Abnormal PLT-H result

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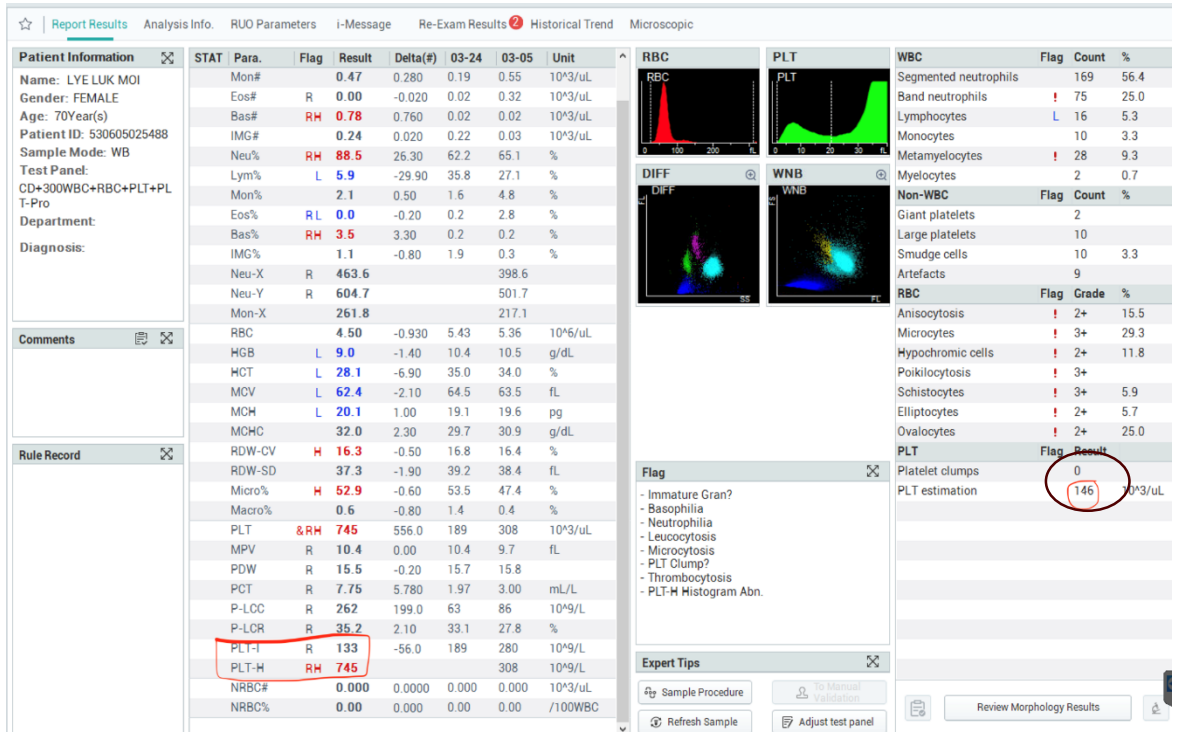
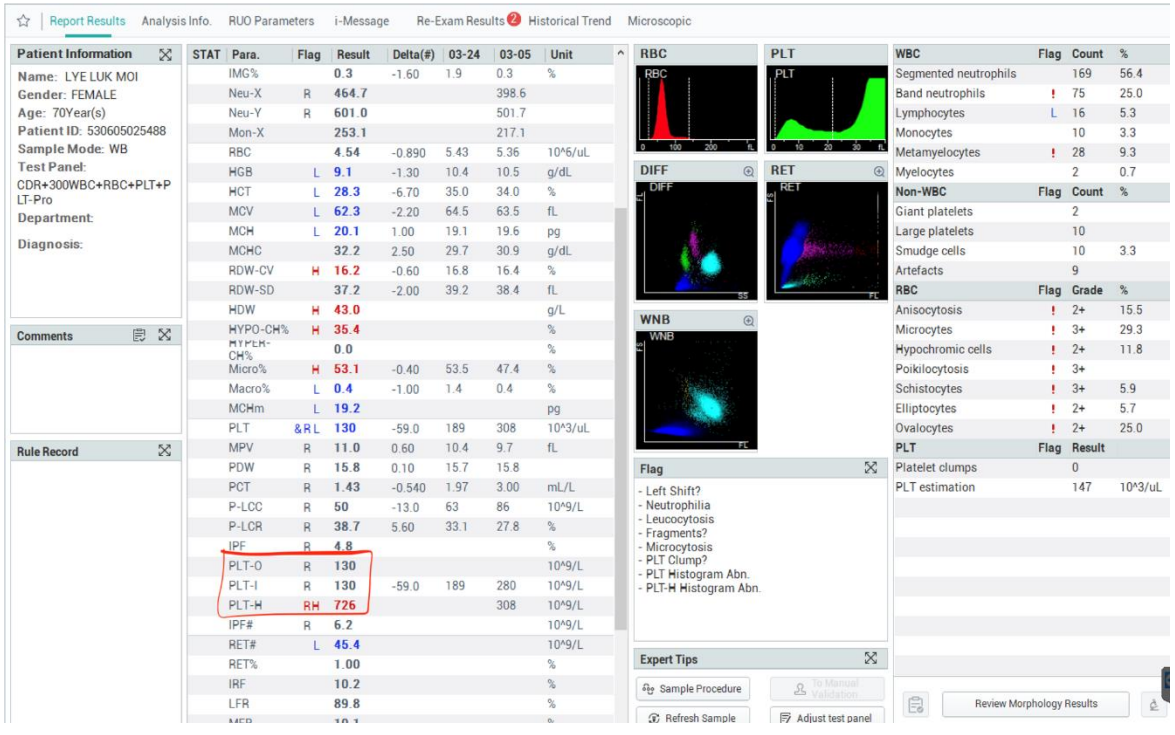
Case Background

