Title:	ACL TOP Series Clot Curve Interpretation		
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Approver(s):	CLIA Director		
Location/Region/Division:	BSWH		
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SCOPE

This procedure applies to Baylor Scott & White System laboratories using the ACL TOP instruments.

DEFINITIONS

When used in this document with initial capital letter(s), the following word(s)/phrase(s) have the meaning(s) set forth below unless a different meaning is required by context. Additional defined terms may be found in the BSWH P&P Definitions document

None.

METHOD/UTILITY

The purpose of this procedure is to provide basic guidelines for the confirmation and/or interpretation of clot curves.

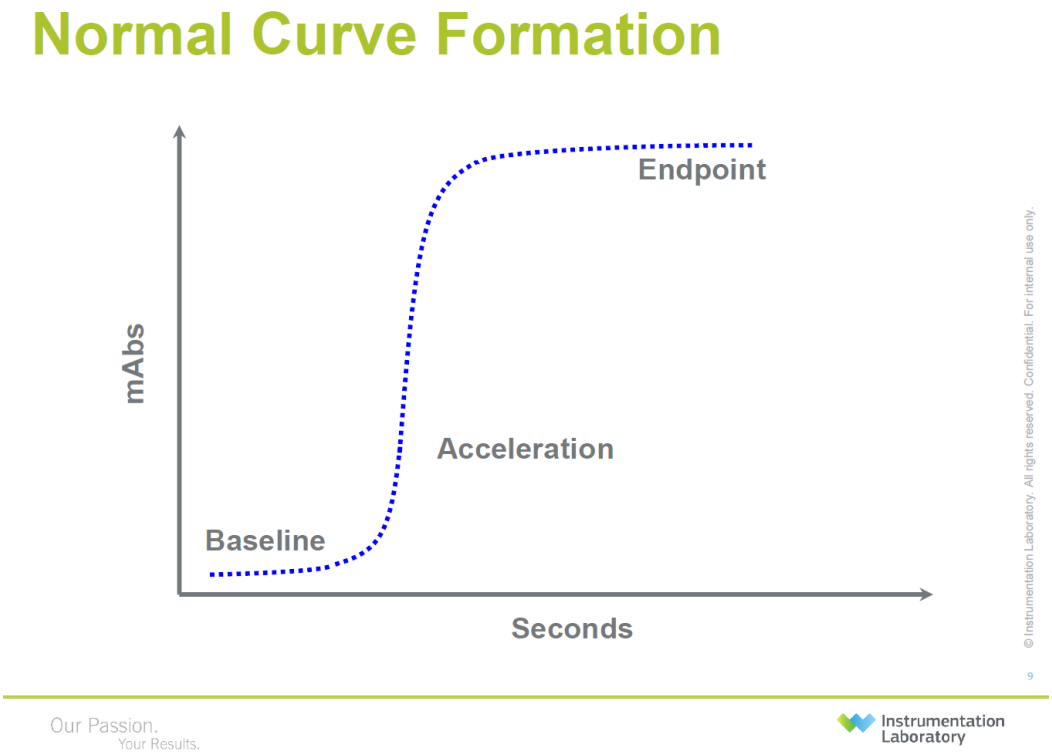
PROCEDURE

Why is Clot Interpretation Needed?

- Not all “failed” results mean there was no clot detected.

Overview of the Clot Curve Formation

- A clot curve is a visual representation of the reaction taking place in the cuvette. The data represented by the clot curve is used to determine the clot end point and the actual result.
- The sequence of events to create a clot curve are as follows:
    1. The last reagent is added to the cuvette in the optical reading unit (ORU).
    2. Acquisition time starts. The analyzer is acquiring data in the form of absorbance readings.
    3. The clot curve is plotted with this data.

