Beaumont

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Dilute Russell's Viper Venom Time (dRVVT)-RO

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. Dilute Russell's viper Venom Time (dRVVT) Screen and dRVVT Confirm are improved dRVVT reagents and intended to simplify and standardize the detection of lupus anticoagulant (LA) in clinical evaluations. The dRVVT Screen is poor in phospholipid, making it sensitive to LA. The additional amount of phospholipid (bi-layers) in dRVVT Confirm neutralizes LA to give shorter clotting times.

B. Russell's viper Venom, in the presence of calcium, directly activates factor X (in the test sample). The dRVVT Screen and dRVVT Confirm are therefore unaffected by contact factor abnormalities, factor VII, VIII and IX deficiencies or inhibitors.

C. Heparin interference up to 1 U/mL is neutralized by polybrene. As a result, dRVVT Screen and dRVVT Confirm are more specific tests for the evaluation of LA than APTT. dRVVT Screen and Confirm are an integrated test as referenced in the ISTH 2009 committee recommendation for Lupus Anticoagulant Detection.

II. ACRONYMS:

A. Distilled Wanter (DI)

B. Dilute Russell's viper Venom Time Screen (dRVVT S)

C. Dilute Russell's viper Venom Time Confirm (dRVVT C)

D. Instrumentation Laboratory (IL)

E. Lupus Anticoagulant (LA)

F. Quality Control (QC)

G. Room Temperature (RT)

III. SPECIMEN COLLECTION AND HANDLING:

A. IL Coagulation Analyzer

B. Cuvette

C. IL Reagent racks and sample racks

D. Cleaning and Rinse solutions

E. Serological and automatic pipettes

IV. REAGENTS:

A. **Reagents:**

1. The HemosIL dRVVT Screen kit consists of 10 x 2mL vials of a lyophilized preparation containing Russell's Viper Venom, phospholipids, calcium, polybrene, buffers, stabilizers, dyes and preservative. Dissolve the contents of each vial in the kit with 2 mL of deionized (DI) water or equivalent. Replace the stopper and swirl gently. Complete reconstitution of the product is required. Keep the reagent at 15-25˚C for 30 minutes and invert to mix before use. Do not shake. Stability after reconstitution:15 days at 2-8˚C or 3 days at 15˚C in their original vials on the ACL TOP® Family. No stirring is required.
2. The HemosIL dRVVT Confirm kit consists of 10 x 2 mL vials of a lyophilized preparation containing Russell's Viper Venom, phospholipids, calcium, polybrene, buffers, stabilizers, dyes and preservative. Dissolve the contents of each vial in the kit with 2 mL of DI water or equivalent. Replace the stopper and swirl gently. Complete reconstitution of the product is required. Keep the reagent at 15-25˚C for 30 minutes and invert to mix before use. Do not shake. Stability after reconstitution: 15 days at 2-8˚C or 3 days at 15˚C in their original vials on the ACL TOP® Family. No stirring is required.

B. **Diluent:**

1. HemosIL Factor Diluent

C. **Controls:**

1. HemosIL LA Negative Control: 10 X 1 mL vials of lyophilized human plasma containing buffer, stabilizers and preservatives. Dissolve the contents of each vial with 1ml of DI water or equivalent. Replace the stopper and swirl gently. Complete reconstitution of the product is required. Keep the control at 15-25˚C for 30 minutes and invert to mix before use. Do not shake to avoid foam formation. Reconstituted material is stable for 24 hours at 15-25˚C on board the ACL TOP Family and 2-8˚C, or 3 weeks at -20˚C in the original vial. Frozen controls may be thawed at 37˚C and gently mixed before use. Do not refreeze.
2. HemosIL LA Positive Control: 10 X 1 mL vials of lyophilized human plasma containing buffer, stabilizers and preservatives. Dissolve the contents of each vial with 1ml of DI water or equivalent. Replace the stopper and swirl gently. Complete reconstitution of the product is required. Keep the control at 15-25˚C for 30 minutes and invert to mix before use. Do not shake to avoid foam formation. Reconstituted material is stable for 24 hours at 15-25˚C on board the ACL TOP Family and 2-8˚C, or 3 weeks at -20˚C in the original vial. Frozen controls may be thawed at 37˚C and gently mixed before use. Do not refreeze.

D. **Standard:**

1. No calibration for dRVVT assay.

V. PROCEDURE:

A. Gently invert vials of reagents and QC. Check for bubbles before loading dRVVT reagents and controls on IL ACL TOP.

B. Load dRVVT S/ dRVVT C in R3-R6 lane.

C. Load LA +/- in D1-D2 lane.

D. Run both levels of QC for dRVVT S/ dRVVT C.

E. Verify that all levels of QC are withing acceptable range before running patients.

F. Document any troubleshooting performed if QC fails.

G. Thaw patients samples for 5- 10 minutes in water bath. It is unacceptable to run samples that are thawed at RT

H. Refer to IL Operations Procedure for any instrumentation details.

VI. QUALITY CONTROL:

A. Quality control consists of HemosIL LA positive and negative controls.

B. Frequency of Control Use:

1. Controls should be run at least once every 8 hours shift.

VII. EXPECTED VALUES:

A. If dRVVT S/C test fails, verify sample integrity and repeat. If test continues to fail, repeat using a different tube (if available). If no results are obtained, add a comment in the result field that states "Unable to preform due to unknown interference."

B. Verify Patient history and medications.

C. Normalized ration is calculated on IL ACL TOP:

1. dRVVT Screen Ratio = Patient dRVVT S results / Mean of dRVVT S Normal Reange
2. dRVVT Confirm Ratio = Patient dRVVT C results / Mean of dRVVT C Normal Reange
3. Normalized dRVVT Ratio = dRVVT S ratio / dRVVT C ratio .

D. Refer to IL Operations Procedure for any additional details.

VIII. NORMAL /REPORTABLE RANGES:

A. Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.

IX. TURN AROUND TIME:

A. dRVVT assays will be performed at least once each week. Completion of results should be available within 7-10 days of specimen collection date.

X. LIMITATIONS:

A. Icteric, lipemic and hemolyzed specimens may give false results. Results on ACL TOP® Family are not affected by:

1. Hemoglobin up to 200 mg/dL
2. Bilirubin up to 10 mg/dL
3. Triglycerides up to 500 mg/dL

4. Heparin unfractionated (UF) and low molecular weight (LMW) up to 1 U/mL

B. LA assays based on different properties appear to be more or less sensitive to certain subgroups of LAs. Therefore at least two screening assays, based on different properties, should be performed before the possibility of LA is excluded.

C. The dRVVT ratios may be elevated in patients on anti-vitamin K therapy. Additional confirmatory tests prior to diagnosing or repeating dRVVT testing might be indicated when the patient is off anti-vitamin K therapy.

XI. REFERENCES:

A. HemosIL dRVVT Screen / dRVVT Confirm,package insert, November 2016.

B. ACLTOP® Family On-Line Help Manual.

C. HemosIL LA Negative Control package insert, January 2019.

D. HemosIL LA Positive Control package insert, January 2019.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
CP Chief Medical Director	Peter Millward: Chief, Pathology Service Line	4/19/2021
Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	4/19/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	3/31/2021
Policy and Forms Steering Committee Approval (if needed)	Tamara Sabih: Medical Technologist Lead	3/24/2021
System Manager	Rebecca Bacarella: Mgr Laboratory	3/19/2021
	Tamara Sabih: Medical Technologist Lead	3/19/2021

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