Problem detail :

1. Distributor perform study of PLT-H. They find out one sample with PLT-H is much higher than PLT-I. After that, they re-run the sample on RET channel. They also check the smear. Finally, PLT-O, PLT-I and smear result are similar while PLT-H is incorrect.
2. General parameter: Other PLT parameters are in the normal range. WBC increase, RBC flag…
3. Overall checking of machine, reagent, IQC, other samples results… indicates that testing condition is good. This problem may happen randomly.
4. The patient medical record is unclear
5. Visual inspection of sample shows no problem

Sample reading: Multiple PLT channel comparison





Test panel: CD+morphology check
PLT-H >> PLT-I ~ Morphology result

Test panel: CDR+morphology check
PLT-H >> PLT-I ~ PLT-O ~ Morphology result

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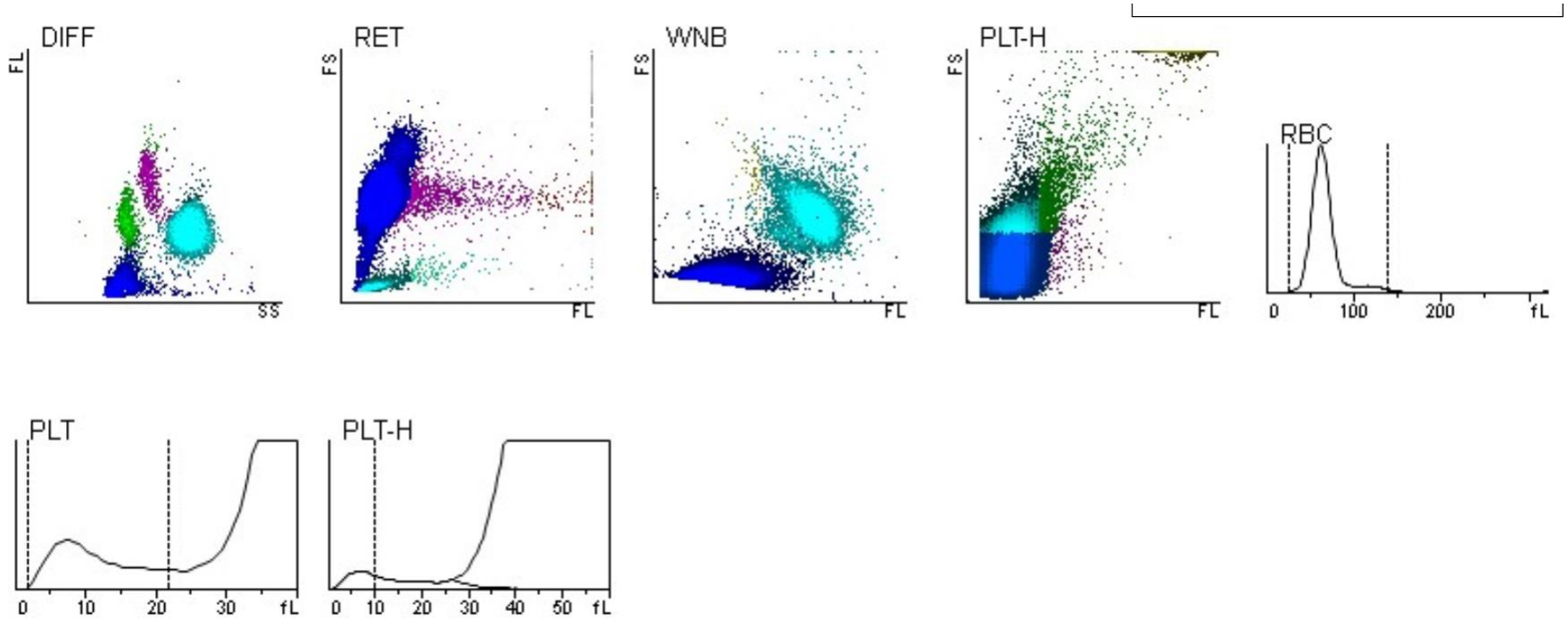
Sample reading: Flags and Graphs

Flag
Left Shift?
Neutrophilia
Leucocytosis
Fragments?
Microcytosis
PLT Clump?
PLT Histogram Abn.
PLT-H Histogram Abn.



Observation:

1. PLT and PLT-H histogram are abnormal, PLT clump
2. PLT-I threshold is ~20fL, PLT-H threshold is >30 fL > result difference