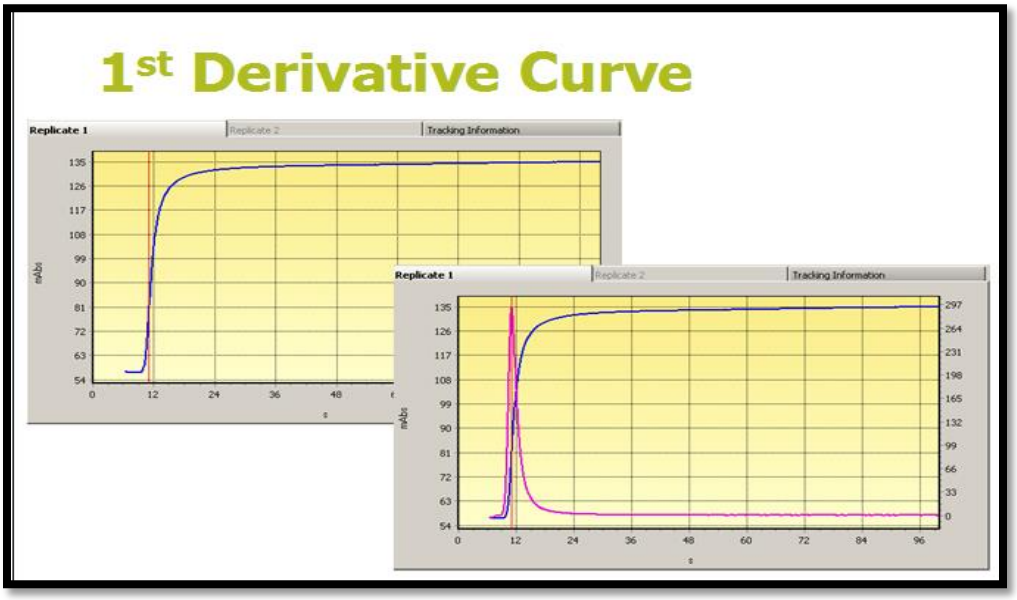


- An algorithm is used to convert the raw optical measurements into a clot time. This process is also referred to as data reduction.
- Each test has a unique algorithm defined in the test definition that is specific to that test. All data is checked before and after the curve is drawn to verify the integrity of the data and results. The data reduction process is verified by a set of warning and error limits defined in the algorithm.
- Measured result data that fail these limits will be displayed with either a:
    1. CW flag (Coagulation Warning) in which case a numerical result is reported with a warning. The clot curve must be reviewed to verify the result reported is appropriate for the clot curve.
    2. CE flag (Coagulation Error) in which case it fails data reduction and there is no result. Reviewing a curve with a CE flag will depend on what follow up was done such as additional rerun or reflex testing.
- CW and CE flags are the only two errors that require interpretation from the technologist related to data reduction.

Overview of Result Determination Using Data Reduction and the Clot Curve

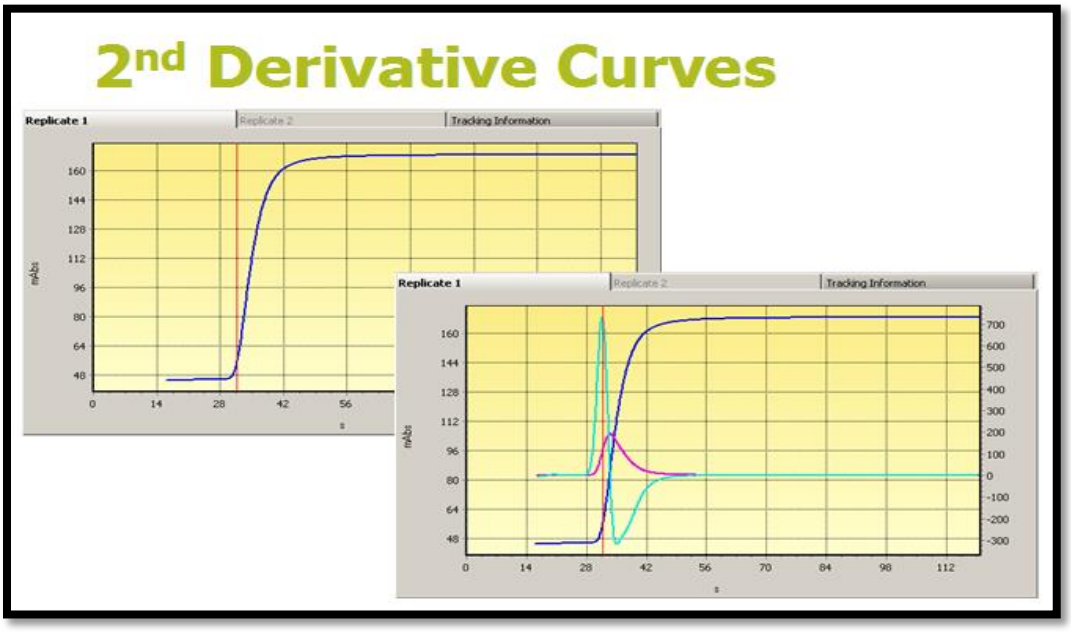
- A clot curve with no CE flags will have an S shape. The 3 parts of the S shape curve are baseline, acceleration, and plateau and these should be clearly identified (only appliable to PT, PTT, and Thrombin.
- The X-axis is the time in seconds and the length of the scale is test dependent.
- The Y-axis is the mAbs readings and it auto scales to fit the data.
- The vertical red line is where the result was obtained from the curve.
- The placement of the vertical red line is determined by using the First Derivative Algorithm or the Second Derivative Algorithm.

First Derivative Curve



- The first derivative algorithm is based on the maximum velocity or the maximum speed of clot formation
- The clot curve appears in blue and the first derivative curve is in fuchsia.
- The red line of the result is drawn through the peak of the first derivative curve. Where it intersects the clot, curve is the point on the curve where the conversion of fibrinogen to fibrin is happening the fastest.
- The Prothrombin Time test using RecombiPlasTin 2G reagent uses the first derivative algorithm to determine the result.

