ESR Comparison Case

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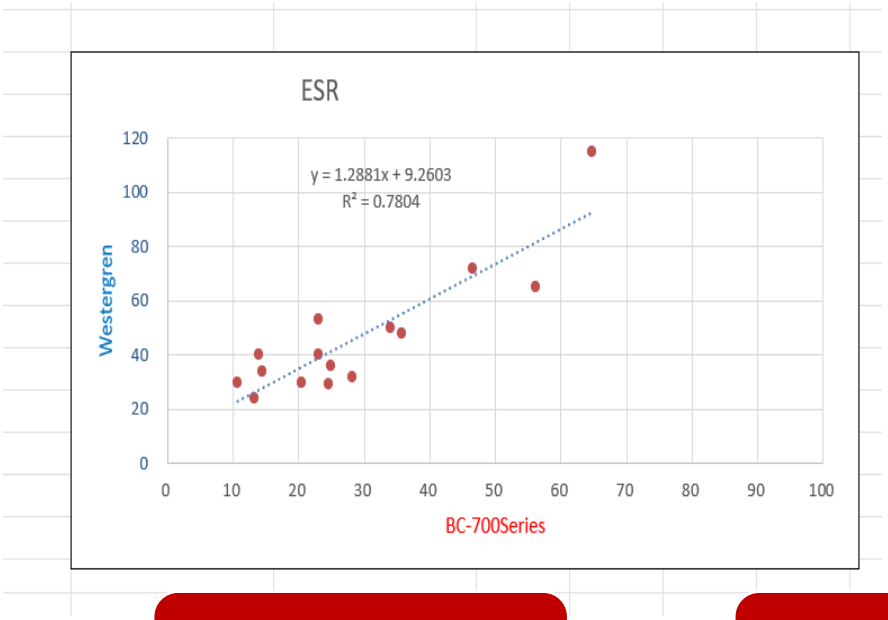
Case Background

- **Equipment: BC-720**
- **Case :**The variation of ESR results between our device and Westergren method
- **Customer Requirement**
  - Performance study for BC-720
  - Solve the problem of variation

Results sent

BC-720 version .
ESR Calibration Interface
No QC
Result of comparison (By customer)



Parameter	ESR		SD	Mean	cv
	Westergren	BC-700Series			
	34	14.39	13.87	24.20	57.3108658
	40	23.12	11.94	31.56	37.8199064
	115	64.8	35.50	89.90	39.4847168
	53	23.12	21.13	38.06	55.5132702
	72	46.59	17.97	59.30	30.3020209
	32	28.2	2.69	30.10	8.92692946
	24	13.17	7.66	18.59	41.2050925
	29	24.59	3.12	26.80	11.6377716
	65	56.22	6.21	60.61	10.2431901
	30	10.7	13.65	20.35	67.0622156
	40	13.97	18.41	26.99	68.208225
	36	24.99	7.79	30.50	25.5295808
	50	33.97	11.33	41.99	26.9975508
	48	35.68	8.71	41.84	20.8211175
	30	20.55	6.68	25.28	26.4378203
		Conclusion	Fail		
r	0.8834				

15 Samples (Not Enough) → More than 10% deviation → Correlation Coefficient (r) not meet claimed requirement, r=>0.9

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Case Ideas

Check preanalytical stage
-Westergren Method
-Sample tube conditions

Check analytical stage
-Calibration
-QC
-Operation

Perform additional investigation:
-Review the customer procedure（on site）
- Run samples according to ESR correlation protocol

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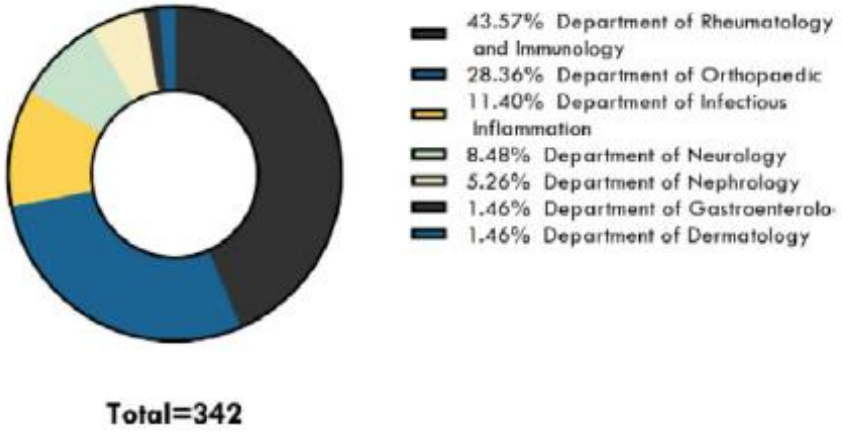
BC-700 Series ESR Performance

