Sysmex CS 5100 Flag Interpretations

By

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What do I do with a sample error

- Evaluate Sample Integrity
 - Tube Fill
 - Check for Lipemia, Hemolysis
- Look at Reaction Curve, Evaluation Data and Error code
- Do you see Typical Clot Progression?
- Does the 50% value fit the reaction curve?

A. EVALUATION ALGORITHM 3 evaluation algorithms –

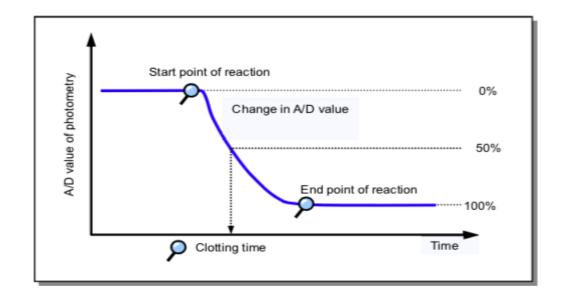
- The Percentage Detection Method for Coagulation Assays
- The Rate Method for Chromogenic Assays
- Immunoassays and the VLin Integral Method for Immunoassays.

Each evaluation algorithm is specified in the preset configuration of the test protocol. Criteria are established to determine either the point of specific clotting time or optical density for the kinetic reaction under measurement.

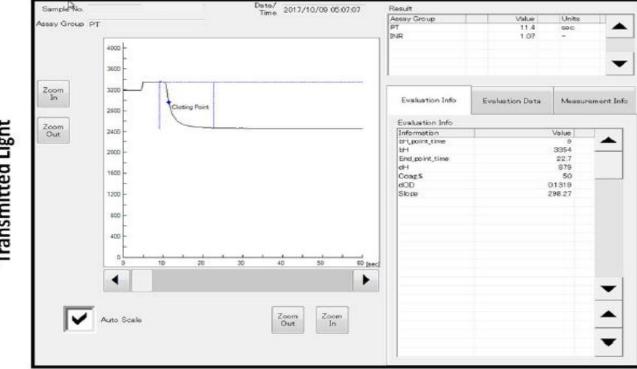
Evaluation Method	Description
Percentage Detection Method	This method is used for the evaluation of Clotting Assays. The clotting time is measured.
Rate Method	This method is used for the evaluation of Chromogenic Assays and Immunoassays. The change in light absorbance is calculated.
VLin Integral Method	This method is used for the evaluation of Immunoassays. The change in light absorbance is calculated.

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 identifies the coagulation end point [when 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
- submitted light is changing due to active clot formation



Example 1: Typical PT



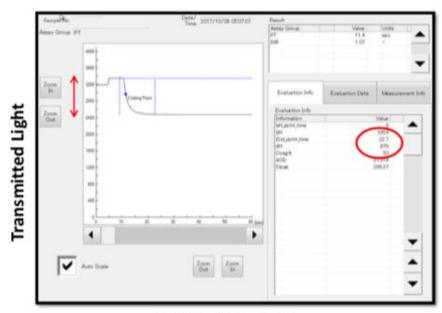
Evaluation Data Evaluation Info Measurement Info Evaluation Data Sec Sec Sec Sec 103 11.0 51 11.5 12.5 11.5 77 104 27 11.0 52 127 11.5 78 11.6 79 11.6 80 11.0 53 105 128 11.0 105 129 106 11.0 130 106 11.0 11.6 13.0 10.6 11.1 11.7 13.1 10.7 11.1 11.7 133 11.8 13.4 10.7 11.1 10.7 11.1 11.8 135 11 10.7 36 112 61 11.9 13.6 11.9 87 108 112 62 13.7 108 112 63 119 88 139 108 112 15 108 112 120 143 109 11.3 12.0 14.6 17 121 109 11.3 67 148 121 18 19 20 21 22 23 109 113 15.1 109 113 122 154 109 45 11.4 70 123 95 15.9 123 96 124 97 109 11.4 16.4 109 47 11.4 17.1 12.4 98 109 48 11.4 73 182 24 109 49 11 4 74 125 99 20.0 109 50 11.4 75 125 100 228

Clotting Time (sec)

Transmitted Light

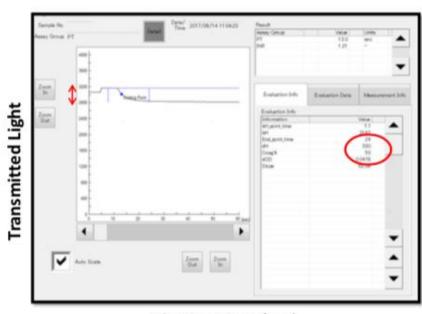
Normal PT: Influence of Fibrinogen





Clotting Time (sec)

dH =879

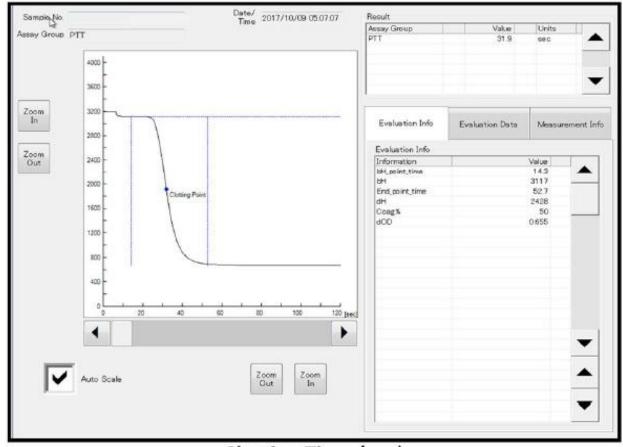


Clotting Time (sec)

PT from sample with Normal Fibrinogen Level

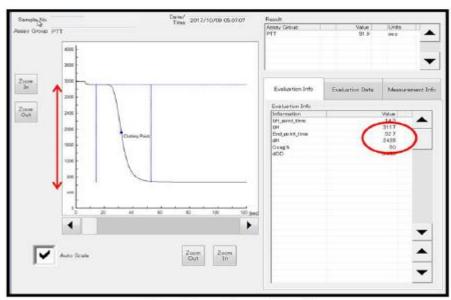
PT from sample with Low Fibrinogen Level dH=330

Example 3: Typical PTT



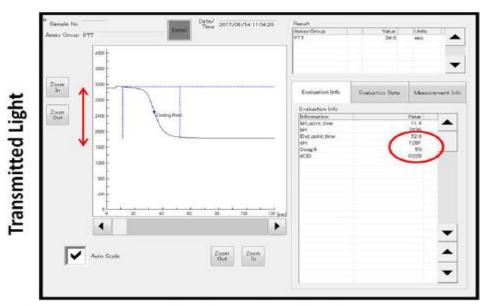
Evaluation Info			Evaluation Data			Measurement Ir	
valuation Data							
%	Sec	*	Sec	%	Sec	%	Sec
1	23.9	26	29.3	51	31.9	76	35.3
2	24.8	27	29.4	52	32.1	77	35.5
3	25.4	28	29.6	53	32.2	78	35.6
4	25.B	29	29.7	54	32.3	79	35.9
5	26.0	30	29.8	55	32.4	80	36.1
6	26.3	31	29.9	56	32.5	81	36.3
7	26.5	32	30.0	57	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	30.5	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

Clotting Time (sec)



Clotting Time (sec)

PTT from sample with Normal Fibrinogen Level dH=2428



Clotting Time (sec)

PTT from sample with Low Fibrinogen Level dH= 1281

A. ERROR MESSAGES:

HL Check for All assays

- 1. Hemolytic Sample Error
- 2. Lipemic Sample Error

for Clotting assays

- 1. Slight Coagulation Error
- 2. Analysis Time Over Error
- 3. Coagulation Curve Error
- 4. Early Reaction Error
- 5. Noise Error
- 6. Turbidity Level Over
- 7. No Coagulation
- 8. Flat Curve
- 9. Range Over
- 10. Trans Light High Error

for Chromogenic assays and Immunoassays

- 1. Trans Light Low Error
- 2. Trans Light High Error
- 3. No Linearity Error
- 4. Reaction Curve Error
- 5. Range Over (Antigen Excess) Error
- 6. No polynomial adjustment Error
- 7. Range is non-linear Error

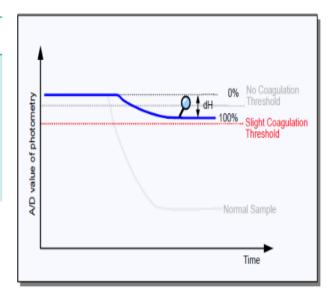
IMPORTANT NOTES;

- Before Re-analysis, ALWAYS
 - Check the sample for possible anticoagulant [e.g. heparin] contamination, hemolysis, lipemia, and clot.
 - Microfuge if lipemic or hemolyzed,

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

1. Slight Coagulation (SC) Error

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.



Action Steps for "Slight Coagulation"

- 1. **Reanalyze** the sample, if ran in micro.
 - --Results without an asterisk (*), REPORT the result,
 - --if "slight coagulation" occurs again for **PT/PTT, -** DO NOT REPORT
 - ---For **Fibrinogen**, change the dilution ratio and reanalyze, if repeat comes out with the same flag, along with other flags like 'Lower report Limit over and dilution ratio was changed'—REPORT the result.

