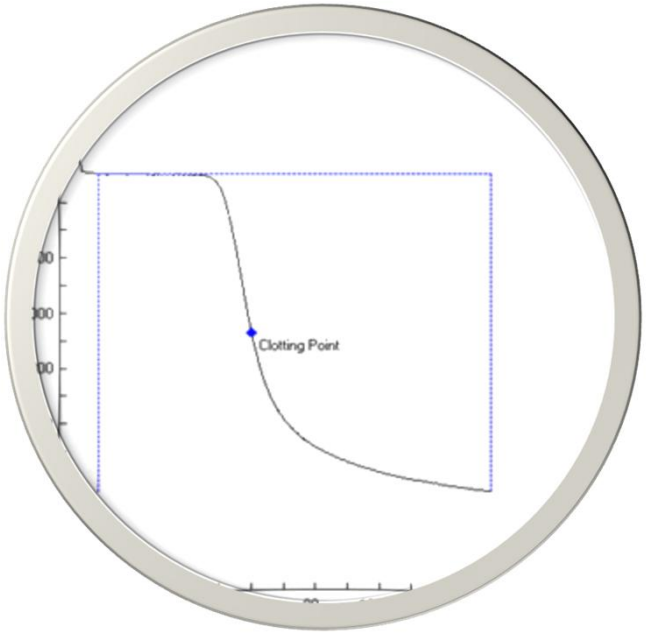
SIEMENS Healthineers

Sysmex® CS Systems

Sample Result Evaluation:
Clotting Assays
Customer Training



Objectives

- *This training is intended to educate you on evaluation of CS-System coagulation reaction curves.*
- *With this knowledge you will be able to review results and develop a "laboratory policy".*
- *Siemens cannot tell the laboratory, what or how to implement their policy. However, as a coagulation expert, Siemens can consult with the laboratory to understand general factors and Siemens assay specific factors that can possibly impact coagulation results and reporting decisions.*
- *The Action Steps are the directions from the CS-Evaluation and Checking Method Guide, the bullet points are considerations that may be appropriate for the technologist to make an educated decision on result reporting and development of a laboratory policy.*
- *It is the laboratory's responsibility to develop an internal policy for result reporting.*

CS Systems Sample Result Evaluation
Table of Contents

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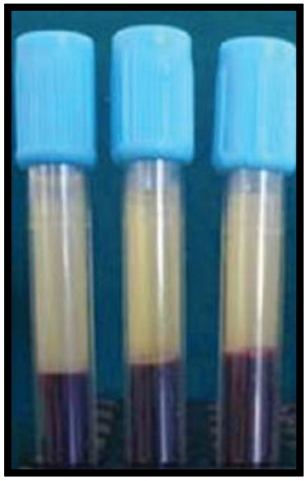
Customer Resources
Training References

Quick Reference Guide
- Sysmex CS-2500 System
- Sysmex CS-5100 System

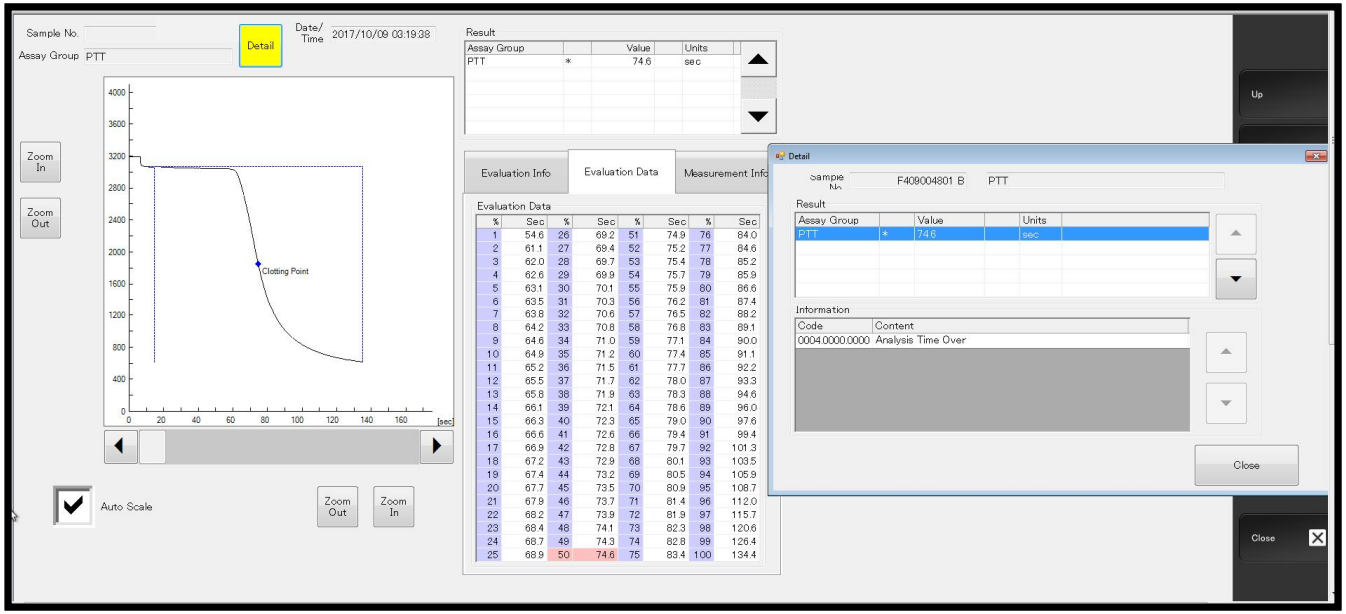
Evaluation and Check Algorithm
- Sysmex CS-2500 System
- Sysmex CS-5100 System

What do I do with a sample error

1. Sample Integrity
2. Clinical Considerations
3. Reagent /Instrument Conditions
   - ✓ QC recovery
   - ✓ System Error Logs



4. Look at Reaction Curve, Evaluation Data and Error Code
   - ✓ Do you see Typical Clot Progression?
   - ✓ Does the 50% value fit the reaction curve?



Sample Integrity Considerations applicable to all sample analysis flagging

Pre-analytical steps involving sample collection, transport, and processing are crucial to ensure accurate results.

Assessing sample integrity should always be the first step in troubleshooting a flagged coagulation sample.

Recommendations regarding sample acceptability for each assay can be found on the Instructions for Use (IFU), the Application Sheets, and current CLSI H21-A5 Guidelines.

Common sample integrity considerations:

- Sample Appearance: Hemolysis, Icterus, or Lipemia
- Verify sample fill volume, or clotted sample.
- Centrifugation process; Evaluate time, speed, and duration and ensure plasma platelet poor.
- Evaluate sample transport and storage
- Frozen Samples – Was it properly quick thawed in a 37°C water bath?
- Frozen Samples – Is the plasma platelet poor?
- Frozen Samples – Is it Sodium Citrated Plasma?
- Exclude sample exposure to extreme temperatures
- Determine sample age at the time of run.

Clinical Considerations applicable to all sample analysis flagging

Clinical information such as patient diagnosis and treatment protocols can be influential in proper evaluation, interpretation and reporting of sample result kinetics.

Questionable results should be reviewed in the context of the patients clinical information, including, but not limited to:

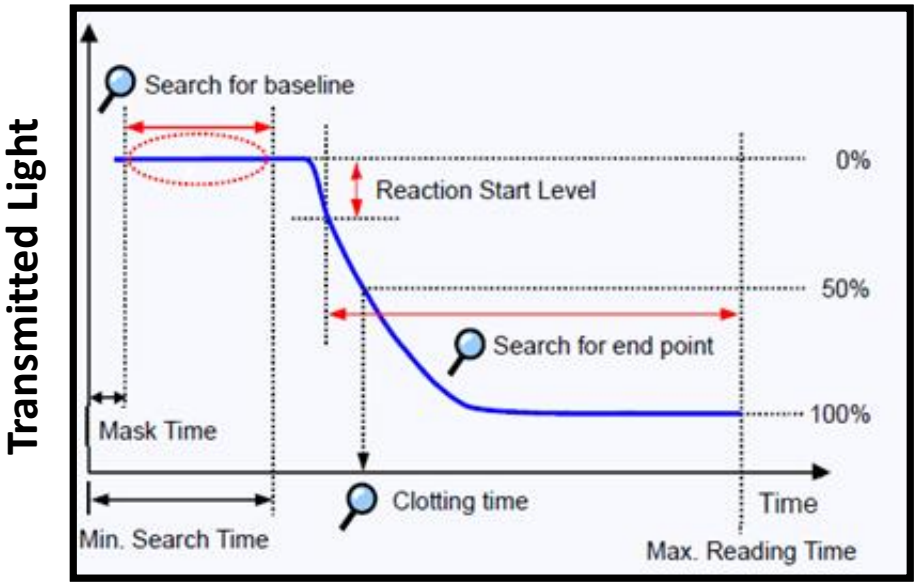
- Patient Diagnosis, history and clinical condition
- Anticoagulant Therapy
- Full Medication Lists (evaluation of interference).
- Evaluate Collection practices for potential heparin contamination (consider collection technique i.e. Peripheral or Line Draw and time of draw).

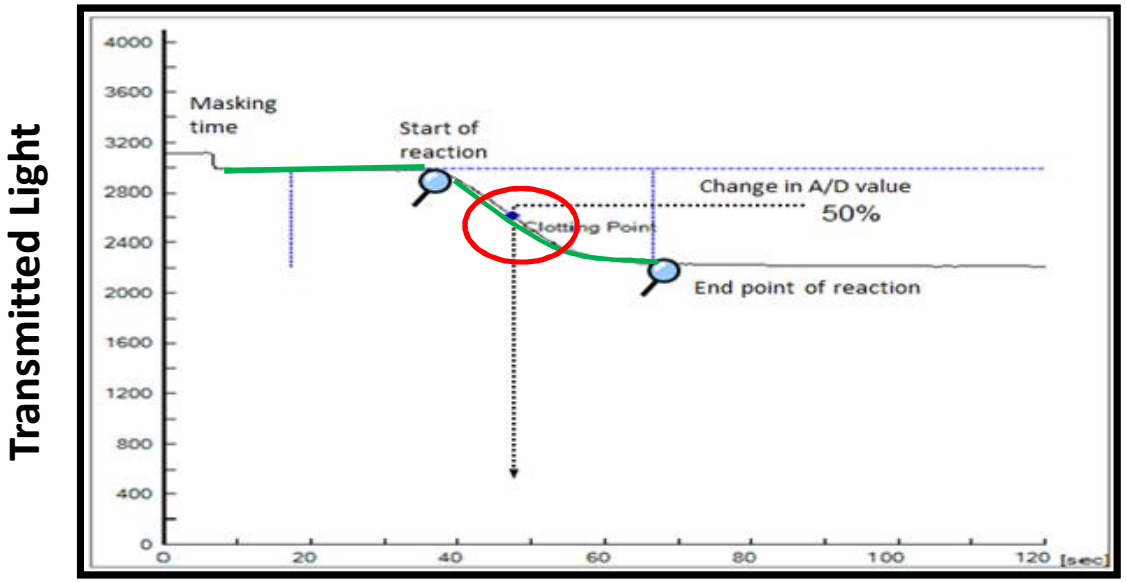
Common Anticoagulants
Unfractionated Heparin
Pradaxa (Dabigatran)
Xarelto (Rivaroxaban)
Savaysa (Edoxaban)
Eliquis (Apixaban)
Bevyxxa (Betrixaban)
Argatroban
Fondaparinux

What is a Typical Reaction Curve

Percentage Detection Method

Measurement Principle for Clotting Assays

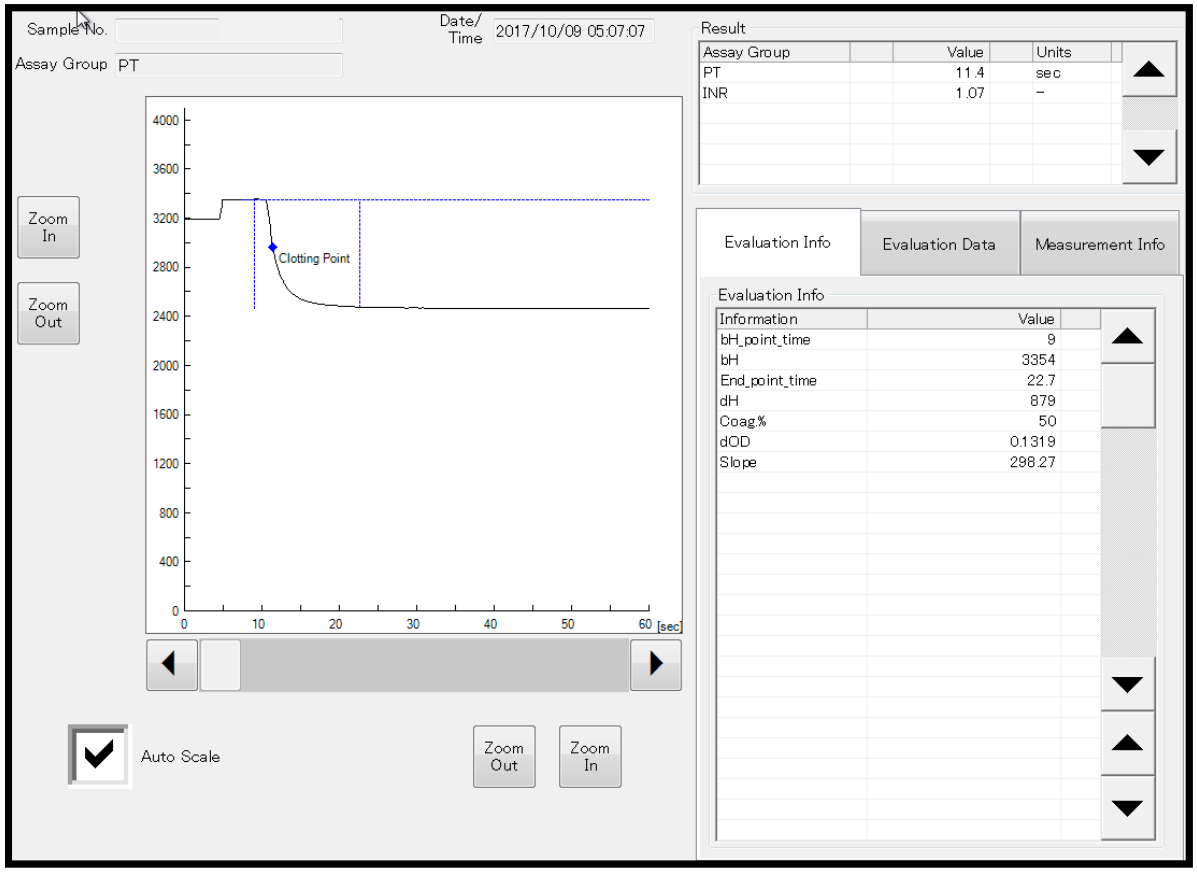




Percentage Detection Method

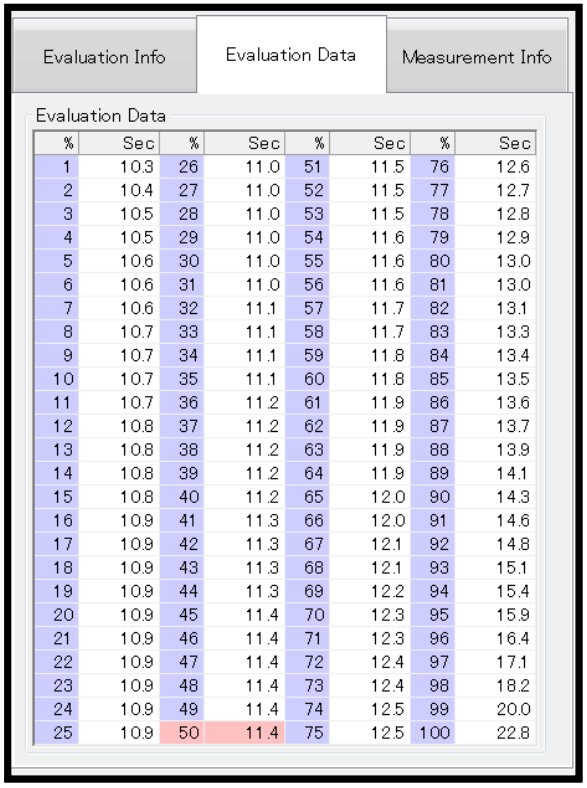
1. **Baseline (0%):** After a pre-defined "Mask Time" a search for the reaction start point begins, this is the baseline.
   - The transmitted light at the baseline (**bH**) is defined as 0%.
2. **Clotting Phase:** The time of the reaction between the baseline and the endpoint; when transmitted light is changing due to active clot formation.
3. **Endpoint (100%):** The CS software search for coagulation end point until the maximum measurement time is met.
   - The transmitted light at the endpoint is defined as 100%
4. **Clotting Point (50%):** The point at which the clotting time (result) is determined. This can be set between 0% and 100%; most assays use 50%.
   - **dH** is the change in transmitted light value between the baseline and the end point

Typical PT



Transmitted Light

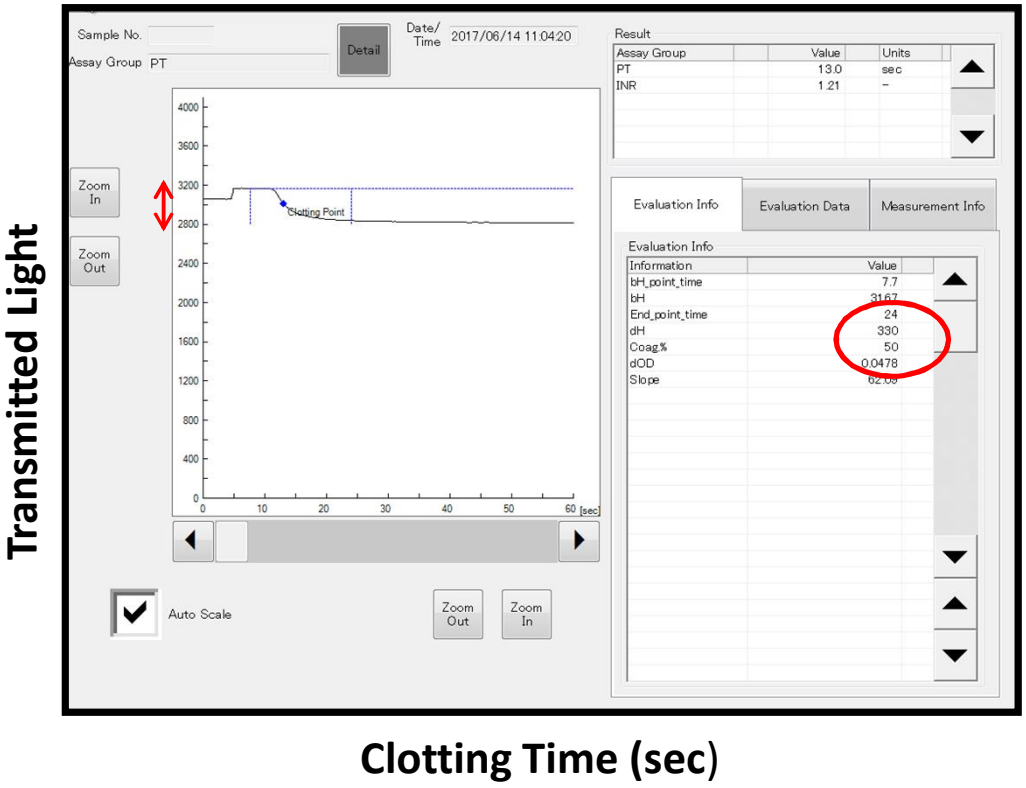
Clotting Time (sec)



%	Sec	%	Sec	%	Sec	%	Sec
1	10.3	26	11.0	51	11.5	76	12.6
2	10.4	27	11.0	52	11.5	77	12.7
3	10.5	28	11.0	53	11.5	78	12.8
4	10.5	29	11.0	54	11.6	79	12.9
5	10.6	30	11.0	55	11.6	80	13.0
6	10.6	31	11.0	56	11.6	81	13.0
7	10.6	32	11.1	57	11.7	82	13.1
8	10.7	33	11.1	58	11.7	83	13.3
9	10.7	34	11.1	59	11.8	84	13.4
10	10.7	35	11.1	60	11.8	85	13.5
11	10.7	36	11.2	61	11.9	86	13.6
12	10.8	37	11.2	62	11.9	87	13.7
13	10.8	38	11.2	63	11.9	88	13.9
14	10.8	39	11.2	64	11.9	89	14.1
15	10.8	40	11.2	65	12.0	90	14.3
16	10.9	41	11.3	66	12.0	91	14.6
17	10.9	42	11.3	67	12.1	92	14.8
18	10.9	43	11.3	68	12.1	93	15.1
19	10.9	44	11.3	69	12.2	94	15.4
20	10.9	45	11.4	70	12.3	95	15.9
21	10.9	46	11.4	71	12.3	96	16.4
22	10.9	47	11.4	72	12.4	97	17.1
23	10.9	48	11.4	73	12.4	98	18.2
24	10.9	49	11.4	74	12.5	99	20.0
25	10.9	50	11.4	75	12.5	100	22.8