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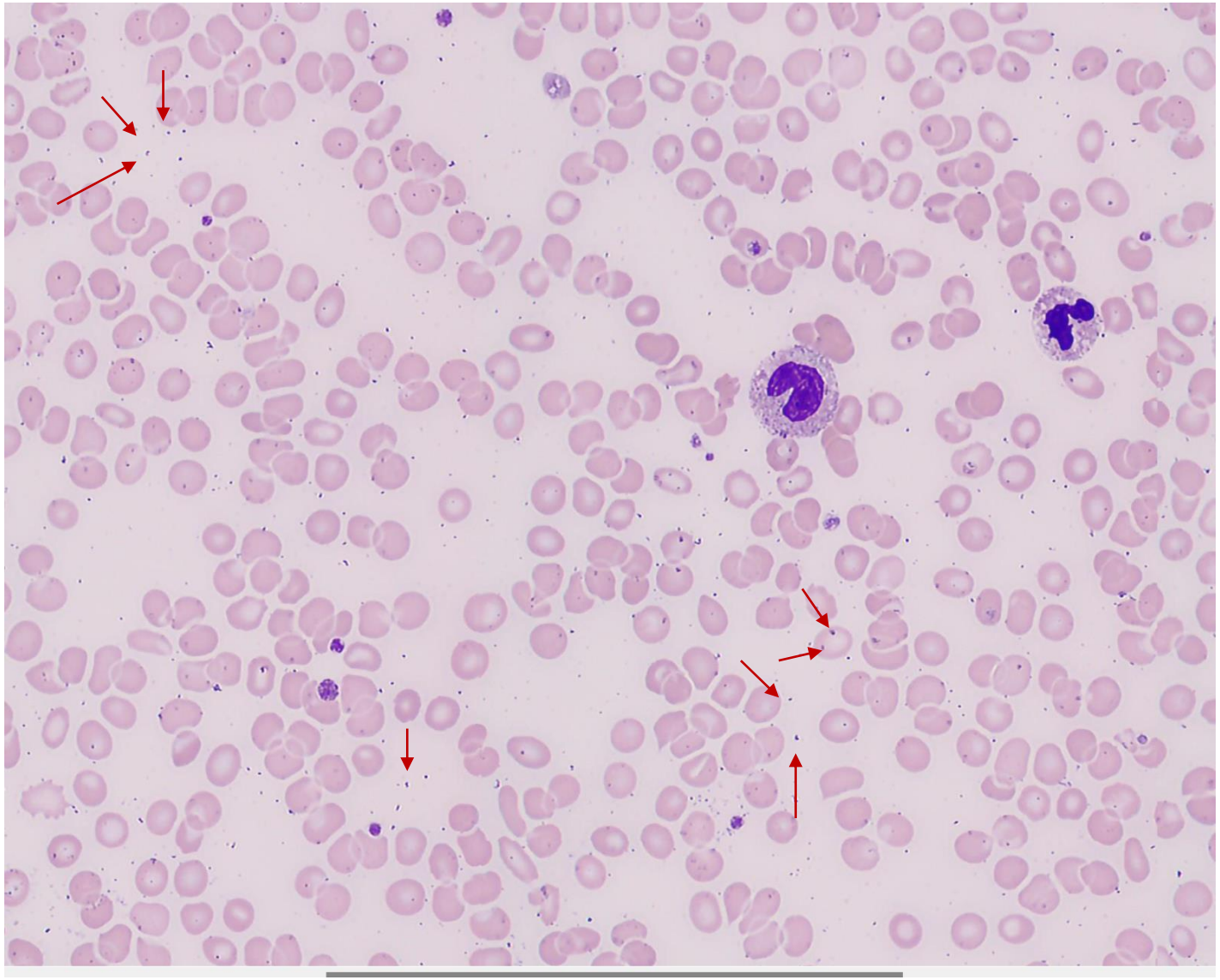
Sample reading: Smear image



Red arrow: Which event? Batch staining quality or contamination

- Since we only obtain the smear image of this sample > cannot go studying deeply > it is impossible to conclude which event is

- Small size particle > may not affect directly to PLT-H counting but there might be large particle that we miss out or any side effect of that “small event”