1)Customer Requirement

Aa Sample distribution of all departments



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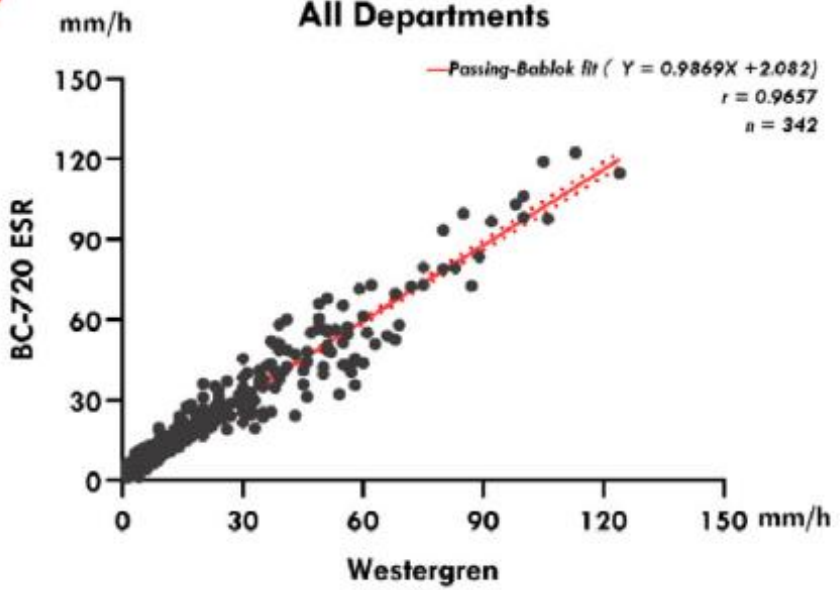

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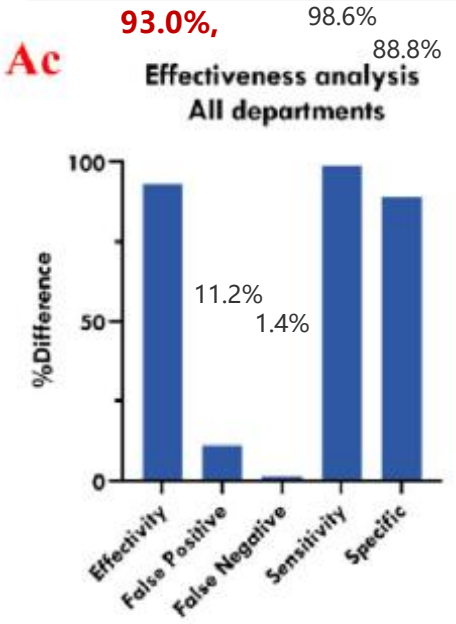