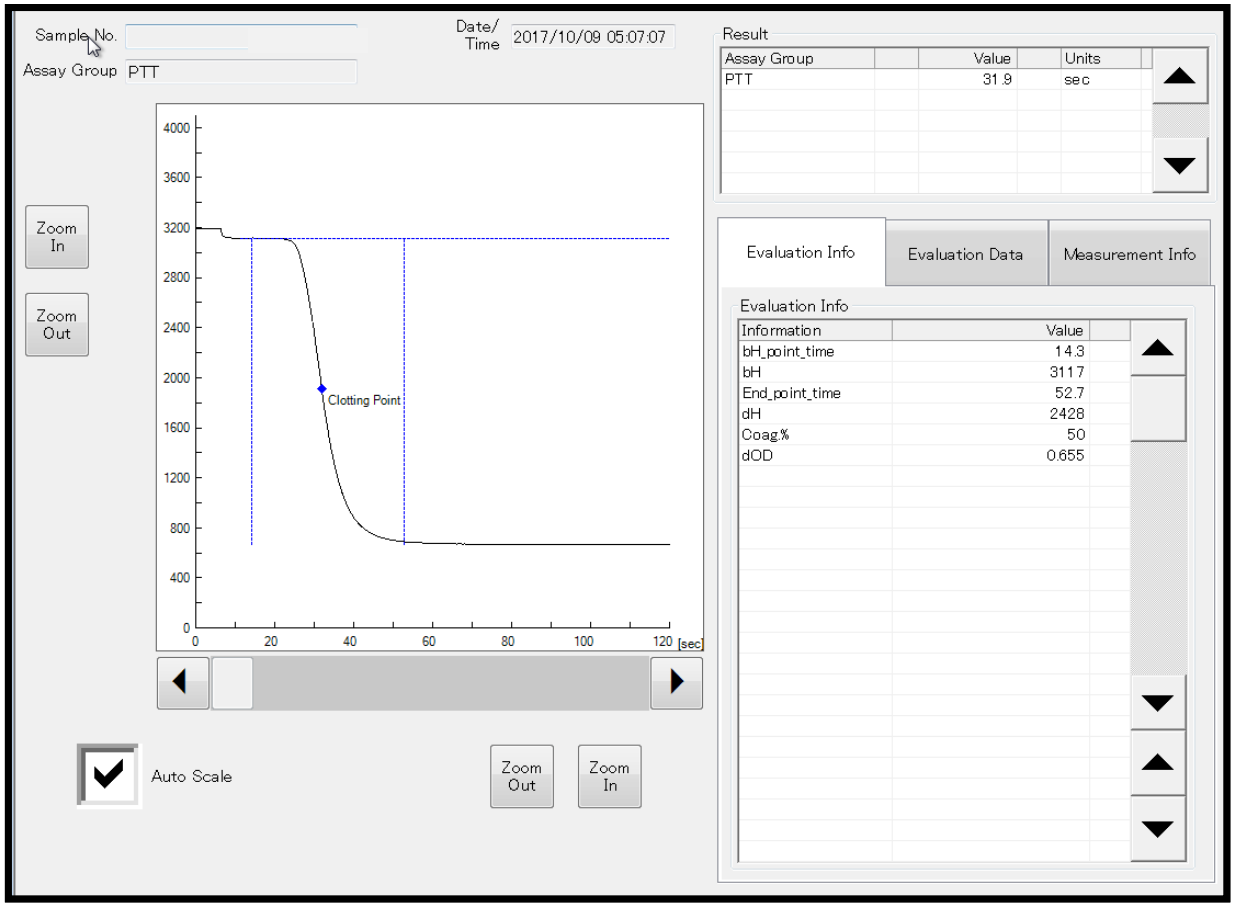
Typical PT: Influence of Fibrinogen

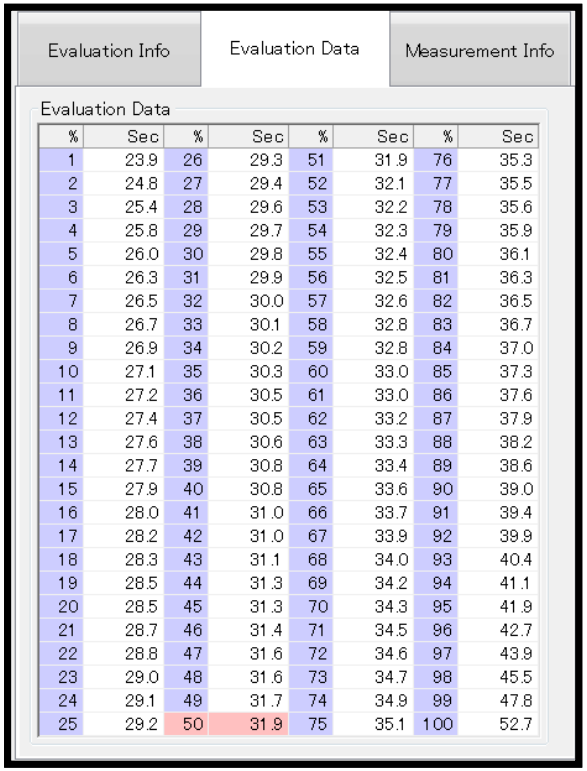
PT from sample with Normal Fibrinogen Level
dH =879



PT from sample with Low Fibrinogen Level
dH=330

Typical PTT

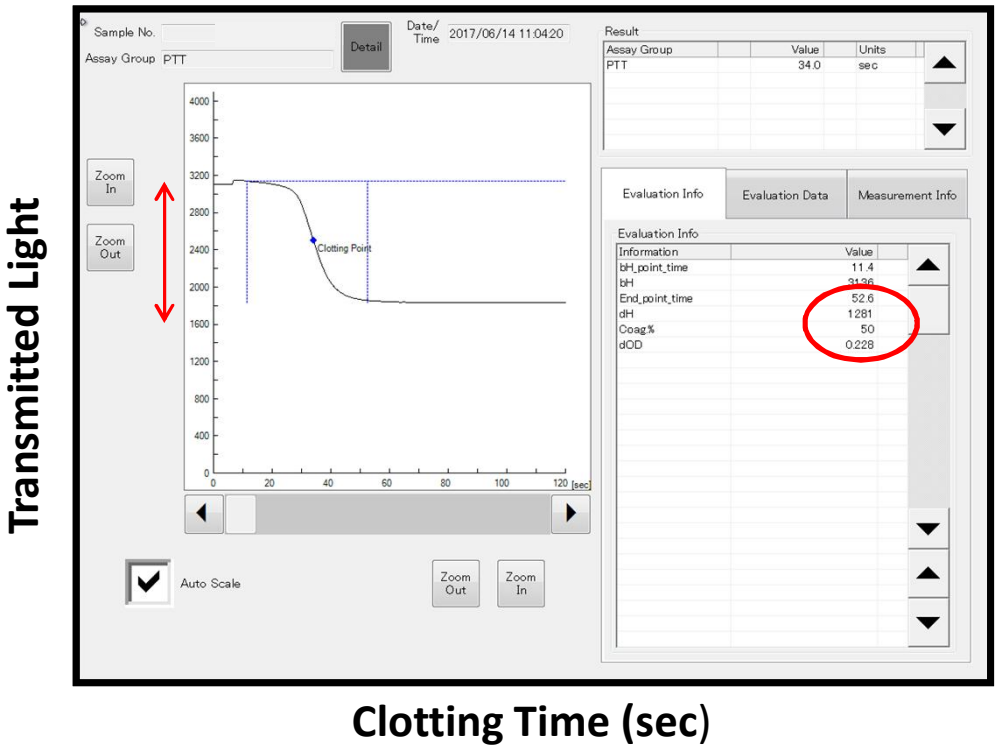




%	Sec	%	Sec	%	Sec	%	Sec
1	23.9	26	29.3	51	31.9	76	35.3
2	24.8	27	29.4	52	32.1	77	35.5
3	25.4	28	29.6	53	32.2	78	35.6
4	25.8	29	29.7	54	32.3	79	35.9
5	26.0	30	29.8	55	32.4	80	36.1
6	26.3	31	29.9	56	32.5	81	36.3
7	26.5	32	30.0	57	32.6	82	36.5
8	26.7	33	30.1	58	32.8	83	36.7
9	26.9	34	30.2	59	32.8	84	37.0
10	27.1	35	30.3	60	33.0	85	37.3
11	27.2	36	30.5	61	33.0	86	37.6
12	27.4	37	30.5	62	33.2	87	37.9
13	27.6	38	30.6	63	33.3	88	38.2
14	27.7	39	30.8	64	33.4	89	38.6
15	27.9	40	30.8	65	33.6	90	39.0
16	28.0	41	31.0	66	33.7	91	39.4
17	28.2	42	31.0	67	33.9	92	39.9
18	28.3	43	31.1	68	34.0	93	40.4
19	28.5	44	31.3	69	34.2	94	41.1
20	28.5	45	31.3	70	34.3	95	41.9
21	28.7	46	31.4	71	34.5	96	42.7
22	28.8	47	31.6	72	34.6	97	43.9
23	29.0	48	31.6	73	34.7	98	45.5
24	29.1	49	31.7	74	34.9	99	47.8
25	29.2	50	31.9	75	35.1	100	52.7

Typical PTT: Influence of Fibrinogen

PTT from sample with Normal Fibrinogen Level
dH=2428



PTT from sample with Low Fibrinogen Level
dH= 1281

Reaction Curve Flagging

Reaction Curve Flags Overview

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Analysis Time Over

- Sample does not develop stable clot within measurement time
- Over anticoagulation or factor deficiency

Early Reaction Error

- For aPTT assays *
- Slow reaction due to anticoagulant

Flat Curve

- For PT assays only.
- Samples with low fibrinogen level or anti-coagulant therapy

No Coagulation Slight Coagulation

- Sample does not clot within measurement time and has no reaction

Slight Coagulation

- Weak clot due to low fibrinogen or interference

Coagulation Curve Error

Trans Light High

Range Over

Noise Error

- Typically hardware related and may require a new lamp or FSE support.

Turbidity Level Over

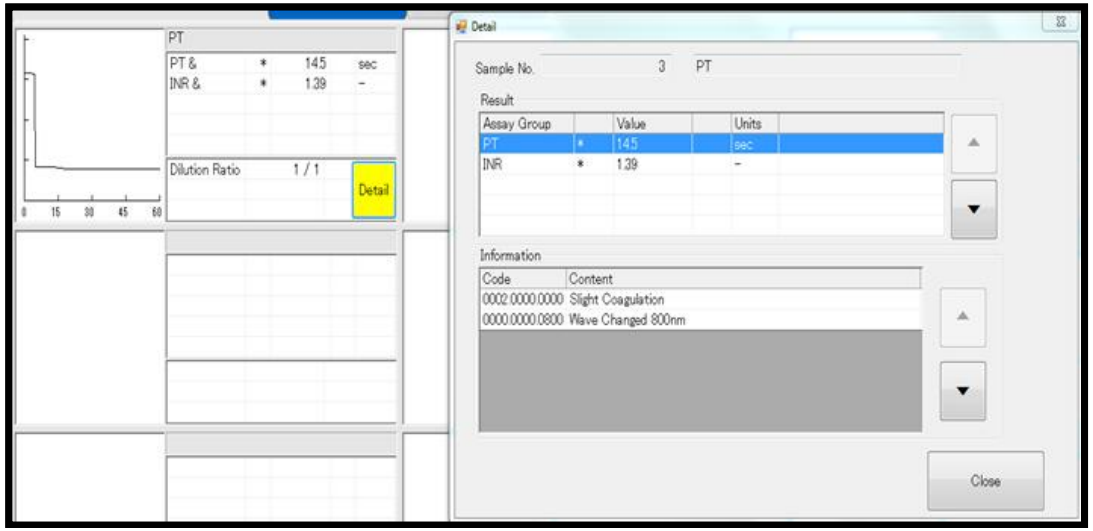
Wavelength Switch

* PT assays may trigger ERE: Start Angle Errors

Wavelength Switch

PT, PTT

- The CS system determines which wavelength produced the most reliable and accurate result.
- If the subwavelength value is the appropriate value to report, this will be the only visible result.
- Flagging of the original wavelength (660 nm) will not be visible to the user.
- Wavelength switch is triggered by specific errors.



Error Code	Benefit of Wavelength Switch
No Coagulation Slight Coagulation	A sample with a weak clot @ 660 nm may demonstrate a stronger clot (higher dH) @ 800 nm and therefore be reportable with the first analysis.
Turbidity Level Over	Optically challenged samples tend to exhibit interference @660 nm; this interference is typically minimized @ 800 nm.
Trans Light High	Extremely clear samples may demonstrate a higher dH with 800 nm

A Note About Measurement Time Action Steps

The Sysmex® CS-Systems Evaluation and Check Algorithm Guides reference the following guidance for numerous error codes:

> *Reanalyze the sample with an extended measurement time (within the range of 100 to 1800 seconds) or set the "Measurement Time (Sub)" in the [Detailed Settings]."*

Siemens has validated all our assays with pre-defined measurement times.

Some assays, such as the PT and PTT have pre-defined Measurement Time (Sub).

Siemens supports the use of pre-defined measurement time settings only!

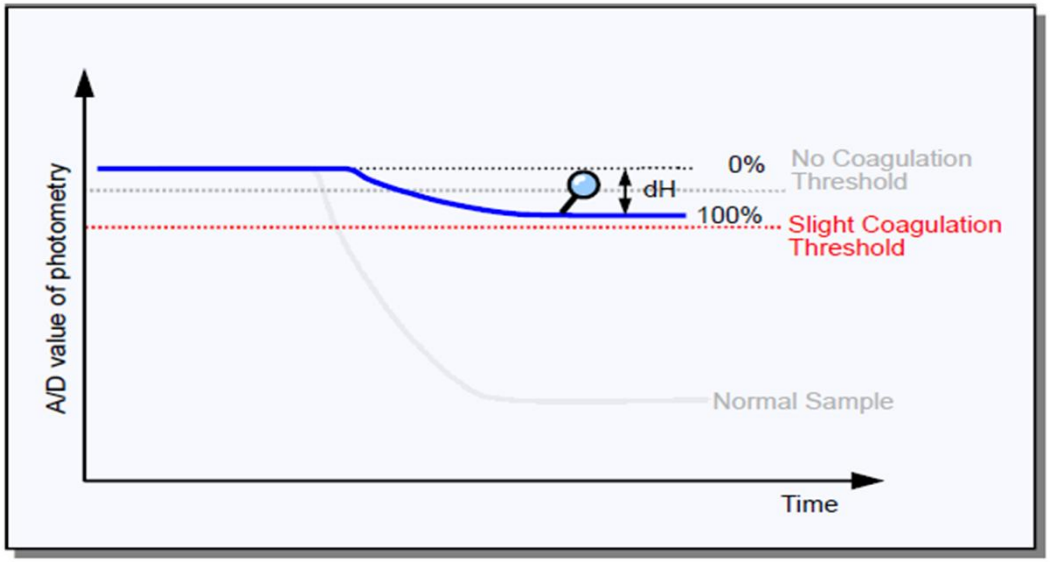
Repeat analysis is typically automatically performed with the (Sub) Measurement time based on instrument settings.

This presentation will use the term "longer time" for the pre-defined sub measurement times.

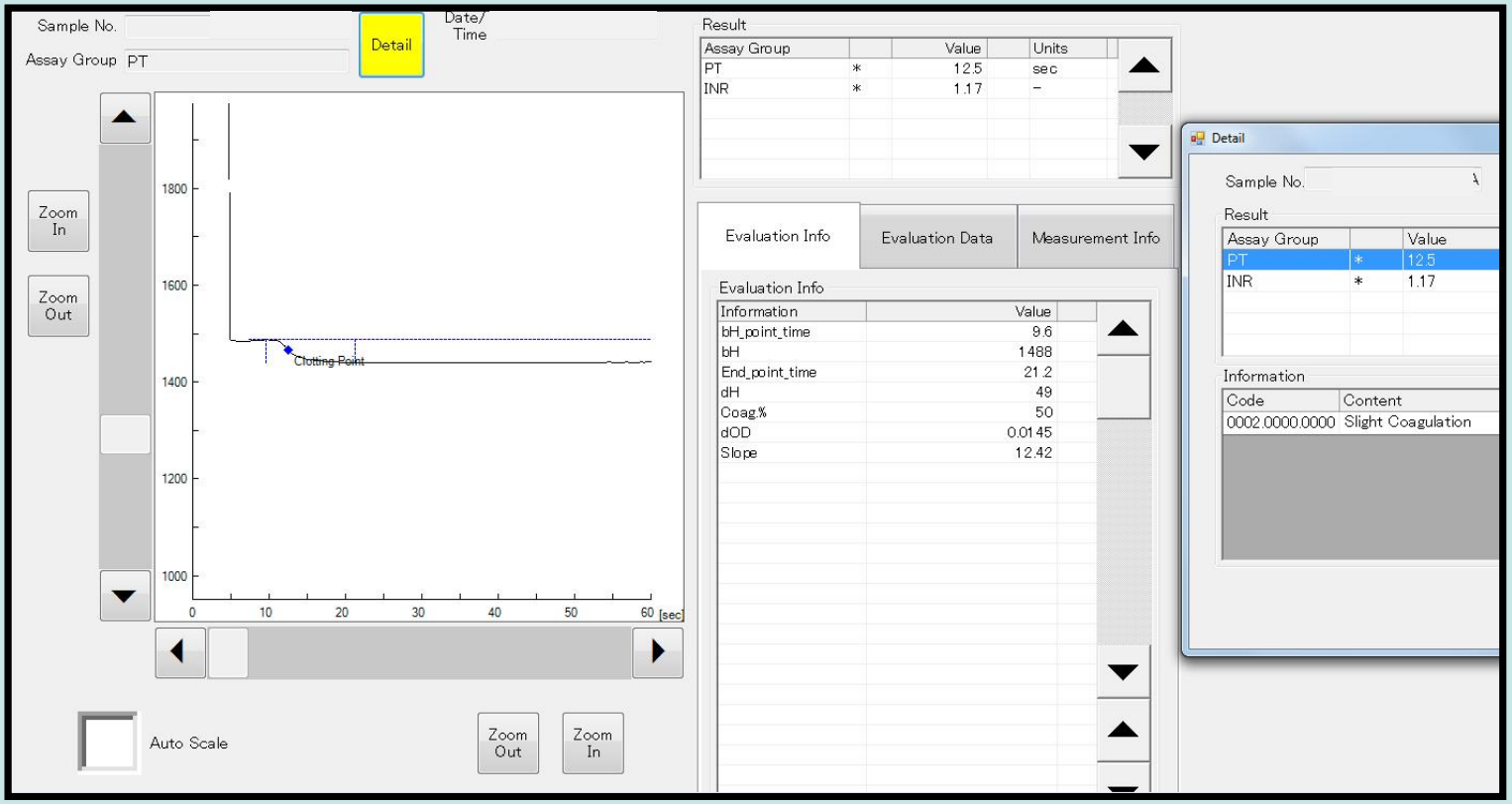
Slight Coagulation (SC) Error

0002.0000.0000

Joblist	Flagged numeric result
Cause	A very weak coagulation reaction. This may be due to a low fibrinogen concentration, factor deficiency, or inhibitor. Possible problem with the reagent.
Kinetic Evaluation	• Baseline established • Clotting phase generally is not as pronounced as typical • An endpoint is observed • dH will be decreased. The dH limit to trigger this flag is assay dependent.



Slight Coagulation Example

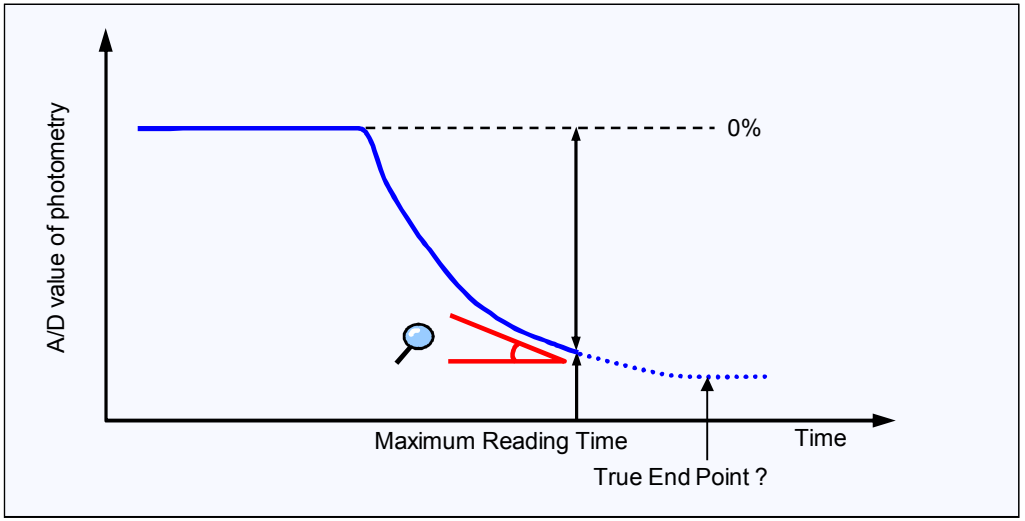


- Repeat PT= 12.5 sec;
- SC Error
- Weak clot: dH 49
- Repeat analysis
- Compare evaluation data @ 50%
- Typical Clot Progression present
- Report PT 12.5 seconds

Analysis Time Over (ATO)

0004.0000.0000

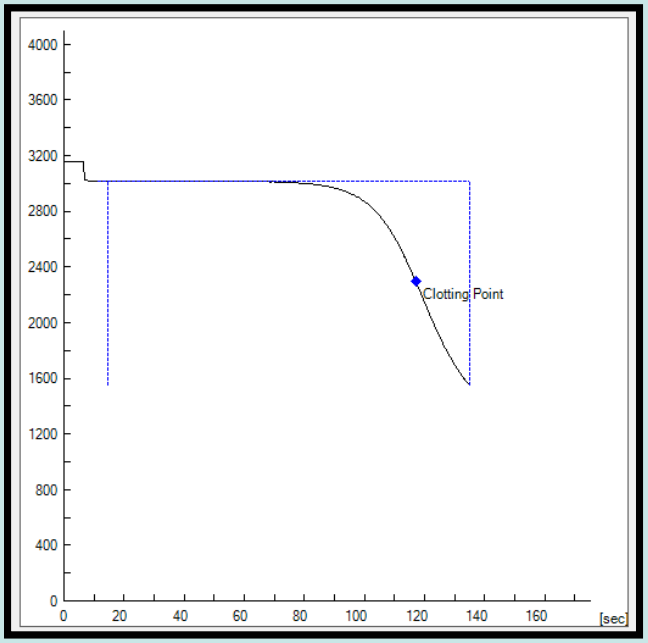
Joblist	Flagged numeric result
Cause	The reaction curve did not achieve an end point before the measurement time was reached. *Prolonged clotting time may be due to low coagulation activity, low fibrinogen concentration, anticoagulation therapy, interfering substance, etc.*
Kinetic Evaluation	• Has a defined baseline • Has a clotting phase • Does not have end point • The result determined at the 50% coagulation time may be inaccurate. • This requires manual evaluation. • Look for typical progression of the curve.



