- 7) Do not reuse the cuvette, reference viscosity fluid, or probe. Reuse may cause inaccurate results and/or instrument damage.

- 8) Mechanical Factors: Fragments of dried blood in the transducer hub of the head assembly can interfere with the electromechanical oscillator and alter the quality control results.
- 9) The SC1/SCP1 Reference Viscosity Oil QC test does not validate performance of activation reagents. Plasma QC testing should be run to QC activation reagents.

BIBLIOGRAPHY

- Sonoclot Analyzer SC1 operator's manual
- Sonoclot Analyzer SCP1 operator's manual
- SonoView operator's manual
- Signature Viewer operator's manual



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