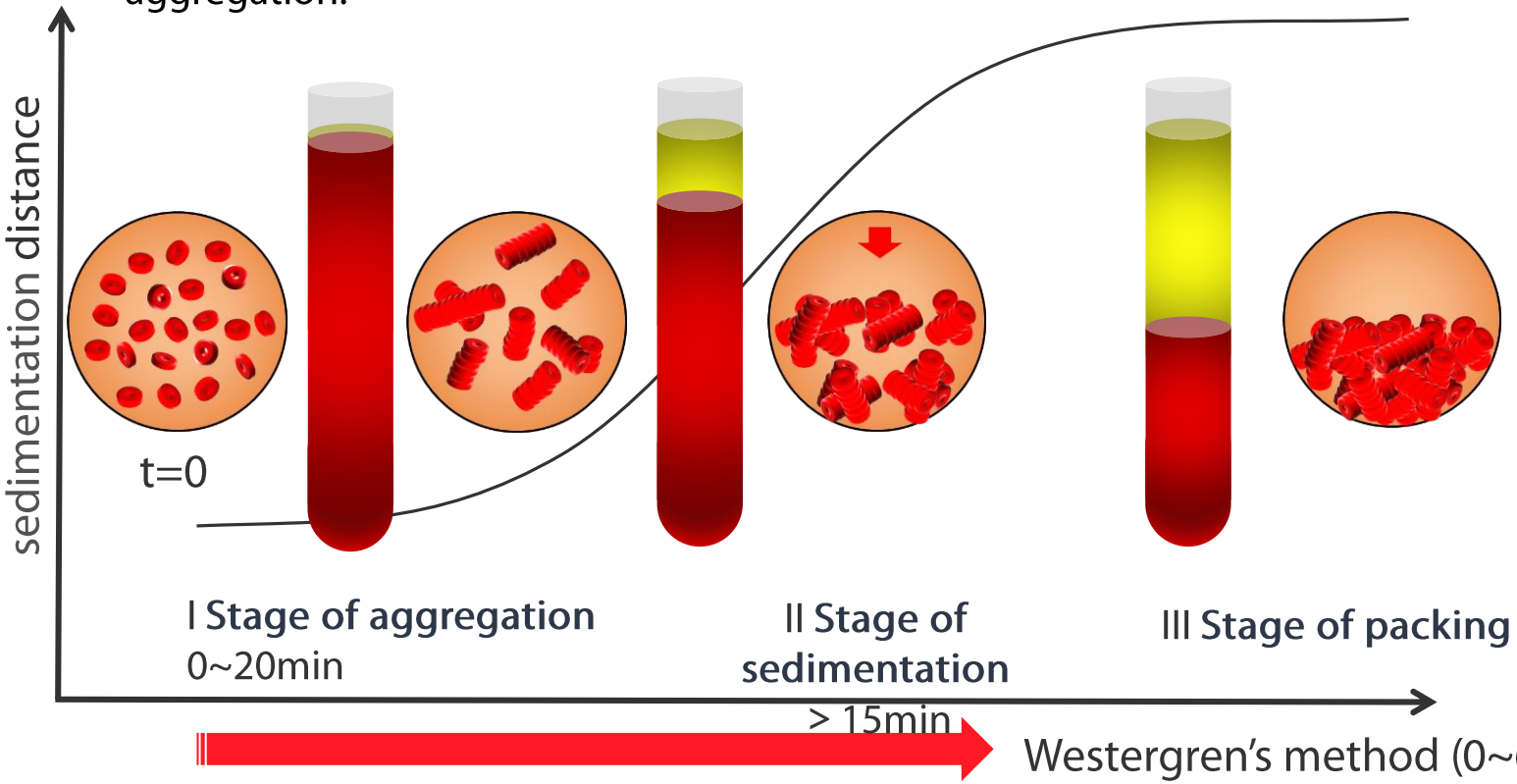
- A total of 342 patient blood samples were collected. The BC-720 results for samples from various departments all **correlated well** with those derived by the Westergren method with Y = 2.082 + 0.9869X, r=0.9657
- The effectiveness, false-positive rate, false-negative rate, sensitivity, and specificity of the BC-720 hematology analyzer compared with the Westergren method were **93.0%**, 11.2%, 1.4%, 98.6%, and 88.8%, respectively.

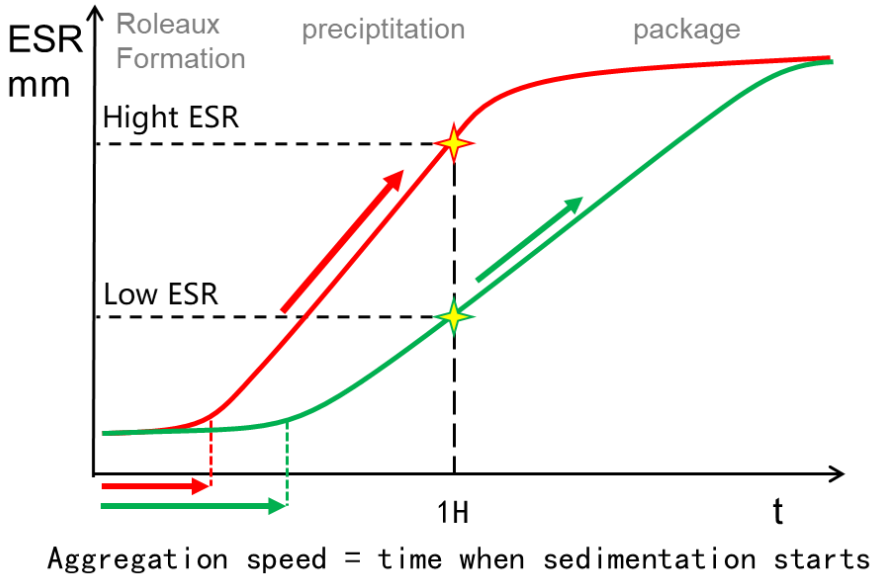
Source: * Clinical application of a new method for determination of the erythrocyte sedimentation rate using the BC-720 automated hematology analyzer