Analysis Time Over (ATO) Example 1

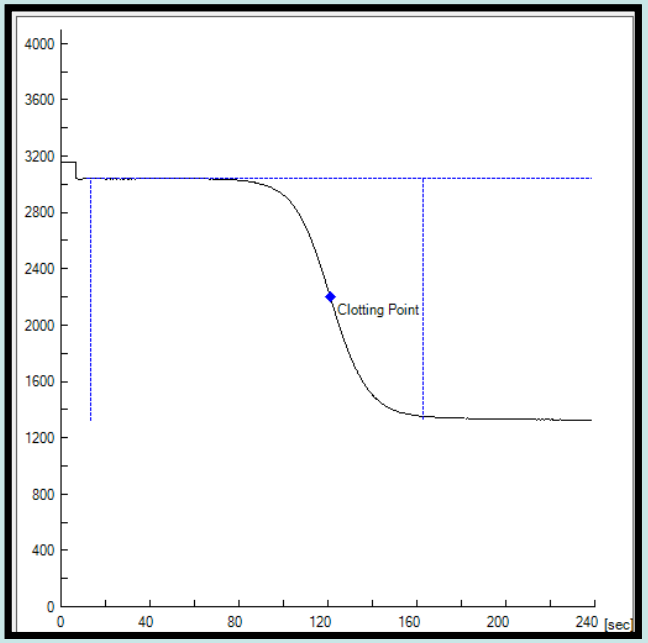
PTT 117.1 seconds

ATO Error



Repeat with the longer time (sub):

PTT 121 seconds; No Error



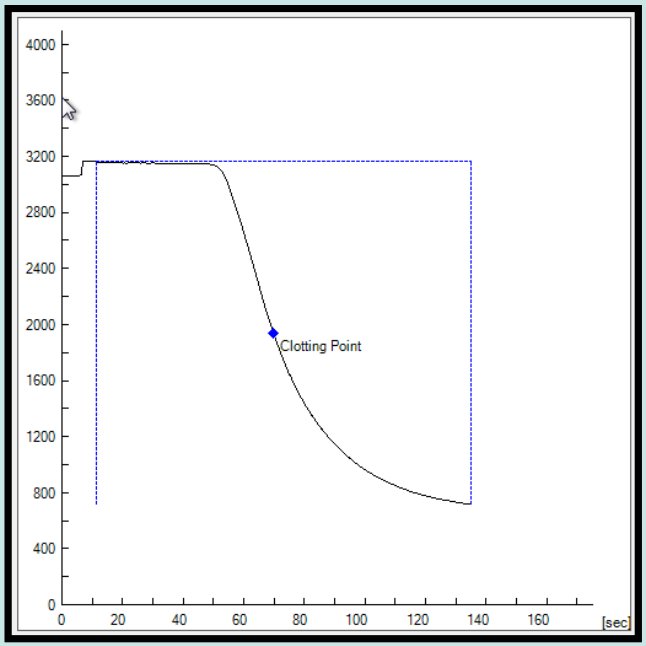
- Reaction curve of repeat analysis has typical clot progression.
  - baseline, clot phase, endpoint
- Transmitted light values are consistent with acceptable sample integrity.
- The result is not flagged.
- The PTT value of 121 seconds can be reported.

Demonstrates the typical effect of anticoagulant on the PTT.

Analysis Time Over (ATO) Example 2

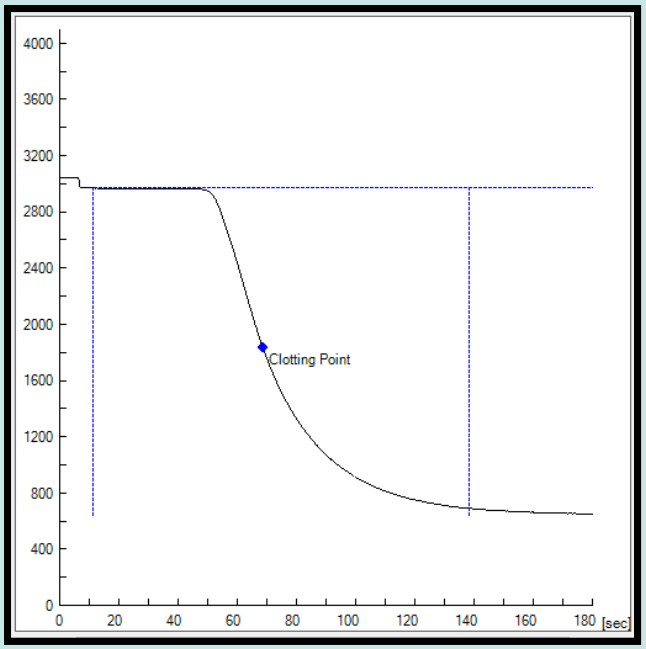
PTT 69.8 seconds

ATO Error



Repeat with the longer time (sub):

PTT 68.6 seconds; No flags.



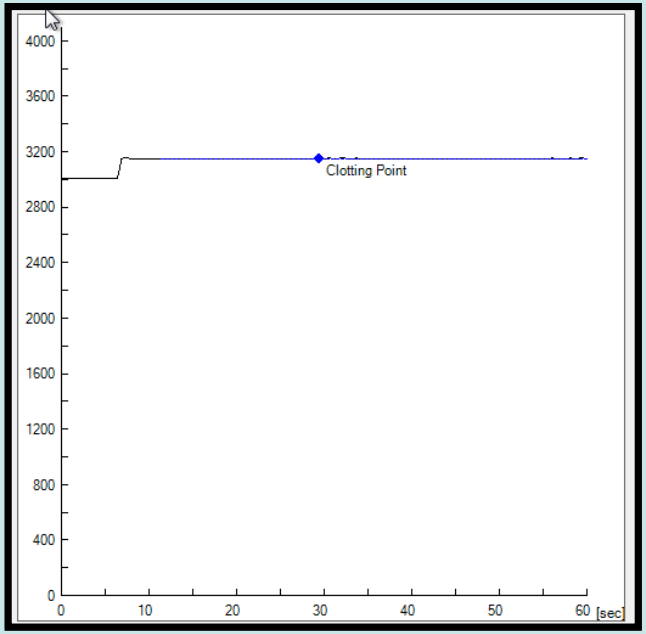
- Repeat analysis reaction curve has a clear baseline, clot phase, and endpoint.
- Result is not flagged.
- Notice the improvement of the endpoint with the longer time.
- Consistent value between repeats.
- The PTT value of 68.6 seconds is reportable.

Analysis Time Over (ATO)
Example 3

PTT; No Coagulation Error

Sample Integrity acceptable

QC in range.

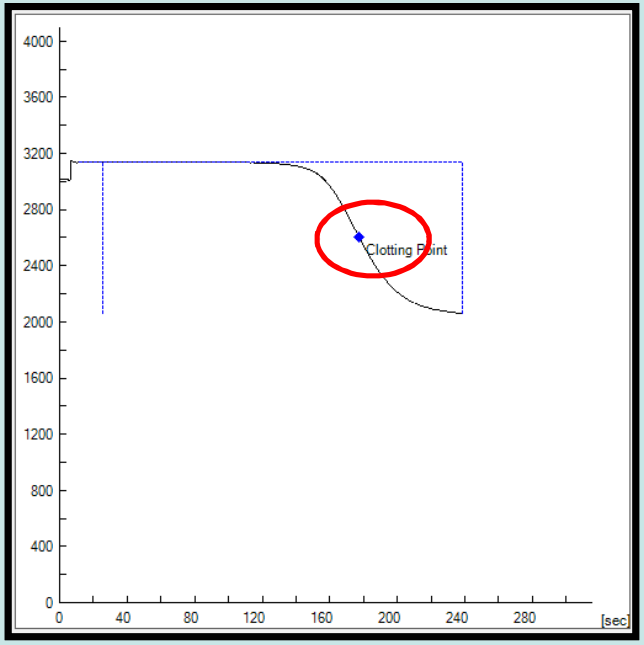


Repeat with the longer time (sub):

Clear baseline/clot phase is visible.

Plateau is starting.

ATO Error occurred



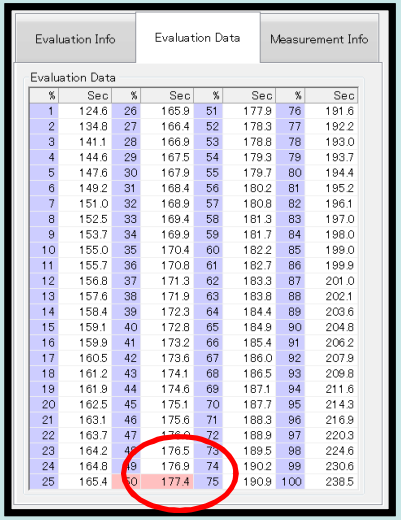
Typical Clot Formation is present.

Evaluation Data 50% = 177.4 sec.

50% value consistent with curve.

Clot is clearly prolonged >URL.

Report as determined by your laboratory policy.



Early Reaction Error (ERE)

Early Reaction Errors are typically for PTT analysis. There are 5 subsets for this error.

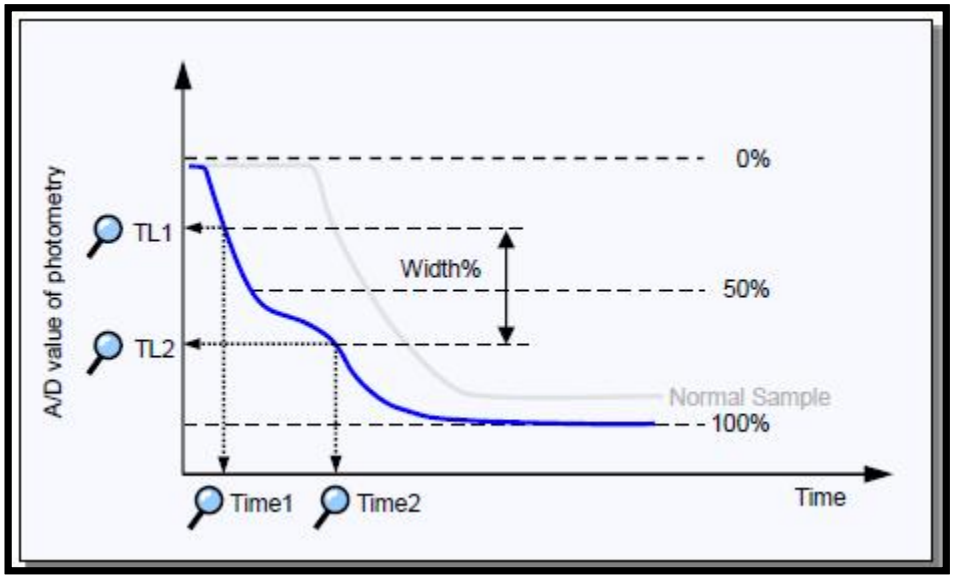
To investigate these errors further check the detail screen of the sample result on the joblist. Identify the specific error code and follow the guidance specific for that code.

ERE Subsets	Description
0008.0128.0001 ERE: Slow Reaction	Slope of coagulation curve around detection point is too low (reaction is too flat)
0008.0128.0002 ERE: Start Angle 1	Angle of coagulation curve is too high at the beginning of the curve; dH is low
0008.0128.0004 ERE: Start Angle 2	Angle of coagulation curve is too high at the beginning of the curve; dH is high
0008.0128.0008 ERE: Drift	Drift (Coagulation curve signal is drifting) ** Not used with Siemens Actin FSL PTT application
0008.0128.0016 ERE: Early %	Start of coagulation is detected too early

ERE: Slow Reaction

0008.0128.0001

Joblist	Masked ****.* result
Cause	Intended to prevent a false short result. Very slow coagulation reaction detected by checking the slope of the reaction around the clotting point. • Possible low fibrinogen, anticoagulant or reagent issue.
Kinetic Evaluation	• Clotting phase is not steep enough around the 50% • Drifting Baseline may be observed. • A bi-phasic curve may be observed. Result determined at the 50% coagulation time may be inaccurate. • This requires manual evaluation to confirm 50% value vs. reaction curve.

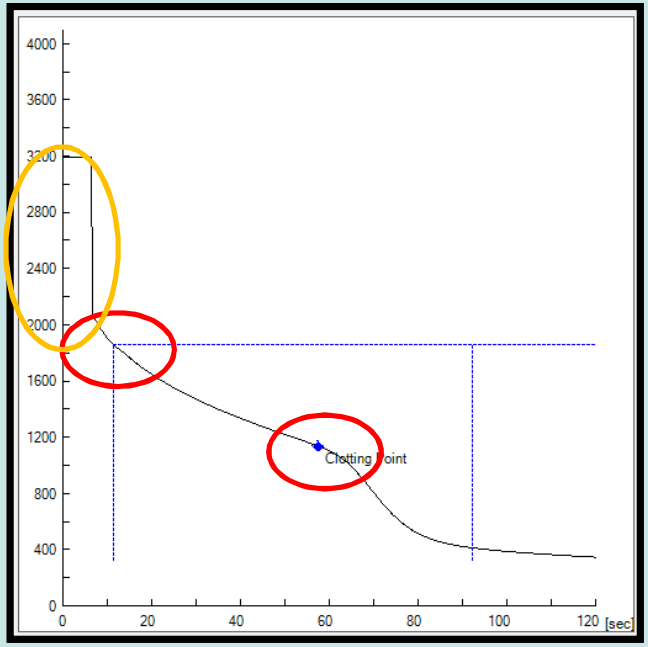


ERE: Slow Reaction Example 1

PTT 57.5 sec

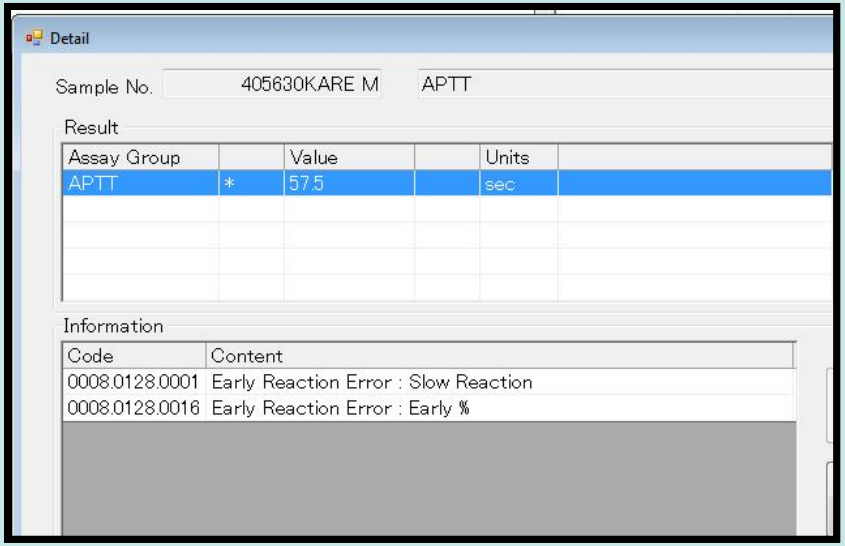
ERE: Slow Reaction

ERE Early %



This sample demonstrates:

- Strongly drifting baseline
- Reaction start determined prematurely
- Clotting phase is after the 50% value
- Endpoint is achieved



This is NOT REPORTABLE.

- 660 nm result
- **Manual review of reaction curve confirms the result of 57.5 seconds is incorrect.**
- Transmission values demonstrate an initial drop which indicates the plasma may need to be clarified.

Resolution:

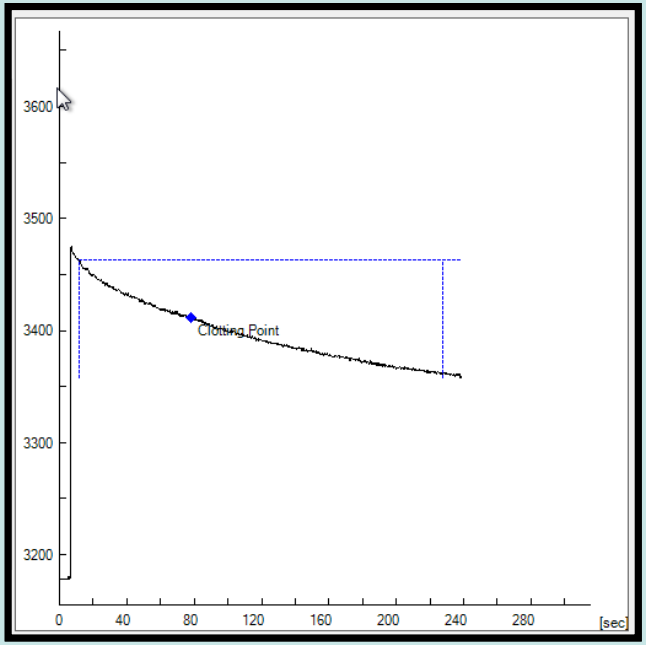
- Verify centrifugation of sample; speed/duration
- Recollection of sample

ERE: Slow Reaction Example 2

PTT with a longer time (sub):

ERE Slow Reaction

ERE Early %



Evaluation Data 50% = 78.0

Evaluation Info | Evaluation Data | Measurement Info

Evaluation Data

%	Sec	%	Sec	%	Sec	%	Sec
1	12.0	26	34.5	51	79.6	76	136.8
2	12.4	27	35.9	52	80.8	77	138.3
3	12.6	28	36.3	53	84.3	78	144.5
4	12.8	29	37.8	54	85.2	79	146.2
5	13.4	30	40.5	55	86.5	80	150.1
6	13.6	31	41.1	56	88.9	81	154.0
7	15.1	32	42.5	57	90.2	82	154.7
8	16.3	33	44.6	58	91.1	83	159.2
9	17.0	34	46.2	59	93.6	84	161.1
10	17.2	35	47.3	60	96.3	85	167.5
11	17.7	36	49.4	61	97.3	86	170.6
12	18.2	37	50.1	62	99.0	87	174.1
13	20.5	38	51.6	63	103.9	88	178.1
14	20.9	39	54.1	64	104.8	89	178.8
15	21.7	40	55.0	65	106.4	90	185.3
16	22.2	41	56.9	66	109.3	91	188.7
17	23.4	42	58.0	67	112.2	92	190.7
18	24.5	43	58.7	68	115.0	93	194.2
19	25.3	44	62.0	69	116.5	94	199.2
20	26.5	45	64.1	70	119.7	95	206.1
21	28.3	46	66.0	71	122.7	96	208.4
22	28.9	47	70.0	72	125.5	97	212.6
23	29.7	48	71.4	73	129.2	98	219.8
24	31.9	49	74.8	74	131.4	99	225.1
25	32.1	50	78.0	75	133.4	100	227.4

This is NOT REPORTABLE.

The instrument has prematurely determined the reaction start, and endpoint.

Not typical clot progression.

The evaluation data 50% value is not correct.

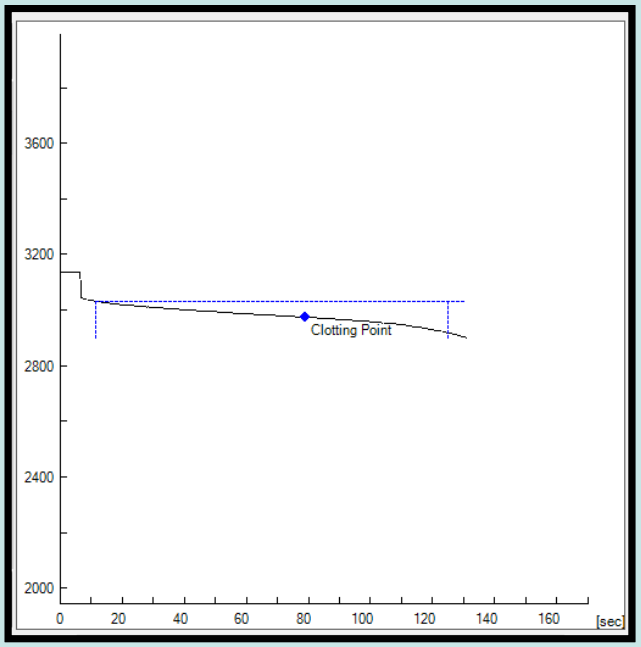
Consider:

- Anticoagulant therapy?
- Is collection technique and time appropriate?
- Consider recollection of the sample.

ERE: Slow Reaction Example 3

PTT Initial Run

Evaluation data 50% = 78.8 sec
Slow Reaction Error



Reaction curve has a drifting baseline through the measurement time.

Clotting phase has not started.

Endpoint is not present.

The reaction start was determined incorrectly.

NOT Typical Clot Progression.

The result of 78.8 seconds is **NOT REPORTABLE.**

This sample may benefit from a longer measurement time.

