Comprehensive Solution for Platelet Count

To address these platelet counting issues, other hematology analyzer manufacturers in the industry have yet to integrate solutions into a single instrument, namely, solutions to abnormally low count (with a low cost + precise measurement), platelet clumps, and interferences are not integrated. Dymind's DH-800CS Series Auto Hematology Analyzer tackles each of these challenges with a 'comprehensive solution for platelet count,' realizing a full-process, all-around, fully automatic, and efficient solution to various platelet counting challenges, greatly enhancing the operational efficiency of laboratory personnel and providing accurate and reliable platelet counts for both laboratory and clinical use (Figure 1).

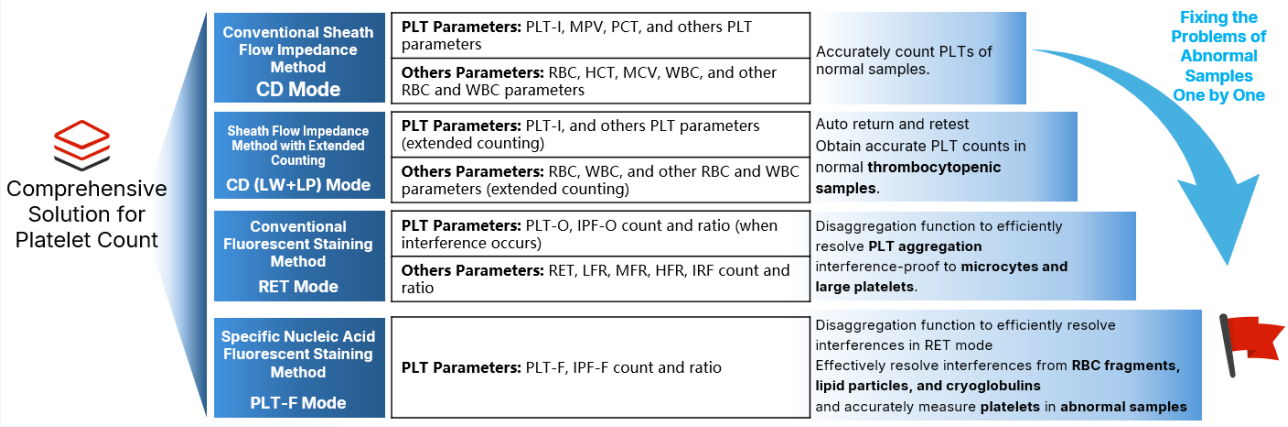


Figure 1 Comprehensive Solution for Platelet Count

Usage Guidelines

The collected samples should be tested under the instrument's default mode 'routine CD' (i.e., CBC+DIFF mode), and thereafter, the instrument report the detection results of

white blood cell count, red blood cell count, and platelet count, along with abnormality/suspect flags.

If the detection results are all within the reference range and there are no abnormality/suspect flags, then they are automatically auto-validated, and a laboratory report can be issued. If the detection results are abnormal or the instrument displays abnormality/suspect flags (Figure 2), the instrument can intelligently determine whether the specimen has abnormalities such as thrombocytopenic, platelet clumps, large platelets, microcytes, and red blood cell fragments. For abnormalities, the instrument can automatically add other modes according to the rules and retest the samples:

1. When both PLT and WBC counts are below the low threshold (customizable), or one of them is, the instrument automatically triggers the CD (LP+LW) mode for retesting, which then precisely measures low WBC or PLT counts.
2. If detection results show abnormal trends (such as PLT↓+PLT histogram low on the left and jagged on the right, PLT↓+ Elevated end of PLT histogram, PLT↑+MCV↓+ No RDW-SD value, and PLT↑+ Elevated end of PLT histogram) and display abnormality/suspect flags, the instrument automatically starts the CDR or CD+PLT-F mode for retesting according to the retesting rules, correcting platelet counts (Figure 3).
3. If after retesting with an additional mode, the detection results are still abnormal (such as when the interference is bacteria/fungi), the instrument will provide a suggestion for the next step of inspection. Laboratory personnel can follow this suggestion to obtain accurate detection results.