First Run

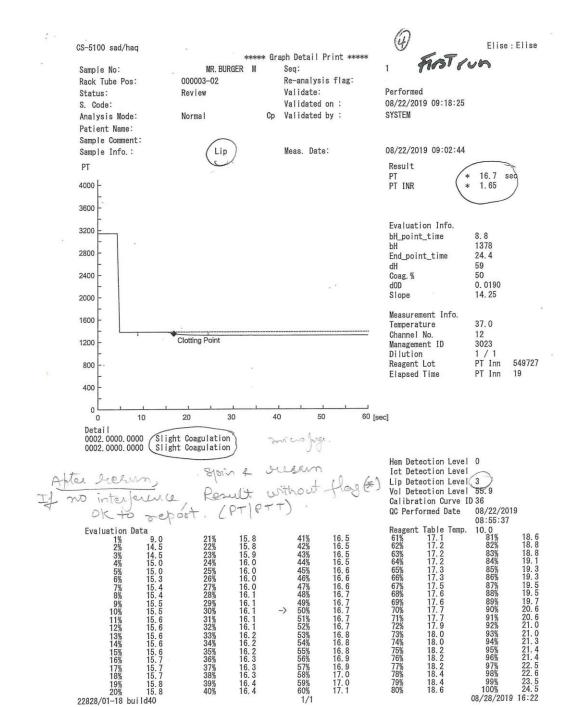
Status: Review

Joblist Result: *16.7 (PT)

Flag: Slight Coag

Lipemia

Action: re-analyze after spin



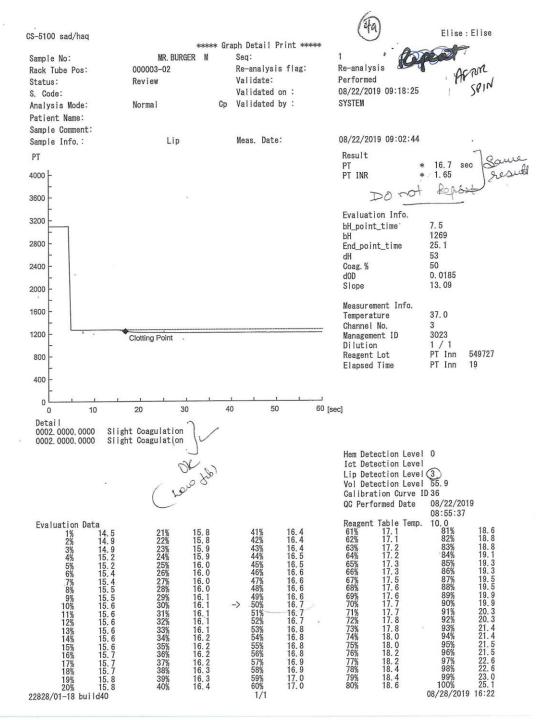
After Spin

Result = *16.7 (PT)

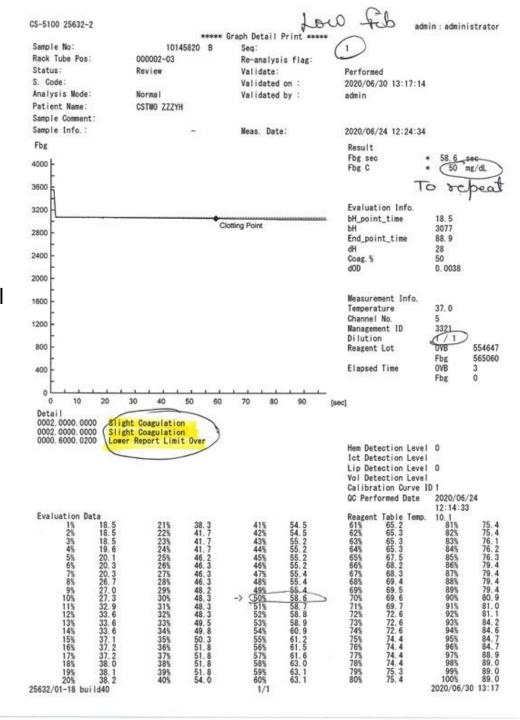
Flag = Slight Coag again

Curve = weak clot

Action = Do Not Report



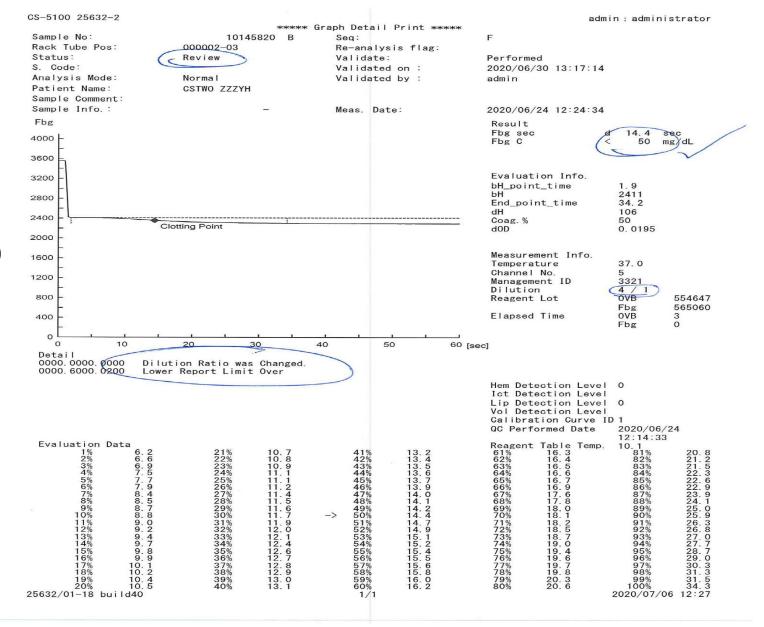
Status = Review
Mode= Normal
Fib Result = *50
Flag = slight coag+Lower report
Dilution = 1:1
Fib<80, always reflexed to 4/1 dil
in normal mode
Action = Review 4/1 dil



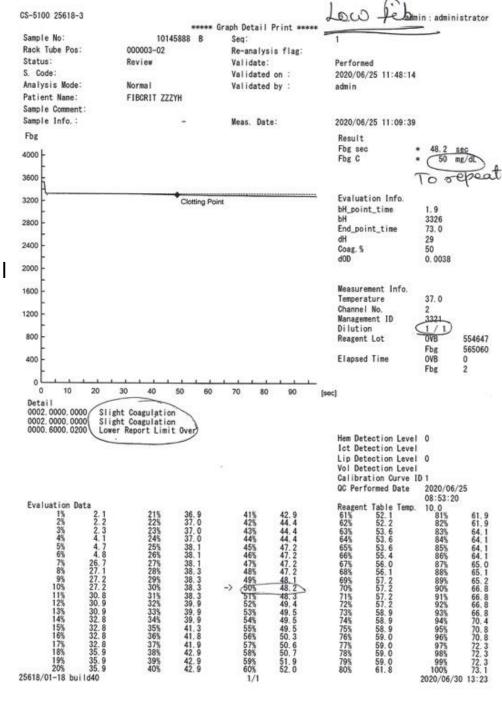
After Re-analysis
Dilution = 4/1
Fib Result <50

Flagged changed to dil and lower report

Action = REPORT the result <50

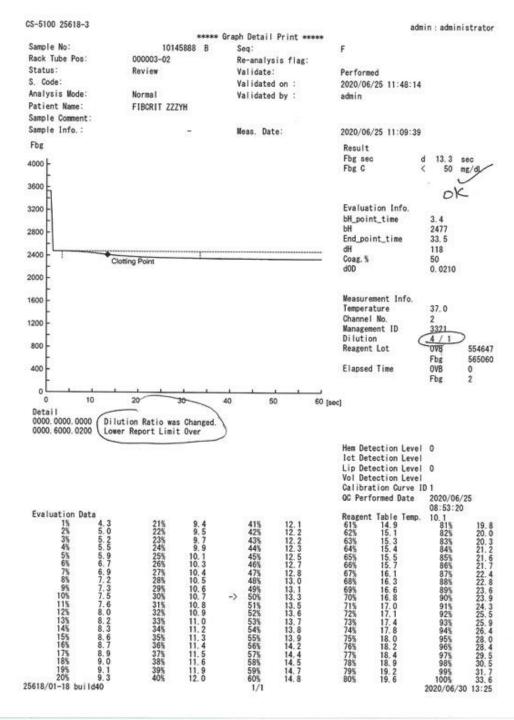


Status = Review
Mode= Normal
Fib Result = *50
Flag = slight coag+Lower report
Dilution = 1:1
Fib<80, always reflexed to 4/1 dil
in normal mode
Action = Review 4/1 dil



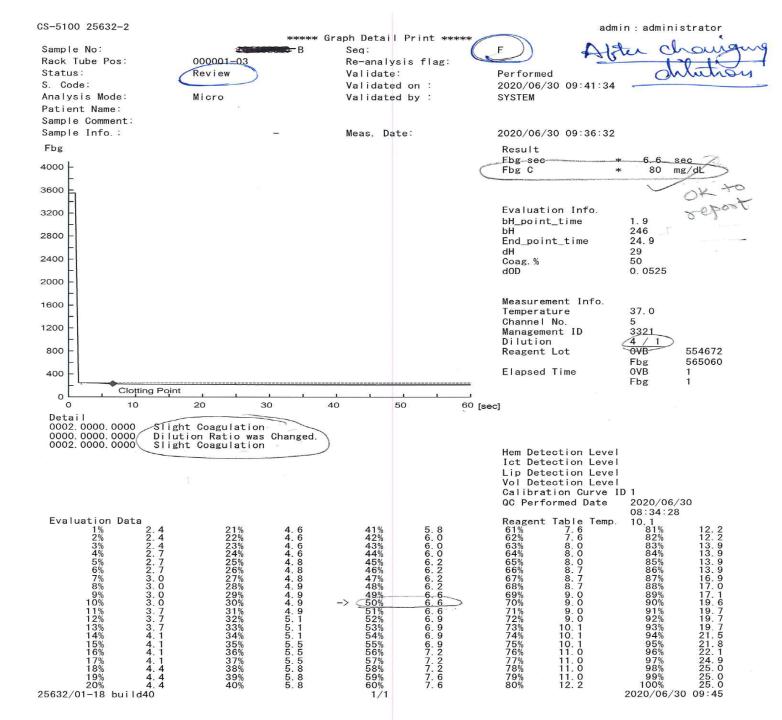
After Re-analysis
Dilution = 4/1
Fib Result <50
Flag changed to dil and
lower report flag

Action = REPORT the result <50



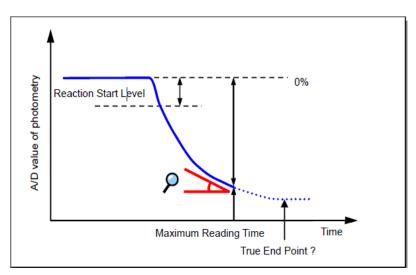
After Re-analysis
Dilution = 4/1
Fib Result = *80
Flag = slight coag +
Dilution ratio

Action = REPORT Fib=80



1. Analysis Time Over Error (ATO)

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. 				

