

Chapter 4 - Quality Control Procedures

Introduction

A quality control protocol should be structured to be comprehensive, well documented, convenient and low cost. Quality control of the Sonoclot Analyzer involves both verification of the Analyzer and verification of the test reagents. Verification of the Sonoclot Analyzer performance can be easily checked using either a reference viscosity oil or reference plasmas. Verification of the activation cuvette performance requires reference plasma QC.

Sienco provides both viscosity fluid and reference plasma quality control products. The reference plasmas are available in both kit and bulk packaging. The bulk packaging is appropriate for laboratory QC. The kit packaging has been designed for non-laboratory personnel using syringes that are provided within the kit rather than pipettes oriented for laboratory use.

Sienco's quality control products for the Sonoclot Analyzer are:

900-1302 Reference Viscosity Oil Quality Control (QC) Kit - This kit provides all necessary materials for running two point verification testing of the Sonoclot Analyzer. The kit contains 24 tests.

900-1318 Reference Plasma Quality Control (QC) Kit - This kit provides all necessary materials for running a two level reference plasma test to verify performance of both the Sonoclot Analyzer and activation test reagent. Level I and Level II reference plasmas, distilled water, calcium chloride, and five 1 ml syringes are included. This test is best run with the Plasma QC Heating Block, 800-0618.

800-0701 Reference Plasma Level I - Package of ten 6 ml vials containing a lyophilized preparation of citrated animal plasma, stabilizers, and buffer. Contains no human material. Level I is a normal control.

800-0702 Reference Plasma Level II - Package of ten 6 ml vials containing a lyophilized preparation of citrated animal plasma, stabilizers, and buffer. Contains no human material. Level II is an abnormal slow control.

800-0703 Distilled Water - Package of ten 6 ml vials containing 5.0 ml laboratory grade distilled water.

800-0704 Calcium Chloride - Package of ten 6 ml vials containing 5.0 ml 0.02 M Calcium Chloride.

800-0618 Plasma QC Heating Block - This reusable heating block is a convenient tool to assist in warming and running plasma tests without the need for water baths or pipettes. This tool is designed to assist quality control testing in point-of-care environments including operating rooms, STAT labs, and intensive care units.

Sienco recommends that quality control procedures be run periodically as specified to ensure confidence in the Sonoclot results. Users should also follow QC requirements of local, state, and federal agencies.

Running a Reference Viscosity Oil QC Verification

The reference viscosity QC or SonoCAL™ test is a simple means of verifying proper operation of the Sonoclot Analyzer and Printer. This test consists of a two point verification of the electromechanical oscillator and also ensures that the platen heating control is operating accurately. The two points are: 1) Probe-In-Air, and 2) Probe-In-SonoCAL. The Probe-In-Air is the response of the electromechanical oscillator to air. This response should be close to zero. The Probe-In-SonoCAL is the response of the electromechanical oscillator to a reference viscosity liquid. This response should be close to 53. Since the viscosity of SonoCAL is significantly temperature dependent, the Probe-In-SonoCAL test point also verifies the platen temperature regulation.

Frequency of Testing

The reference viscosity QC procedure is simple, easy to perform and requires little operator time. This verification takes less than a minute to setup, and results are available in about 10 minutes. Sienco recommends that you run the reference QC procedure once each day prior to sample testing. More frequent testing may be required to comply with local, state and federal QC requirements.

Initial Preparation Before Running a Reference Viscosity QC Test

In order to run the reference viscosity QC procedure you need the Sonoclot Analyzer System and the following components found within the Quality Control Kit (P/N 900-1302):

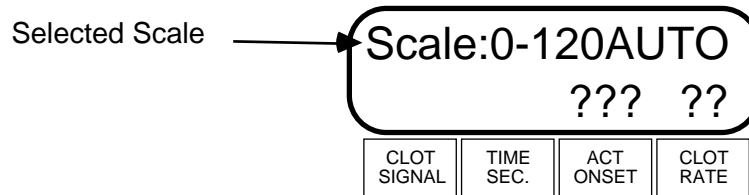
1	Probe
1	Quality Control Cuvette
1	SonoCAL fluid vial
1	Quality Control Instructions and Record Form

Running a Reference Viscosity Oil QC Test

The Sonoclot Analyzer should maintain the platen temperature at 37 °C. If the Sonoclot Analyzer has just been turned on, allow the instrument to warm up with the head assembly in the down position until the LCD displays the “Ready” message. (Warm-up takes approximately 15 minutes).

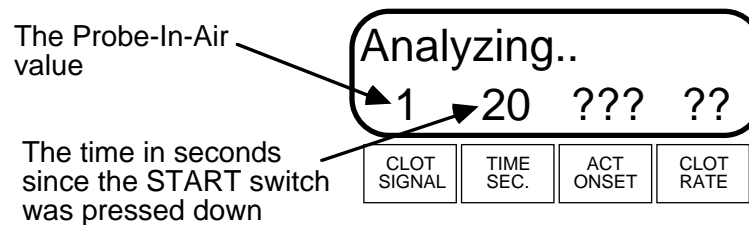
Check that the Printer is ON and ON-LINE.