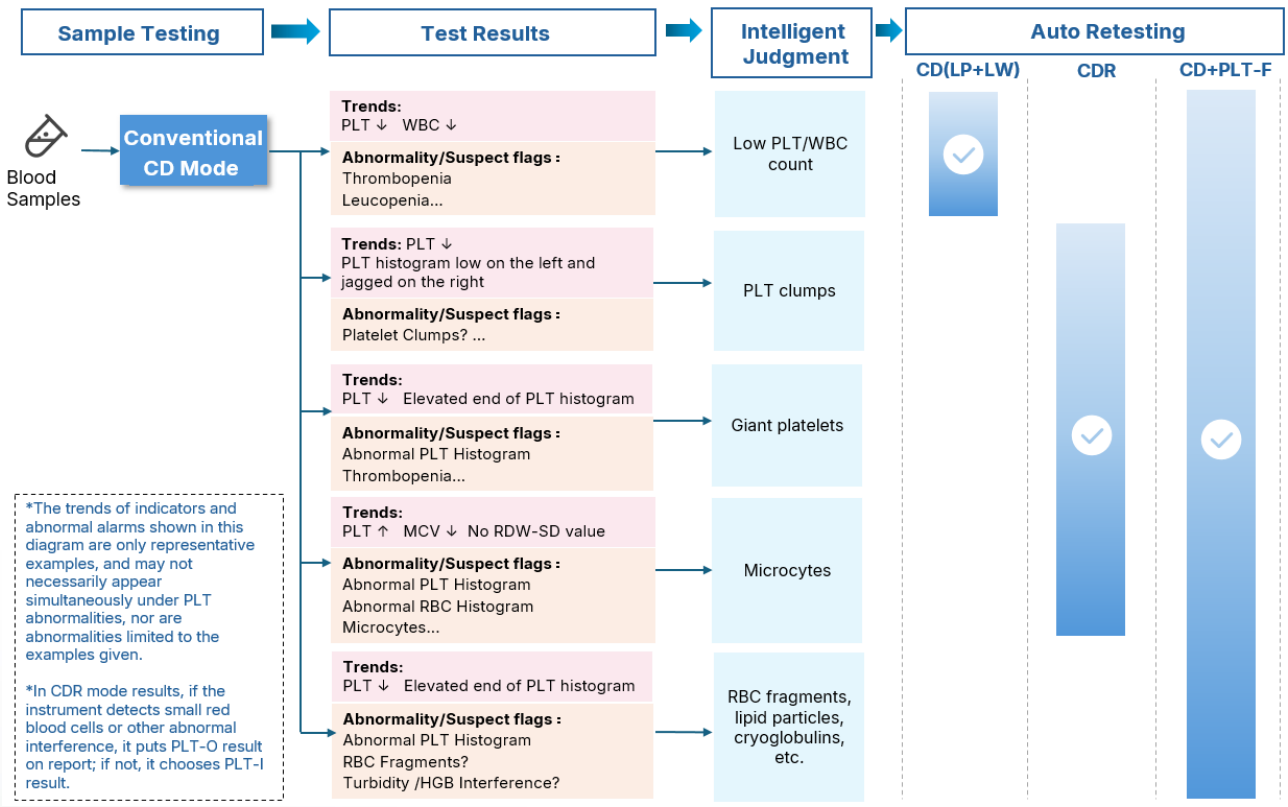


Figure 2 Usage Guidelines

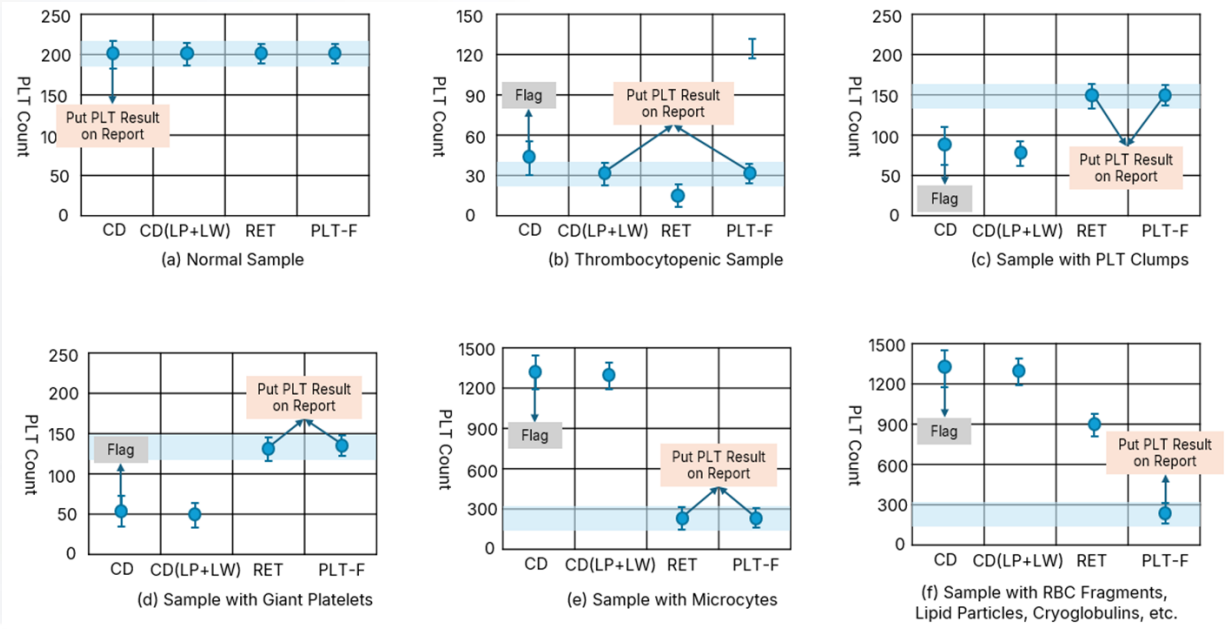


Figure 3 Parameter Reporting Rules

Note: The dot plot shows the platelet counts and error ranges for each type of sample in each mode, with the blue shaded bar representing the final parameters on report.
(a) For normal samples, accurate platelet counts can be obtained in all modes.

(b) The CD mode detection results for thrombocytopenic samples are only used for flags, and the subsequent CD (LW+LP) and PLT-F detection results for platelets are the final parameters on report.
(c), (d), and (e) The CD mode detection results for samples with platelet aggregation, large platelets, and microcyte interferences are only used for flags, and the subsequent RET and PLT-F detection results for platelets are the final parameters on report.
(f) The CD mode detection results for samples with interferences such as those with red blood cell fragments are only used for flags, and the subsequent PLT-F detection results for platelets are the final parameters on report.
Note that as long as the PLT-F channel is activated, the PLT-F detection results for platelets are considered the parameters on report by default.

Experiments and Evaluation

Precision of PLT-F Method in Thrombocytopenic Samples

Five fresh anticoagulated whole blood samples with PLT<70×109/L were selected and tested 10 times consecutively under the CBC+DIFF+PLT-F mode. The coefficient of variation was calculated to compare the precision differences between the impedance method (PLT-I) and the specific nucleic acid fluorescent staining method (PLT-F) for counting thrombocytopenic samples. The detection results are shown in Table 1.

Table 1 Precisions of Conventional PLT-I Method vs. PLT-F Method in Counting Thrombocytopenic Samples (Unit: 10^9/L)

No./Statistics	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	PLT-I	PLT-F	PLT-I	PLT-F	PLT-I	PLT-F	PLT-I	PLT-F	PLT-I	PLT-F
1	9	12	24	16	30	32	46	30	56	70
2	7	12	23	15	28	33	46	31	59	71
3	7	12	25	15	32	32	45	31	53	70
4	7	12	23	15	28	32	45	30	51	71
5	7	13	25	14	29	32	43	30	58	67
6	7	12	24	15	29	32	43	30	56	70
7	9	13	26	15	32	31	43	30	59	69