Second Derivative Curve

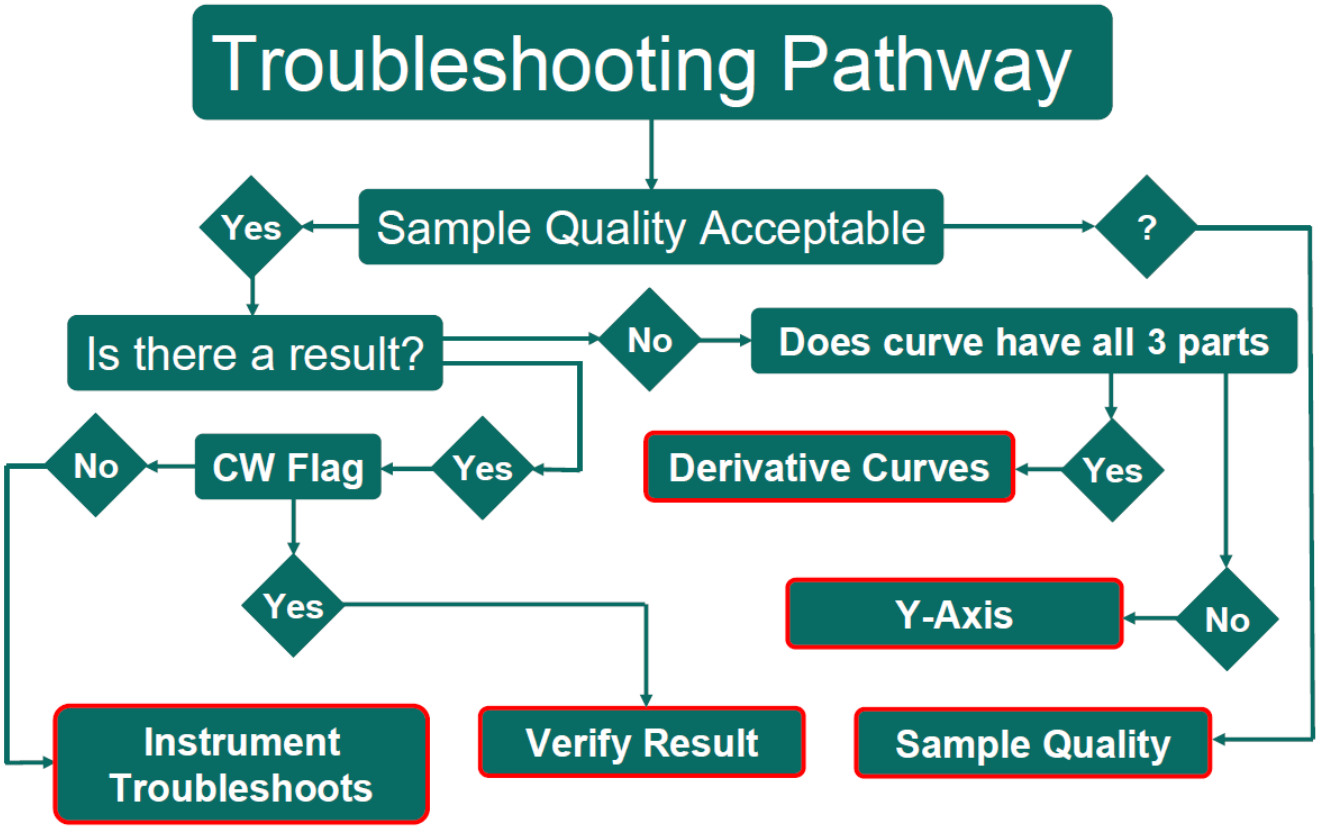


- The second derivative algorithm is based on maximum acceleration or the point on the curve where the conversion of fibrinogen to fibrin is accelerating the fastest
- Acceleration is the rate of change of velocity; therefore, the first derivative must be calculated first. The second derivative is drawn from the first derivative curve. It is a derivative of the first derivative.

- The clot curve appears in blue, the first derivative curve is in fuchsia, and the second derivative is in turquoise.
- The red line of the result is drawn through the peak of the second derivative curve.
- The second derivative curve is used for determining the result of the APTT test using SynthASil and CaCl2 reagents, Thrombin Clot Time using Thrombin Time reagent,

Interpretation of "Failed" Results

- Techs are trained initially on how to interpret a clot curve before releasing results. The technologist then spends time reviewing normal clot curves of the various assays, before moving on to troubleshooting failed results.
- A troubleshooting pathway flow chart is used for a systematic approach to determining a result.



- The Troubleshooting Pathway can be found in the Clot Curve Interpretation manual. The Pathway is broken down into sections each with an example.
- All clot curves that are interpreted should be printed. The printed copy should show the result to be entered and the tech's initials. Document instrument errors in system LIS per facility's policy. Any critical result would be called per lab policy.
- Prothrombin Time results determined by clot curve interpretation will be in seconds only. The INR must be calculated manually.
- Any clot curve that indicates clotting beyond the AMR does not need further interpretation. The result can be entered in as >X secs (facilities reportable range).
- It is recommended that completed clot curve interpretations are reviewed by designee.

- Clot curve interpretation competency assessment is evaluated annually.

ATTACHMENTS

None.

RELATED DOCUMENTS

None.

REFERENCES

None.

REVISION HISTORY

Version #	Effective Date	Description of Change	Revised By	Removed Date
V2	See Signatures	Removed PT MELD Updated flow chart to curve having 3 parts	Hematology Sub-Council	NA