Set the Clot Signal scale to 0-100, 0-100 Auto, 0-120 or 0-120 Auto by turning the scale knob on the back of the unit until the LCD display shows the desired scale. Whenever the scale knob position is changed, the new selected scale is shown on the top line of the LCD display. The selected scale message will be displayed for 2 seconds after turning the scale knob.



Open head assembly by tilting it backwards.

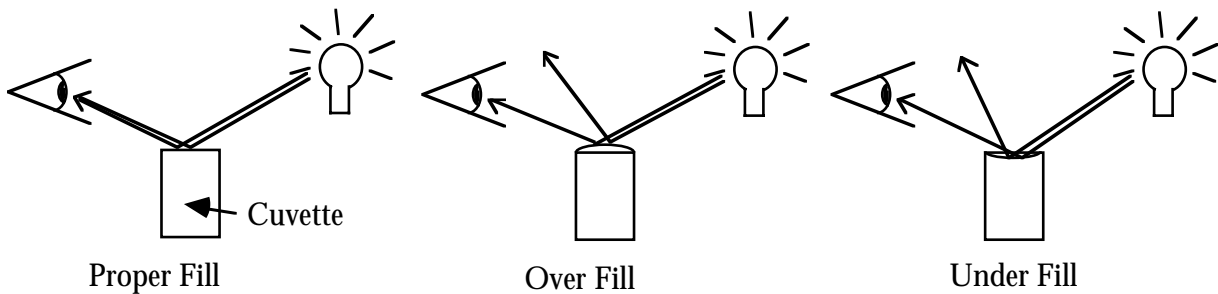
With a slight twisting motion, insert a clean disposable tubular probe onto the probe mount hub inside the head assembly until it is fully seated. Close the head assembly and momentarily depress the START/STOP switch to the START position. Wait at least 20 seconds. The LED display will now show the Probe-In-Air value above the Clot Signal legend:



Record this Clot Signal Value on the Quality Control Record form in the Probe-In-Air column. This result should be ≤ 3 .

Next, insert a red quality control cuvette 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.

Fill the cuvette with the SonoCAL liquid so that the fluid is exactly level with the rim of the cuvette. Accurate fill can be observed by noticing the reflection of light off the fluid surface. A properly filled cuvette will have a flat surface with minimum reflection distortion (see diagram below). There should be no air bubbles in the SonoCAL liquid in the cuvette.



Visual Verification of Accurate SonoCAL Fill

Close head assembly to lower the probe into the SonoCAL liquid. Immediately depress the START switch to begin timing the QC verification. The stir motor will run for the first 10 seconds of the verification. No stirring will occur since the QC cuvette does not contain a stir bar. As the test proceeds, the measurement results are taken from the Sonoclot Signature on the Printer. During the verification analysis no Onset or Clot RATE will be found.

After at least 10 minutes have passed, the display will read something like:

The time in Seconds since the START switch was pressed.

Analyzing 37.0°
53 600 ??? ??

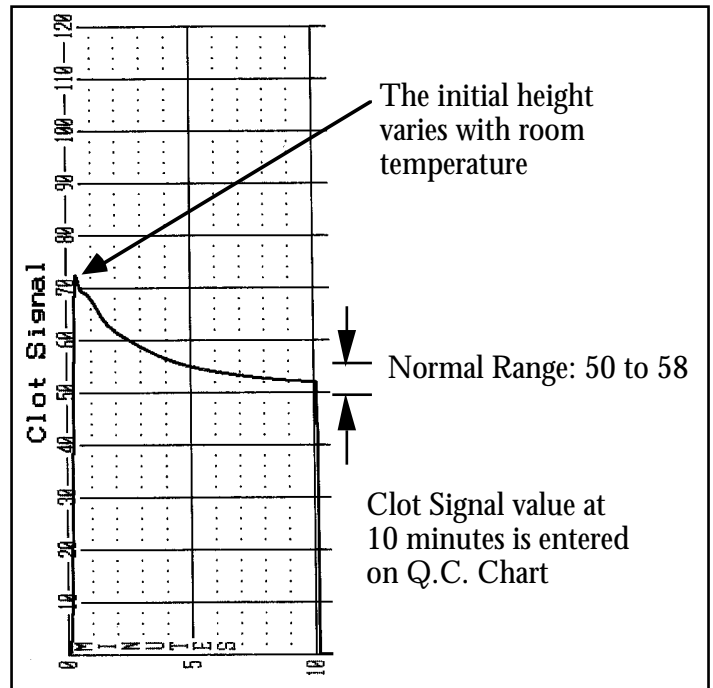
CLOT SIGNAL	TIME SEC.	ACT ONSET	CLOT RATE
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After the time displayed exceeds 600 seconds (10 minutes), momentarily press the STOP switch up to end the test.

Open the head assembly. Using the probe extractor, remove the tubular probe and the red cuvette and discard them. Lower the head assembly to maintain temperature control of the head assembly.