No./Statistics	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	PLT-I	PLT-F	PLT-I	PLT-F	PLT-I	PLT-F	PLT-I	PLT-F	PLT-I	PLT-F
8	7	12	25	15	31	31	42	30	56	67
9	5	12	25	15	31	32	41	30	56	65
10	7	12	24	15	31	30	46	30	54	64
Mean	**7.2**	**12.2**	**24.4**	**15.0**	**30.1**	**31.7**	**44.0**	**30.2**	**55.8**	**68.4**
SD	**1.07**	**0.400**	**0.917**	**0.447**	**1.446**	**0.781**	**1.732**	**0.400**	**2.441**	**2.375**
CV	**15.8 %**	**3.5%**	**4.0%**	**3.1%**	**5.1%**	**2.6%**	**4.1%**	**1.4%**	**4.6%**	**3.7%**

From the above results, it can be seen that for thrombocytopenic samples, the precision of PLT-F method is clearly higher than that of PLT-I.

Correlation of PLT Counts in Thrombocytopenic Samples

Collected from a hospital, 87 fresh anti-coagulated venous whole blood samples with PLT<100×109/L were tested with DH-800CS and an analyzer of another manufacturer on the conventional PLT-I and PLT-F channels (Table 2). The correlations between the PLT-I result of DH-800CS, the PLT-F result of DH-800CS, and the other analyzer's PLT-F result were calculated respectively (Figure).

Table 2 Results of PLT-I vs. PLT-F in Counting Thrombocytopenic Samples

Statistics	**DH-800CS**		**Other Analyzer**
	PLT-I	PLT-F	PLT-F
Mean ± SD (109/L)	46.42±25.33	48.78±25.93	48.38±26.12
Mean Deviation	4.0%	0.8%	/

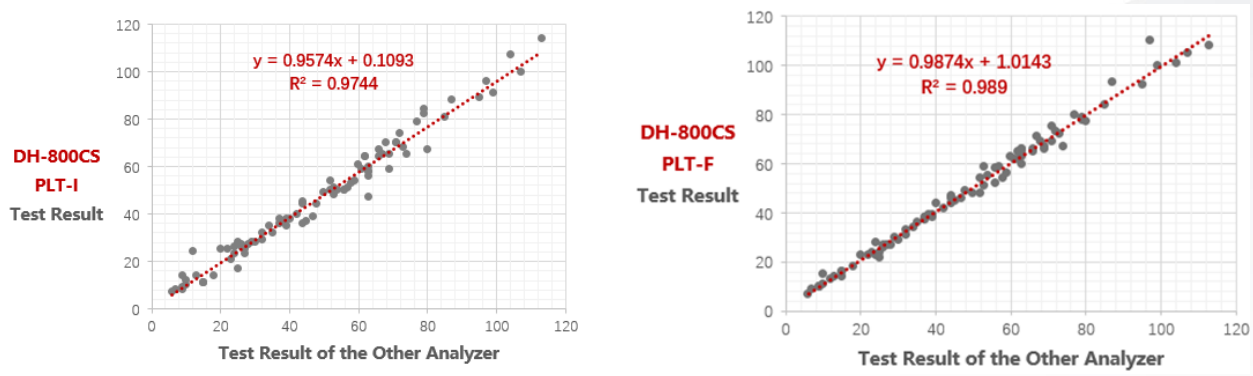


Figure 4 Correlations Between PLT Counts Obtained from DH-800CS and Other Analyzer

For DH-800CS's sheath flow impedance method and specific nucleic acid fluorescent staining method to count thrombocytopenic samples, the results correlate well with the one obtained from the PLT-F channel on the other analyzer.

Clinical Cases

Case One: Thrombocytopenic Samples

This case is from a physical examination specimen.

The test results indicated thrombocytopenia. According to the retesting rules, the PLT-F measurement was automatically triggered for retesting. The results are shown in Figure 5: The PLT-F count was as low as 19×109/L; abnormality/suspect flags indicated Abnormal PLT Histogram and Thrombopenia.

Additionally, a blood smear was prepared and observed under the microscope (platelets are rarely observed, as shown in Figure 6). The PLT result estimated for the smear was

consistent with the result of PLT-F channel, confirming the reliability of the latter. Based on the result of PLT-F channel, a report was issued with a note stating “Platelets are rarely observed under microscope. This is a corrected result from the PLT-F channel”.

