SIENCO, Inc. CE IVD CONTROL

Reference Plasma Quality Control Kit

REF 900-1318 (▽1)

Expected Values for Lot # I-84-14

INTENDED USE

The Reference Plasma Quality Control Kit is for use with the Sonoclot® Analyzer System to verify performance of activation cuvettes. Testing should be performed prior to the use of a new shipment and monthly throughout use of the stock. More frequent testing may be required to comply with local, state, and federal QC requirements.

Performance of the Sonoclot Analyzer should be verified with the Reference Viscosity Oil Quality Control Kit for the correct instrument model (PNs 900-1302, 900-1303, 900-1323, 900-1343). The Reference Viscosity Oil Quality Control Kit is the primary control test for the Sonoclot Analyzer itself. Verification of activation cuvette performance requires the use of reference plasmas.

SUMMARY AND PRINCIPLES

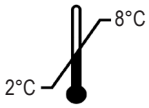
Reference plasma quality control is important to properly verify proper performance of coagulation test activators. A two level testing approach is used to perform quality control of the activator used in an activated coagulation test. Level I is run with the activator on the reference plasma. Level II is run with the non-activated test on the reference plasma. These two tests confirm the effectiveness of the activator to perform its intended coagulation activation.

CONTENTS

Each Kit contains:

- 1 vial Reference 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 ml syringes
- 2 non-activated test cuvettes (blue with clear caps, stir bars, and probes)

STORAGE



When stored at 2-8° C, all unopened vials are stable to expiration date. Before reconstitution, 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.

RUNNING A QC TEST

A. Equipment Required:

1) Sonoclot Analyzer
2) *For Model DP-2951: Reference Plasma QC Heating Block (Sienco part #800-0618)*

B. Procedure:

The procedure below references all volumes in ml units. The syringes provided in this kit and labeling on the Heating Block (#800-0618) may indicate volume in either ml or cc units. These units are equivalent.

Sonoclot Analyzer model DP-2951 requires pre-warming of the plasma samples. Sonoclot Analyzers models SC1, SCP1, SCP2, and SCP4 do not require warming of the plasma samples. Model specific variations in the following procedure are indicated in italics.

1) *Model DP-2951: 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.*
2) Remove the metallic seal and rubber stopper from the reference plasma and distilled water vials.
3) Reconstitution: Add 1.2 ml of distilled water to the reference plasma control. Use one 1 ml syringe provided in the kit to add 0.6 ml distilled water two times to achieve a total volume of 1.2 ml. Avoid contact between the syringe tip and plasma solution. Discard syringe. Allow plasma vial to stand until the contents are dissolved. This will take approximately 5 minutes. Gently swirl vial.
4) Carefully draw 0.18 ml reconstituted reference plasma into a new syringe and set aside Draw an additional 0.18 ml reconstituted reference plasma into a second syringe. *Model DP-2951: Place the plasma filled syringed into the heating block wells labeled Plasma-I and Plasma-II.*

   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.
5) Remove the metallic seal and rubber stopper from the calcium chloride vial. Carefully draw 0.18 ml calcium chloride into a new syringe and set aside. Repeat this step with a second syringe. *Model DP-2951: Place the filled $CaCl_2$ syringes into the heating block wells labeled CaCl2-II and CaCl2-II.*
6) *Model DP-2951: Allow the syringes to warm for 5 minutes.*
7) Prepare the Sonoclot Analyzer to run the activation test cuvette. You can perform this quality control testing on several different activated tests including Sienco's gbACT+, SonACT, kACT, or aiACT tests.
   a) Make sure that the Sonoclot Analyzer is turned on and warmed up with the head assembly in the down position. Check that the analyzer is correctly connected to the desired output device (see operator's manual).
   b) Sharply tap the cuvette against a hard surface, cap side up, to dislodge activation powder from the sides and lid.

c) Place the cuvette into a warming or convenience well. *Model DP-2951: Allow the cuvette to warm in the well for at least 5 minutes before beginning a test. Model SC1, SCP1, SCP2, or SCP4: Allow the cuvette to warm in the cuvette holder for 30 seconds before beginning a test.* Probes fit into the cuvette lids for convenient storage. Multiple cuvettes may be placed in the wells.

d) Open the head by tilting it backwards. With a slight twisting motion, seat the probe on the mount hub. This motion should result in the probe sliding straight over the probe mount hub. The hub should not move sideways. The probe must be fully seated for proper operation.

e) While the cuvette is still in the well, remove the cuvette lid by popping it off with your thumb and forefinger. *Model DP-2951:* ***Do not remove the cuvette lid while the cuvette is in the cuvette holder; the cuvette holder may break.*** Insert the opened cuvette into the cuvette holder with a slight twisting motion. Make sure that it is fully seated. Check that the cuvette contains a stir bar.

f) Please refer to the Operator's Manual for more detailed instructions if necessary.

8) Sequentially dispense the contents of the Plasma-I and CaCl2-I syringes into the activation cuvette. Immediately press Start. After the test results are available, repeat this step using a non-activated test cuvette and the Plasma-II and CaCl2-II syringes. Note: Tests may be run simultaneously on Models SCP2 and SCP4, or if multiple single channel Sonoclots are available.

EXPECTED VALUES

The Plasma I measures contact activation performance of the specific activated cuvette being tested. The non-activated Plasma II test gives control results with no contact activation. Expected value ranges for the activated clotting time (Onset/ACT) are provided in the table below.

EXPECTED VALUES for Reference Plasma lot #I-84-14

Type of Test	Onset/ACT Acceptance Specification DP-2951	ACT Acceptance Specification SC1, SCP1, SCP2, SCP4
Non-Activated (control)	480 - 875 seconds	425 - 800 seconds
gbACT+ or gbACT	250 - 450 seconds	260 - 410 seconds
SonACT	155 - 245 seconds	170 - 260 seconds
kACT	155 - 245 seconds	170 - 260 seconds
aiACT	130 - 220 seconds	155 - 240 seconds

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

PERFORMANCE

The Onset/ACT CV should not exceed 15%. Each user should establish a mean and standard deviation on a periodic basis as a quality control monitor.

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 value, check the following items:

1) Only properly trained lab personnel and health care professionals should operate the analyzer.
2) 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 results.
3) Not allowing the plasma to become fully reconstituted or to reach room temperature prior to running the QC test will affect the results.
4) *DP-2951: Failure to prewarm the plasma and calcium chloride syringes prior to running the QC test will affect the results.*
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) 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.
8) The Reference Plasma QC test does not validate performance of the Sonoclot Analyzer. Reference Viscosity Oil QC testing should be run validate performance of the Sonoclot Analyzer.

BIBLIOGRAPHY

Sonoclot Analyzer operator's manuals

Manufactured for:

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Sonoclot® Coagulation & Platelet Function Analyzer

Quality Control Report for
Reference Plasma Testing of Activated Coagulation Tests

Institution: _____ Sonoclot Analyzer Model #: _____ Serial #: _____

Department: _____ Lab Supervisor: _____

By	Time	Date	Reference Plasma Lot # / Exp Date	Type of Activated Test	Lot Number of Activated Test	Acceptance Specification	Onset/ACT Result (seconds)	Non-Activated Control* Onset/ACT Result (seconds)	Accept ✓ if OK

*A non-activated control should be run for each set of QC tests performed. It is not necessary to perform more than one non-activated control if QC testing is being performed on multiple ACT tests from the same plasma vial.