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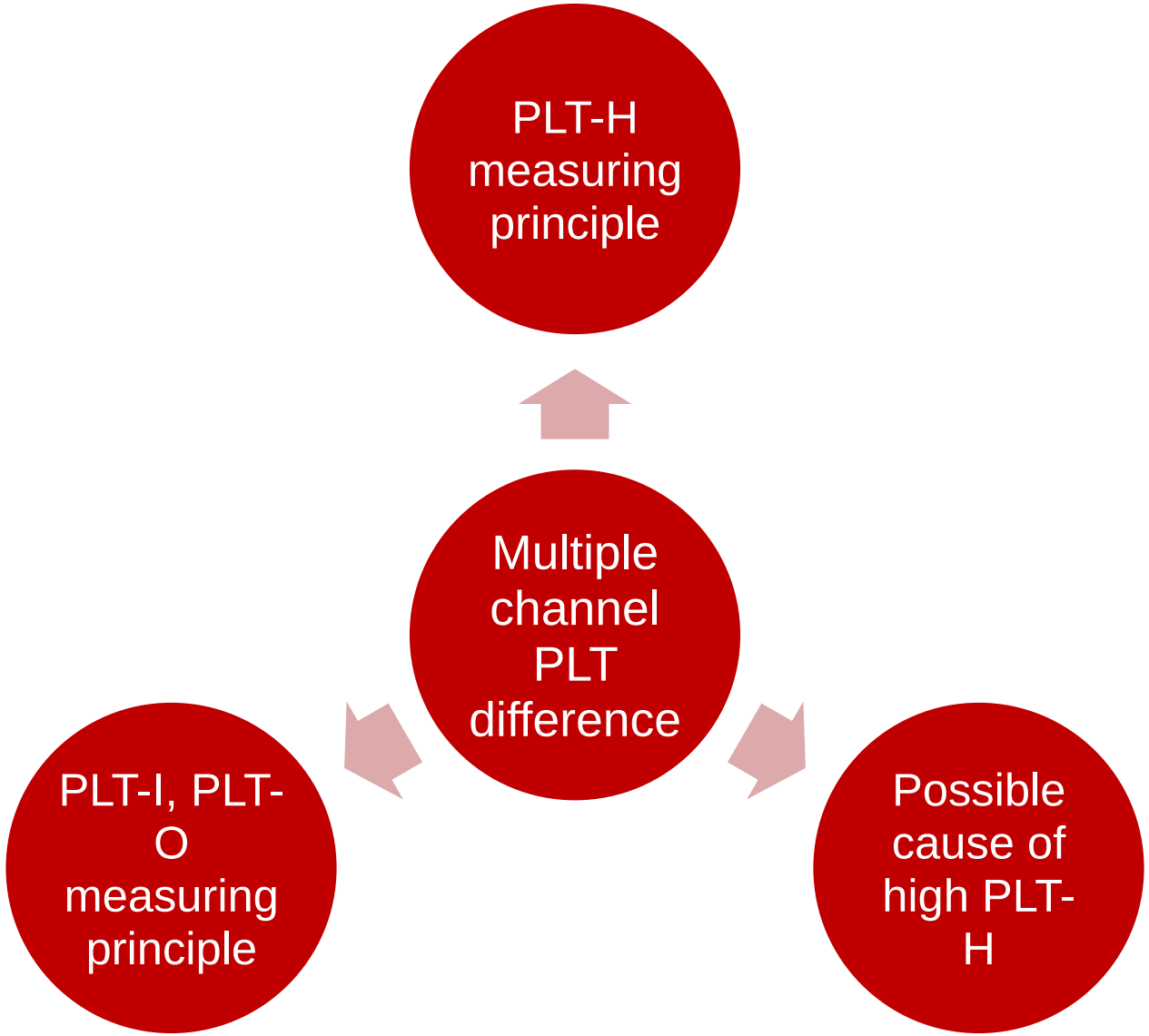
Case Ideas



