SIENCO, Inc.

CE IVD CONTROL

Reference Viscosity Oil Quality Control Kit

REF 900-1302 (24)

INTENDED USE

The Reference Viscosity Oil QC test is a simple means of verifying proper operation of the Sonoclot Analyzer. These instructions are written for the Sonoclot Analyzer Model DP-2951 connected to either a graphics printer or Signature Viewer data collection program.

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 ≤ 3.

The Probe-In-Oil is the response of the electromechanical oscillator to the reference viscosity liquid and should be between 50 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 Reference Viscosity Oil 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 10 minutes. The QC test should be run each day the Sonoclot Analyzer is used or as required by your institution.

CONTENTS

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

STORAGE

RUNNING A QC TEST

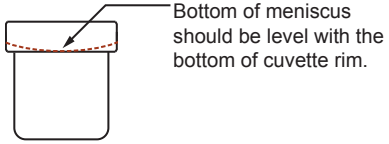
A Reference Viscosity Oil QC test should be run DAILY on the Sonoclot Analyzer. Follow these instructions for all instrument configurations except where noted.

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) *Graphics Printer:* Set the Clot Signal scale to 75 or greater by turning the scale knob on the back of the unit until the LCD display shows the desired scale.

   Signature Viewer 3.X: Repeatedly press the SELECT TEST switch until "ViscQC" appears on the LCD display.

3) Holding the cuvette at eye level, fill an empty cuvette with the reference viscosity oil so that the fill 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 level with 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.



4) Place the filled cuvette in a warming well. Do not place in the cuvette holder.

5) 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 the probe is fully seated on the probe mount hub for proper operation.

6) Close the head assembly and momentarily depress the START switch.

7) *Graphics Printer or Signature Viewer 2.X:* Wait at least 20 seconds. The LCD display will show a Clot Signal value by the Clot Signal legend. This value is the Probe-In-Air result.

   Signature Viewer 3.X: After about 10 seconds, the LCD display will show the Probe-In-Air result. This result will also be displayed in the Signature Viewer test summary table.

7) Record the Probe-in-Air result on the Reference Viscosity Oil Quality Control Record form in the Clot Signal Probe-in-Air column. This value should be ≤ 3.

8) Open the head assembly and place the filled cuvette from the warming well into the cuvette holder with a slight twisting motion. Ensure that the cuvette is fully seated in the cuvette holder with the bottom of the cuvette in contact with the cuvette holder. Close the head assembly to lower the probe into the liquid.

9) *Graphics Printer or Signature Viewer 2.X:* Depress the START switch to begin timing the Probe-in-Oil test. The stir motor will run for the first 10 seconds of the test. No stirring will occur since the cuvette does not contain a stir bar.

   Signature Viewer 3.X: It is not necessary to restart the Sonoclot Analyzer to complete the test.

11) *Graphics Printer or Signature Viewer 2.X:* At 10 minutes (600 seconds), the Clot Signal value displayed on the LCD below the Clot Signal legend is the Probe-In-Oil result. This value can also be read from the Sonoclot Signature on the graphics printer output. To read the Probe-In-Oil result from the Sonoclot Signature, read the Clot Signal value on the graph that corresponds to 10 minutes.

    Signature Viewer 3.X: After 10 minutes, the Probe-In-Oil result will be displayed on the Sonoclot Analyzer LCD display and in the Signature Viewer test summary table.

12) Record the Probe-In-Oil result on the Reference Viscosity Oil Quality Control Record form. This value should be between 50 to 58.

13) *Graphics Printer or Signature Viewer 2.X:* Press the STOP switch to terminate the test.

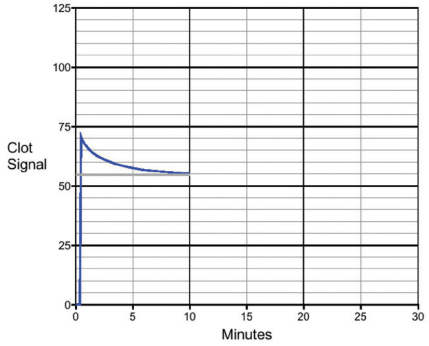
    Signature Viewer 3.X: The test will automatically stop after 10 minutes.

14) Open the head assembly. Remove the cuvette and discard. Remove the probe using the probe extractor and discard. Keep the head assembly closed between samples to maintain thermal stability of the instrument.

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

ACCEPTED VALUES

The reference viscosity test produces a graph that looks similar to this graph. The Clot Signal value typically is above 60 at the beginning of the test and levels off to a value between 50 to 58 after 10 minutes.



Reference Viscosity Oil QC Test 900-1302	
Result	**Acceptance Range**
Probe-in-Air	≤ 3
Probe-in-Oil	50 to 58

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

OPERATIONAL PRECAUTIONS AND LIMITATIONS

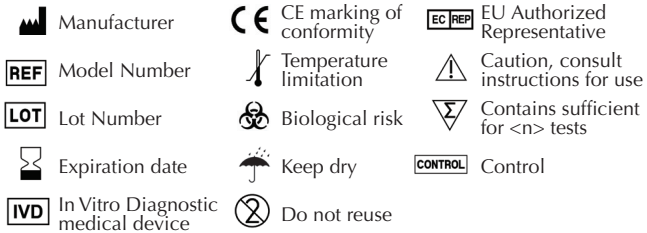
The Sonoclot Analyzer is a sensitive instrument, even slight variation in procedural technique can produce noticeable differences during quality control tests. If the test results are outside of the acceptance range, check the following items:

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 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. To maintain a temperature of 37°C Sienco recommends leaving the Sonoclot Analyzer on continuously.
4) If the light bulb under the head assembly is not on, the Clot Signal at 10 minutes will be slightly elevated. See the operator's manual or contact Sonoclot for instruction on replacing the light bulb.
5) 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.
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 Reference Viscosity Oil QC test does not validate performance of coagualtion activation reagents. Plasma QC testing should be run to QC reagents.
10) If the Sonoclot Analyzer is being used with Signature Viewer 3.X and the START/STOP switch is pressed after inserting the filled cuvette into the cuvette holder, Signature Viewer will start a new QC test. This will result in the calculation of a new Probe-in-Air value. Since the cuvette is now filled with oil, the new Probe-in-Air value will be incorrect. Should this happen, record the Probe-In-Air result for the previous test (or another test) that was run in air.

BIBLIOGRAPHY

Sonoclot Analyzer DP-2951 Operator's Manual
Signature Viewer Operator's Manual

SYMBOL GLOSSARY



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Reference Viscosity Oil Quality Control Record
Sonoclot® Coagulation & Platelet Function Analyzer DP-2951

Institution ______________________ Department ______________________

Lab Supervisor ______________________ Sonoclot Analyzer Serial Number ____________

Reference Viscosity Oil QC Kit REF 900-1302 SonoCal™ Fluid Lot # ______________

By	Time	Date	Clot Signal Probe-in-Air result ≤ 3	Clot Signal Probe-in-Oil result @ 10 min 50 ≤ result ≤ 58	Plot Probe-in-Oil Result @ 10 min.														
					46	47	48	49	50	51	52	53	54	55	56	57	58	59	60

Comments:

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