What is ESR?

Principle of Easy-W ESR:

Erythrocyte aggregation determines the process of erythrocyte sedimentation, and ESR can be predicted by measuring aggregation.





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Preanalytical stage

Sample

1-Fresh EDTA-K_2 anticoagulated venous whole blood samples remaining after completion of routine hospital testing.
2- A sample volume of not less than 2.0 ml and no more than 4 hours in sample collection time.
3-Commonly interfering samples of obvious hemolysis, coagulation and lipemia.

Westergren method

1) **Blood sedimentation tube.**
a- Colorless round in appearance.
b -Having a sufficient length, at least 200 mm erythrocyte settling distance.
c-Blood sedimentation tubes shall have a clear scale of 1 to 200 mm.
d-Blood sedimentation tube diameter of not less than 2.55 mm (no upper limit, but minimum blood consumption should be considered).

2) Blood sedimentation frame.

A-The need to keep the tube in a vertical position throughout the measurement.

B-The construction of the frame must ensure that no blood leakage occurs from the tube.

Analytical stage

- **BC-720**
  Visit the customer with CS
- Review the device status and and Westergren method
- ESR Calibration (Fresh Samples) , New Calibration factor
- Sufficient blood collection from blood collection tubes and mixing of blood

Westergren method

Influencing Factors of Westergren Method

A-ETDA anticoagulant (negligible effect) and Sodium citrate 1:4 dilution.

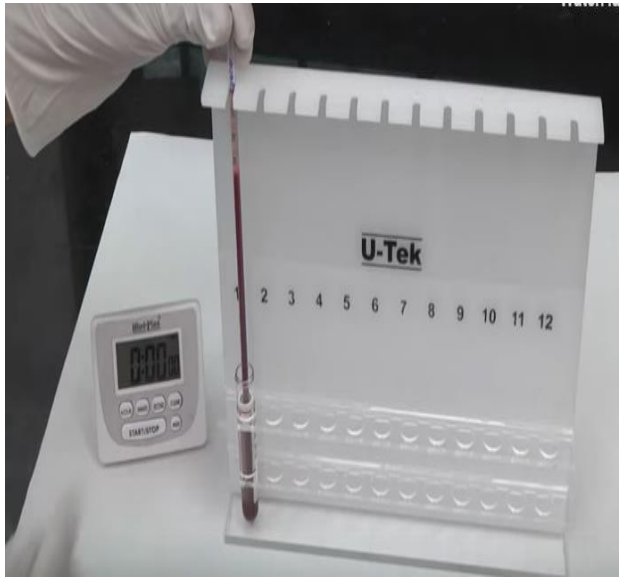
Insufficient blood collection from blood collection tubes; uneven mixing of blood and diluent.

B-Sample storage is required to start the test within 4 h (RT).Refrigerated storage for 24 h.

C-guaranteed in the temperature range of 18 to 25° C and maintained at a constant temperature (±1° C).

D-Ensuring that the table is stable and free from vibration.

E-Ensure that the hematocrit tube is in a vertical position, as even a 2° deviation can have an impact on the results.



Analytical stage

Correlation analysis protocol between BC-700 series ESR and Westergren method

Protocol

1. Followed by the ICSH 2017 User ESR Evaluation Guidelines, selected at least 30 fresh whole blood samples (EDTA anticoagulant samples) from the below table;
2. Tested them under CD/CD+ESR mode;
3. Took the Westergren ESR result as the reference method result;
4. Calculate the correlation.