1. PLT-H measuring principle

PLT-H: combination of PLT from 2 channels

=

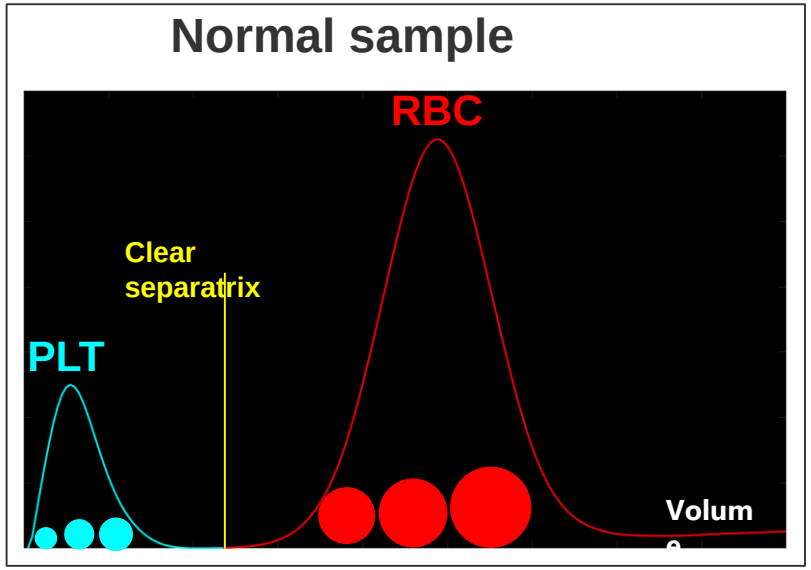
DC: to count small PLT, ≤ 10 fL

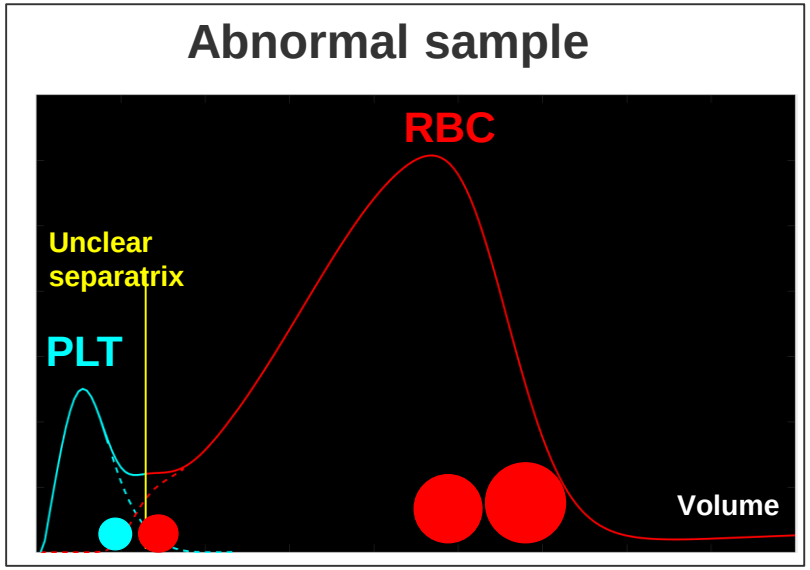
+

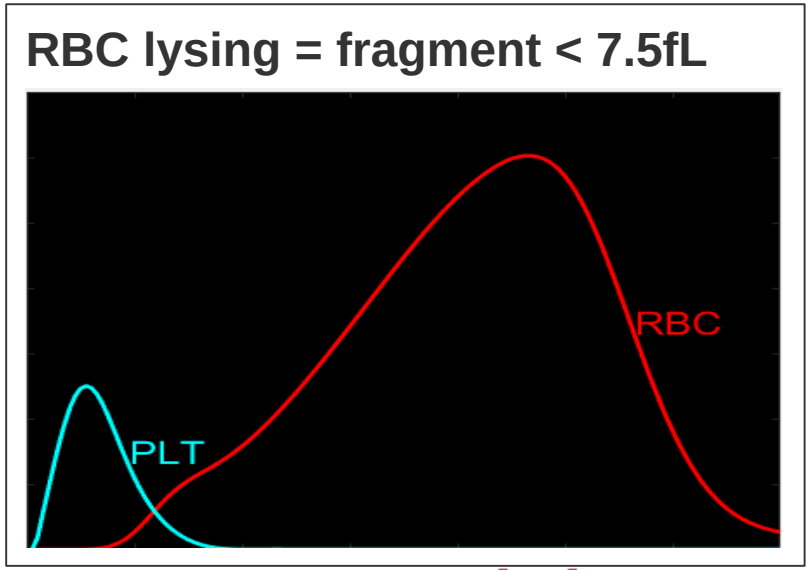
DIFF: To count large PLT, >10 fL

Left site PLT (small): free of RBC interference = DC

Right site PLT (large): possible to get RBC interference > remove RBC by lysing = DIFF







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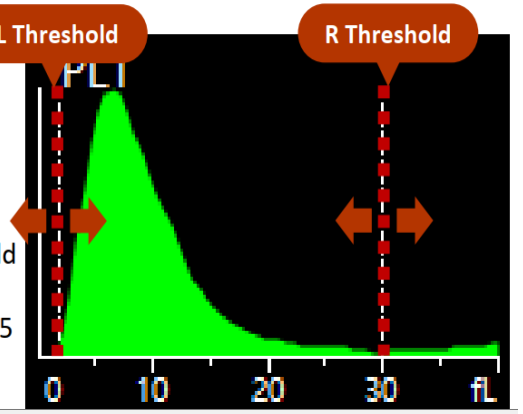
PLT-I and PLT-O measuring principle

PLT-I parameter: impedance method

- **PLT counting area**, all the particles that measured between L and R thresholds.