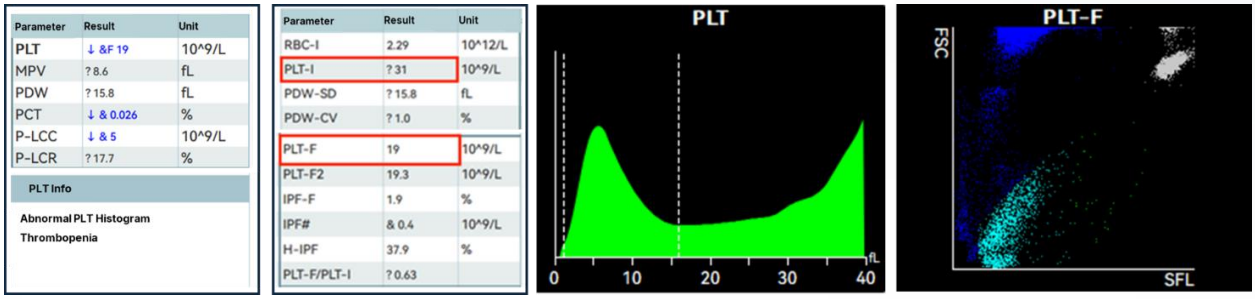


Figure 5 Detection Result of CD+PLT-F Mode

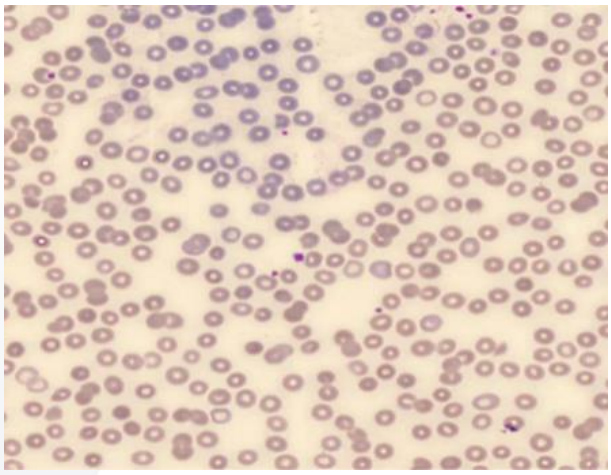


Figure 6 Microscopic Examination Result of Blood Smear

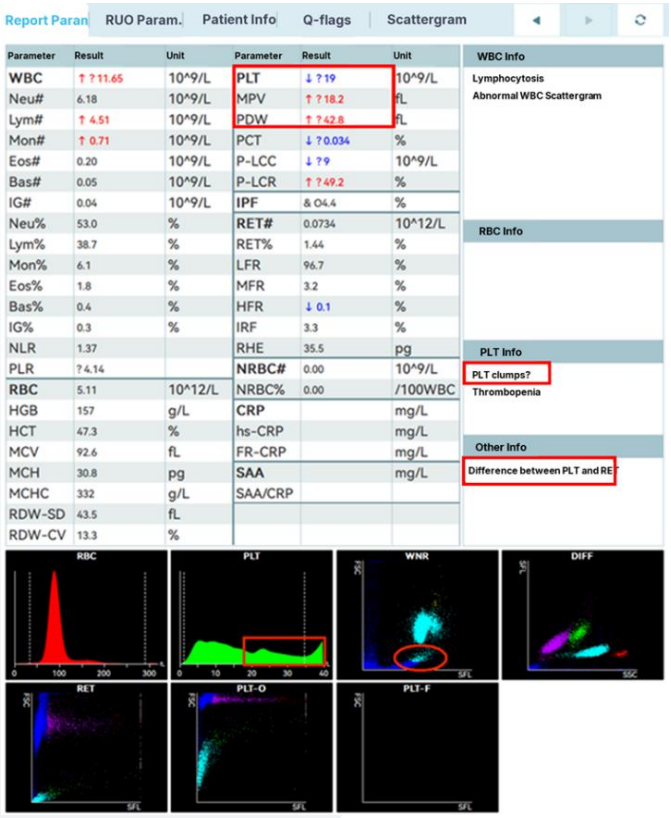
Case Two: Platelet Disaggregation

- **Clinical information**

Male, 48 years old, presented with pain in both knee joints, with a preliminary clinical diagnosis of 1) arthritis; 2) meniscus injury.