When the Printer paper has stopped advancing, tear off the paper and look at the Signature. It should look something like the Sonoclot Signature to the right.

On the Quality Control Record Form, record the Signature value at 10 minutes in the column marked "Clot Signal SonoCAL @ 10 min."



The value should normally be between 50 and 58. If the value is outside this range, see the Operational Precautions and Limitations at the end of this section. 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. at 1-800/432-1624.

Operational Precautions and Limitations

Since the Sonoclot Analyzer is a very sensitive instrument, the slightest variation in procedural technique can produce noticeable differences during quality control tests. If the test results are outside of the stated value of 50-58, check the following items:

- 1: Use of the Sonoclot Analyzer should be limited to properly trained laboratory personnel and/or other appropriate health care professionals.
- 2: The SonoCAL 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 QC test.
- 3: The probe must be fully seated on the probe mount hub.
- 4: The cuvette must be fully seated in the cuvette holder.
- 5: 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 Analyzer on continuously.
- 6: Mechanical factors: Fragments of dried blood in the transducer hub of the head assembly can interfere with the electromechanical oscillator and alter the results.
- 7: The Reference Viscosity Oil QC test does not validate the performance of activation reagents. Plasma QC testing should be run to QC activation reagents.
- 8: If the lamp bulb under the head assembly is not on, the Clot Signal at 10 minutes will be slightly elevated. See Chapter 6 for instructions on replacing the lamp bulb.

Running a 900-1318 Reference Plasma QC Kit

This procedure describes how to validate and document the performance of the Sonoclot Analyzer and activation cuvettes using Sienco's 900-1318 Reference Plasma QC Kit. This procedure has been designed for use with syringes—no pipettes or water baths are needed. This kit contains both a Level I, normal, and a Level II, abnormal slow, lyophilized animal plasma. Initial test result acceptance ranges are provided for reference purpose only. Actual test result ranges should be determined based on historical performance of the reference plasmas with the specific activation cuvette.

Intended Use

This Reference Plasma Quality Control Kit is for use with the Sonoclot[®] Analyzer System to verify performance of activation cuvettes and/or the Sonoclot Analyzer. If it is being run to QC activation cuvettes only, testing should be performed prior to the use of a new shipment and monthly throughout use of the stock. If this plasma kit is being run to QC both the Sonoclot Analyzer and activation cuvettes, then testing should be performed once

each day prior to sample testing. In either case, more frequent testing may be required to comply with local, state and federal QC requirements.

Summary and Principles

The use of coagulation controls in coagulation testing is an important quality control procedure. The Level I Plasma Control is recommended as a normal control for the Sonoclot Analyzer and disposable activation test cuvettes. The Level II Plasma Control is recommended as a prolonged abnormal control for the Sonoclot Analyzer and disposable activation test cuvettes.

Reagents

Each Kit contains:

1 vial Level I Plasma Control - 6 ml vial containing a lyophilized preparation of citrated animal plasma, stabilizers and buffer. Contains no human material.

1 vial Level II Plasma Control - 6 ml vial containing a lyophilized preparation of citrated animal plasma, stabilizers and buffer. Contains no human material.

1 vial Distilled Water - 6 ml vial containing 5.0 ml laboratory grade distilled water.

1 vial 0.02 M Calcium Chloride - 6 ml vial containing 5.0 ml 0.02 M Calcium Chloride.

5 plastic 1 cc syringes

The Level I and Level II reference plasmas are manufactured for Sienco, Inc. by Analytical Control Systems, Inc., Fishers, Indiana 46038.

Storage and Stability

When stored at 2-8° C, all unopened vials are stable to expiration date. Unreconstituted plasma control vials are stable for 7 days when stored at room temperature. After reconstitution, the plasma controls are stable for 4 hours at room temperature. Calcium chloride and distilled water are good until expiration date after opening and may be stored at room temperature.

Caution: To avoid contamination, a clean syringe should be used with each reagent. If the distilled water or calcium chloride looks cloudy, there is evidence of contamination and the vial should be discarded.

Additional Equipment:

- (1) Sonoclot Analyzer
- (2) Reference Plasma QC Heating Block (Sienco part #800-0618)

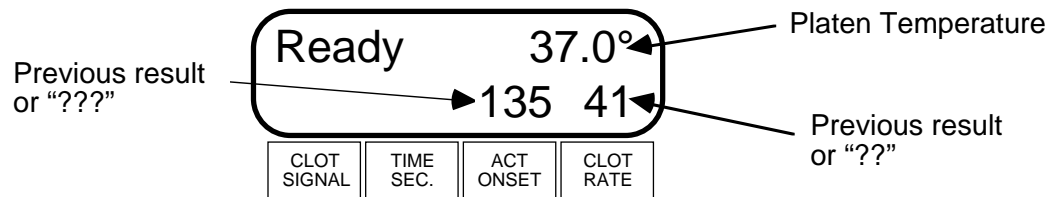
Sonoclot Analyzer Preparation Before Running a Reference Plasma QC Test

Cuvettes should be placed in the warming holes in advance so they will be warm and ready for immediate use. **Sharply tap** the cuvette on a hard surface to dislodge any activator powder from the sides and lid of the cuvette. Prior to placing each cuvette in the warming well, insert a probe into the recess of the cuvette cap for convenient storage.