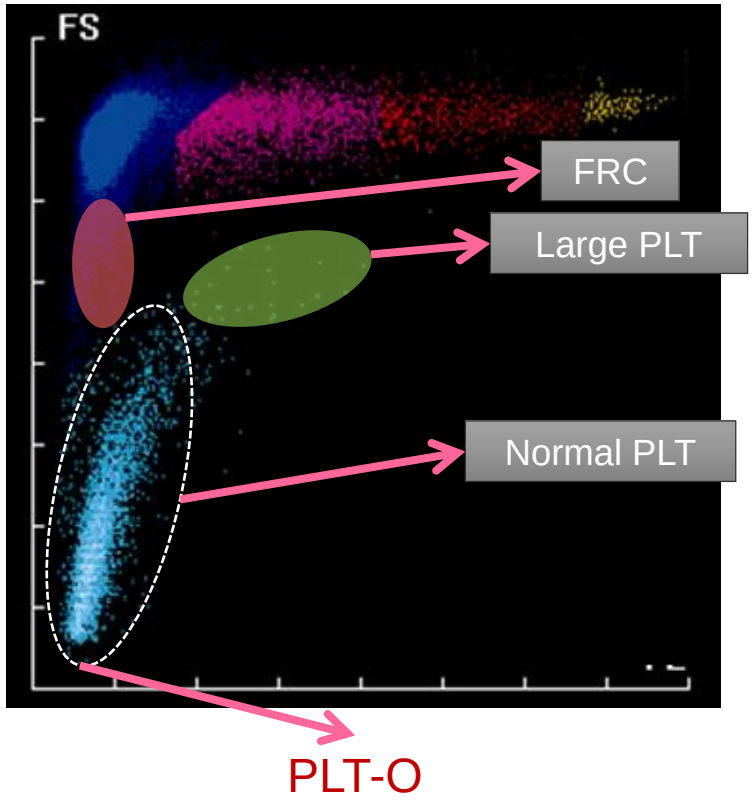


- 【**Left threshold**】: the L threshold moving range is between 0-2 fL to find the first particle of PLT
- 【**Right threshold**】: the R threshold will search for the lowest point between PLT and RBC peak within 15 ~ 32 fL

PLT-O parameter*

Optical + Fluorescence measurement

+ anti-clump technology



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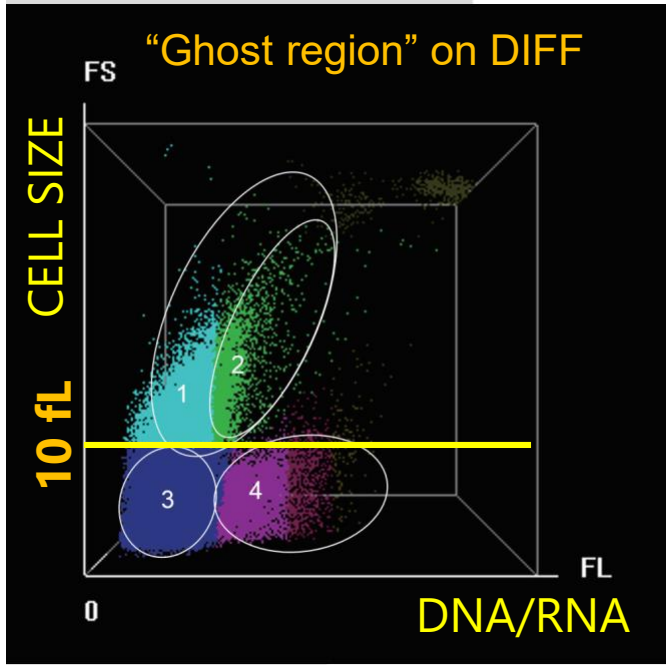
Common interference factors of PLT