- **Test Results**

Parameters



Parameter	Result	Unit	Parameter	Result	Unit
WBC	↑ ? 11.65	10^9/L	PLT	↓ ? 19	10^9/L
Neu#	6.18	10^9/L	MPV	↑ ? 18.2	fL
Lym#	↑ 4.51	10^9/L	PDW	↑ ? 42.8	fL
Mon#	↑ 0.71	10^9/L	PCT	↓ ? 0.034	%
Eos#	0.20	10^9/L	P-LCC	↓ ? 9	10^9/L
Bas#	0.05	10^9/L	P-LCR	↑ ? 49.2	%
IG#	0.04	10^9/L	IPF	& 04.4	%
Neu%	53.0	%	RET#	0.0734	10^12/L
Lym%	38.7	%	RET%	1.44	%
Mon%	6.1	%	LFR	96.7	%
Eos%	1.8	%	MFR	3.2	%
Bas%	0.4	%	HFR	↓ 0.1	%
IG%	0.3	%	IRF	3.3	%
NLR	1.37		RHE	35.5	pg
PLR	? 4.14		NRBC#	0.00	10^9/L
RBC	5.11	10^12/L	NRBC%	0.00	/100WBC
HGB	157	g/L	CRP		mg/L
HCT	47.3	%	hs-CRP		mg/L
MCV	92.6	fL	FR-CRP		mg/L
MCH	30.8	pg	SAA		mg/L
MCHC	332	g/L	SAA/CRP		
RDW-SD	43.5	fL			
RDW-CV	13.3	%			

Research Parameters

PLT-O	? 158	10^9/L
RBC-O	5.12	10^12/L
RBC-He	32.8	pg
Delta-He	2.7	pg
HGB-O	187	g/L
Delta-HGB	-30	g/L

- **Report Analysis**

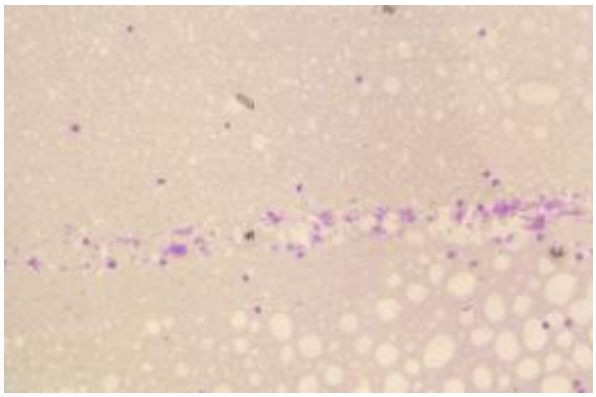
Results: Increased WBC, Lym# and Mon#; decreased PLT, increased MPV and PDW.

Graph Analysis: WBC information is suggestive of "Abnormal WBC Scattergram"; PLT information is suggestive of "PLT clumps?"; in the PLT histogram, the tail shows a wavy pattern, suggesting possible PLT clumps; abnormal scatter points appear below the WBC

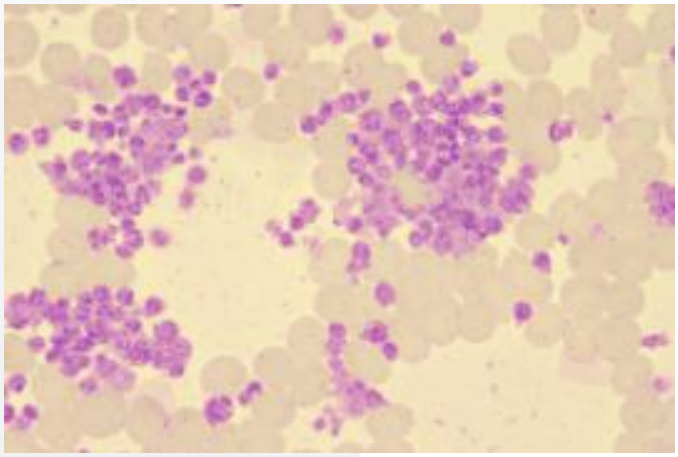
region in the WNR scattergram, suspecting possible PLT clumps. Other information is suggestive of "Difference between PLT and RET."