If the Sonoclot Analyzer has just been turned on, allow it to warm up with head assembly in the down position until the Sonoclot Analyzer reaches the desired controlled temperature.

Check that the Printer is ON and ON-LINE.

Prior to running a sample, the Sonoclot Analyzer display should display the following:



The Time Scale and Clot Signal Scale settings affect scaling of the Sonoclot Signature. These settings normally will be pre-set to the operator's desired values. The default settings are appropriate for plasma QC tests. See Chapter 5 - Configuring the Sonoclot Analyzer if you wish to modify these settings.

Place the Reference Plasma QC Heating Block onto the Sonoclot Analyzer. Allow about 5 minutes for the heating block to reach operating temperature. Check the temperature indicator strip to ensure the heating block is within the 35-39 °C operating range before inserting syringes. The heating block and its orientation on the Sonoclot Analyzer are shown below.

35 36 **37** 38 39

GREEN
EXACT
TEMP.

Plasma QC Heating Block Part #: 800-0618

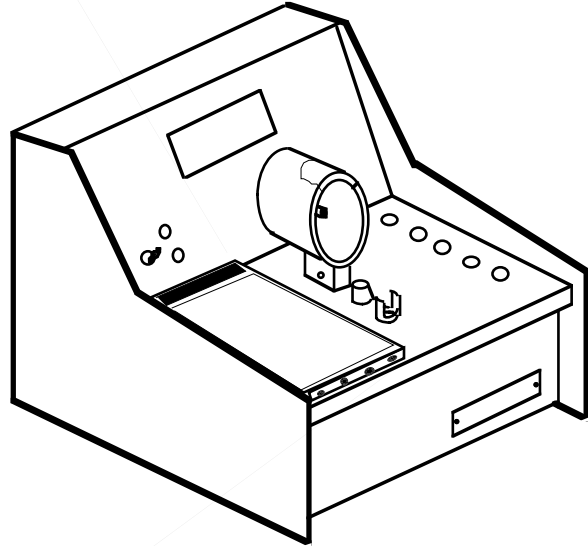
- 1: Allow Heating Block to reach operating temperature (35 - 39°C).
- 2: Reconstitute Plasma-I and Plasma-II with 0.5cc distilled water each.
- 3: Draw 0.2cc Plasma-I into new syringe and place in labelled heating block well. Repeat this step with Plasma-II.
- 4: Draw two syringes with 0.2cc CaCl₂ each and place in labelled heating block wells.
- 5: Allow syringes to warm for 5 minutes.
- 6: Prepare Sonoclot® Analyzer to run activation cuvette test (see Operator's Manual for detailed instructions).
- 7: Sequentially dispense contents of Plasma-I and CaCl₂-I syringes into activation cuvette. Immediately press the Start Switch. After results are available, repeat this step using new activation cuvette and level-II syringes.

Plasma-I

CaCl₂-I

Plasma-II

CaCl₂-II

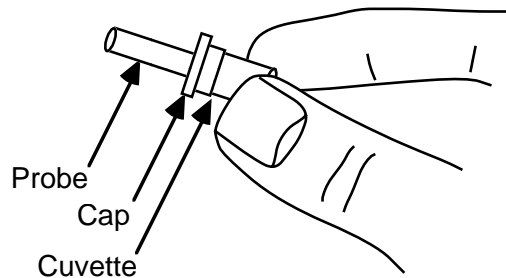


Heating Block for Syringes

Cuvette and Probe Setup

Open head assembly by tilting it backwards.

Insert a clean disposable tubular probe over the probe mount hub inside the head assembly. The probe must be fully seated on the probe mount hub for proper operation. If the probe had been placed into the recess of the cuvette cap, then the cuvette can be used to mount the probe to the probe mount hub. Use the cuvette as a convenient probe mounting tool, as pictured, by holding the cuvette to position the probe over the probe mount hub. Gently push the cuvette to push the probe fully over the probe mount hub. When the probe is fully seated on the probe mount hub, remove the cuvette; the probe remains on the hub.



If you are using an activated test cuvette, the activated cuvette contains a stir bar and activation powder. **Sharply tap** the cuvette on a hard surface to dislodge any activation powder from the sides and lid of the cuvette.

Remove the lid from the cuvette before placing the cuvette in the cuvette holder. To remove the cuvette lid, place the cuvette in a warming hole and pop the lid off with your thumb. **Do not remove the cuvette lid while the cuvette is in the cuvette holder;** the cuvette holder may break.

With a slight twisting motion, insert the cuvette into the cuvette holder. Ensure that the cuvette is fully seated in the cuvette holder.