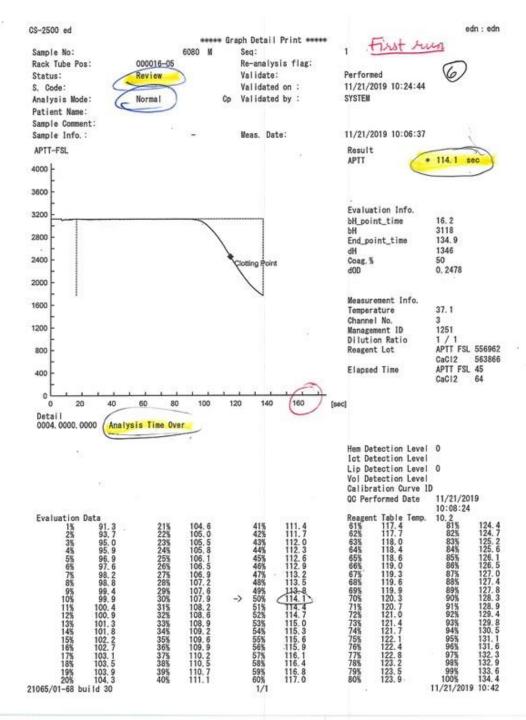


Action Steps for "Analysis Time Over"

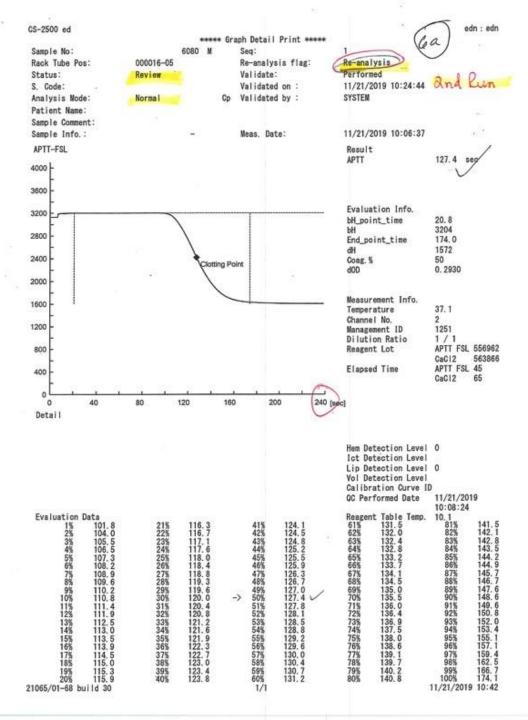
1. Set the "Measurement Time" to a longer time (within the range of 100 to 1800 seconds) or set the "Measurement Time (Sub)" in the [Detailed Settings] on the operation panel and reanalyze the sample. This step is effective to confirm whether the coagulation curve becomes a plateau in the longer time.

- Review reaction curve and Evaluation Data after reanalysis.
- Results in a numerical value without an asterisk (*), Report the result.
- Result with same ATO flag, but the result is without the asterisk (*) Report the result.
- If reanalysis gives a different flag than the ATO flag, result is (*****), Review reaction curve and Evaluation Data. If the evaluation data is greater than laboratory reportable range, Report the highest point of linearity.
- 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. **DO NOT report the result. v**

Status = Review
Result PTT = *114
Flag = ATO
Curve – no end point
Action = run at Longer wavelength



Re-analysis
No Flag
Result without star
Ok to report result.



Status = Review

Mode = Normal

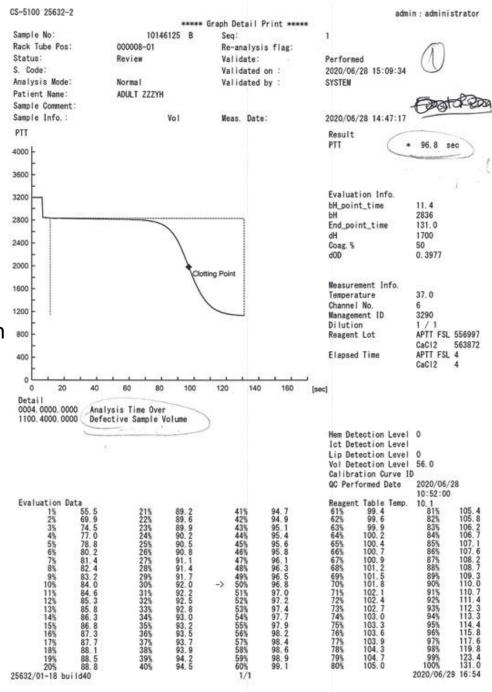
Result = *PTT

Flag = ATO and Vol

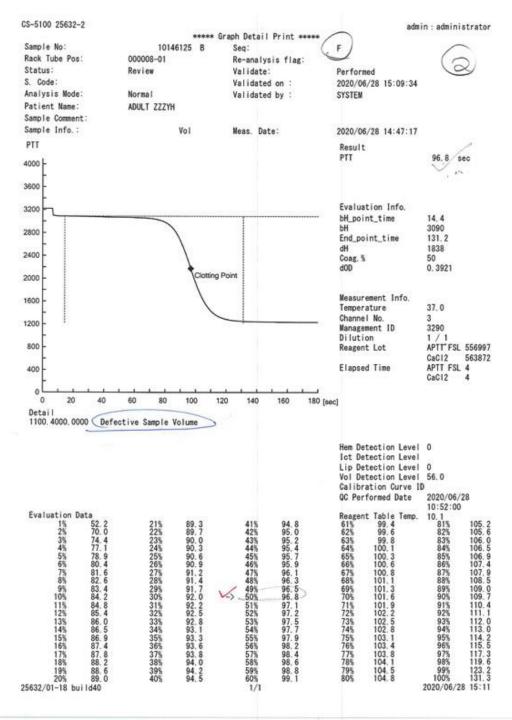
Action: Check vol, if ok, Review the

Re-analysis result

As mode is normal, instrument will run
On longer measurement by itself



After Re-analysis
Result without *
-ok to report



Status = Review

Mode = normal

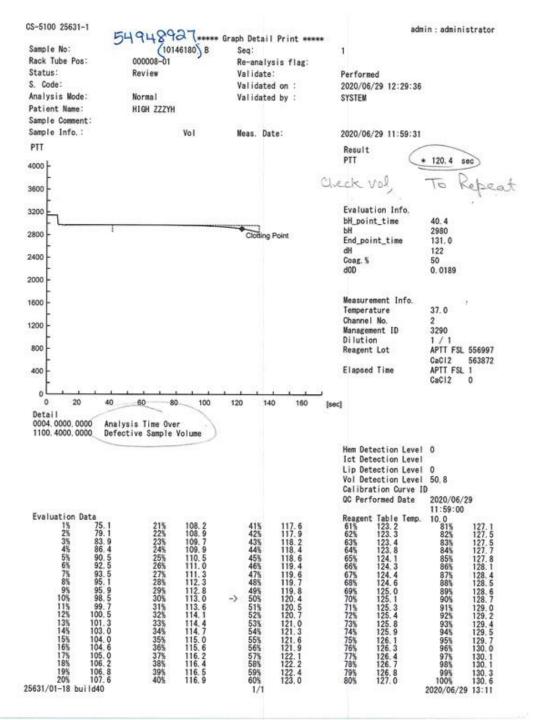
Result PTT = *120.4

Flag = ATO and vol

Curve — no end point

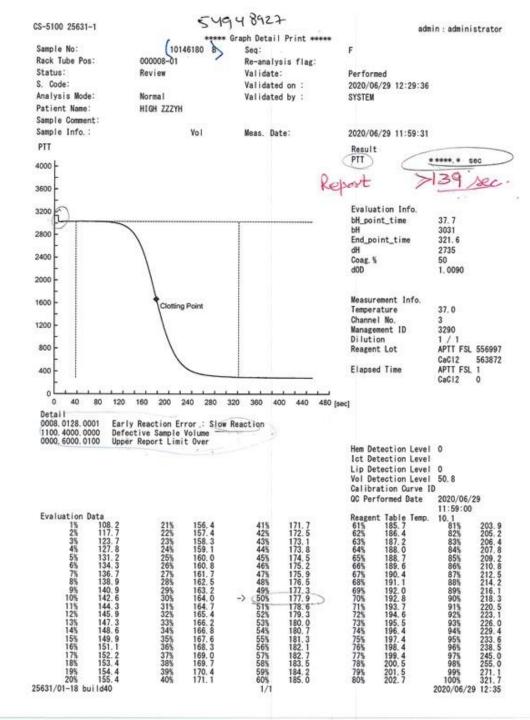
Action = Review at Longer

wavelength

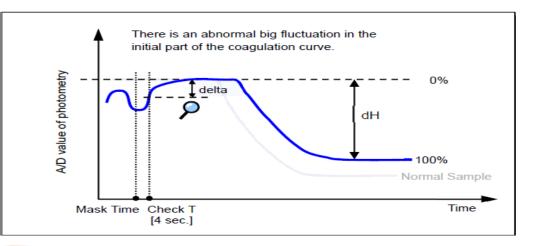


Report PTT>139

After Re-analysis Result **** Flag: Changed to ERE-Slow reaction and Upper report limit Evaluation data value = 177.9



Coagulation Curve error



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

This check can detect such an abnormal fluctuation. When this situation occurs, no numerical results will be given; instead ***.* will print along with the "Coag. Curve Error" message.

Action Steps for "Coagulation Curve Error"

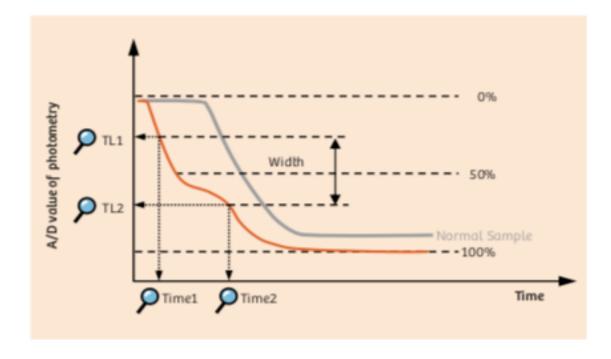
- 1. After Re-analysis,
 - --Results Without an asterisk (*) --- REPORT Result
 - -- Same flag and asterisk--DO NOT Report the result.

4. Early Reaction Error (ERE)

This message occurs when abnormally short **PTT** patient results may be caused by an early reaction. Patient results with an early reaction can be identified in the Evaluation Data and additional information (an Early Reaction Error code) will be shown. When this situation occurs, no numerical results will be given; instead ***.* will print along with the "Early Reaction Error" message.

If the reaction time (Time2 - Time1) within the range of Width% is longer than the Slow Reaction Time Limit, the result will be flagged with an "Early Reaction Error" error.

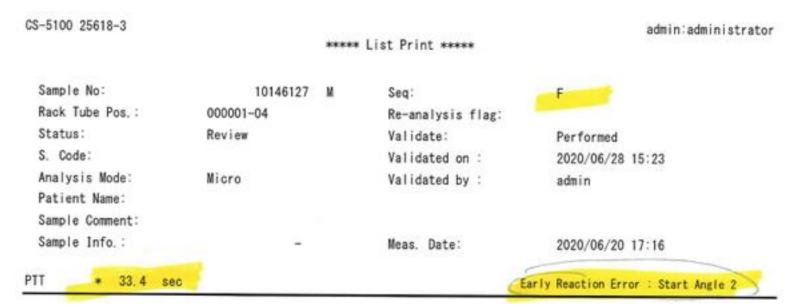
All ERE will have non numerical result. (***.*) except Start Angle 2



ERE - Start Angle 2, respin if lipemic or hemolyzed and rerun, check to see if the result matches what is listed at the 50%. If it does, report the result.