*If run in micro-mode repeat analysis must be selected manually!

The short drop of the kinetic line after the masking time does not indicate this reaction will benefit from high speed centrifugation.

Consider:

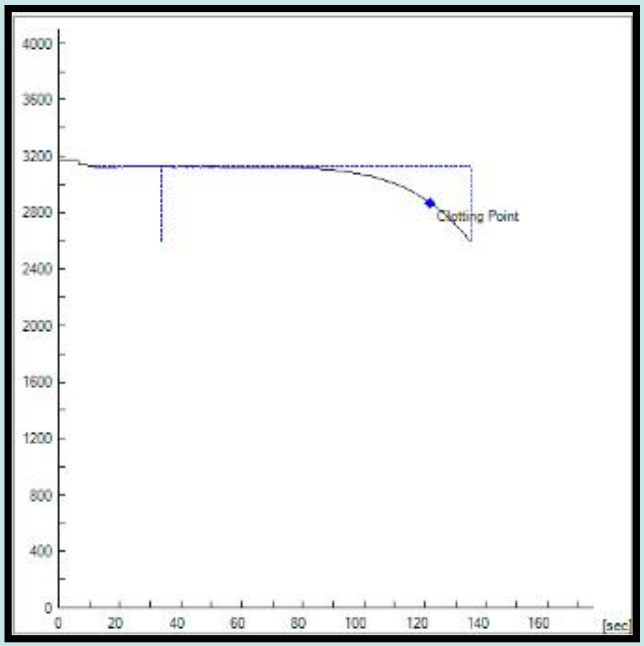
- Anticoagulant therapy?
- Is collection technique and time appropriate?

ERE: Slow Reaction Example 4

PTT:

Evaluation data 50% = 121.6 sec

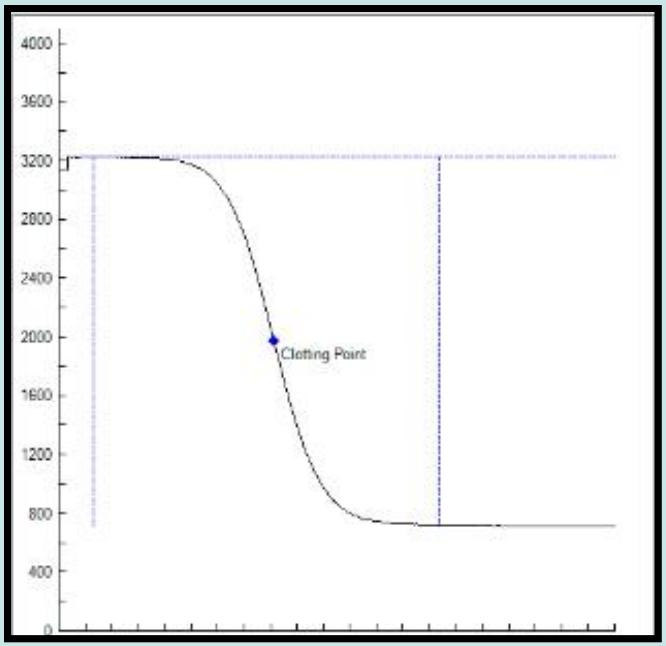
Analysis Time Over Error



Repeat with the longer time (sub):

50% evaluation = 162.5 seconds

Slow Reaction Error

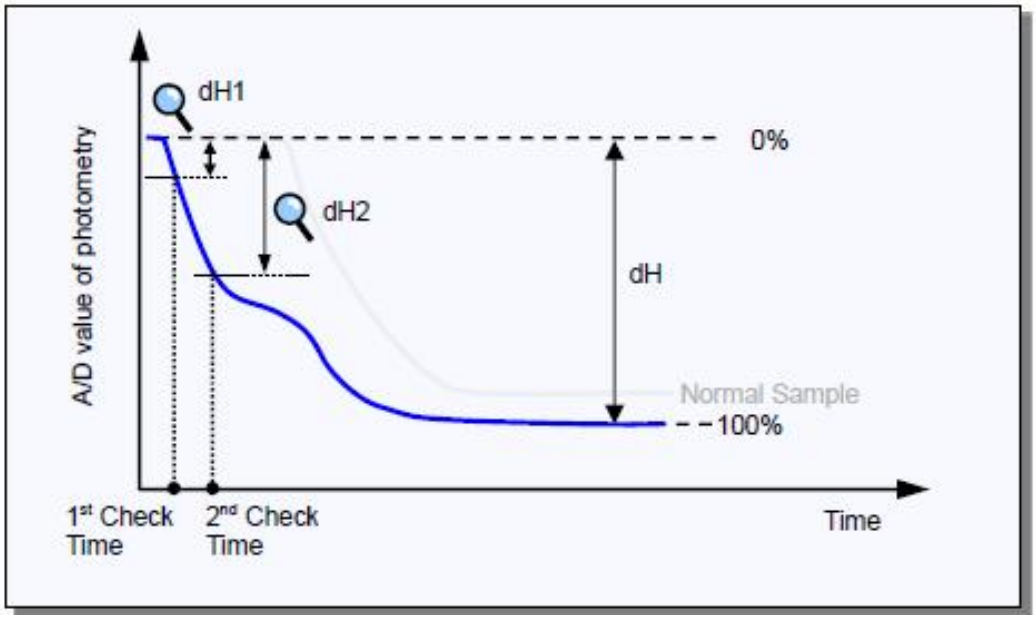


- Repeat analysis reaction curve has a clear baseline, clot phase, and endpoint.
- Typical Clot Formation Present
- 50% value accurate
- Compare 50% to PTT Upper Report Limit
- Consider clinical context
- Question sample collection to determine if result is plausible.
- Report as determined by your laboratory policy.

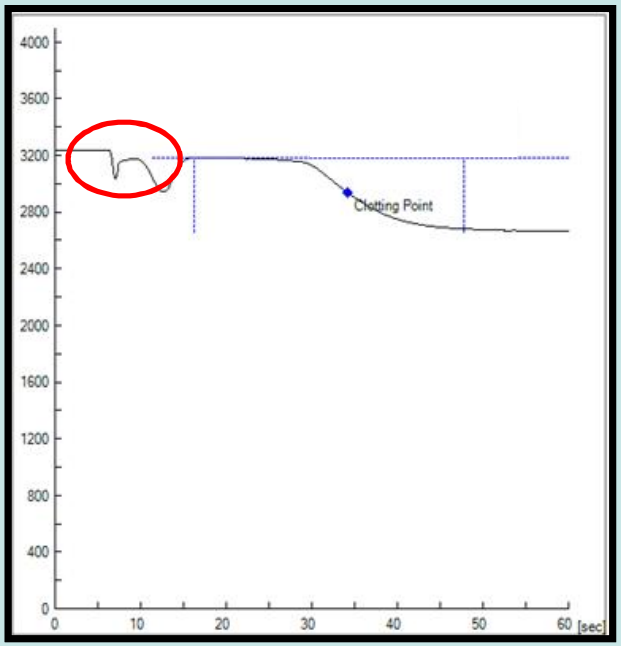
ERE: Start Angle 1

0008.0128.0002

Joblist	Masked ****.* result
Cause	• Typically Artifact
Kinetic Evaluation	• The coagulation curve is evaluated at pre-determined times (4 seconds and 8 seconds). • Angle of coagulation is high at the beginning of the curve • **Low dH** (Clot is weak) • The probability of an incorrect result is high. • Rare Error



ERE: Start Angle 1
Example 1



- Reaction curve has unusual behavior in the beginning of the reaction.
- Clear baseline, clot phase, and endpoint are visible.
- Start of the reaction is marked pre-maturely.
- Notice the weak dH.

The result determined of 32.8 seconds is accurate as compared to the curve.

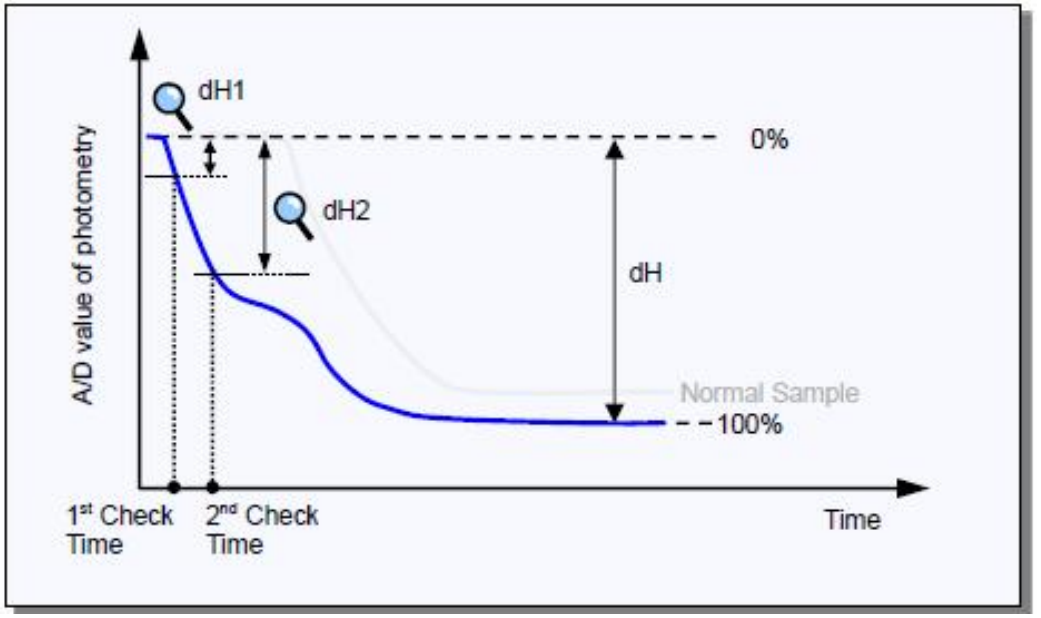
Reanalyze the sample.

Typically error will not re-occur.

ERE: Start Angle 2

0008.0128.0004

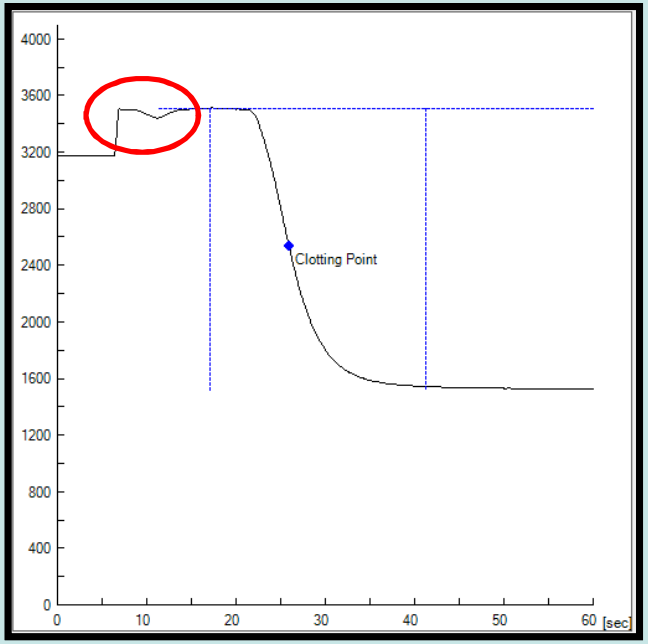
Joblist	Flagged numerical result
Cause	• Typically Artifact
Kinetic Evaluation	• The coagulation curve is evaluated at pre-determined times (4 seconds and 8 seconds). • Angle of coagulation is high at the beginning of the curve • ***high dH (***Strong coagulation signal) • The probability of an incorrect result is moderate.



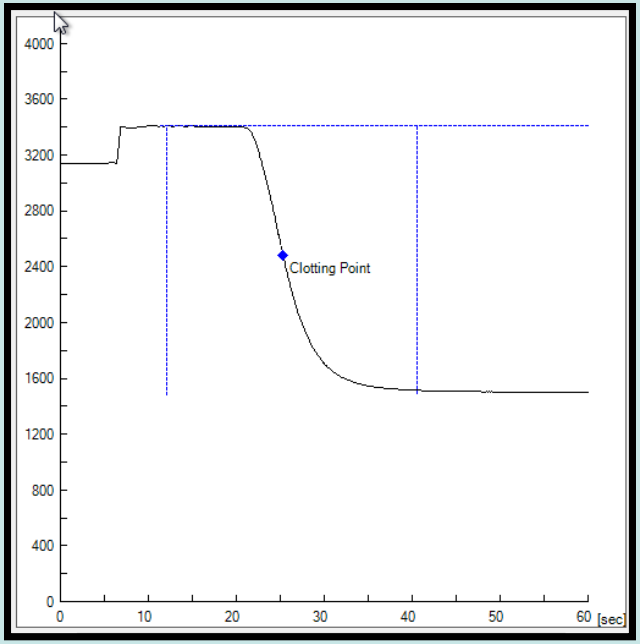
ERE: Start Angle 2 Example

PTT 25.9 Start Angle 2 Error

PT 9.9 sec; No error



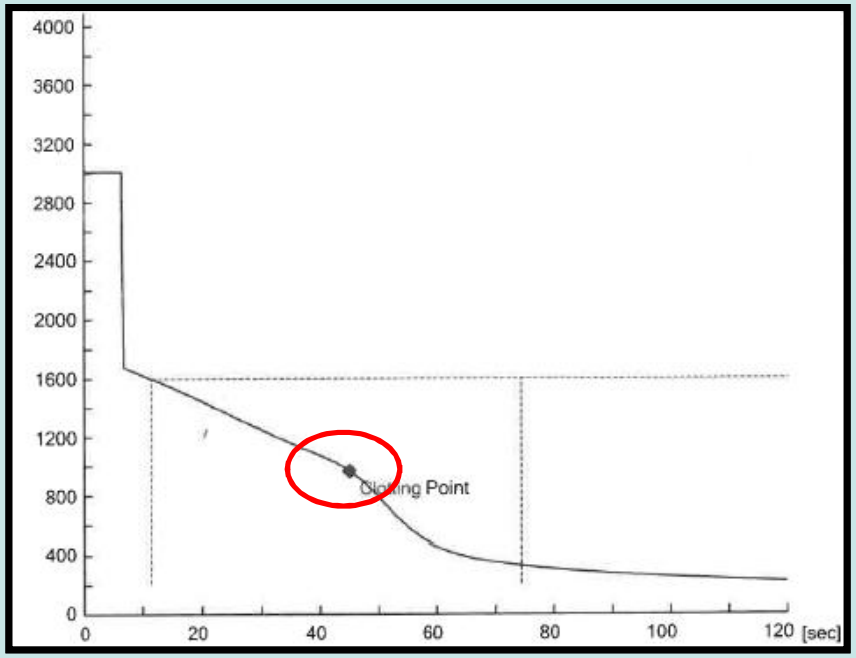
Repeat PTT 25.3 No Flag Report



- Initial analysis has clear baseline, clotting phase and endpoint.
- The clot time of 25.9 seconds is consistent with the reaction curve.
- The value was reportable.
- The customer elected to repeat the sample, and error was not present. Value of 25.3 is also reportable.

ERE: Start Angle 2
Example 2

PTT 45.0 Start Angle 2 Error



Result		
PTT	*	45.0 sec
Evaluation Info.		
bH_point_time		11.4
bH		1598
End_point_time		74.4
dH		1267
Coag.%		50
dOD		0.6837

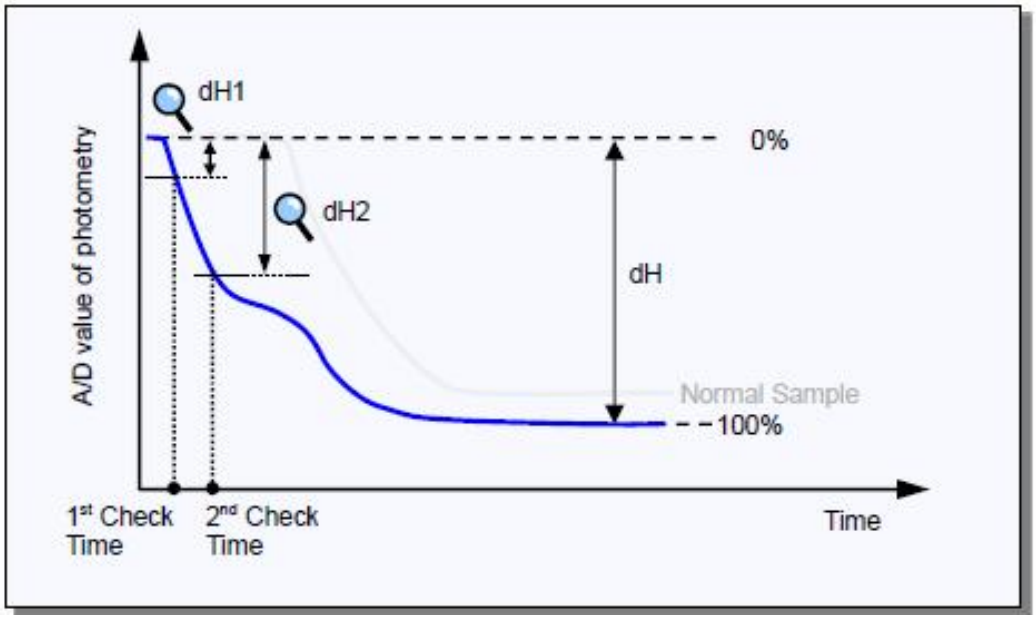
- Reaction curve demonstrates a strongly drifting baseline.
- Clotting phase and endpoint are visible.
- **Evaluation data 50% point is not determined correctly**.
- Consider centrifugation for a longer duration and higher speed.
- The value is **NOT REPORTABLE**.

ERE : Early %

0008.0128.0016

Joblist	Masked ****.* result
Cause	The increase in signal is detected early. • **Possible pre-activation of sample.** • Poor sample collection/handling

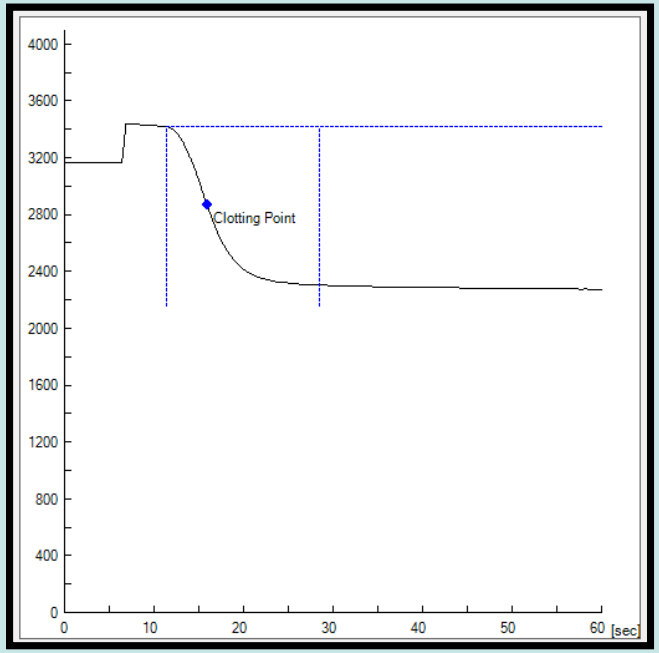
Kinetic Evaluation	Actin FSL:
	• Evaluation Data at 8% is < 16.8 sec
	  • May have drifting baseline
	  • May have sharp decline at start of reaction curve.
	• Reaction start determined too early
	• Evaluation Data 50% may be erroneous
	• Requires Manual Evaluation of curve



ERE: Early %
Example 1

PTT 15.9 sec Error Early %

Evaluation Data 8%= 13.0 seconds



Evaluation Info | Evaluation Data | Measurement Info

Evaluation Data

%	Sec	%	Sec	%	Sec	%	Sec
1	11.9	26	14.4	51	16.0	76	17.8
2	12.1	27	14.5	52	16.0	77	18.0
3	12.3	28	14.5	53	16.1	78	18.0
4	12.5	29	14.6	54	16.1	79	18.2
5	12.6	30	14.7	55	16.2	80	18.3
6	12.7	31	14.8	56	16.2	81	18.4
7	12.8	32	14.8	57	16.3	82	18.5
8	13.0	33	14.8	58	16.4	83	18.6
9	13.1	34	14.9	59	16.5	84	18.8
10	13.1	35	15.0	60	16.5	85	19.0
11	13.3	36	15.1	61	16.6	86	19.1
12	13.4	37	15.1	62	16.7	87	19.3
13	13.4	38	15.1	63	16.8	88	19.5
14	13.5	39	15.2	64	16.8	89	19.7
15	13.6	40	15.3	65	16.9	90	19.9
16	13.7	41	15.4	66	17.0	91	20.2
17	13.7	42	15.4	67	17.1	92	20.4
18	13.8	43	15.4	68	17.1	93	20.8
19	13.9	44	15.5	69	17.2	94	21.1
20	14.0	45	15.6	70	17.3	95	21.6
21	14.1	46	15.7	71	17.4	96	22.2
22	14.2	47	15.7	72	17.4	97	22.9
23	14.3	48	15.8	73	17.6	98	23.9
24	14.3	49	15.8	74	17.7	99	25.7
25	14.3	50	15.9	75	17.7	100	28.5

PTT <20 seconds

- Check sample for clot
- Evaluate collection process.