Plasma Preparation

Remove the metallic seal and rubber stopper from the Level I, Level II, and distilled water vials. Add 0.5 cc of distilled water to the Level I plasma control. Avoid contact between the syringe tip and plasma solution. Using the same syringe, add 0.5 cc of distilled water to the Level II plasma control. Discard syringe. Allow Level I and II vials to stand until the contents are dissolved. This will take approximately 5 minutes. Gently swirl vials.

Carefully draw 0.2 cc reconstituted Plasma I into a new syringe and place in heating block well labelled Plasma-I. Repeat this step with Plasma II, placing syringe in heating block well labelled Plasma-II.

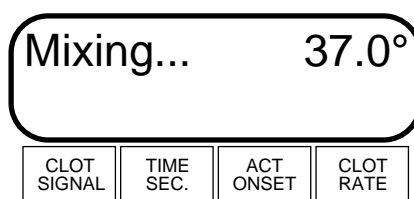
Remove the metallic seal and rubber stopper from the calcium chloride vial. Carefully draw 0.2 cc calcium chloride into a new syringe and place in heating block well labelled CaCl₂-I. Repeat this step with a second syringe, and place in heating block well labelled CaCl₂-II.

Allow the syringes to warm for 5 minutes.

Running the Sonoclot Analyzer

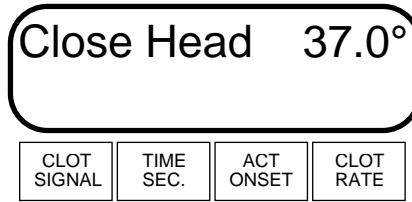
At this point, an activation cuvette should already be inserted in the cuvette holder and a probe should be attached to the probe mount hub. If not, then review this section for proper test setup. Sequentially dispense the contents of the Plasma-I and CaCl₂-I syringes into the activation cuvette. Immediately depress the Start/Stop switch. The magnetic stirrer will automatically rotate and the Printer will begin to print.

The display will now read:



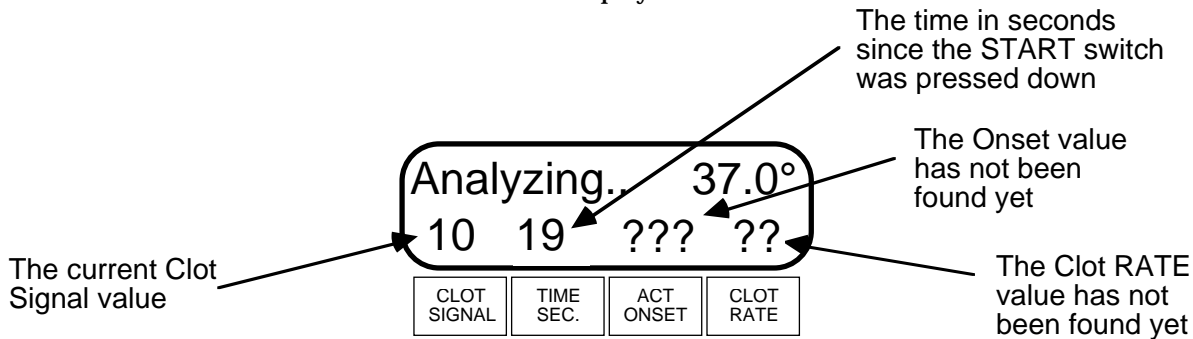
and the Printer will start printing.

After 10 seconds, the Sono clot Analyzer will beep and the display will read:



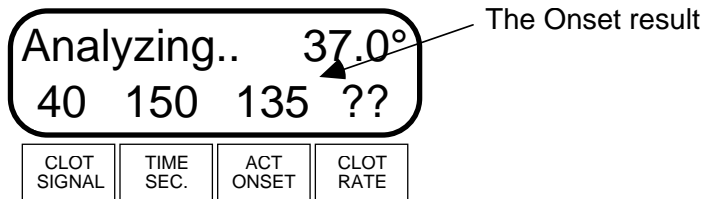
Close the head assembly.

After another 5 seconds, the display will read:



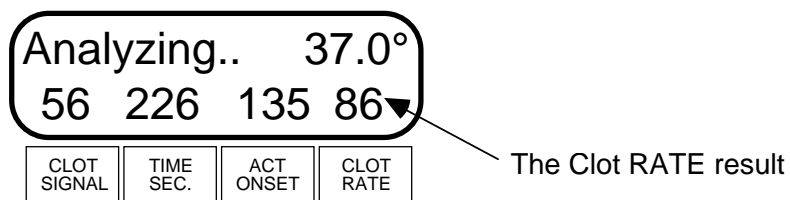
The question marks are displayed because no results have been found at this time.

The plasma sample is initially a liquid. After several minutes, the sample begins to evolve into a clot. The instrument detects this initial clot formation, beeps and displays the time that the sample remained a liquid above the ACT legend on the front panel.