• If the result does not match the 50% point, it may be greater than the upper report limit. **DO NOT** report.

Example 1



Example 1 at longer measurement

Status = Review

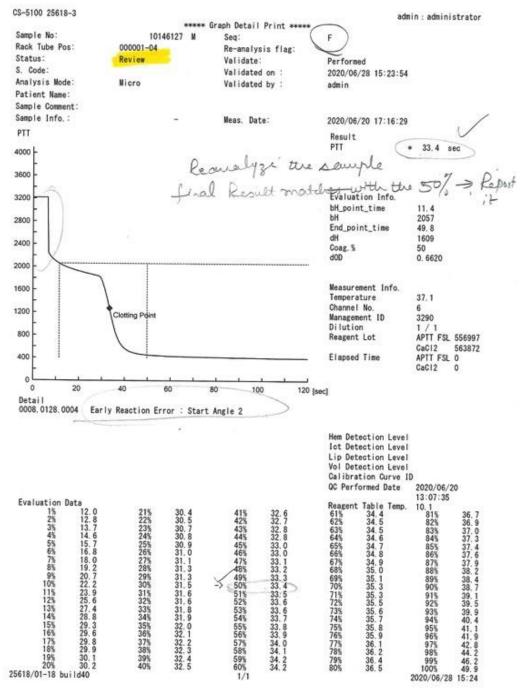
Mode = Micro

Result PTT = *33.4

Flag = ERE; Start Angle2

Action = Report the result

(Only ERE flag where the ** result can be reported is if it matches the 50% point)



Example 2 at longer measurement

Status = Review

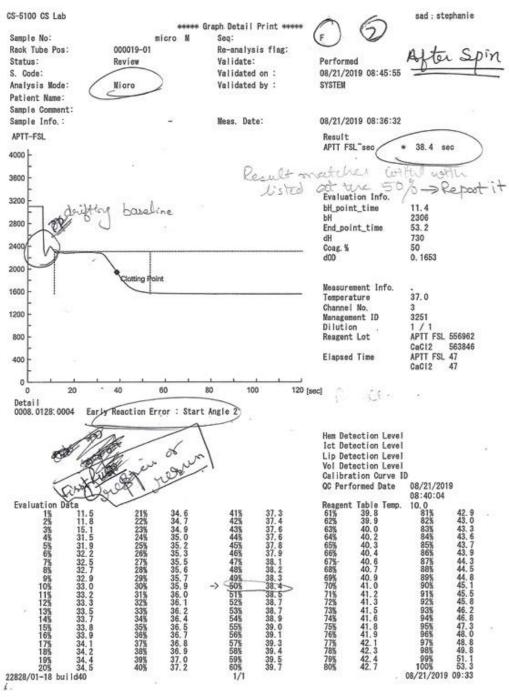
Mode = Micro

Result PTT = *38.4

Flag = ERE; Start Angle2

Action = Report the result

(Only ERE flag where the *numeric result can be reported is if it matches the 50% point)



ERE: Early %

Check sample for clot, lipemia and hemolysis.

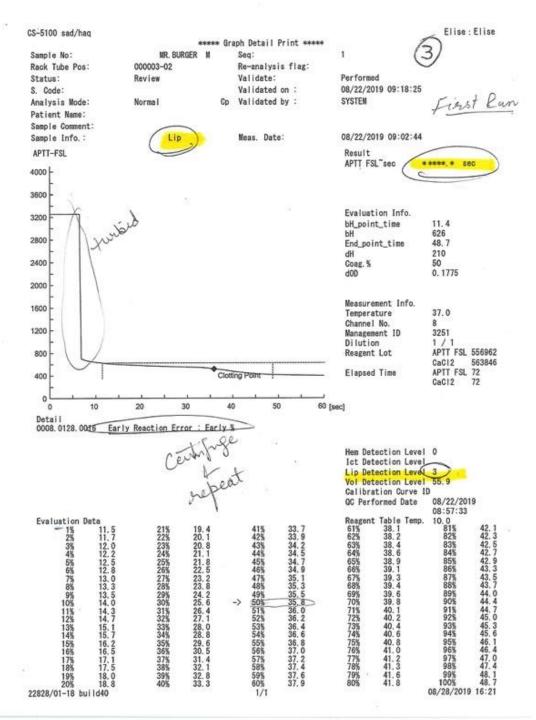
If not clotted, microfuge if lipemic or hemolyzed,

- After reanalysis, numerical result without an asterisk (*), --Report the result.
- If result with the 50 % value is <20 seconds, the sample is clotting too quickly possibly due to pre-analytical variables. Recollect sample. **DO NOT REPORT.**

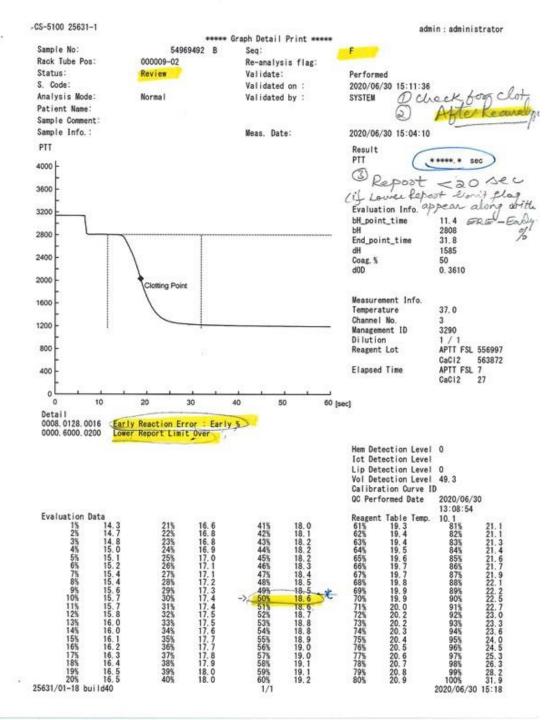
• If reanalysis of the sample results has a different flag (Lower report Limit Over) along with ERE – Early %, and the 50% value is <20 seconds PTT, Report <20 seconds.

Status = Review
Mode = Normal
Result PTT = ****
Flag = ERE; Early%
Lipemia
Drifting baseline

Action: Check for clot
Microfuge and re-analyze



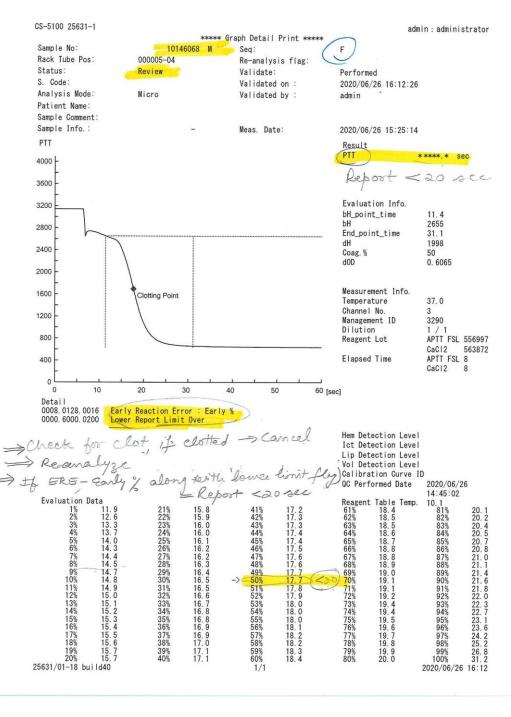
After re-analysis,
Result=***
Flag= ERE; early% with Lower
report limit error
Action: check eval data,
PTT 50% value =18.6
Report = <20 sec



This is after re-analysis

Already check the clot
Result = ***(PTT)
Flag = ERE-early% with lower
report limit
Evaluation data = PTT 17.7

Report = PTT<20 sec



Status = Error

Mode = Normal

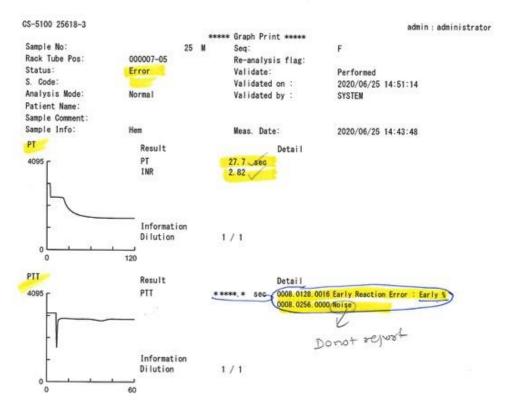
Result PTT =***(but

normal PTINR)

Flag = ERE; Early%

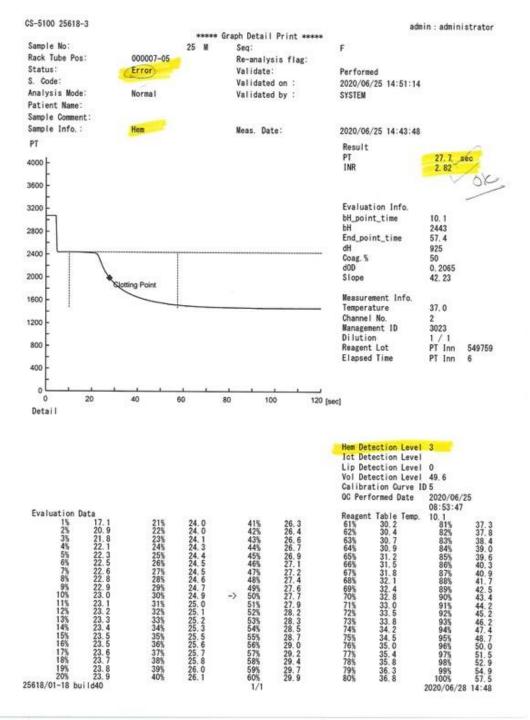
Noise

Action: re-analyze sample If re-analysis results with the **same NOISE flag**, DO NOT report the result

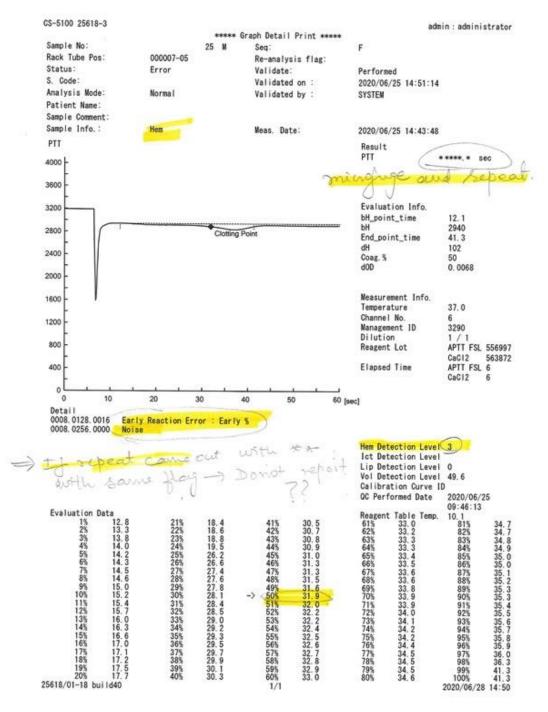


25618/01-18 build40 1/1 2020/06/25 14:59

Ok to report



Re-analysis
Same Noise flag—DO NOT Report



ERE – Slow Reaction

- Joblist result shows (***)
- Check the analysis data. Respin if interference or repeat the sample on sub wavelength.
- After reanalysis,
 - Results in a numerical value without an asterisk (*), -Report the result.
 - Same flag and result shows (***)—Do Not report the result.
 - Same flag along with Upper Report limit flag check PTT with data 50% above the linearity, Reanalyze the curve -----Report PTT Upper limit, >139 sec.