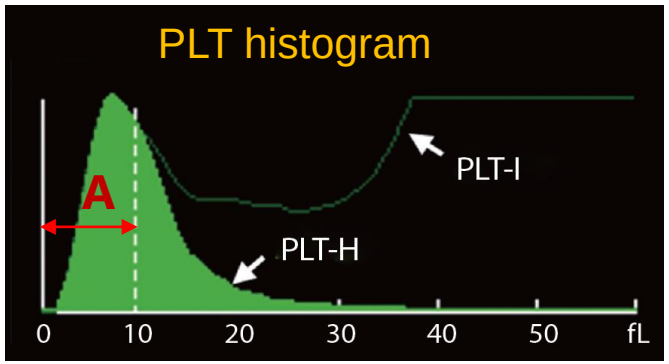
Which PLT channel can solve those interference?

Common interference substances		PLT-I	PLT-H	PLT-O
PLT reported Falsely low	PLT clump			√
	Large/giant PLT		√	√
PLT reported Falsely high	Microcytosis		√	√
	RBC fragment		√	√
	WBC fragment		√	√
	Cryoglobulin		?	√

- *PLT-O is most reliable results to report on the final report.*
- *However, still need combine with microscopic results*

False high PLT-H





Small PLT (A) ← PLT-H → Large PLT and IPF (1+2)

PLT-H can solve most RBC interference, how about other factor?

If PLT-H is falsely increased:

1. Interference in region 1 and 2 – Any particles, which character is similar as *large PLT and IPF* (size > 10fL)
   - Non-lysing RBC/fragment of RBC, nucleated cell
   - Bacteria/fungi/Cryoglobulin/lipid/ disease (leukemia, lymphoma..)
   - Foreign subject (from tube, environment?)
2. Machine reading problem

False high PLT-H root cause

R&D analysis and solution:

1. No problem of machine reading for this sample
2. The root cause could be interference but cannot identify which type of interference is
3. Upcoming plan for software update

Solution

Short-term action: set the re-exam rule

1. Set system flag rule to exclude abnormal sample check, system error.. (aspiration abnormal/clot…)
2. Panic value check rule for parameter with value is out of clinical range: e.g. PLT < 50 or PLT > 500-600 (*10^9/L)
3. Set Parameter/Flag check: out of reference range + self-definitive flag + suspected flag: e.g, RBC+PLT related flag and low/high count
4. Set range delta check to exclude pre-analytical error…

⇒ Re-exam mode for PLT: Smear, run on CDR/CR mode

⇒ Or PLT-H abnormal histogram: check sample by decision

⇒ ([PLT-H]-[PLT-I])/[PLT-H]>30%, could automatic reflux PLT-O

Long-term action: HQ further investigation

Collect the INF file, log file of normal sample and abnormal sample and send to HQ for analysis for **software upgrade**

Test panel	Report PLT result	
CD	PLT-H	Original logic

Test panel	Report PLT result	
CD	PLT-H PLT-I when “PLT-H histogram abnormal”	Upgrade logic

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Summary:

Abnormal PLT-H result

Algorithm or non-Algorithm cause?

Check the pre-analytical phase: Tube, whole blood collection procedure…to remove the external interference factor

Review result, graph, flags, imess, smear image…to see the abnormality

Check the patient clinical record to see if any treatment, disease that can affect to PLT-H

Setup the re-exam rule

Collect the INF file, log file for R&D further analysis and improvement

Multiple channel parameter: result difference

Single sample

Confirm which channel report the correct parameter (re-exam, smear, hemocytometer, flowcytometry)

Analysis the result, graph, flags, patient information, pre-analytical error, collect the INF file

Re-exam rule set-up

Report to HQ

Batch sample

Operation: SOP, people

Machine: Calibration Software hardware

Environment: Temperature humidity Electromagnetic

Materials: Reagent, consumables

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Thanks!

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