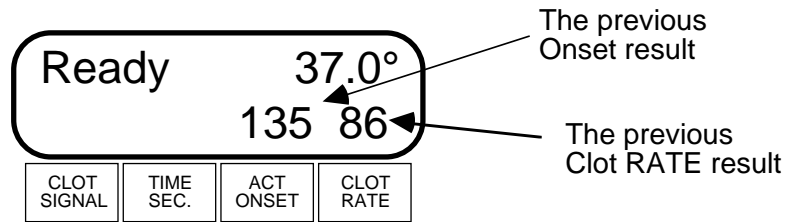


During the next several minutes of the analysis, the fibrinogen converts into a fibrin gel. The rate of the fibrin formation is clinically significant for some Sono clot tests. The Sono clot Analyzer determines this rate of formation by calculating the rate of change in the Clot Signal value. When the Clot RATE result is available, the Analyzer beeps and reports the result on the LCD display and Graphics Printer.

After the Clot RATE has been determined, the Analyzer beeps and the display appears as:



After the ACT and Clot RATE results are found, the analysis is complete. At this time terminate the analysis by momentarily pressing the START/STOP switch to the STOP position to stop the Printer. The display will not contains results from the test and the “Ready” message as shown below.



Open the head assembly. Remove the tubular probe (using the probe extractor) and the cuvette and properly discard them. Lower the head assembly to maintain temperature control of the head assembly.

After the Level I test results are available, repeat this procedure using a new activation test cuvette and the Level-II syringes.

Expected Values

The Level I Plasma Control gives results in the normal range for Onset. Clot Rate results for plasma are substantially higher than for whole blood. The Level II Plasma Control gives prolonged Onset results in the abnormal range. Expected value ranges are provided in the table below for Sienco’s SonACT Test (part #800-0432). These values are provided only as a guideline. Each Sonoclot user should determine their own expected values for the particular tests being used.

EXPECTED VALUES	
	SonACT Test
Level I Onset	85-145 seconds
Level I Clot Rate	> 60 Clot signal units/minute
Level II Onset	≤ 450 seconds
Level II Clot Rate	≥ 18 Clot signal units/minute

In-house studies have demonstrated that the Level II Plasma Control differentiates good reagents from bad reagents more dramatically than the Level I Control. Level II’s more discriminating nature is attributed to its markedly longer onset of clot formation time.

Limitations of the Procedure

Failure to obtain the expected control values may be an indication of product deterioration or improper testing. A study of each component of the system (reagents, instrument and technical procedure) should be performed so that the actual problem may be identified.

Performance

The Onset CV should not exceed 15%. The Clot Rate CV may be greater since the Clot Rate parameter is more technique dependent. Each user should establish a mean and standard deviation on a month-to-month basis as a quality control monitor.

The test results should provide confidence in the performance of the activation cuvette. This testing should confirm that the stock performed as intended prior to its initial use and continued to perform as intended throughout the stock use or shelf life.

Documenting the Reference Plasma QC Test Results

The results of the reference plasma QC test for the Level I and level II plasmas should be recorded on a Quality Control Record form. A sample form is included below.

Sienco, Inc. 4892 Van Gordon St. - Unit 203 Wheat Ridge, CO 80033 USA 303/420-1148 303/420-2204(Fax) 800/432-1624				Sonoclot® Coagulation & Platelet Function Analyzer Quality Control Record for 800-0432 SonACT Activation Cuvettes using Level I and Level II Reference Plasmas								QA 15 (rev 1)	
Institution _____						Sonoclot Analyzer Serial Number _____							
Department _____						Lab Supervisor _____							
By	Time	Date	800-0432 Lot #	Level I Lot #	ACT (seconds)	85 ≤ ACT ≤ 145 √ if OK	Clot RATE	Clot RATE > 60 √ if OK	Level II Lot #	ACT (seconds)	ACT ≤ 450 √ if OK	Clot RATE	Clot RATE ≥ 18 √ if OK

Operational Precautions and Limitations

The quality of the Sonoclot Analyzer test results depend heavily on proper technique. Carefully observe or apply the following precautions.

- 1: Use of the Sonoclot Analyzer should be limited to properly trained laboratory personnel and/or other appropriate health care professionals.
- 2: Handle the reference plasmas as if capable of transmitting infectious agents.
- 3: Proper incubation of the sample is important to obtain accurate results.
- 4: Proper recalcification is important to obtain accurate results. Either too little or too much calcium chloride will prolong the Onset and attenuate the Clot RATE.
- 5: The plasma sample should not be exposed to any activating reagent prior to recalcification in order to obtain accurate results.
- 6: The disposable probe must be fully seated against the shoulder of the probe mount hub to avoid interference between the probe and stir bar.
- 7: The disposable cuvette must be fully seated in the cuvette holder to avoid interference between the probe and stir bar.
- 8: Never reuse either a disposable probe or disposable cuvette. Thrombin contamination may result.
- 9: Use proper handling techniques when disposing of probes and cuvettes to avoid contact.
- 10: Avoid contaminating the electromechanical transducer in the head assembly by keeping blood, dirt or other contaminants away from the probe mount hub.