This example is after re-analysis

```
Status = Review

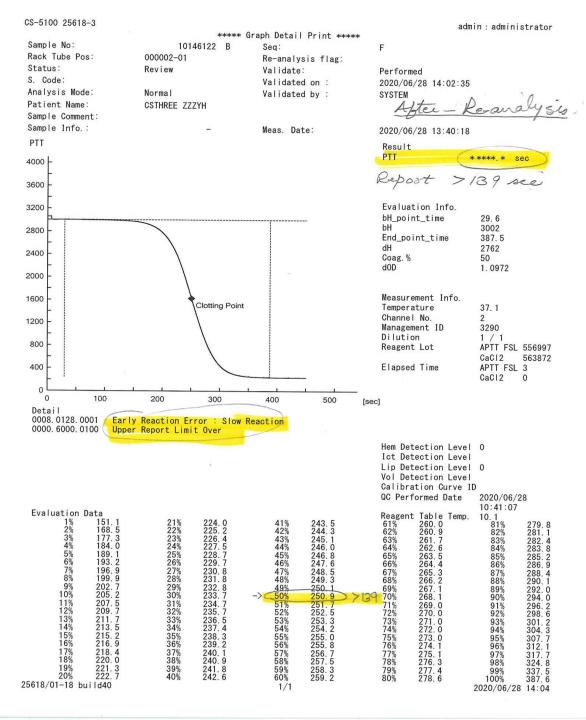
Mode = Normal

Result = **** (PTT)

Flag = ERE-Slow reaction and upper report limit (combination of both flag)

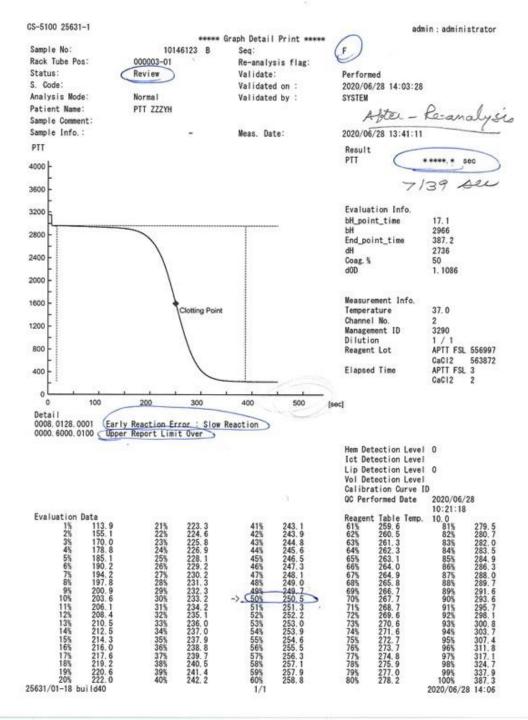
Evaluation data = PTT=250.9

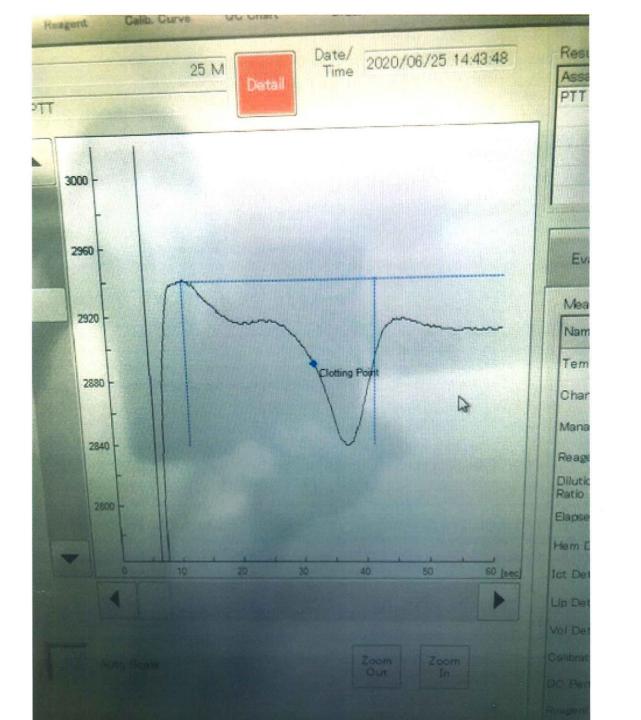
Report > 139 sec
```



This example is after re-analysis

```
Status = Review
Mode = Normal
Result = **** (PTT)
Flag = ERE-Slow reaction and
upper report limit
(combination of both flag)
Evaluation data = PTT=250.5
Report > 139 sec
```





This example is after re-analysis Ran on longer measurement

```
Status = Review

Mode = micro

Result = **** (PTT)

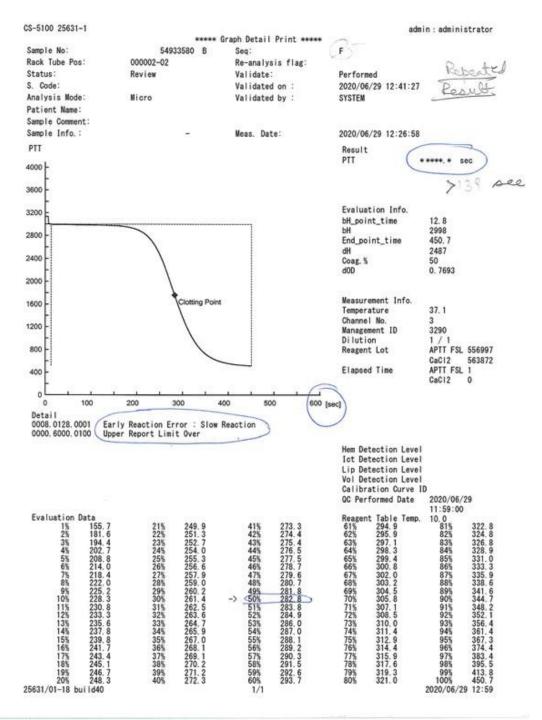
Flag = ERE-Slow reaction and

upper report limit

(combination of both flag)

Evaluation data = PTT=282.8 sec

Report > 139 sec
```

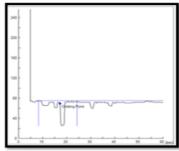


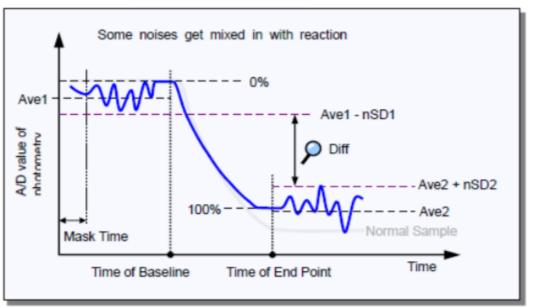
ERE angle 1 and drift flag:

- Joblist result shows (***)
- Check the analysis data. Respin if interference or repeat the sample on sub wavelength
- If reanalysis of the sample results in a numerical value without an asterisk (*), Report the result.
- If reanalysis of the sample result with same flag—Do Not report the result.

Noise Check Error

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



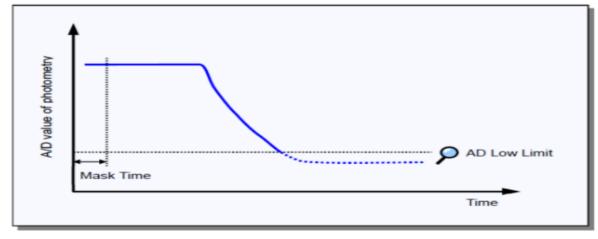


Action Steps

- When this condition is detected **DO NOT** Report.
- Recalibrate the lamp or replace it with a new lamp. perform calibration or QC analysis, then check the analysis data.
- If changing the lamp, rerun on the other instrument
- If recalibrating the lamp, **Reanalyze the sample**
 - Results without an asterisk (*) Report
 - If same flag **Do Not Report and rerun on the other instrument**

Turbidity Level Over Error

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



Action Steps for "Turbidity Level Over Error"

- 1. Reanalyze the sample after microfuge or ultracentrifuge.
 - -Numeric result without an asterisk (*), Report the result
 - -Same flag again **DO NOT** Report

DO NOT REPORT RESULTS WITHOUT NUMERICAL VALUES

No Coagulation Error

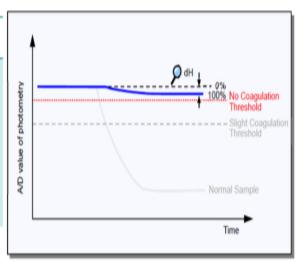
Joblist	Masked ****.* result
Cause	No coagulation or a weak coagulation was detected. Due to possible low fibrinogen concentration, presence of anticoagulant, or a reagent issue.

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.



Action Steps for "No Coagulation Error"

- For PT/PTT, Reanalyze the sample with an extended measurement time (within the range of 100 to 1800 seconds) or set the "Measurement Time (Sub)" in the test protocol.
- **For fibrinogen**, if auto-redilution is not set, change the dilution ratio and reanalyze.
- After reanalysis,
 - **-Numerical result** without an asterisk (*), --- Report the result
 - "No Coagulation" again Report 'No Clot' result.
- If reanalysis gives a (***) result with different flag, follow the rules for those flags.

