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Reference Plasma Quality Control Kit #900-1318

For In Vitro Diagnostic Use

Expected Values for **Lot # I-84-14**

INTENDED USE

This Reference Plasma Quality Control Kit is for use with the Sonoclot® Analyzer System to verify performance of activated cuvettes. Testing should be performed prior to the use of a new shipment of actiavted cuvettes 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 may also be verified with the Reference Viscosity Oil Quality Control Kit, Sienco part #900-1302. The SonoCAL test is a reference viscosity test designed for verification of the Sonoclot Analyzer, not activation cuvettes. 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.

REAGENTS

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 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.

PROCEDURE

A. Equipment Required:

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

B. Procedure Outline:

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

1. 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. A 1 ml syringe provided in the kit may be used by adding 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 vials.
4. Carefully draw 0.18 ml reconstituted reference plasma into a new syringe and place in heating block well labelled Plasma-I. Draw an additional 0.18 ml reconstituted reference plasma into another 1 ml syringe and place the syringe in heating block well labelled Plasma-II.

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 place in heating block well labeled $CaCl_2$-I. Repeat this step with a second syringe, and place in heating block well labeled $CaCl_2$-II.
6. 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.) Sharply tap the activation cuvette against a hard surface, cap side up, to dislodge any activation powder from the sides and lid of the cuvette. Place activated cuvette in warming wells and allow to warm for 5 minutes.
    b.) Open the head assembly by tilting it backwards on its hinge. With a slight twisting motion, push a clean disposable tubular probe over the probe mount hub inside the head assembly. This motion should result in the probe sliding straight over the probe mount hub.
    c.) While the cuvette is still in the warming well, remove the cuvette lid by popping it off with your thumb and forefinger. **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. Ensure that the cuvette is fully seated in the cuvette holder.
    d.) Please refer to the Operator's Manual for more detailed instructions if necessary.
8. Sequentially dispense the contents of the Plasma-I and $CaCl_2$-I syringes into the activation cuvette. Immediately press the Start Switch. After the test results are available, repeat this step using a non-activated test cuvette and the Plasma-II and $CaCl_2$-II syringes.

EXPECTED VALUES

The Plasma I test gives results in the normal range for Onset for the specific activated cuvette being tested. The Plasma II test gives prolonged Onset results in the abnormal range. Expected value ranges are provided in the table below

EXPECTED VALUES for Reference Plasma lot #I-84-14	
Type of Test	**ACT Result Acceptance Specification**
Non-Activated (control)	480 - 875 seconds
gbACT+	250 - 450 seconds
SonACT	155 - 245 seconds
kACT	155 - 245 seconds
aiACT	130 - 220 seconds

LIMITATIONS OF THE PROCEDURE

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

BIBLIOGRAPHY

1. Pakzaban, P., et al., The Use of a Viscoelastic Coagulation Analyzer (Sonoclot) to Measure the Kinetics of Human Fibrin Glue Clotting. AJCP 90: 505, 1988.
2. Saleem, A., et al., Viscoelastic Measurement of Clot Formation: A New Test of Platelet Function. Ann. of Clinical & Laboratory Sci. 13:2, pp 115-124, 1983

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Sonoclot® Coagulation & Platelet Function Analyzer

Quality Control Report for
Reference Plasma Testing of Activated Clotting Tests

Institution: _____

Department: _____

Sonoclot Analyzer Serial Number: _____

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.