Blood Smear Microscopic Exam

PLT clusters are clearly observed at the edge of the blood smear.



10x10 magnification (under low power lens)



10x100 magnification (under oil-immersion lens)

- **Summary**

Based on the instrumental test results and graphical characteristics, combined with microscopic examination results, the PLT count of the estimation method (average number of platelets at the tail junction of blood smears under the oil immersion lens in 10 fields

×15×109/L) is 125×109/L. When ratio of the impedance channel PLT-I and the RET channel PLT-O is ≥2, it shows a notification of "channel difference between PLT and RET", which should draw clinical attention and must be confirmed in conjunction with microscopic examination. As platelet aggregation samples can cause falsely low PLT results when tested by impedance method, which is also the most common influencing factor in clinical practice, it is possible to retest by adding the test of PLT-O in the RET channel. The reagent used in the RET channel contains disaggregating substances, which have the capability to disaggregate PLT clumps and can specifically stain PLTs, effectively eliminating the interference caused by platelet clumps. Therefore, it provides reliable test results for platelet clump samples (reversible) for clinical use.

Case Three: Resistance to RBC Fragment Interference

- **Clinical information**

Female, 55 years old, admitted to the hospital for liver cirrhosis and gastrointestinal bleeding.

DYMIND

- **Test Results**

Report Paran | RUO Param. | Patient Info | Q-flags | Scattergram

Parameter	Result	Unit	Parameter	Result	Unit
WBC	↑ 11.39	10^9/L	PLT	& 0148	10^9/L
Neu#	↑ ? 9.99	10^9/L	MPV	↑ 12.6	fL
Lym#	↓ 0.57	10^9/L	PDW	15.9	fL
Mon#	↑ ? 0.79	10^9/L	PCT	& 0.203	%
Eos#	↓ 0.01	10^9/L	P-LCC	& 60	10^9/L
Bas#	0.03	10^9/L	P-LCR	37.5	%
IG#	? 0.60	10^9/L	IPF	& 05.2	%
Neu%	↑ ? 87.7	%	RET#	0.0375	10^12/L
Lym%	↓ 5.0	%	RET%	1.19	%
Mon%	? 6.9	%	LFR	89.1	%
Eos%	↓ 0.1	%	MFR	6.6	%
Bas%	0.3	%	HFR	4.3	%
IG%	? 5.2	%	IRF	10.9	%
NLR	? 17.53		RHE	29.5	pg
PLR	& 282.44		NRBC#	0.00	10^9/L
RBC	↓ 3.16	10^12/L	NRBC%	0.00	/100WBC
HGB	↓ 85	g/L	CRP		mg/L
HCT	↓ 26.8	%	hs-CRP		mg/L
MCV	84.6	fL	FR-CRP		mg/L
MCH	27.0	pg	SAA		mg/L
MCHC	319	g/L	SAA/CRP		
RDW-SD	↑ 60.7	fL			
RDW-CV	↑ 20.2	%			