Running a Reference Plasma QC - Laboratory Procedure

This procedure describes how to validate and document the performance of the activation cuvettes using Sienco's bulk packaged lyophilized animal plasmas. Level I is a normal reference plasma. Level II is an abnormal reference plasma that approximates an anticoagulated patient. Initial test result acceptance ranges are provided for reference purpose only. Actual test result ranges should be determined based on historical performance of the reference plasma with the specific activation cuvette. Use both Level I and Level II testing for two point normal and abnormal verification.

Frequency of Testing

The activation cuvettes contain inert materials and have a one year expiration date. Testing should be performed prior to use of a new shipment of stock and monthly throughout the use of the stock. More frequent testing may be required to comply with local, state and federal QC requirements.

If the reference plasma QC is being run to QC both the Sonoclot Analyzer and the activation cuvette, then the QC procedure should be run once each day prior to sample testing or as required to comply with local, state and federal QC requirements.

Equipment to Run Reference Plasma QC Test

In order to run this QC procedure you need the following:

Equipment:

1	Sonoclot Analyzer System
1	vial or test tube incubator
1	25 µl pipette for 0.25M CaCl ₂
1	1.0 ml pipette
1	400 µl pipette

Reagents:

1 vial	Level I lyophilized plasma
1 vial	Level II lyophilized plasma
2.0 ml	purified, distilled or deionized water
stock	0.25M CaCl ₂

Supplies:

1 each	activation cuvette test consisting of probe and cuvette taken from stock being verified
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Forms:

1	Activation test QC record form
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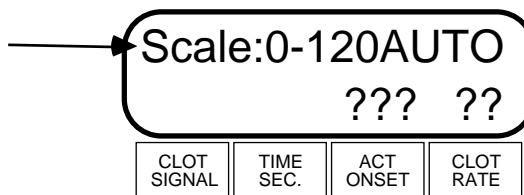
Initial Preparation Before Running Reference Plasma QC Test

Reconstitute the Level I and Level II lyophilized plasmas with 1.0 ml purified water. Swirl gently and allow to stand at room temperature for 5 minutes to assure complete hydration. If testing will be delayed, the reconstituted product should be stored at 2-8 °C or on ice. The reconstituted product is stable for 24 hours when stored on ice or at 2-8 °C.

The Sonoclot Analyzer should be powered on at least 20 minutes prior to testing. Check that the Printer is ON and ON-LINE.

If you want a hard copy of the Sonoclot Signature, then set the Clot Signal scale to either 0-100, 0-100 Auto, 0-120, or 0-120 Auto by turning the scale knob on the back of the unit until the LCD display shows the desired scale. The selected scale message is written on the top line of the LCD display.

Selected Scale



The selected scale message will be displayed for 2 seconds after turning the scale knob.

Open head assembly by tilting it backwards.

With a slight twisting motion, insert a clean disposable tubular probe onto the probe mount hub inside the head assembly until it is fully seated.

Take the activation cuvette (with lid still attached). Sharply tap the cuvette on a hard surface to distribute the activator powder to the bottom of the cuvette. Remove the lid from the cuvette before placing the cuvette in the cuvette holder. To remove the cuvette lid, place the cuvette in a warming hole on the Analyzer and pop the lid off with your thumb. Do not remove the cuvette lid while the cuvette is in the cuvette holder; the cuvette holder may break. Place the cuvette in the cuvette holder with a slight twisting motion. Ensure that the cuvette is fully seated in the cuvette holder.

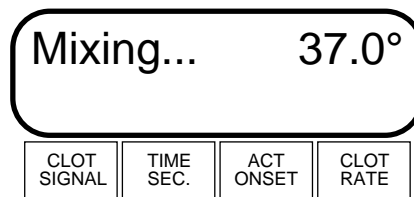
Pipette 25 μl of 0.25M CaCl_2 (or 20 μl of 0.35M CaCl_2) into the cuvette. Close the head assembly so that the head assembly is properly warmed.

Just prior to testing, incubate the reference plasma at 37 °C in either it's vial or a non-activating test tube. Allow sufficient incubation time for the sample to reach 37 °C.

Running the Reference Plasma QC Test

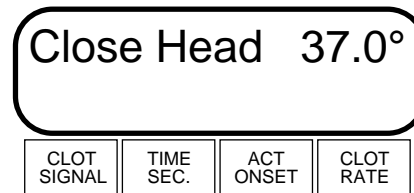
Pipette 400 μl of the reference plasma into the cuvette and depress the START Switch immediately. The magnetic stirrer will automatically turn on and the Printer will begin to print.