DO NOT REPORT

Recollect

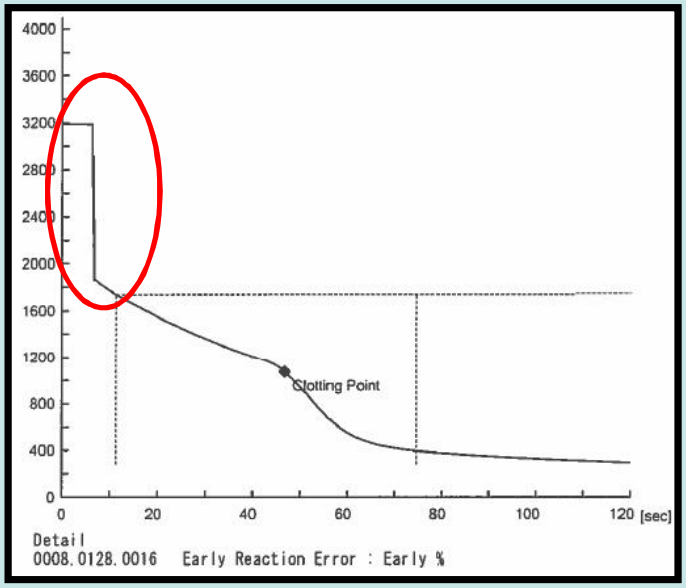
- If recollected sample is also short, consider other factors such as reagent lot or patient condition.

If customer has a high occurrence of this error; they need to evaluate their facilities sample collection practices!!

ERE: Early %
Example 2

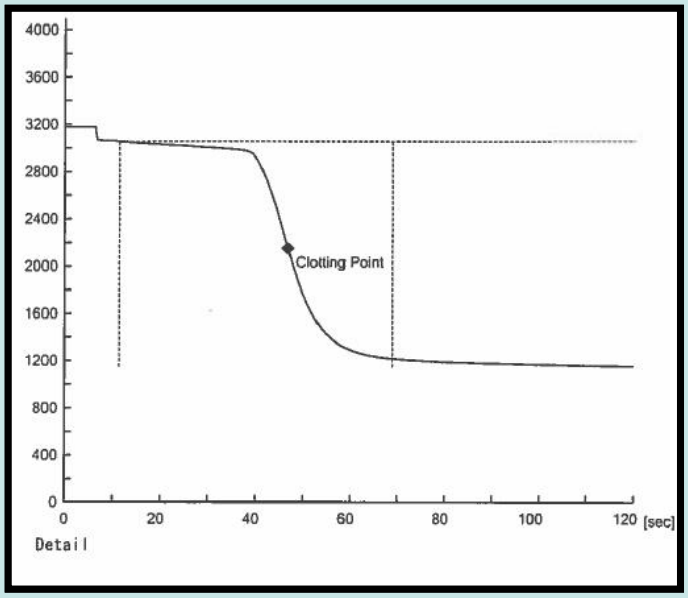
PTT 46.7; Error 128 ERE 16

First Run



PTT 46.7;

Repeat after longer centrifugation

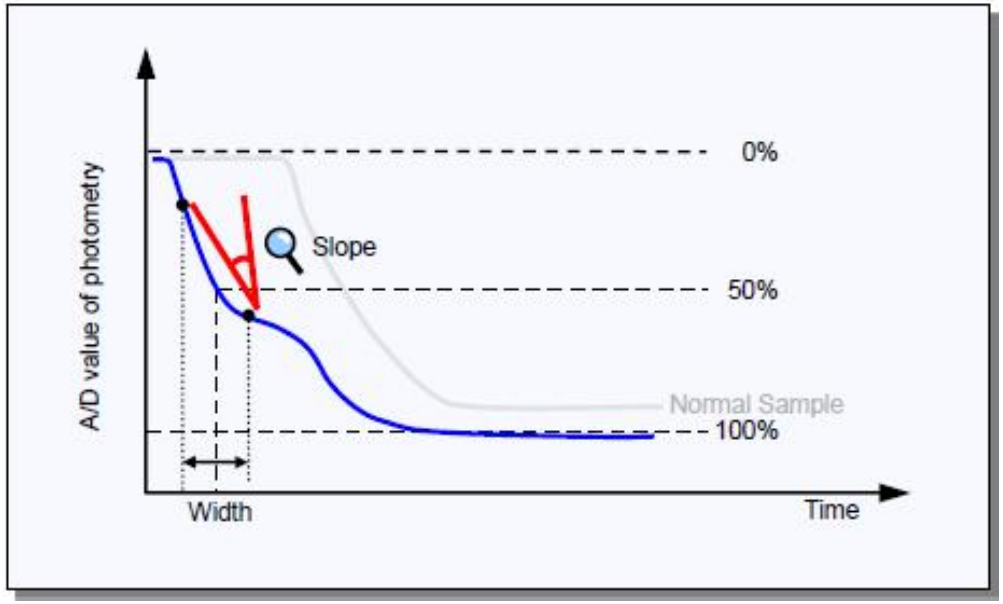


- Drifting baseline and the sharp drop at start of kinetic may indicate need for centrifugation with longer time and higher speed.
- Repeat of clarified plasma
  - Typical clot progression
  - 50% value is accurate
  - No Flags
  - Repeat analysis is reportable.

Flat Curve

0032.0002.0000

Joblist	Masked ****.* result Numeric for Calibration/QC
Cause	*PT analysis check only.* • Slow clotting phase detected. • Low fibrinogen concentration • Low Factor Activity • Anti-coagulants (i.e. Coumadin). • *Intended to prevent a false short result from being reported.*
Kinetic Evaluation	• Checks the slope of the coagulation curve around the 50% detection point. If too flat; flag occurs. • Low dH value may suggest a low Fib • Bi-phasic curve may be observed.

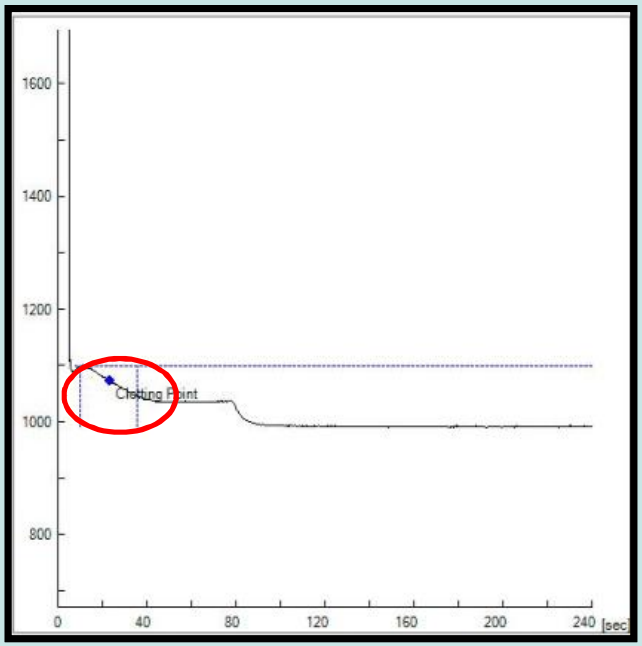


Note: Zoom in to view the reaction of the curve to better determine if baseline, clotting phase and endpoint are visible. This makes comparison with the evaluation data 50% value easier.

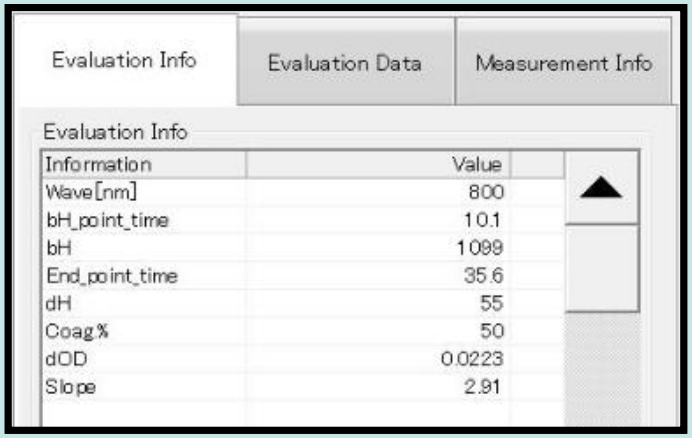
Flat Curve
Example 1

PT – longer time (sub):

Flat Curve; Slight Coagulation Error



Note: Review of curve with a zoom to better determine if 3 phases of clotting are visible and 50% point easier to see on curve.

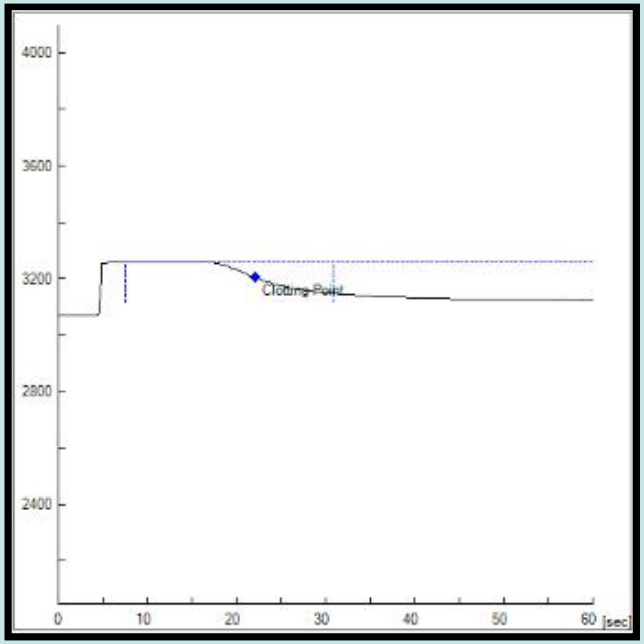


- Reaction Curve has bi-phasic appearance.
- Reaction start (bH) and endpoint are determined incorrectly.
- Evaluation Data 50% =23.1 sec
- Wave[nm] 800
- Comparison of reaction curve with the 50% value 23.1 sec is not acceptable.
- **Not Reportable**
- Rare occurrence

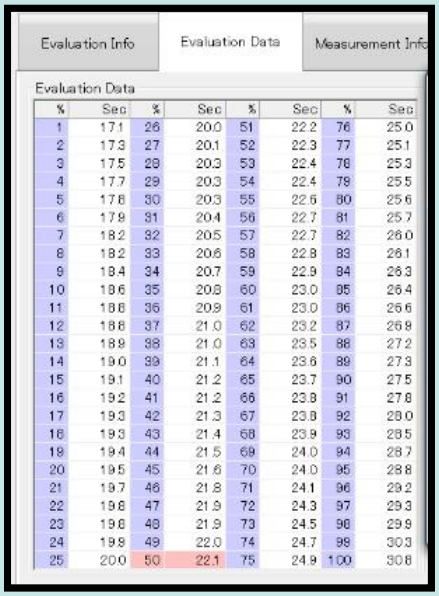
Flat Curve Example 2

PT 50%= 22.1 sec

Flat Curve Error



Note: Review of curve with a zoom to better determine if 3 phases of clotting are visible and 50% point easier to see on curve.



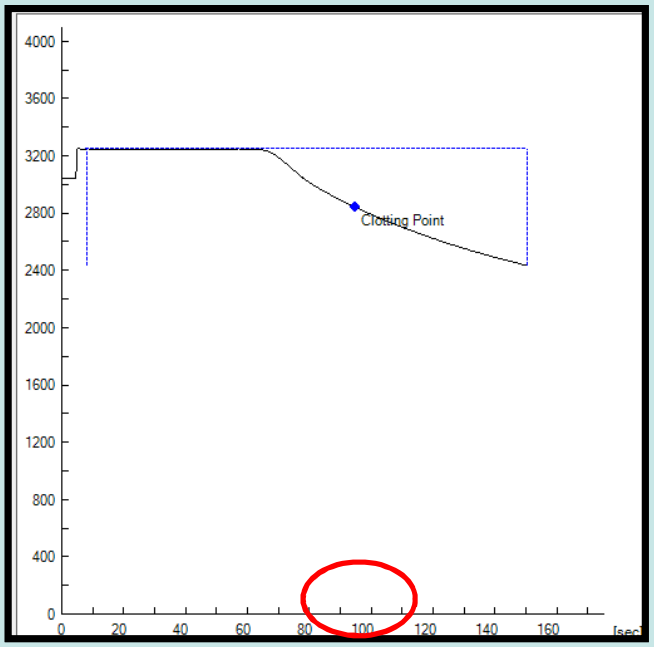
%	Sec	%	Sec	%	Sec	%	Sec
1	17.1	26	20.0	51	22.2	76	25.0
2	17.3	27	20.1	52	22.3	77	25.1
3	17.5	28	20.3	53	22.4	78	25.3
4	17.7	29	20.3	54	22.4	79	25.5
5	17.8	30	20.3	55	22.5	80	25.6
6	17.9	31	20.4	56	22.7	81	25.7
7	18.2	32	20.5	57	22.7	82	26.0
8	18.2	33	20.6	58	22.8	83	26.1
9	18.4	34	20.7	59	22.9	84	26.3
10	18.6	35	20.8	60	23.0	85	26.4
11	18.8	36	20.9	61	23.0	86	26.6
12	18.8	37	21.0	62	23.2	87	26.9
13	18.9	38	21.0	63	23.5	88	27.2
14	19.0	39	21.1	64	23.6	89	27.3
15	19.1	40	21.2	65	23.7	90	27.5
16	19.2	41	21.2	66	23.8	91	27.8
17	19.3	42	21.3	67	23.8	92	28.0
18	19.3	43	21.4	68	23.9	93	28.5
19	19.4	44	21.5	69	24.0	94	28.7
20	19.5	45	21.6	70	24.0	95	28.8
21	19.7	46	21.8	71	24.1	96	29.2
22	19.8	47	21.9	72	24.3	97	29.3
23	19.8	48	21.9	73	24.5	98	29.9
24	19.8	49	22.0	74	24.7	99	30.3
25	20.0	50	22.1	75	24.9	100	30.8

- *Comparison of reaction curve and 50% value are acceptable.*
- *Plateau is stable through end of measurement time.*
- *Inquire on patient clinical context.*
- *Ensure sample integrity is acceptable and sample is not diluted.*
- *Follow laboratory policy to confirm data. Report as determined by your laboratory policy.*

Flat Curve Example 3

PT 50% = 94.7 sec

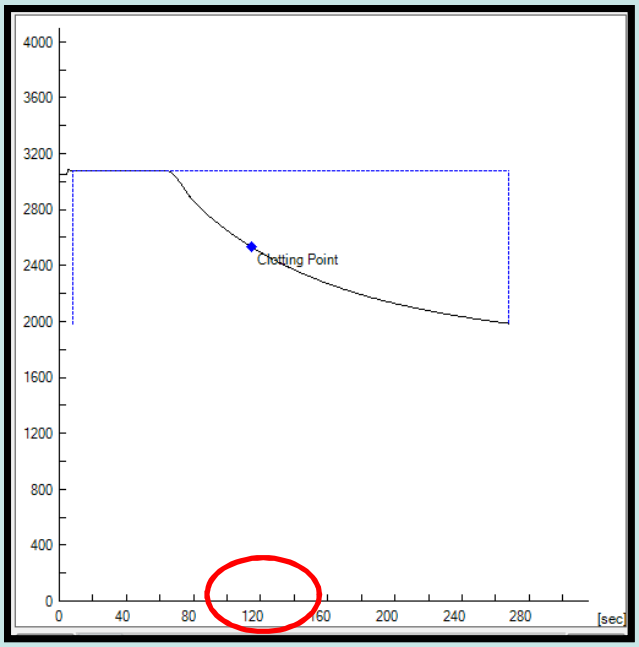
Flat Curve Error



Repeat on longer time (sub):

PT 50% = 114.3 seconds

Flat Curve Error

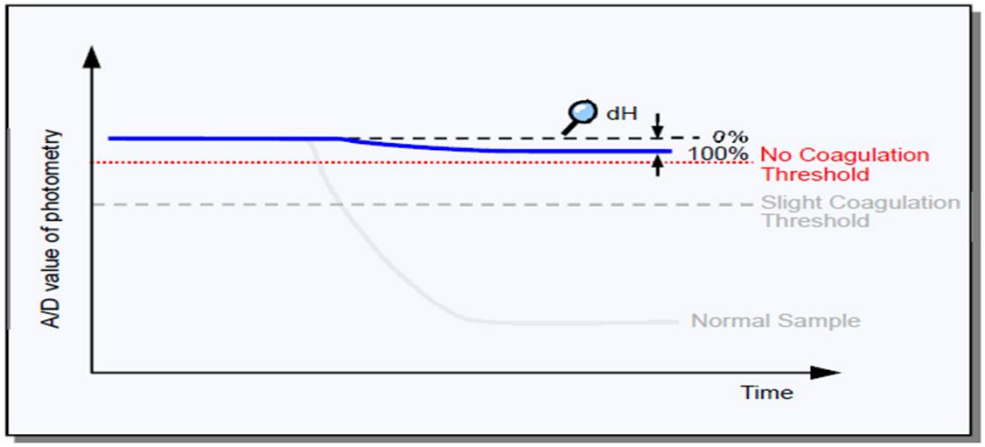


- Reaction curve has defined baseline and clotting phase
- End-point is not fully achieved.
- Slow clot formation.
- Check patient history for possible factor deficiency.
- PT Report Limit 90 Seconds
- Unclear where true coagulation occurs. Clinically it is helpful to know coagulation is prolonged.
- Follow your laboratory policy to *confirm data. Report as determined by your laboratory policy.*

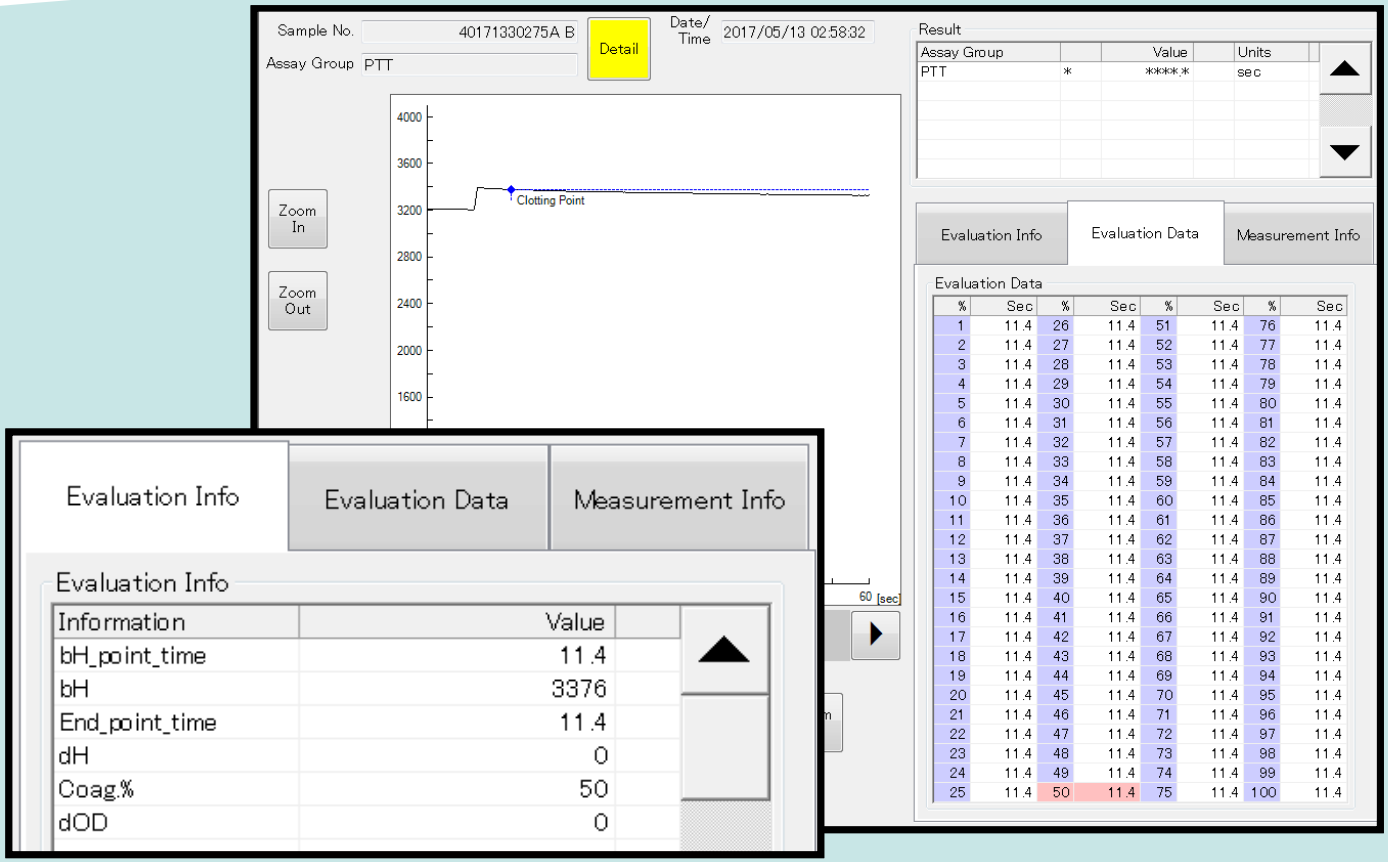
No Coagulation (NC)

0032.0000.0000

Joblist	Masked ****.* result
Cause	No coagulation or a weak coagulation was detected. Due to possible low fibrinogen concentration, presence of anticoagulant, or a reagent issue.
Kinetic Evaluation	• Reaction curve has no change or possible a very weak reaction if the view is zoomed in. • Requires manual evaluation and further consideration to determine how to report. • dH will be decreased. The dH limit to trigger this flag is assay dependent.



No Coagulation (NC)
Example – Review of Sysmex CS System Data



- No Coagulation Error will be noted in the detail tab.
- Typical clot progression is not demonstrated.
- Baseline, clot phase and end point not present.
- The reaction start and end point will be the same time in the reaction.