WBC Info

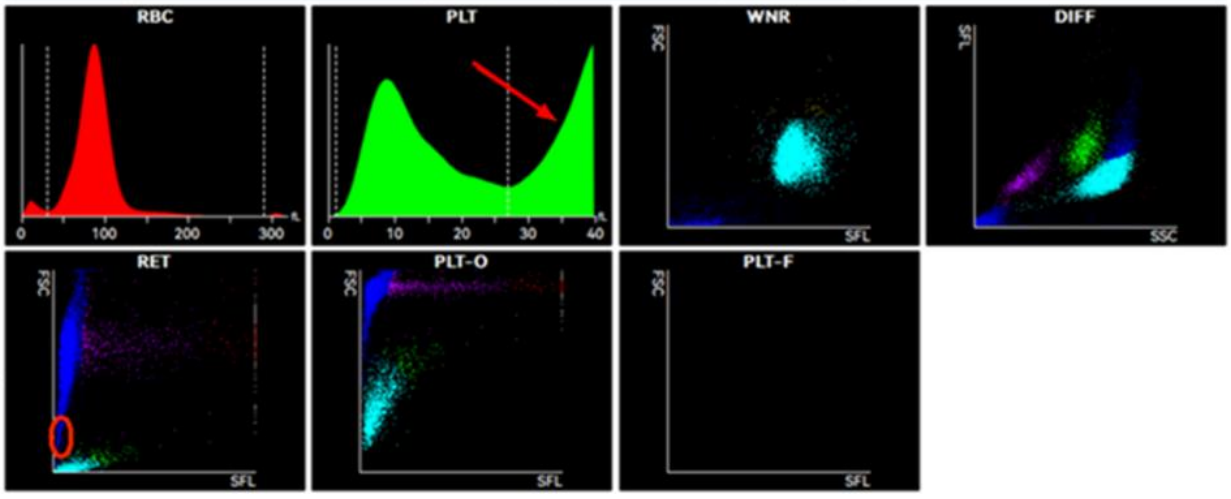
Left shift?
Immature granulocytes?
Lymphopenia

RBC Info

RBC Fragments?
Anemia

PLT Info

Other Info



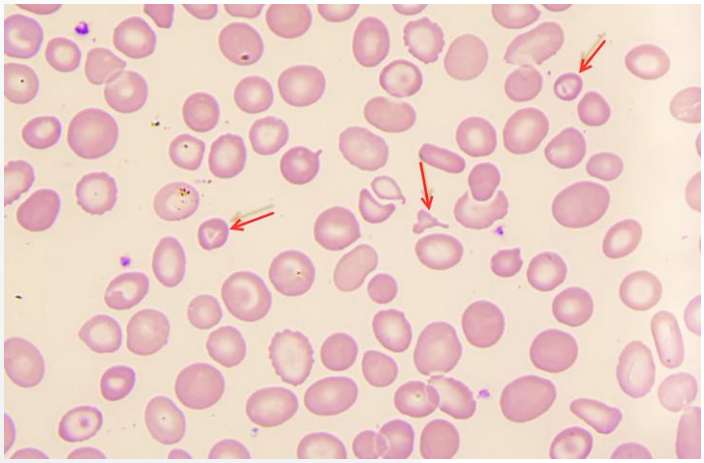
- **Report Analysis**

Results: Mildly increased WBC, Neu# and Mon#, and elevated Neu%; reduced RBC and Lym#, and increased RDW.

Graph Analysis: WBC information is suggestive of "immature granulocytes? " and "left shift? "; RBC information is suggestive of "RBC fragments? " and "anemia". The upward tailing of the PLT histogram indicates the presence of small RBCs or RBC fragments; the centroid of the RBC region shifts downward in the RET scattergram.

Blood Smear Microscopic Exam

Schistocytes are observed under the microscope.



- **Summary**

Based on the results of the instrumental test results and graphical characteristics, combined with microscopic examination results and clinical information, it indicates that the PLT-I result is affected by RBC fragments (fRBC is 2.16%), which causes a falsely increase. Solution: The following step is retesting the sample by optical method (PLT-O) in the RET channel to eliminate the interference of RBC fragments. PLT count results for this case: PLT-I is 161×109/L and PLT-O is 148×109/L. The optical channel result is reported.

Summary

Dymind's DH-800CS Series Auto Hematology Analyzer incorporates advanced technologies such as sheath flow impedance CD (LW+LP) mode, RET method and the PLT-F method with disaggregating function, offering solutions for platelet counting challenges posed by thrombocytopenic samples, platelet aggregation, small RBCs, RBC fragments, large platelets, and other interferences. Based on this, the analyzer integrates intelligent automatic retesting rules to achieve a fully automated operation throughout the entire process, from sample processing, testing, data analysis, to automatic retesting and result reporting. Not only has it significantly improved the efficiency of testing, but through precise algorithms and calibration, it also ensures the precision and accuracy of platelet

counts.

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