Parameter	Scale	Quantity
ESR	0 - 30 mm/h	≥10
	30 - 60 mm/h	≥10
	60 - 90 mm/h	≥8
	90 - 140 mm/h	≥2

Evaluation Program

Acceptance criterion

Parameter	Correlation coefficient - r
ESR	≥ 0.90

Template

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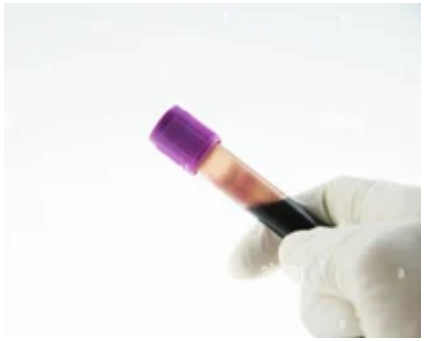
Notes (on site)

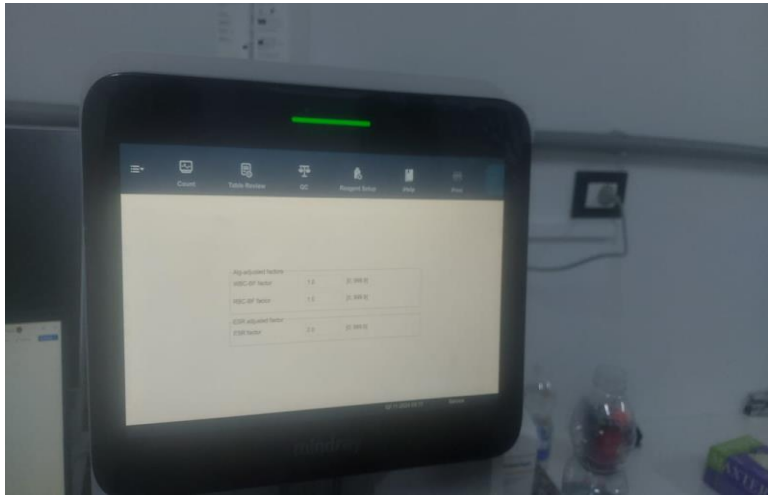
Review the customer procedure of ESR sampling Westergren Method and BC_720

1- **Vibration** beside the Westergren tube

2- Collection of blood using intravenous blood collection tubes containing sodium citrate (4:1) then run sample on BC-720 (sample volume **less than 2.0 ml**



- Run samples (Deviation >10%)
- 1)ESR Calibration (Fresh Samples)
- New Calibration factor
- Run the same samples (Good comparison)