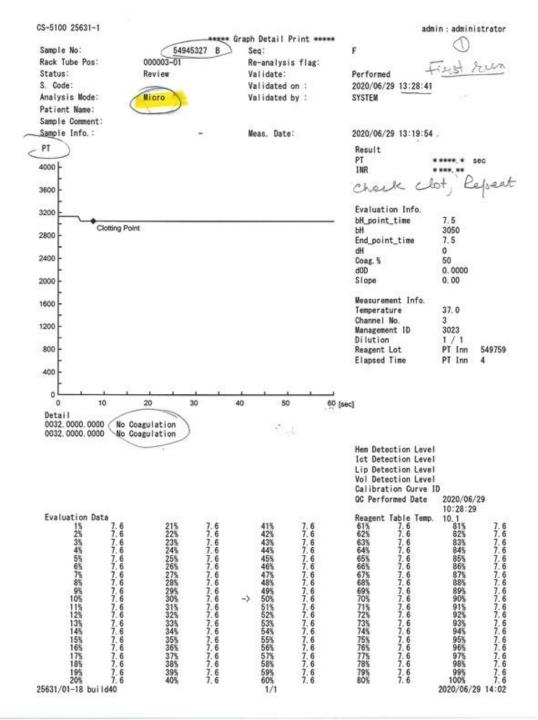
Status = Review

Mode = Micro

Result = ****(PTINR)

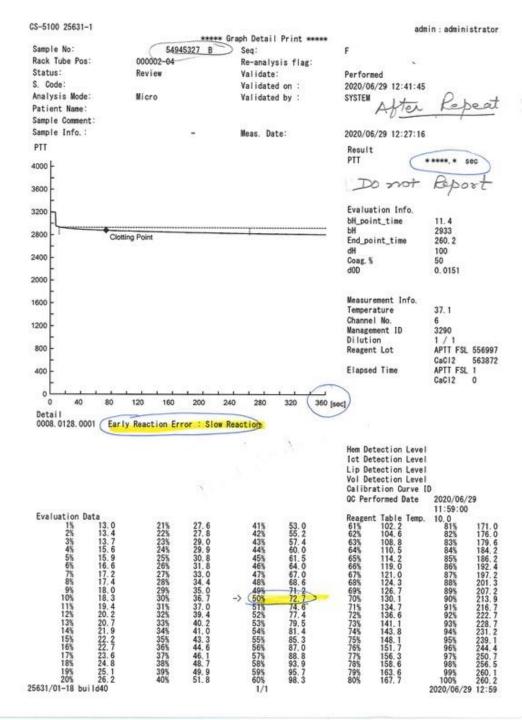
Flag = No Coagulation

Action = check for clot, Re-analyse, Run @ longer measurement



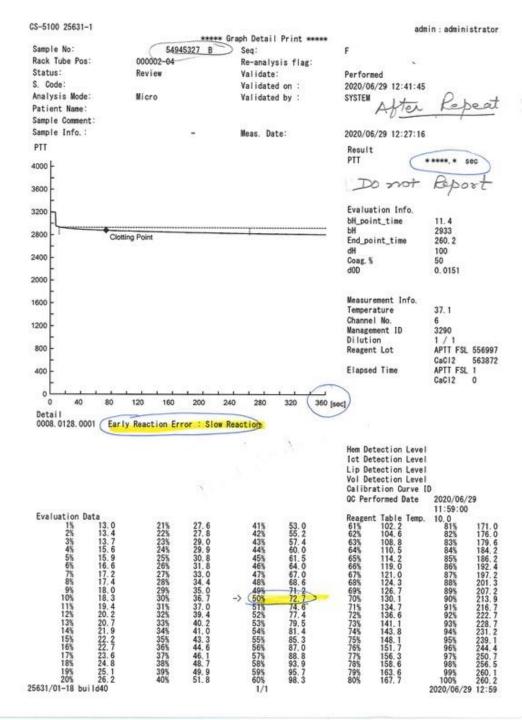
After re-analysis,

Result **** (PTT)
Flag changed to ERE –Slow
reaction
DO NOT Report the result



After re-analysis @ longer measurement,

Result **** (PTT)
Flag = **ERE** -**Slow** reaction
DO NOT Report the result



After re-analysis

Mode = micro

Result = ***

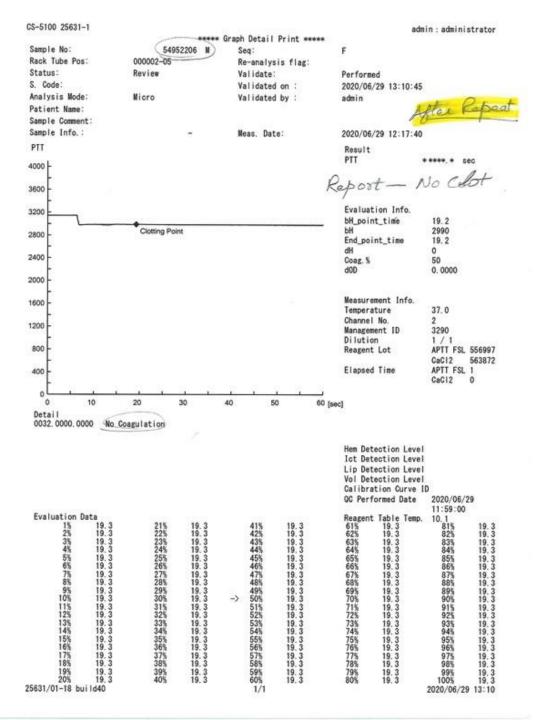
Flag = No Coag again

Curve = Staright line

Evaluation data = no progression,

same number

Report = No Clot



After re-analysis

```
Mode = micro
```

Result = ***

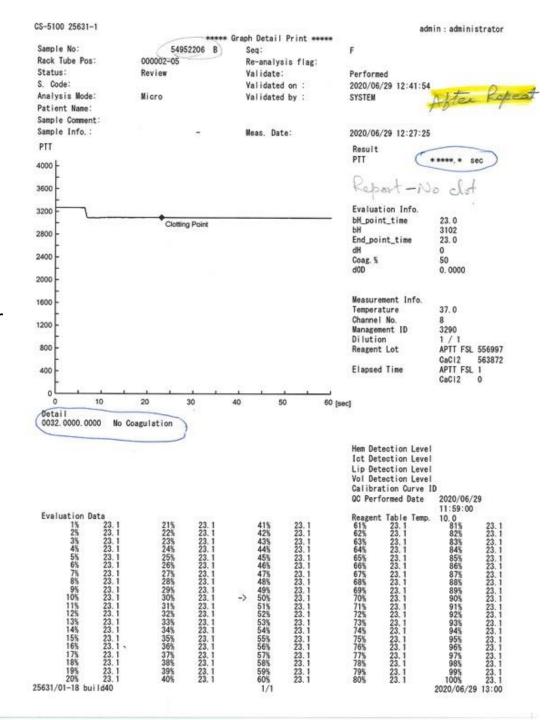
Flag = No Coag again

Curve = Straight line

Evaluation data = no progression,

same number

Report = No Clot



Status = Review

Mode = Micro

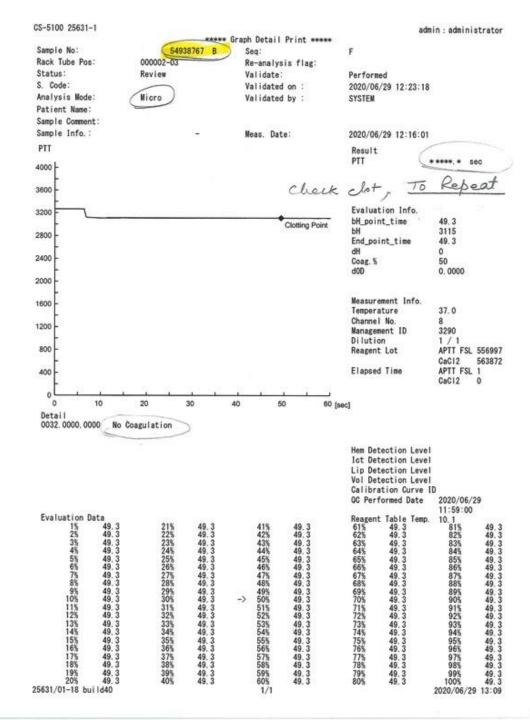
Result = ***(PTT)

Flag = No Coagulation

Evaluation data = shows no progression, single value

Curve = st line

Action = check clot, re-analyze at longer wavelength



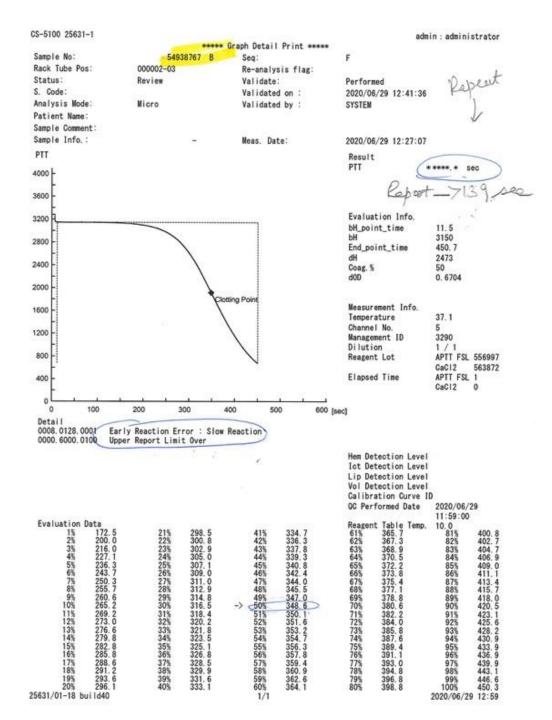
After re-analysis,

```
Result = ***(PTT)

Flag = Changed to ERE – slow reaction
and Upper report

Evaluation data = PTT at 50% 348.6 sec

Report = >139 sec
```



Status = Review

Mode = Micro

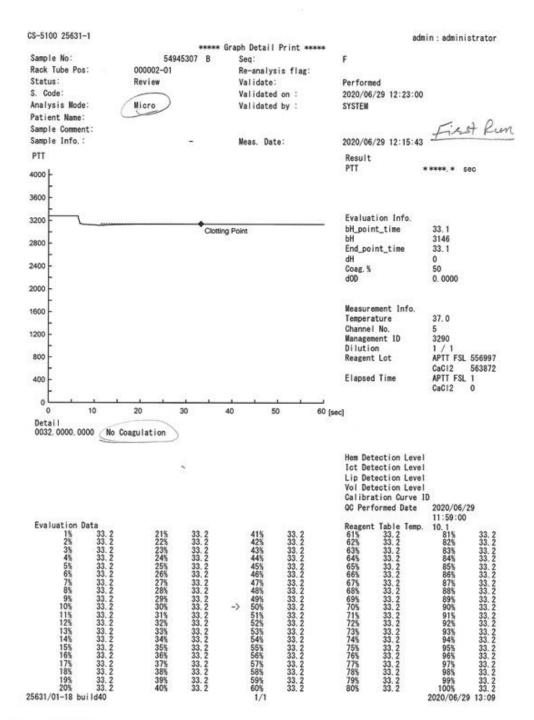
Result = ****(PTT)