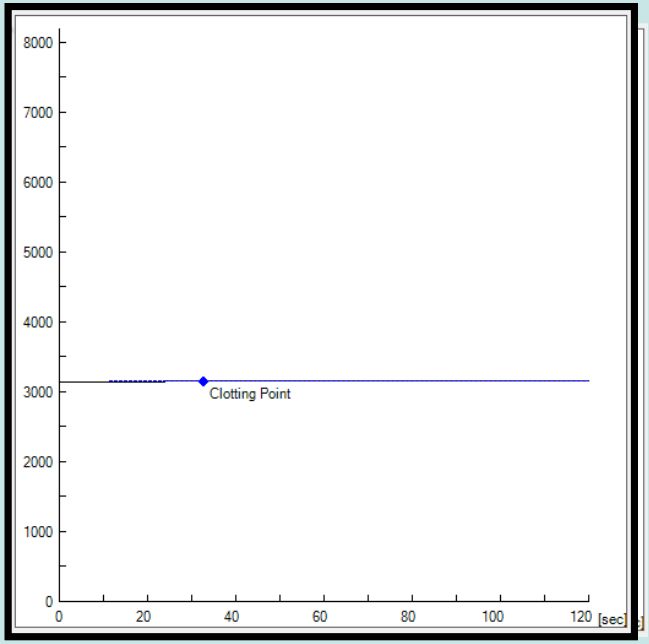
The 50% value of the evaluation data is not valid or reportable!!

Consider alternate actions and facts for verification of the result as appropriate including sample rejection and recollection.

No Coagulation (NC)
PTT Example

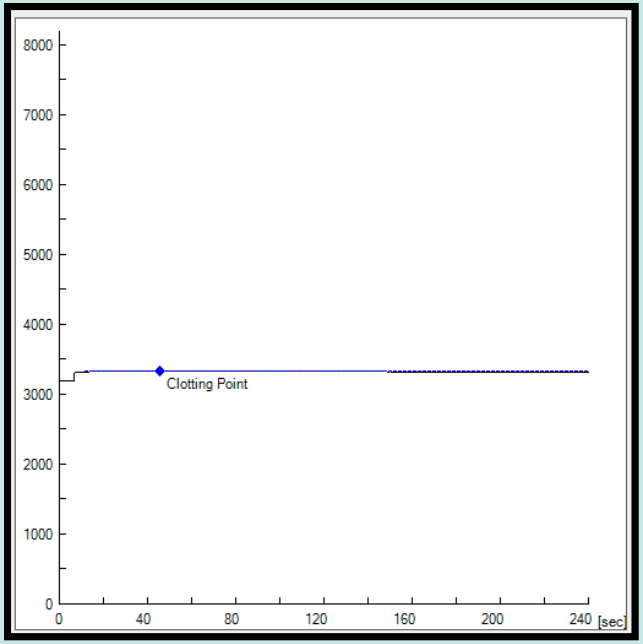
PTT No Coagulation

PT 15.2 seconds; No error



Repeat PTT with longer time (sub):

No Coagulation Error again



Verify Instrument/Reagent condition:

- QC Recovery prior run in range
- Other samples analyzed in same run produce normal range, believable results.

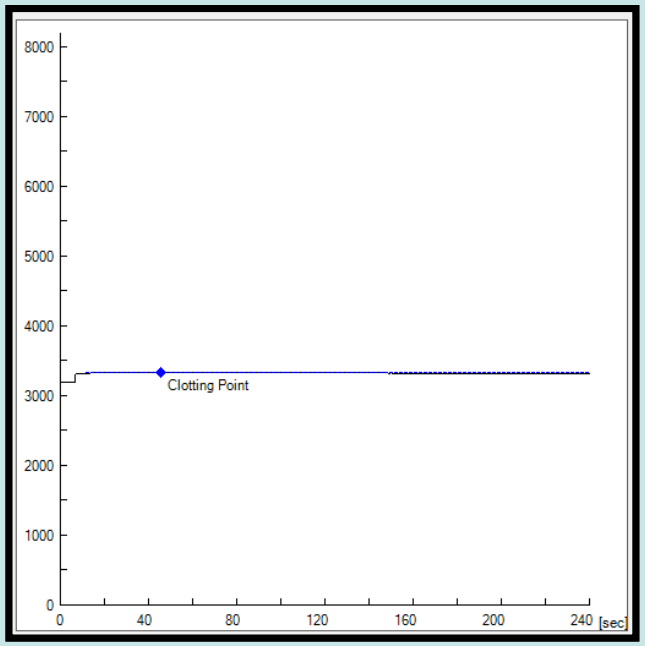
Patient Clinical Information:

- Critical Care Patient
- UF Heparin Therapy
- Past 2 PTT values: 101/127 sec
- Sample Integrity is acceptable.
- PT value is without error
- Chemistry results from same draw do not demonstrate dilution effect.

Report as determined by your laboratory policy.

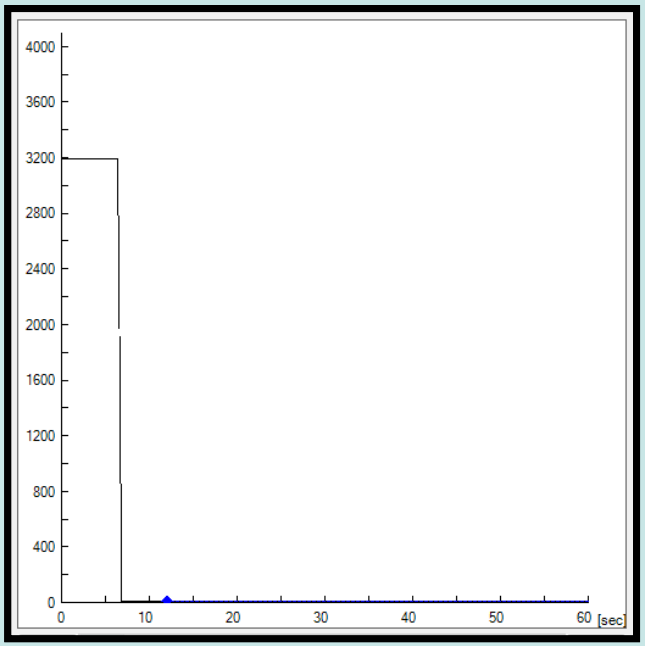
No Coagulation (NC)
Not Plausible Example

Two examples of samples which produced No Coagulation error for PTT analysis.



The below example is clearly optically challenged.

This is not plausible.



Examples of Non-Reportable Situations:

- Sample Integrity is unacceptable.
- Sample tube fill is low
- QC Recovery prior run out of range
- Other samples analyzed in same run produce markedly abnormal, unbelievable results.
- Instrument Errors i.e. Lamp, Reagent Volume etc.
- Other lab results (i.e. Hematology, Chemistry) from same draw are unbelievable.

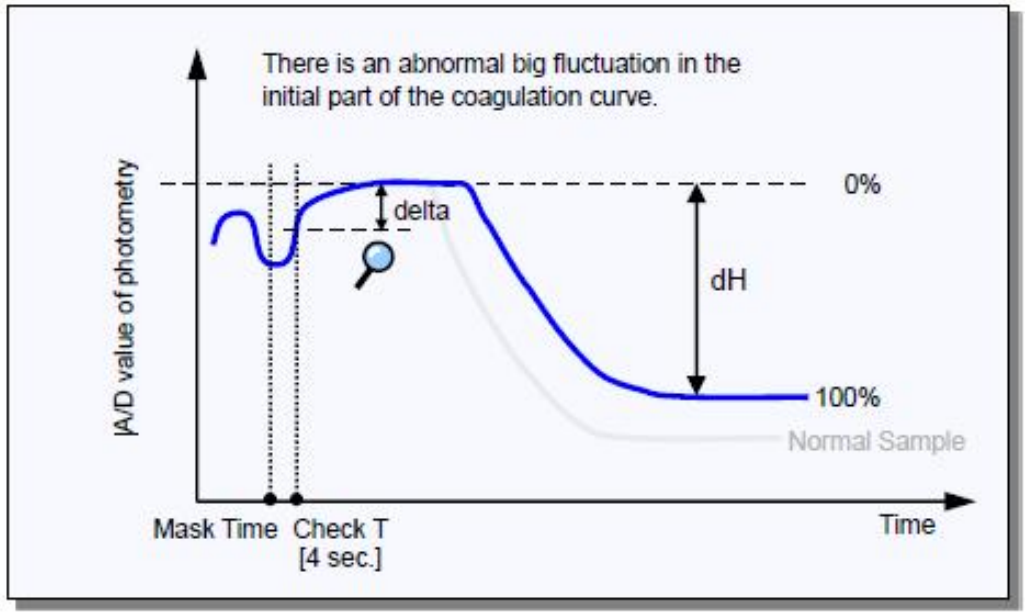
Consider alternate actions as appropriate including sample rejection and recollection.

Additional Flags

Coagulation Curve (CCE) Error

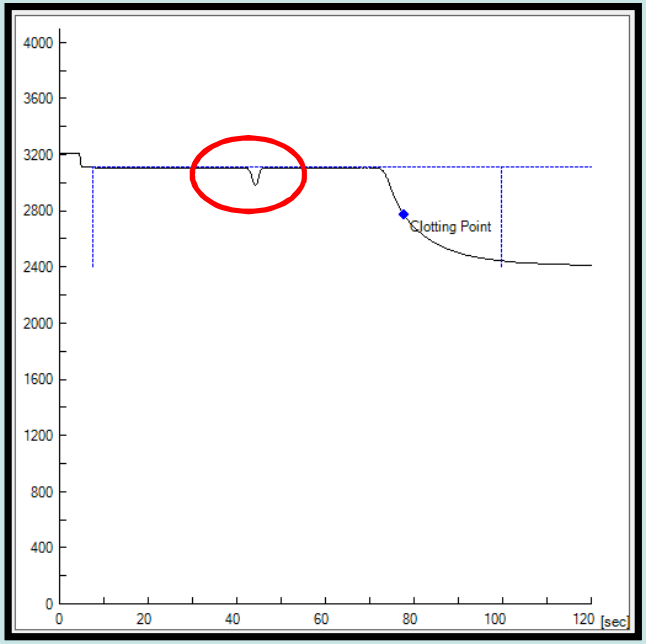
Joblist	Flagged numeric result
Cause	Occurs when there is unexpected curve fluctuation. Common cause is an air bubble in the reaction cuvette.

CCE Subsets	Error Code
Initial Fluctuation Drop	0008.0001.0000
Sharp Drop	0008.0002.0000
Jump Up	0008.0008.0000
Stepping Curve	0008.0016.0000
Terrace Check	0008.0064.0000
Fbg Curve Error	0008.0032.0000



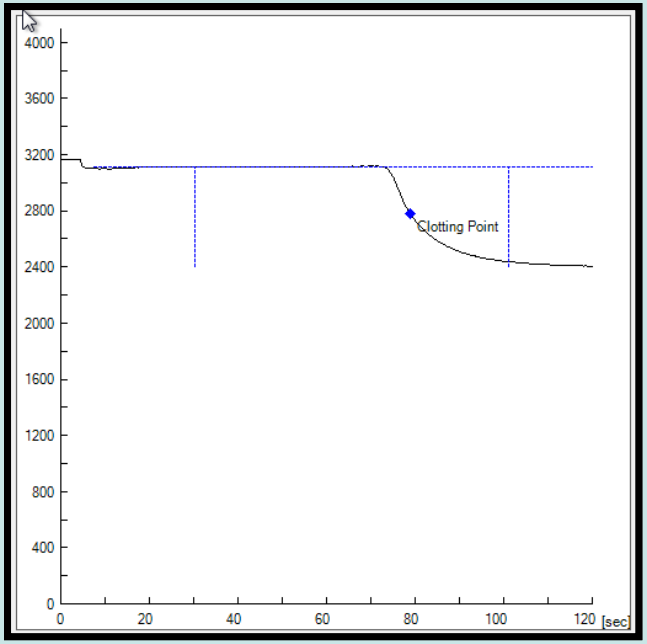
CCE: Sharp Drop

Initial analysis PT 77.6 seconds
Flagged with CCE: Sharp Drop



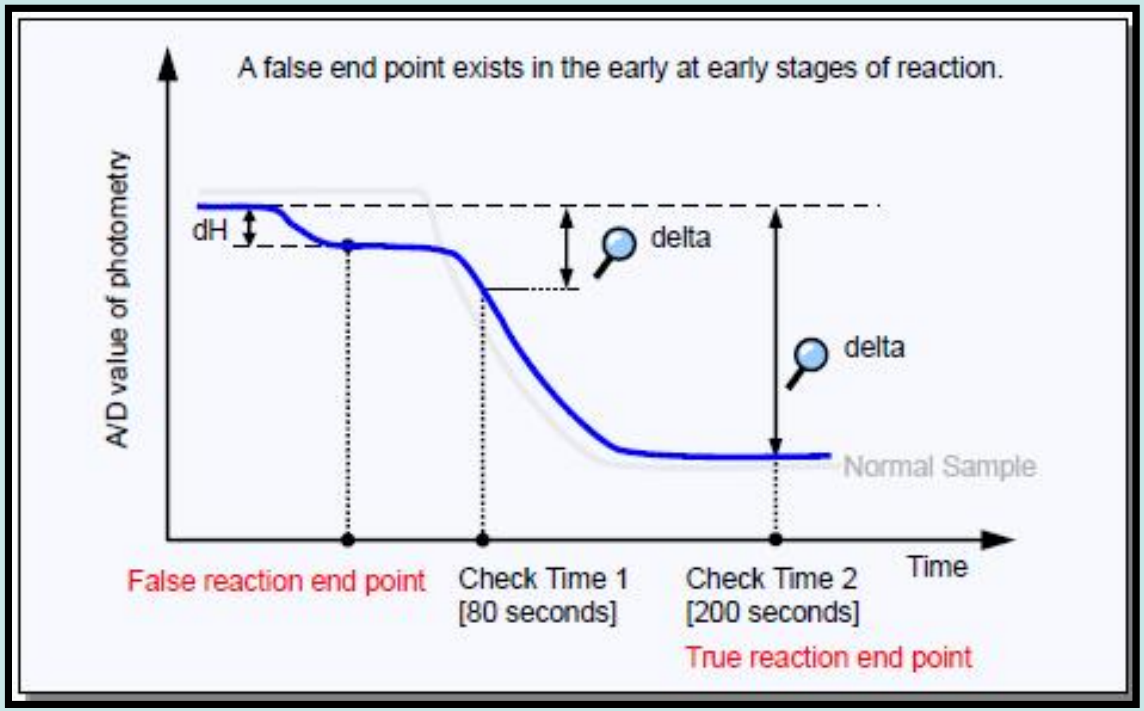
Repeat analysis PT 78.9 seconds

No Flag = Report



Sharp Drop check detects a sudden change in the curve.
Typically they resolve with repeat analysis.
Review of the reaction curve in this example shows an accurate 50% value for the result.

CCE: Stepping Curve



Stepping curve check is to prevent a false end point detection in the early stages of a reaction.

If the dH continues to increase after detecting an endpoint it may be a false reaction. This is checked from the time of 80 seconds until the end of the measurement time.

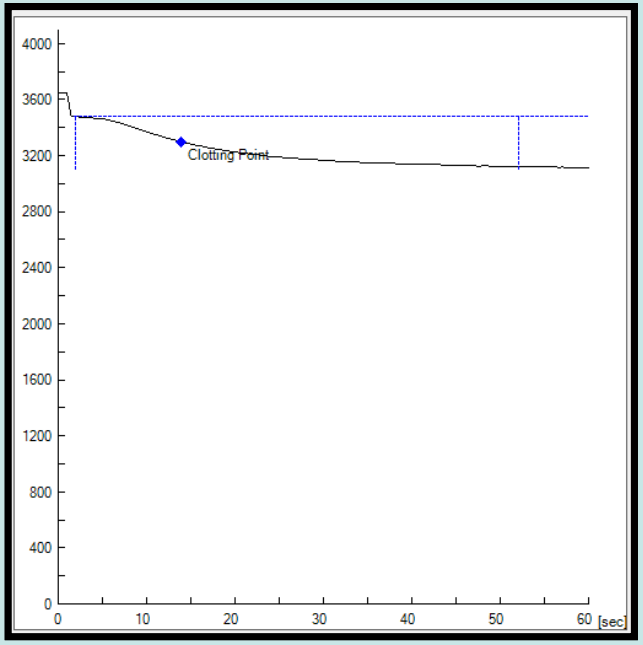
If the CS system recognizes a "stepping curve" in the reaction, it will automatically review the reaction curve again, and determine the appropriate end point.

CCE: Fibrinogen Curve Error

Initial analysis:

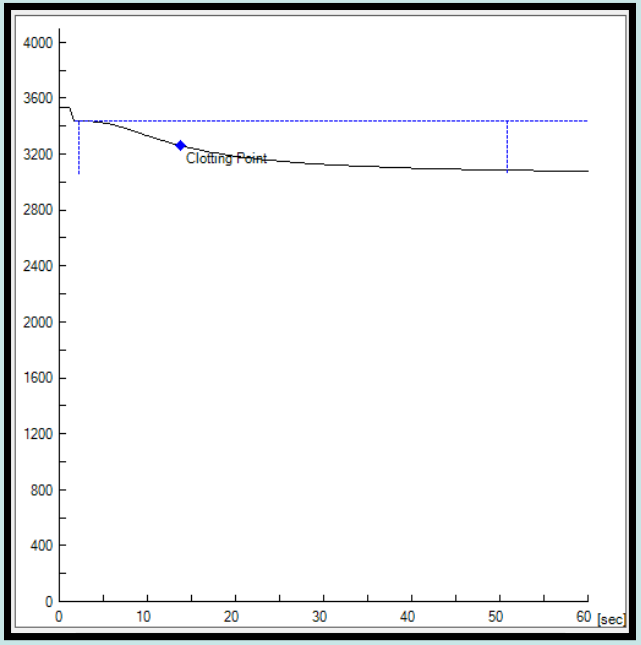
Fbg sec 13.9; 117 mg/dl

CCE Fbg Curve Error



Repeat analysis:

Fbg 13.7 sec; 119 mg/dl



Fbg curve error check is specific for the fibrinogen assay.

Typically this is due to:

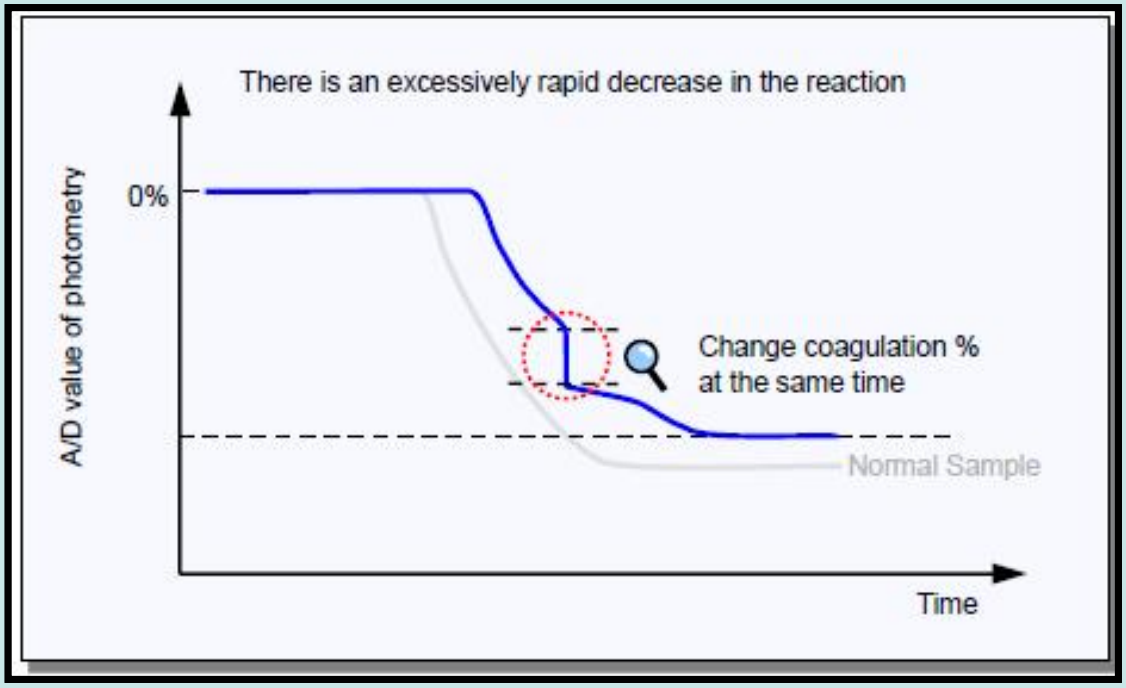
- Cold OVB
- Sample with an inhibitor
- High fibrinogen concentration.

This is triggered if the dH is above system threshold AND the reaction end point is > 50 seconds.

Evaluation data has 50% value that is comparable with repeat analysis.

Reaction curve is acceptable.

CCE: Jump Up



Jump Up check is able to detect a sudden increase.

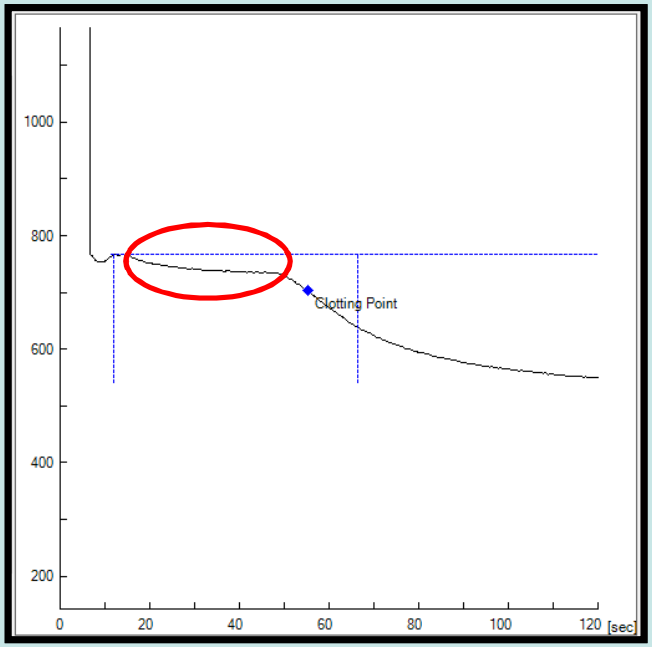
If the same clotting time is obtained continuously 10 times (20 times for Innovin) or more in the 2-80% detection range this flag will occur.

