



Coagulation Control Plasmas

Contains one of the following:

Level 1 (Normal), Level 2 (Abnormal), or Level 3 (Abnormal)

I. Intended Use

Pacific Hemostasis® Coagulation Controls, Level 1, Level 2, and Level 3, are intended for use as controls to monitor the performance of routine coagulation assays.

II. Summary and Principles

The use of controls is a valuable tool for assuring quality in coagulation testing. Coagulation Control Level 1 and at least one abnormal control such as Coagulation Control Level 2 or Coagulation Control Level 3, are an integral part of a complete quality assurance program.

III. Reagent

For *in vitro* diagnostic use.

Composition: Level 1, Level 2, and Level 3 Controls are processed from human plasma collected with <0.4% sodium citrate anticoagulant.

Level 2 and Level 3 controls are appropriately adjusted to produce prolonged prothrombin and partial thromboplastin times. <1.0% Stabilizers and buffers are added prior to lyophilization.

Store unopened vials at 2-8°C. Reconstitute with 1.0 mL of distilled water. Swirl gently and let stand undisturbed for 15 minutes at room temperature. Do not invert vial or mix vigorously. After proper reconstitution, Level 1, Level 2, and Level 3 Controls are stable for 8 hours when stored in capped vial at 2-8°C.² Gently mix contents prior to each use.

Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test system.

Caution: Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit hepatitis, AIDS, or other infectious diseases. This product, like all materials of human origin, should be handled as potentially infectious biological material.

IV. Test Procedure

Materials Provided:

Coagulation Control, Level 1, 10x1mL, Level 2, 10x1mL or Level 3, 10x1mL

Materials Required, But Not Provided:

Distilled water

Pipette capable of accurately delivering 1.0 mL

Test Level 1, Level 2, and Level 3 Controls should be run at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. Follow instructions provided by instrument and reagent manufacturers.

V. Results

Results depend on reagents, instruments, and individual laboratory protocols. However, Level 1 results should closely resemble normal patient samples. Level 2 and Level 3 will be moderately and significantly prolonged, respectively. Each laboratory should have a troubleshooting procedure to follow when results fall outside the established range.

VI. Limitations

All Controls are subject to the limitations of the test system. Variables such as temperature, reagent stability, instrument performance, and individual technique can influence final results. Always follow instrument and reagent manufacturers guidelines.

VII. Expected Values

Values for Level 1 Control are expected to be normal, Level 2 Control is moderately abnormal, and Level 3 is highly abnormal. Actual results depend on many factors, including lot number, type of reagent, and instrument. Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument.

VIII. Performance Characteristics

Level 1 Control is formulated to have PT, APTT, and Fibrinogen values in the normal range. Level 2 and Level 3 Controls have been adjusted to have prolonged prothrombin and partial thromboplastin times. Actual values recovered depend on the instrument and reagent used.

IX. References

1. NCCLS: *Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays*. 4th edition. Approved guideline. NCCLS Document H21-A4. Wayne, PA, 2003.
2. Stability data found in DHF.1.

Ordering Information

Cat. No.	Description	Contents
100595	Coagulation Control (Normal), Level 1	10 x 1 mL
100596	Coagulation Control (Abnormal), Level 2	10 x 1 mL
100597	Coagulation Control (Abnormal), Level 3	10 x 1 mL

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