Flag = No Coagulation

Eval data = single value

Curve = straight line

Action = check for clot, Re-analyse, Run @ longer measurement

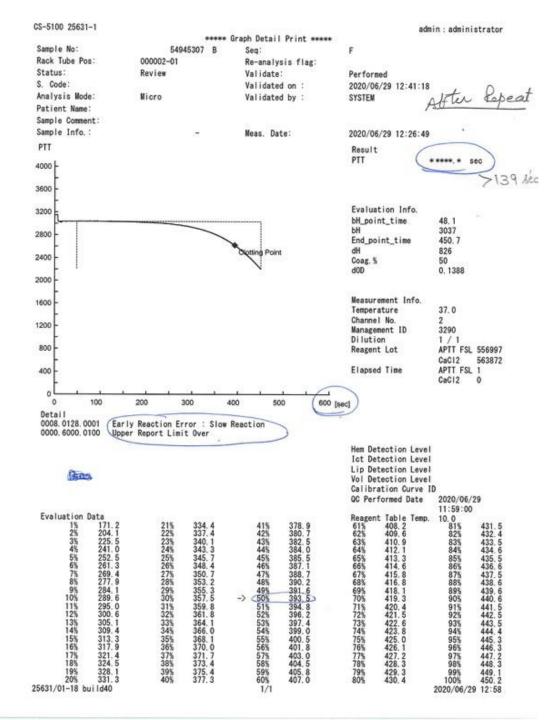


After re-analysis:

Result = ****

Flag changed to ERE-slow with Upper report

Evaluation data = 393.5 at 50% Report = PTT>139 sec

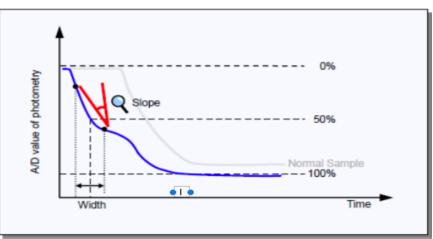


1. Flat curve

This method checks the slope of the coagulation curve around the detection point (50%). When this condition is detected results will be flagged with a "Flat Curve" error. This check is effective for PT assay only.

This message appears when the analyzer detected a weak clot although it is not a true coagulation reaction. If the slope of reaction is bigger than "Limit slope" in time width, the result will be flagged with a "Flat curve" error. When this condition is detected the result will not be reported.

	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. 	



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.

Action Steps for Flat Curve

Re-analyze sample after setting the "Measurement Time" to a longer time,

- -Numeric results without an asterisk (*) –Report the result
- Same "Flat curve" message again Do Not Report

Status = review

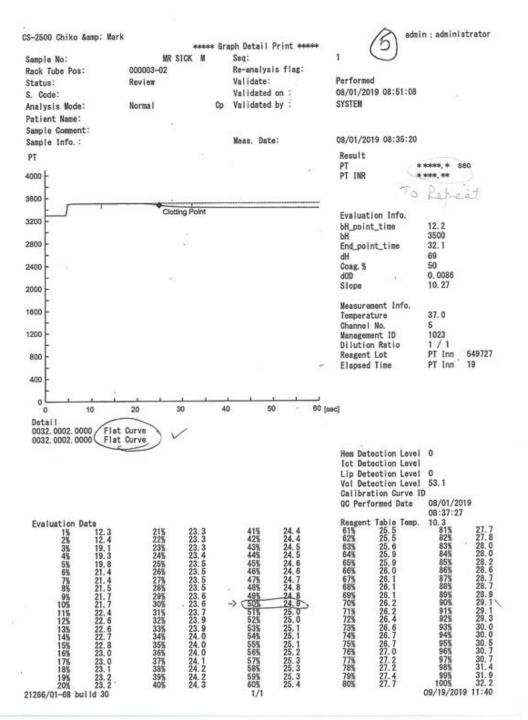
Mode = Normal

Result = *** (PTINR)

Flag = Flat curve

Action = check for clot and re-

analyze

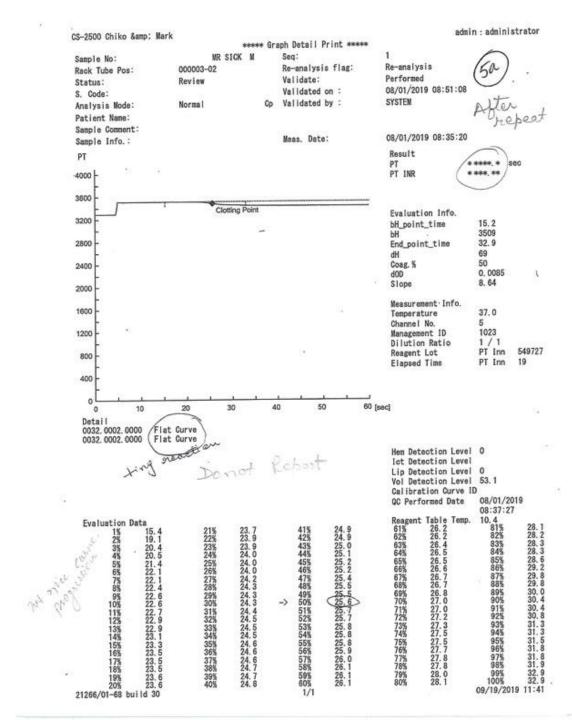


After re-analysis

If flat curve again = **Do Not**report the result

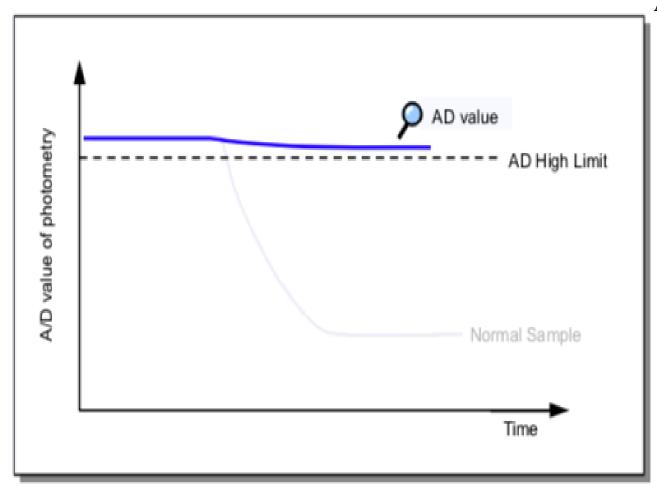
even though you see some PT

value at 50%



Trans Light High Check

If the A/D value of the measurement data is at threshold value or above, the result will be flagged with a "Trans Light High" error. When this condition is detected the result will not be reported.



Action Steps for "Trans Light High"

- 1. Recalibrate the lamp or replace depending upon the condition. Follow lamp replacement procedure.
- 2. Run sample on the alternate instrument.

1. Miscellaneous Flags:

Test	Flag	Action
D-Dimer assays	Antigen Excess	Report >35.2 mg/L FEU
Any Test	Upper Reportable Limit Over	Report >highest point of linearity PT>90sec, INR>10.3, PTT>139sec, FIB>860 mg/dL DDI>35.2 mg/LFEU,
Heparin Assay	Extrapolation Boundary over (upper)	Report >1.5 IU/mL
Arixtra	Extrapolation Boundary over (upper)	Report >1.0 mg/L
Any Test	Lower Report limit over	Check for clot, if ok, report PTT <20 sec, Fib <50 mg/dL,, DDI<0.19 mg/L FEU PT <8.7 sec

Heparin assay

Status = Error
Code = extrapolation boundary
over
Result = >----

Check sample integrity

- Validate if ok
- It will auto verify as >1.5 IU/mL





Report >1.50 W/ML

25632/01-18 build40

1/1

2020/06/28 12:27

<u>Test = Heparin</u>

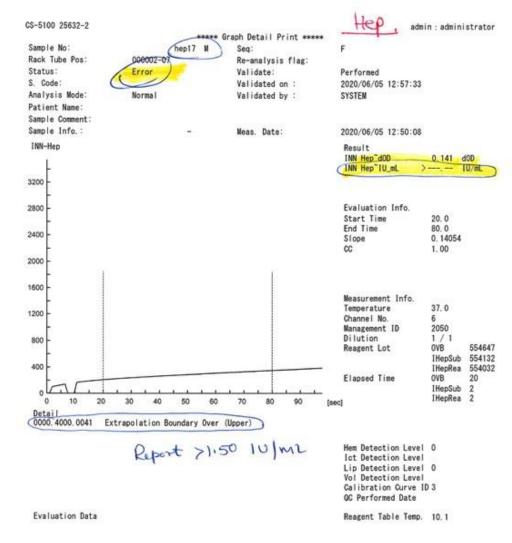
Status = Error

<u>Code = extrapolation boundary</u> over

<u>Result = >----</u>

Check sample integrity

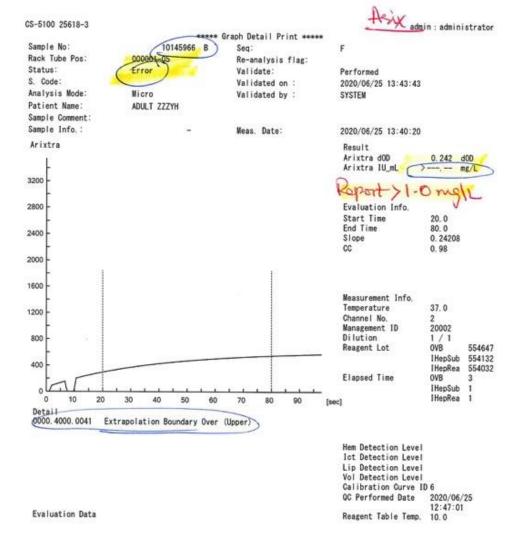
- Validate if ok
- It will auto verify as >1.5 IU/mL



Arixtra

Status = Error
Code = extrapolation boundary
over
Result = >---Check sample integrity

- Validate if ok
- It will auto verify as >1.0 mg/mL



CS-5100 25618-3 ***** List Print ***** Sample No: 10145911 B Rack Tube Pos. : 000001-01 Re-analysis flag: Mellow Alices 09/25/20 4:46 PM Status: Error Validate: Performed S. Code: Validated on : 2020/06/25 12:53 Analysis Mode: Micro Validated by : SYSTEM Patient Name: JANUARY ZZZYH Sample Comment: Sample Info.: Meas Date: 2020/06/25 12:50 Arixtra >--- mg/L 0.194 dOD Extrapolation Boundary Over (Upper)