CCE: Terrace

PTT 55.2 seconds

CCE: Terrace

Wavelength Change



Evaluation Info | Evaluation Data | Measurement Info

Evaluation Data

%	Sec	%	Sec	%	Sec	%	Sec
1	15.0	26	48.3	51	55.2	76	60.5
2	15.2	27	48.7	52	55.5	77	60.6
3	15.6	28	49.3	53	55.6	78	60.8
4	16.0	29	49.8	54	55.8	79	61.2
5	16.2	30	50.1	55	56.1	80	61.4
6	16.5	31	50.4	56	56.3	81	61.5
7	16.8	32	50.7	57	56.4	82	61.7
8	17.5	33	51.0	58	56.7	83	62.0
9	17.9	34	51.1	59	57.0	84	62.3
10	18.4	35	51.3	60	57.2	85	62.4
11	18.9	36	51.9	61	57.3	86	62.9
12	20.1	37	52.2	62	57.5	87	63.1
13	20.5	38	52.4	63	57.6	88	63.3
14	21.8	39	52.5	64	57.8	89	63.5
15	23.4	40	52.7	65	58.1	90	63.7
16	23.9	41	53.2	66	58.3	91	63.8
17	24.9	42	53.3	67	58.5	92	63.9
18	26.2	43	53.5	68	58.9	93	64.2
19	26.9	44	53.7	69	58.9	94	64.7
20	28.8	45	53.8	70	59.1	95	64.9
21	29.9	46	54.1	71	59.3	96	65.1
22	35.5	47	54.3	72	59.8	97	65.5
23	37.9	48	54.4	73	59.9	98	65.7
24	39.6	49	54.6	74	60.0	99	65.8
25	47.3	50	55.2	75	60.2	100	66.4

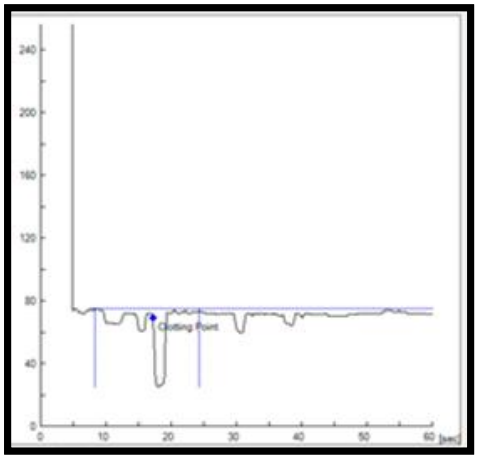
The Terrace check is able to detect a sudden prolongation of the clotting time within a 1% interval.

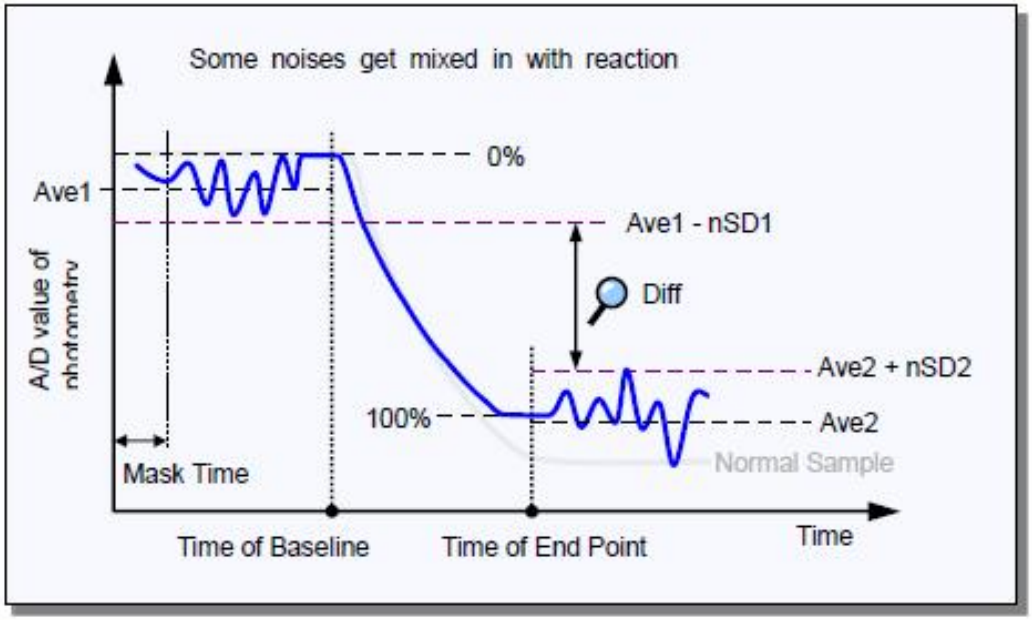
- Notice the start of the reaction appears premature.
- Notice the steep increase in the evaluation data starting at 22% through 25%.
- Repeat analysis should be conducted.

Noise Error

0008.0256.0000

Joblist	Masked ****.* result
Cause	This occurs typically when the reaction may have some unusual artifacts or “noise”. Related to hardware failure (i.e. lamp).
Kinetic Evaluation	Unusual waviness is observed in the beginning and/or end of the reaction

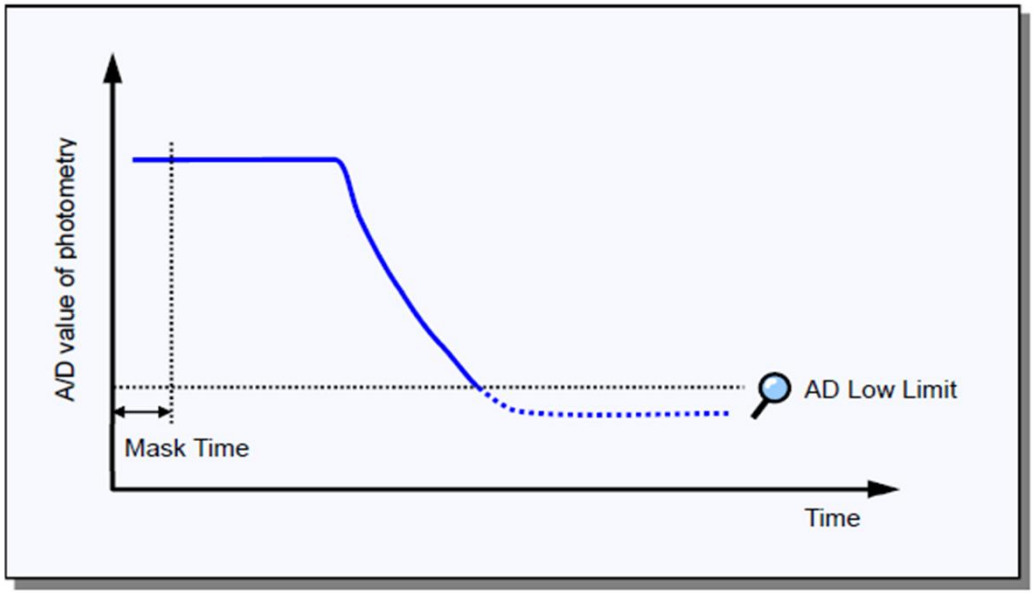




Turbidity Level Over Error

0016.0000.0000

Joblist	Masked ****.* result
Cause	This occurs typically when a sample is turbid or lipemic.
Kinetic Evaluation	• Reaction is occurring beyond the optical ability of the system

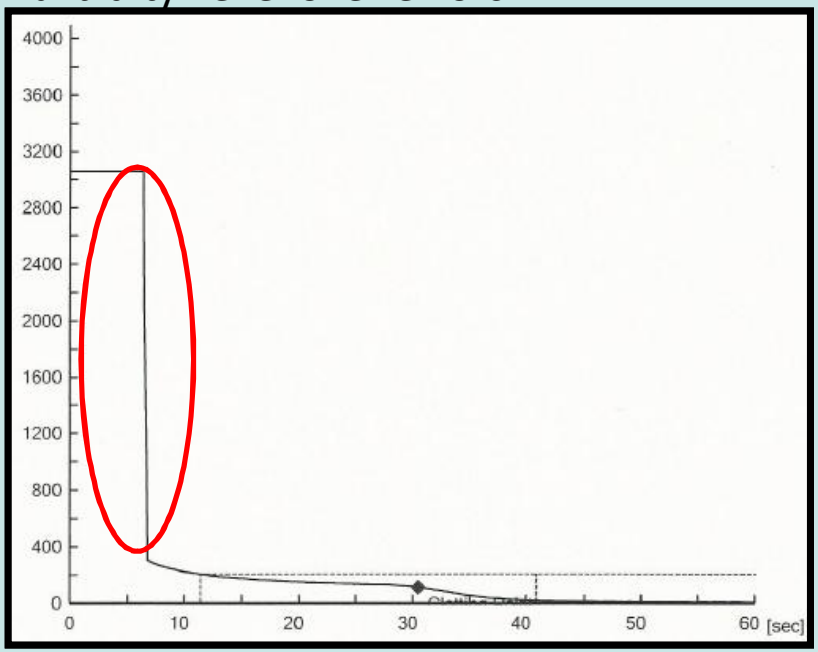


Turbidity Level Over

PTT

ERE: Early %

Turbidity Level over errors



Notice the sharp drop after the masking time.

Sample is optically challenged.

Wavelength change occurred.

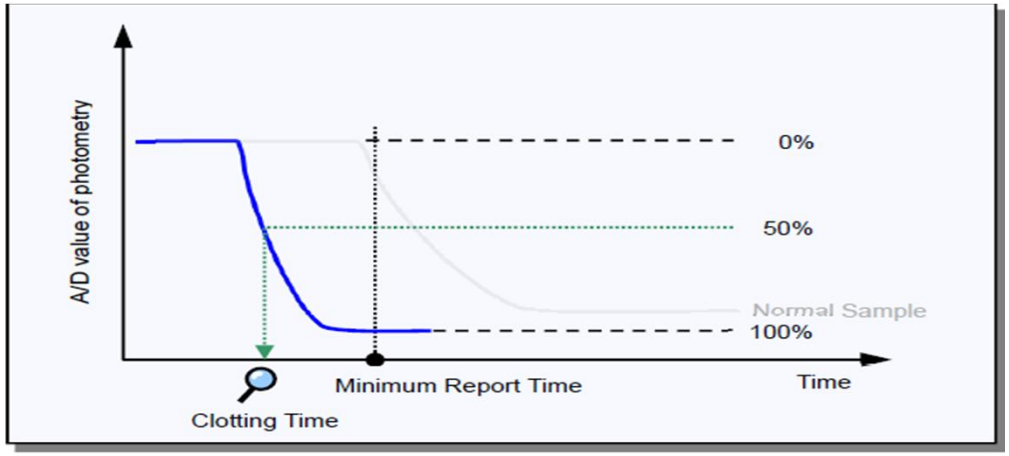
Result resolution:

- Clarify plasma with longer duration and higher speed of centrifugation and repeat analysis.
- If available, use the BFT II® System.

Range Over Error

0128.0000.0000

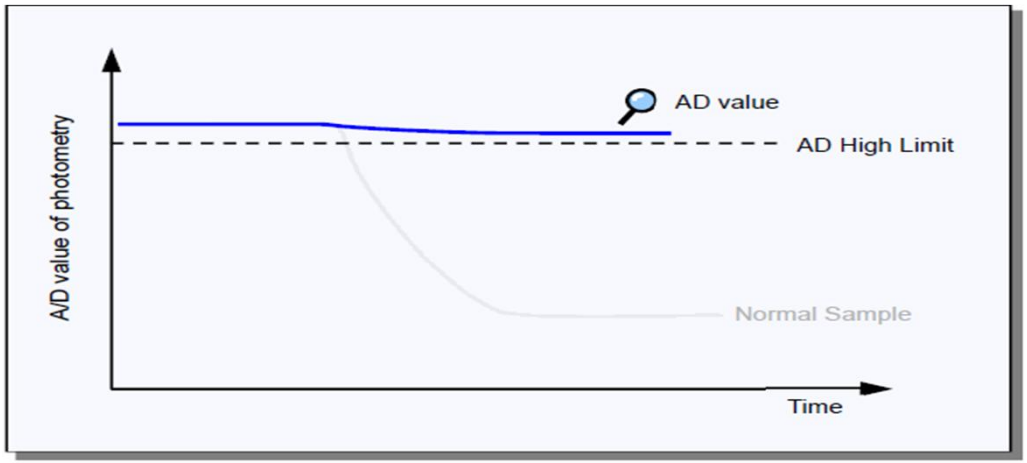
Joblist	Masked ****.* result
Cause	Occurs if the clot time at the 50% detection point is shorter than the minimum reportable time. Possible pre-analytical issue and typically re-collection is indicated. Veterinary samples may demonstrate this frequently.
Kinetic Evaluation	• Reaction curve may demonstrate typical baseline, clotting phase, and endpoint • Evaluation data 50% values will occur before the minimum reportable.



Trans Light High

0256.0000.0000

Joblist	Masked ****.* result
Cause	The A/D value of the measurement data is at the threshold value or above it. This may be observed with a plasma sample that is extremely clear. Possible incorrect sample (not plasma).
Kinetic Evaluation	• Reaction curve is very high, above the upper transmission limit • Typically it will not have a clotting phase or endpoint.



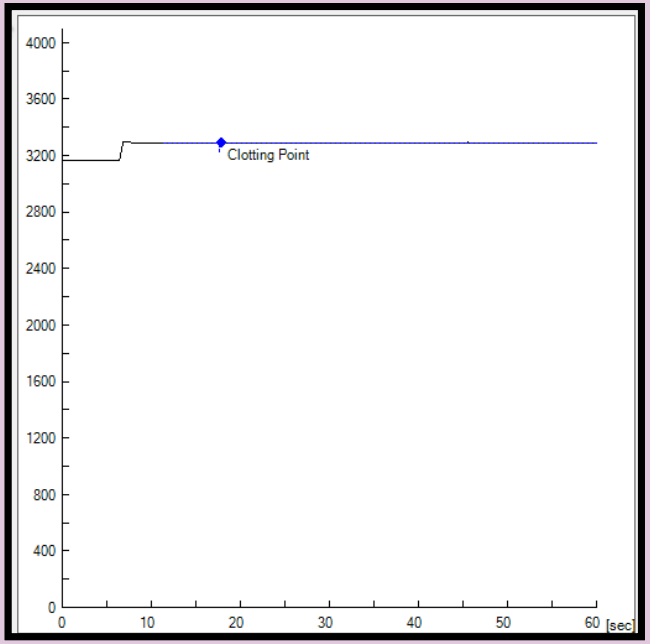
Appendix

Pathological Patient Example 1

PTT No Coagulation Error

Sample Integrity acceptable

QC in range.

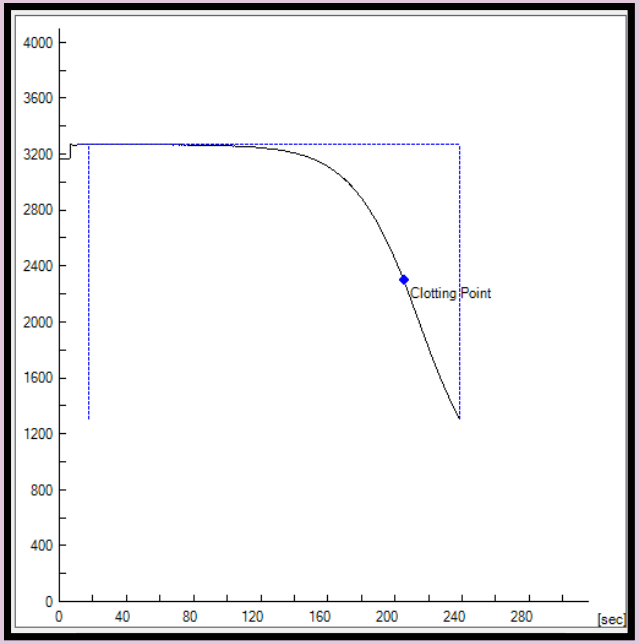


Repeat with longer time (sub): ATO

Clear baseline clot phase is visible.

Endpoint is not achieved

Plateau is not started

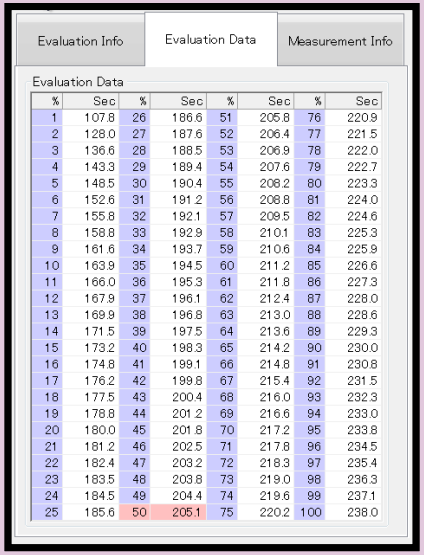


Evaluation data 50% = 205.1 sec.

Upper Report Limit = 139.0 sec

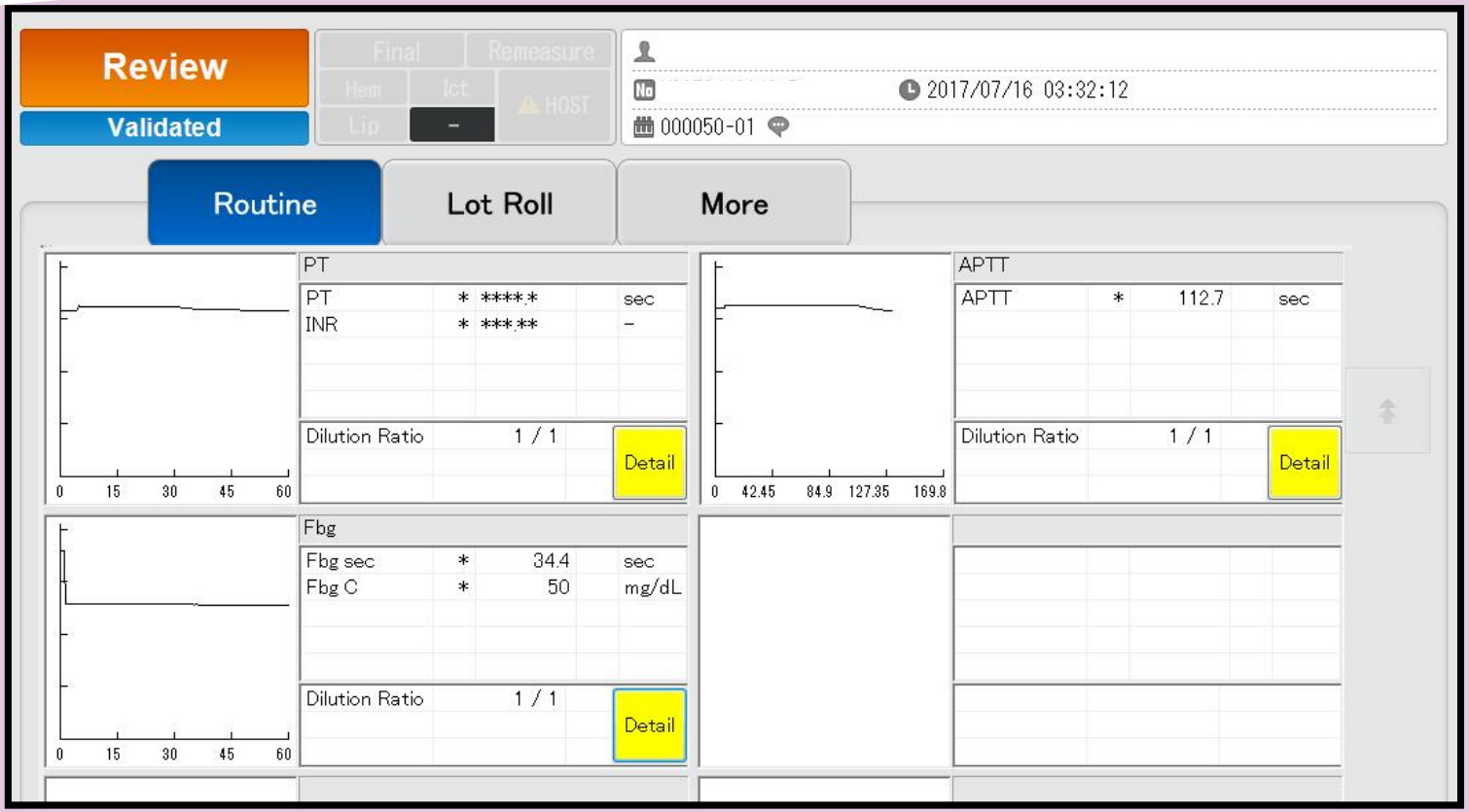
Clotting is clearly underway, not complete, but clearly >URL.

Report as determined by your laboratory policy.