The display will now read:



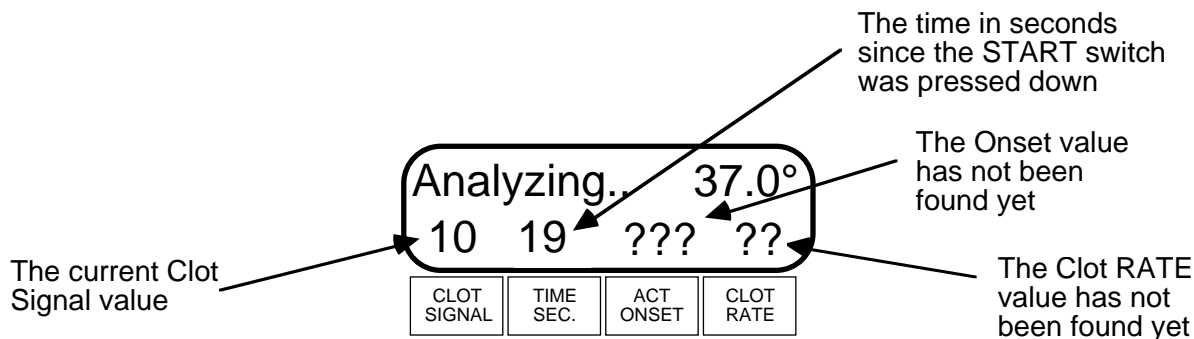
and the Printer will start printing.

After 10 seconds, the Sonoclot Analyzer will beep and the display will read:



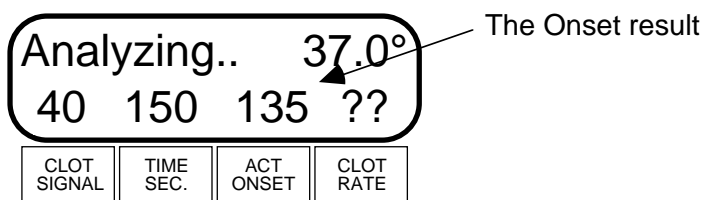
Close the head assembly.

After another 5 seconds, the display will read:



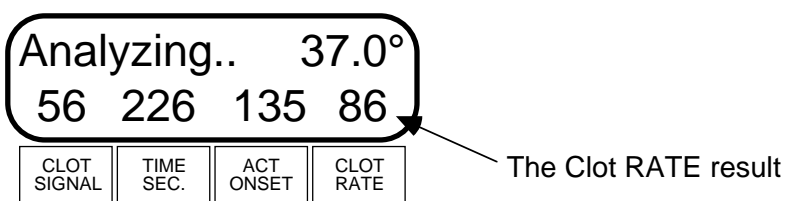
The question marks are displayed because no results have been found at this time.

The sample is initially a liquid. After several minutes, the sample begins to evolve into a clot. The instrument detects this initial clot formation, beeps and displays the time that the sample remained a liquid above the ACT legend on the front panel.

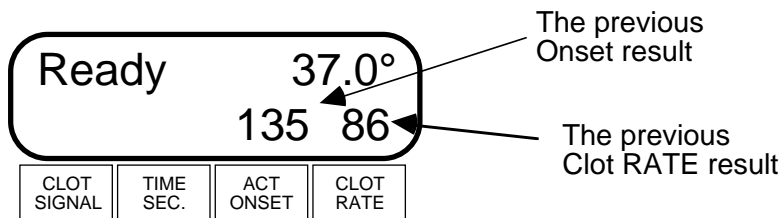


During the next several minutes of the analysis, the fibrinogen converts into a fibrin gel. The rate of this conversion from fibrinogen into a gel is clinically significant for some Sonoclot tests. The Sonoclot Analyzer determines this rate of conversion by calculating the rate of change in the Clot Signal value and reports this rate automatically above the Clot RATE legend.

After the Clot RATE has been determined, the display appears as:



After the Clot RATE result is calculated and displayed on the Analyzer, all test results are completed. At this time momentarily press the START/STOP switch to the STOP position to stop the Printer. The display contains results from the test and the "Ready" message as shown below.



Open the head assembly. Remove the tubular probe (using the probe extractor) and the cuvette and properly discard them.

Operational Precautions and Limitations

The quality of the Sonoclot Analyzer test results depend heavily on proper technique. Carefully observe or apply the following precautions.

- 1: Use of the Sonoclot Analyzer should be limited to properly trained laboratory personnel and/or other appropriate health care professionals.
- 2: Handle the reference plasmas as if capable of transmitting infectious agents.
- 3: Proper incubation of the sample is important to obtain accurate results.
- 4: Proper recalcification is important to obtain accurate results. Either too little or too much calcium chloride will prolong the Onset and attenuate the Clot RATE.
- 5: The plasma sample should not be exposed to any activating reagent prior to recalcification in order to obtain accurate results.
- 6: The disposable probe must be fully seated against the shoulder of the probe mount hub to avoid interference between the probe and stir bar.
- 7: The disposable cuvette must be fully seated in the cuvette holder to avoid interference between the probe and stir bar.
- 8: Never reuse either a disposable probe or disposable cuvette. Thrombin contamination may result.
- 9: Use proper handling techniques when disposing of probes and cuvettes to avoid contact.
- 10: Avoid contaminating the electromechanical transducer in the head assembly by keeping blood, dirt or other contaminants away from the probe mount hub.