25618/01-18 build40

1/1

2020/06/25 16:44

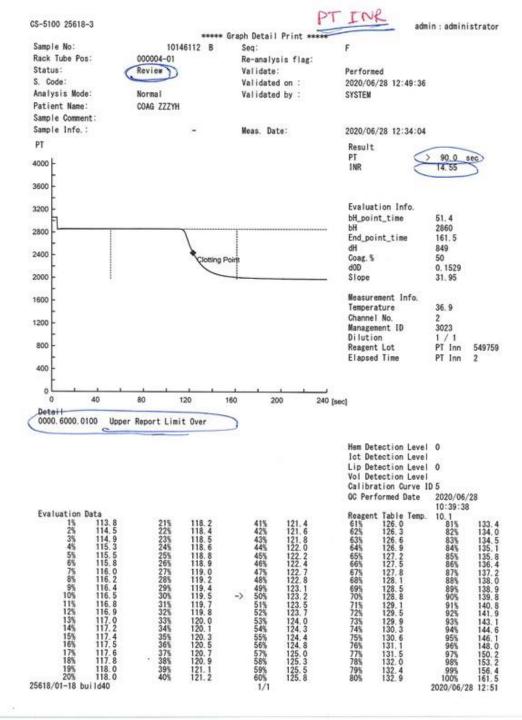
PTINR

Status = Review

Flag = Upper report Limit error

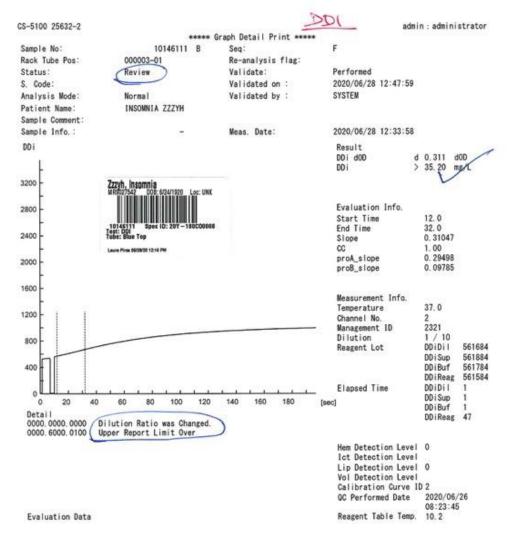
Action = check the integrity of
the sample, clot

Action = send to host



DDI **Example 25**

Status-Review
Flag = Upper report limit and
dilution changed
Validate = send to host



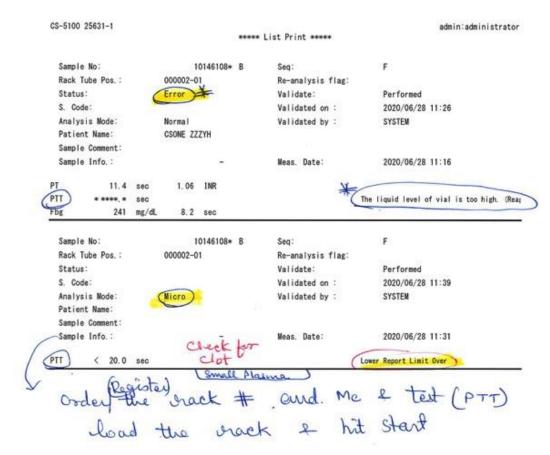
Status = Error

Mode = Normal

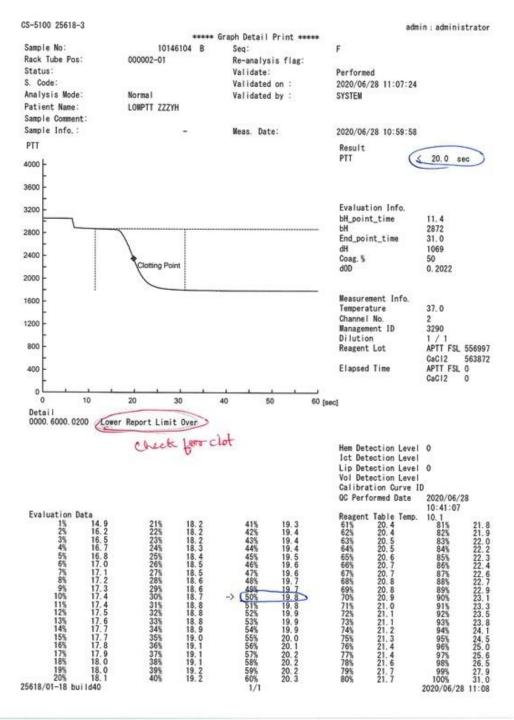
Flag = The liquid level high risk

Result = *** for PTT

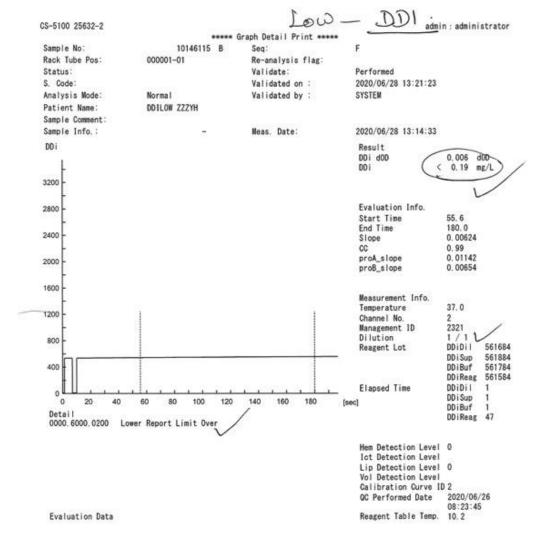
Action = re-analyze



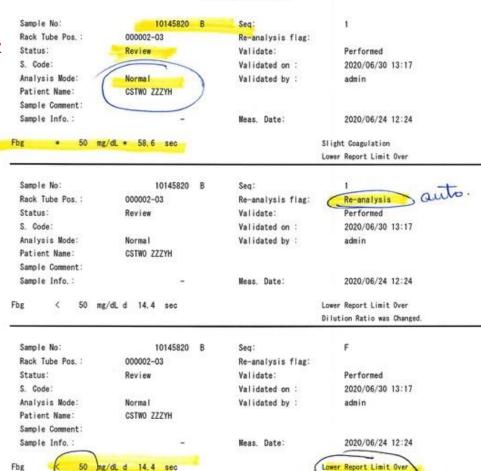
Action = Check for clot



Verify



Normal vs. Micro sample



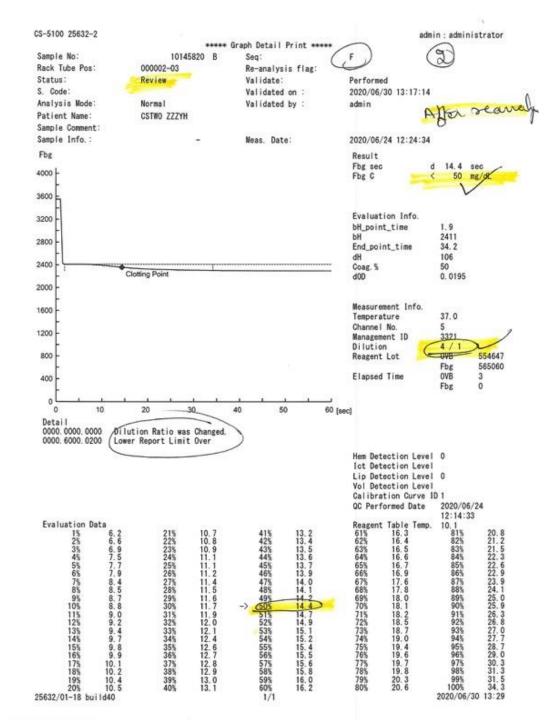
***** List Print *****

Lution Ratio was Change

After Re-analysis

Status = Review Result = Fib<50 Check Dilution = 4/1

Action = send to host



Status = review

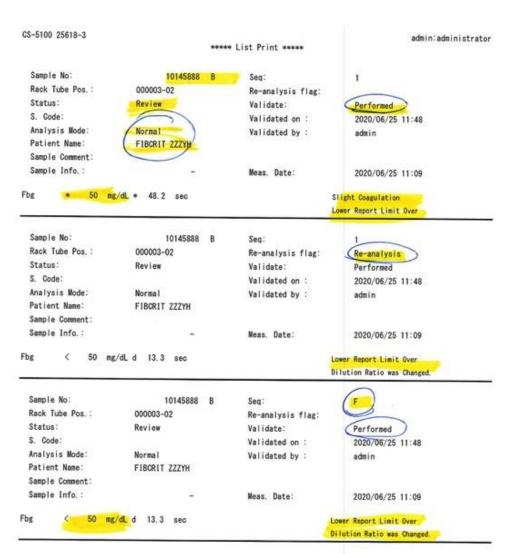
Mode = Normal

Result = Fib ***50

Flag = Slight coag and lower report

Action = as sample is in normal mode, will re-analyse 4/1 dil

Results <50, report



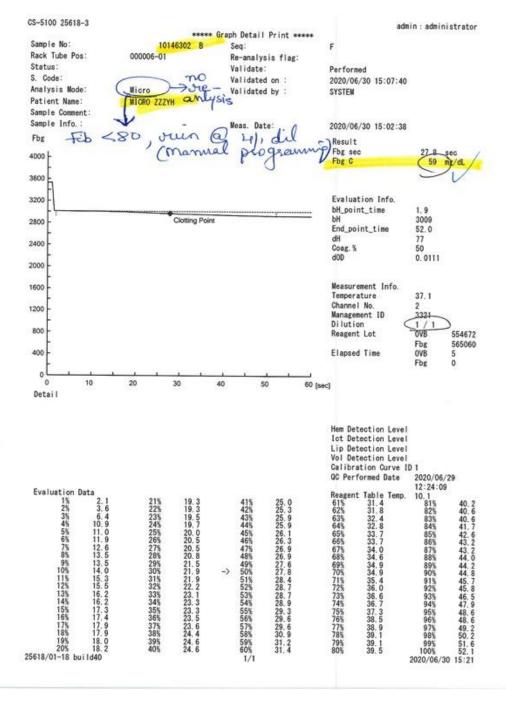
25618/01-18 build40 1/1 2020/06/30 13:23

Mode = Micro Fib 59 Dil = 1/1

Alert** there is no flag and no status but sample in micro mode

DO NOT REPORT

Action =RUN at 4/1 dil



Dilution = 4/1
No other flag other than dilution changed
Report Fib = 68