%	Sec	%	Sec	%	Sec	%	Sec
1	107.8	26	186.6	51	205.8	76	220.9
2	128.0	27	187.6	52	206.4	77	221.5
3	136.6	28	188.5	53	206.9	78	222.0
4	143.3	29	189.4	54	207.6	79	222.7
5	148.5	30	190.4	55	208.2	80	223.3
6	152.6	31	191.2	56	208.8	81	224.0
7	155.8	32	192.1	57	209.5	82	224.6
8	158.8	33	192.9	58	210.1	83	225.3
9	161.6	34	193.7	59	210.6	84	225.9
10	163.9	35	194.5	60	211.2	85	226.6
11	166.0	36	195.3	61	211.8	86	227.3
12	167.9	37	196.1	62	212.4	87	228.0
13	169.9	38	196.8	63	213.0	88	228.6
14	171.5	39	197.5	64	213.6	89	229.3
15	173.2	40	198.3	65	214.2	90	230.0
16	174.8	41	199.1	66	214.8	91	230.8
17	176.2	42	199.8	67	215.4	92	231.5
18	177.5	43	200.4	68	216.0	93	232.3
19	178.8	44	201.2	69	216.6	94	233.0
20	180.0	45	201.8	70	217.2	95	233.8
21	181.2	46	202.5	71	217.8	96	234.5
22	182.4	47	203.2	72	218.3	97	235.4
23	183.5	48	203.8	73	219.0	98	236.3
24	184.5	49	204.4	74	219.6	99	237.1
25	185.6	50	205.1	75	220.2	100	238.0

Pathological Patient
Example 2



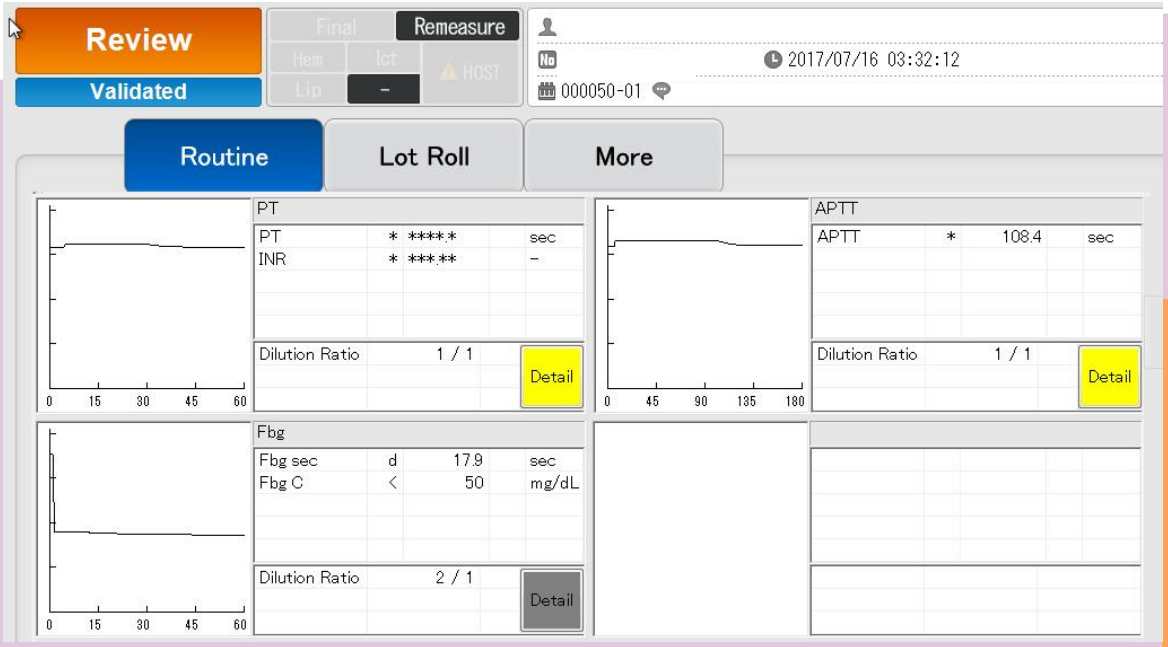
Initial Analysis

PT: Flat Curve

PTT : 112.7 second ATO /SC

Fbg: < 50 mg/dl SC Error

Pathological Patient Example 2



The fibrinogen of 50 mg/dL supports the weak clot observed on the PT as well as the PTT assays.

The PTT repeated with extended time produced 108.4 seconds, which is comparable to the original result.

Laboratory must exclude the potential the sample was diluted.

Repeat Analysis Results and Error:

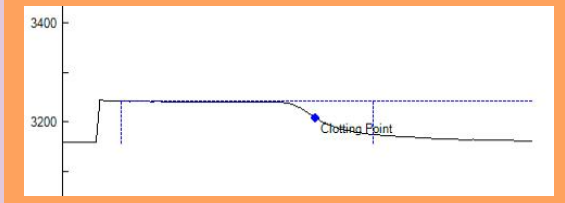
PT Extended Time: Flat Curve Error

PTT Extended Time: 108.4 second SC Error

Fbg: <50 mg/dl 2/1 dilution No Error

Patient history must be considered for reporting decision

PT Reaction Curve:
Baseline, clotting phase and endpoint are visible. Evaluation Data 50% value 32.3 seconds is consistent with reaction curve.



Evaluation Info | Evaluation Data | Measurement Info

Evaluation Data

%	Sec	%	Sec	%	Sec	%	Sec
1	7.5	26	30.5	51	32.3	76	34.4
2	12.4	27	30.6	52	32.4	77	34.5
3	19.3	28	30.8	53	32.5	78	34.8
4	19.8	29	30.8	54	32.5	79	34.8
5	27.7	30	30.8	55	32.6	80	35.0
6	28.2	31	30.9	56	32.7	81	35.1
7	28.2	32	30.9	57	32.7	82	35.1
8	28.7	33	31.0	58	32.8	83	35.3
9	29.1	34	31.2	59	32.9	84	35.5
10	29.1	35	31.2	60	32.9	85	35.5
11	29.3	36	31.3	61	32.9	86	36.0
12	29.4	37	31.4	62	33.1	87	36.2
13	29.4	38	31.4	63	33.1	88	36.2
14	29.5	39	31.5	64	33.2	89	36.3
15	29.7	40	31.6	65	33.4	90	36.7
16	29.7	41	31.6	66	33.4	91	36.7
17	29.8	42	31.7	67	33.5	92	37.1
18	30.0	43	31.8	68	33.6	93	37.2
19	30.0	44	31.8	69	33.6	94	37.2
20	30.1	45	31.9	70	33.8	95	37.4
21	30.2	46	32.0	71	34.0	96	38.2
22	30.2	47	32.0	72	34.0	97	38.2
23	30.3	48	32.1	73	34.1	98	38.7
24	30.4	49	32.2	74	34.3	99	39.0
25	30.5	50	32.3	75	34.4	100	39.8

SC Error

0002.0000.0000

Action Steps

1. Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.

2. Verify delivery of sample and reagent.

3. Review the analysis data for clot formation. A weak clot formation may be due to an abnormally low fibrinogen level, factor deficiency, or the presence of inhibitors.

4. Reanalyze the sample. If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported. When you reanalyze fibrinogen, change the dilution ratio and reanalyze.
   - If the value determined at the 50% is greater than the reportable range, report as determined by your laboratory's policy

5. If slight coagulation occurs again, evaluate the kinetic curves and the value at the 50% coagulation detection point. If the curves are acceptable and the repeat results and initial results are equivalent at the 50% coagulation detection point, the mean of the two results may be reported as determined by your laboratory policy.

Analysis Time Over (ATO)

0004.0000.0000

Action Steps

1. Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.
    - Was this sample a line draw, possible heparin anticoagulant contamination.
    - Is patient being dosed with anticoagulant drugs; i.e. Heparin. Are samples collected at proper time compared to dosing (Refer to Slide 7)
    - Check patient history for factor deficiency or known coagulation disorder.
    - Redraw the sample if possible anticoagulant contamination and repeat the analysis.
2. Verify delivery of sample and reagent.
3. Reanalyze with a longer time (sub).
    - Repeat analysis is typically automatically performed with the Measurement Time (Sub) based on instrument settings.

    Note: if a sample is ordered in micro analysis mode, re-analysis rules will not be applied, and the longer Measurement Time (Sub) will need to be requested manually.
4. If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported.
    - If the value determined at the 50% is greater than the reportable range, report per your laboratory's policy.
5. If reanalysis gives an "Analysis Time Over" message again, the sample may not be capable of forming a firm clot. Follow your laboratory's policy.
    - **Review reaction curve and Evaluation Data** with consideration of the clinical context of the patient.
    - If the result **is greater than** laboratory reportable range, the reaction curve demonstrates typical clot progression and is consistent with patient clinical condition consider the result may be correct. Report as determined by your laboratory policy.
    - If the result **is less than** the reportable range and the ATO flag remains the 50% value is not accurate. The true result is potentially longer. Follow your laboratory policy.
    - If the reaction curve does not demonstrate typical progression and /or does not match the 50% value **DO NOT REPORT** the result.

ERE: Slow Reaction

0008.0128.0001

Action Steps

1. Verify sample and reagent integrity along with maintenance procedures:
    - Was this sample a line draw; possible heparin anticoagulant or other contamination.
    - **Is patient being dosed with anticoagulant drugs (Heparin). Are samples collected at proper time compared to dosing.** (Refer to Slide 7)
    - Redraw the sample if possible contamination and repeat the analysis.

2. The software of your system has detected an unusual early or slow reaction. Reanalyze with a longer time (sub).
    - Repeat analysis is typically automatically performed with the Measurement Time (Sub) based on instrument settings.

    Note: if a sample is ordered in micro analysis mode, re-analysis rules will not be applied, and the longer Measurement Time (Sub) will need to be requested manually.

3. If error 0008.0128.0001 is reproduced, this might be due to a sampling artifact. Please repeat sampling of your patient (or reconstitute a new vial of control), and repeat the measurement.
    - If the result obtained is now free from error 0008.0128.0001 report the result.

    Note: This may be observed on control material.

4. If analysis of the recollected sample produces error 0008.0128.0001 you have detected an unusual early or slow reaction that is reproducible and seems to be due to the quality of the sample used. The reason for this might be an unusual clinical situation, excluding the sample from optical coagulation measurements. Follow your laboratory policy.

    Check the Evaluation Data and Reaction Curve for typical progression of clot formation and the evaluation data 50% value:
    - If the result **is greater than** laboratory reportable range, the reaction curve demonstrates typical clot formation with an accurate 50% value and is consistent with patient clinical condition the result may be correct. Report the result as determined by your laboratory policy.
    - If the result **is less than** the reportable range and the flag remains without typical clot formation the 50% value may not be accurate. **DO NOT REPORT.** Follow your laboratory's policy for verification of the true value.

ERE: Start Angle 1

0008.0128.0002

Action Steps

1. Verify sample and reagent integrity
    - Redraw the sample if possibly compromised.

2. The software of your system has detected an unusual early or slow reaction. Please repeat the measurement.
    - Repeat analysis is typically automatically performed based on instrument settings.

    Note: if a sample is ordered in micro analysis mode, re-analysis rules will not be applied, and will need to be requested manually.
    - If the result obtained is now free from error 0008.0128.0002 report the result.

3. If error 0008.0128.0002 is reproduced, this might be due to a sampling artifact. Please repeat sampling of your patient (or reconstitute a new vial of control), and repeat the measurement.
    - If the result obtained is now free from error 0008.0128.0002 report the result.

    Note: This error may be observed on control material.

4. If analysis of the recollected sample produces error 0008.0128.0002 you have detected an unusual early or slow reaction that is reproducible and seems to be due to the quality of the sample used. The reason for this might be an unusual clinical situation, excluding the sample from optical coagulation measurements. Follow your laboratory's policy.

    Check the Evaluation Data and Reaction Curve for typical progression of clot formation and the evaluation data 50% value:
    - If the flag remains with questionable clot formation and/or inaccurate 50% read point, **DO NOT REPORT**.

ERE: Start Angle 2

0008.0128.0004

Action Steps	*Additional Considerations*
1. Verify sample and reagent integrity along with maintenance procedures.	
2. Check the Analysis data on the screen to determine the ERE code.	
3. Error (ERR) 128, Early Reaction Error (ERE) code 4 is indicative of a detected early reaction, which under many circumstances does not necessarily invalidate the clotting time result. Check if the coagulation time fits with the displayed curve in your coagulation analyzer. If it does fit, you may release the result. • Review the reaction curve and ensure typical clot formation (baseline, clotting, end point). • Ensure the Evaluation Data 50% value is comparable to the reaction curve. • *If desired*, repeat analysis. The error may not recur.	

ERE: Early %

0008.0128.0016

Action Steps

1. Verify sample and reagent integrity along with maintenance procedures.
    - How was this sample collected? This error is frequently due to a pre-activation of the sample due to poor collection technique.
    - Check sample for clot? Check for hemolysis?
    - Ensure proper mixing and centrifugation of sample collection tubes. (Collection tubes with narrow diameters require slow inversion to properly mix)
    - **Strongly consider recollection of the sample, unless patient history indicates otherwise.**

2. Check the Evaluation Data

    The value at 8% is less than 16.8 seconds
    - If the 50 % value is ***<20*** seconds, the sample is clotting too quickly possibly due to pre-analytical variables.
        - If collection tube has a narrow diameter (i.e. BD 1.8 mL tube) remix, re-centrifuge and reanalyze.
        - Recollect sample . **DO NOT REPORT.**
    - If the 50% value is ***≥ 20*** seconds: *Check sample for lipemia or excess anticoagulant and consider centrifugation* with longer duration and speed.
        - Repeat analysis.
        - If reaction curve indicates, use longer time (sub) for repeat analysis.
    - Consider recollection for possible anticoagulant contamination if applicable.

3. If the repeated result obtained is now free from error 128 report the result.

4. If repeat analysis produces Error 128, the software of your system has detected an unusual early or slow reaction this might be due to a sampling artifact. Please repeat sampling of your patient (or reconstitute a new vial of control), and repeat the measurement.
You have detected an unusual early or slow reaction that is reproducible and seems to be due to the quality of the sample used. The reason for this might be an unusual clinical situation, excluding the sample from optical coagulation measurements. Follow your laboratory's policy
    - If error reoccurs and the 50% value is >20 seconds, clot formation is not typical or comparable and/or the 50% value is not repeatable **DO NOT REPORT.**

Flat Curve

0032.0002.0000

Action Steps

1. Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.
    - Was this sample a line draw, possible contamination/ sample dilution.
    - Is patient being dosed with anticoagulant drugs; i.e**. Coumadin**. (Refer to Slide 7).
    - Check patient history for **fibrinogen concentration**, factor deficiency or known coagulation disorder.
    - Redraw the sample if possible contamination and repeat the analysis.

2. Verify delivery of sample and reagent.

3. . Reanalyze with a longer time (sub).
    - Repeat analysis is typically automatically performed with the Measurement Time (Sub) based on instrument settings.

    Note: if a sample is ordered in micro analysis mode, re-analysis rules will not be applied, and the longer Measurement Time (Sub) will need to be requested manually.

4. If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported.
    - If the value determined at the 50% is greater than the reportable range, report as determined by your laboratory's policy.

5. If reanalysis with the extended measurement time gives a "Flat curve" message again, use your laboratory's policy to confirm the data.

    Review reaction curve, evaluation data 50% value, and dH:
    - If the Flat Curve flag remains with a questionable clot formation and/or poor comparison with the 50% value, **DO NOT REPORT.**
    - Consider the strength of the reaction; Slight coagulation threshold for PT with Innovin is dH < 60.
    - Repeat analysis with the longer measurement time allows the technologist to look for a continuous plateau and exclude a bi-phasic reaction.
    - Ensure sample integrity is acceptable. Specifically, evaluate for the potential of sample dilution (i.e. line collection, etc.).
    - If available consider use of alternate system (i.e. Backup CA-600 or BFT II) to confirm the data.

No Coagulation (NC)

0032.0000.0000

Action Steps

1. Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.
    - Was this sample a line draw, possible heparin anticoagulant contamination or sample dilution.
    - Is patient being dosed with anticoagulant drugs; i.e. Heparin. (Refer to Slide 7.)
    - Check patient history for factor deficiency or known coagulation disorder.
    - Redraw the sample if possible anticoagulant contamination and repeat the analysis.

2. Verify delivery of sample and reagent.
    - Ensure system issues can be excluded as a cause. If system may be cause, troubleshoot accordingly.

3. Reanalyze with a longer time (sub). For fibrinogen, if auto-redilution is not set, change the dilution ratio and reanalyze.
    - Repeat analysis is typically automatically performed with the Measurement Time (Sub) based on instrument settings.

    Note: if a sample is ordered in micro analysis mode, re-analysis rules will not be applied, and the longer Measurement Time (Sub) will need to be requested manually.
    - If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported.

4. If reanalysis with the extended measurement time gives “No Coagulation” message again, the sample is below the detection limits of the detector. Make a comprehensive judgement, taking sample and reagent, etc. into consideration. ***If the result is plausible*** it may be reported as “greater than” per the established laboratory policy.

    Determination of result plausibility should include, but is not limited to the following considerations:
    - Sample integrity and age as well as patient clinical condition and history including but not limited to diagnosis, current procedures, and anticoagulant therapy.
    - Ensure reagent integrity, instrument performance, QC is in range and there is no indication of a general system issue.

6. If additional verification is indicated, use your laboratory’s policy to confirm the data.

Coagulation Curve (CCE) Error:

Applicable to all CCE

Action Steps

1. Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.
    - Refer to Slide 6 and 7.

2. Verify delivery of sample and reagent.
    - Fibrinogen analysis: Check if OVB is cold or aged

3. Review the analysis data.

4. Reanalyze the sample. If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported.
If the value determined at the 50% is greater than the reportable range, report per your laboratory's policy.

5. If Coagulation Curve Error occurs upon reanalysis, and if the curves are acceptable and the repeat and initial results are equivalent at the 50% coagulation detection point, the mean of the two results may be reported as determined by your laboratory policy.
    - Review clot measurement curve under Evaluation Data

Noise Error

0008.0256.0000

Action Steps

1. Check the sample, reagents and instrument condition.

2. Recalibrate the lamp or replace it with a new lamp. A new lamp requires calibration. After performing the lamp calibration, perform calibration curve analysis and QC analysis, then check the analysis data.

3. Reanalyze the sample. If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported.

4. If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported.
   - The system will automatically use the sub-wavelength of 800 nm if appropriate for the sample in question.

5. If sample, reagent and instrument conditions are acceptable, reanalyze the sample and confirm clot formation in the reaction cuvette or follow your laboratory's policy.
   - If this error reoccurs after replacement of the lamp, consider to contact technical solutions for further evaluation of the system.

Turbidity Level Over Error

0016.0000.0000

Action Steps

1. Check the sample for turbidity, lipemia, etc.

2. Verify delivery of sample and reagent.

3. Reanalyze the sample diluted with appropriate diluent.
This step is available only for parameters that are using diluted sample in the original test protocol such as the Fibrinogen assay (Clauss method). Check the Test Protocol for the diluent used.

4. If reanalysis of the sample results in a numerical value without an asterisk (*), the result can be reported.
- The system will automatically use the sub-wavelength of 800 nm if appropriate for the sample in question.

5. If reanalysis gives a "Turbidity Level Over" message again, the sample may not be capable of forming a firm clot. Follow your laboratory's policy.
    - **Consider ultracentrifugation or repeat centrifugation of the sample; ensure actions are compliant with laboratory policy.**

Range Over Error

0128.0000.0000

Action Steps

Additional Considerations

1. In rare instances, a PT and aPTT "Range Over" (short time) error message may indicate that the PT result was <7 seconds, or the aPTT result was <15 seconds

2. Reagent contamination or lack of analyzer maintenance could cause this message. Check the sample, reagents and instrument condition.
    - Consider recollection of the sample.
    - Consider sample source (i.e. human or animal)

3. Review the analysis data for clot formation.

4. If sample, reagent and instrument conditions are acceptable, reanalyze the sample and confirm clot formation in the reaction cuvette or follow your laboratory's policy.

Trans Light High

0256.0000.0000

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Action Steps

Additional Considerations

1. Check the sample, reagents and instrument condition.
    - Verify the provided sample is plasma collected in the appropriate tube.
    - Ensure dilution of the sample was not inappropriately conducted.
    - Consider recollection of the sample if indicated.

2. Recalibrate the lamp or replace it with a new lamp. A new lamp requires a lamp calibration. After performing the lamp calibration, perform calibration curve analysis and QC analysis, then check the analysis data.

3. Reanalyze the sample. If upon reanalysis results without an asterisk (*) are obtained, the result may be reported.

4. If sample, reagent and instrument conditions are acceptable, reanalyze the sample and check the reaction cuvette. If the mixture is clear, follow your laboratory's alternate protocol.
    - The sample may be above the detection limits of the detector.
    - Consider review the system error log for recent possible hardware errors

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References:

1) Sysmex CS-2500 System Evaluation and Check Algorithm (For US Only) Version 1.0
2) Sysmex CS-5100 System Evaluation and Check Algorithm (For US Only) Version 1.0
3) Dade® Innovin® Reagent Instructions for Use, 2017-10
4) Dade® Actin® FSL Activated PTT Reagent Instructions for Use, 2016-09
5) CS-2500/ CS-5100 Application Sheet for PT seconds with Dade® Innovin®
6) CS-2500/ CS-5100 Application Sheet for PTT seconds with Dade® Actin® FSL
7) Pre-analytical Variables in Coagulation Testing Associated With Diagnostic Errors in Hemostasis. Favaloro. Lab Medicine February 2012, Volume 43 Number 2
8) Sysmex Automated Blood Coagulation Analyzer CS-2500 Instructions for Use
9) Sysmex Automated Blood Coagulation Analyzer CS-5100 Instructions for Use

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