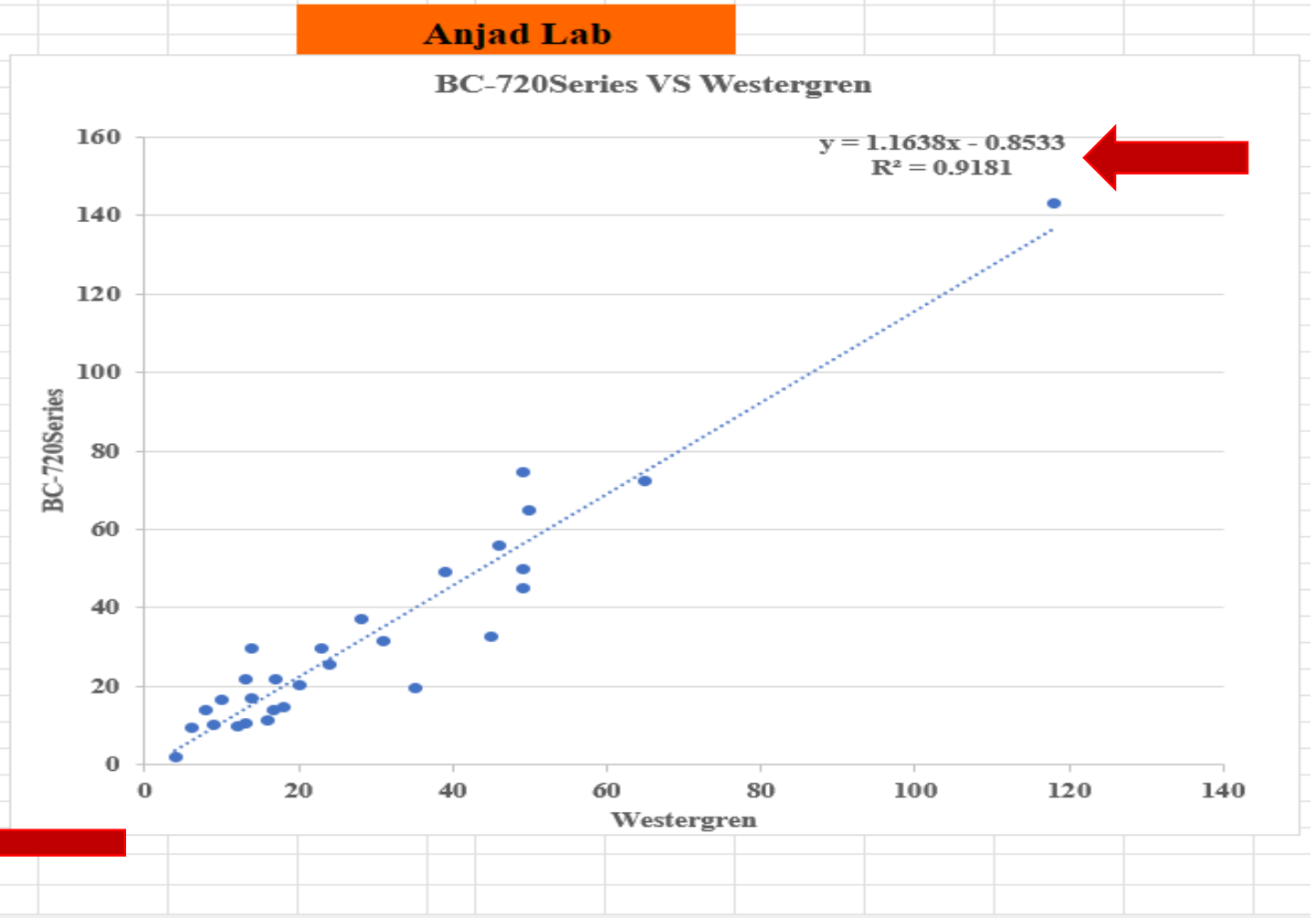
Ask the customer to follow Westergren method requirements and run samples (compare)

Solution:

- The customer sent the sample results (available)
- r>0.9

The customer satisfied

sample	Instrument method	Reference method
	BC-720Series	Westergren
4526	9.47	6
4523	65	50
4525	19.6	35
4329	13.89	8
4529	10.74	13
4536	49.07	39
4537	29.57	14
4550	9.97	12
4544	21.8	13
4543	31.71	31
4555	50	49
4576	2	4
13	11.45	16
4573	143	118
4497	45	49
4652	16.83	14
4579	10.3	9
4588	16.52	10
4652	14	16.83
4594	29.7	23
4599	20.18	20
4603	72.39	65
4651	25.5	24
4621	21.74	17
4623	37.32	28
4624	32.84	45
4625	14.9	18
4626	56	46
4631	74.5	49
4635	31.45	38
Correlation coefficient	0.955	
Judgment Criteria≥	0.90	
Conclusion	Pass	



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Case Summary

In conclusion:

- The Westergren method is the only reference method for ESR.
- For Correlation study (ESR) , follow the protocol
- Pay attention to Influencing Factors of Westergren Method

B.20.2 ESR Tests

Erythrocyte sedimentation rate (ESR) is not only a non-specific inflammation index, but also one of indicators of erythrocyte aggregation. The analyzer measures the erythrocyte sedimentation rate by detecting the signals from erythrocyte aggregation process. However, the analyzer has limitations when analyzing the following samples:

1. Samples from patients with plasma cell diseases (e.g., multiple myeloma). In these samples, the erythrocytes may have already accumulated to rouleaux formation; therefore the analyzer may not be able to detect the process of erythrocyte aggregation, and may produce wrong results. The analyzer will give an alarm and may shield the results. To ensure accurate ESR results of these samples, it is recommended to use the traditional Westphal method to measure such samples.
2. Samples in which red blood cell agglutination has occurred (e.g., patient's blood containing cold agglutinin, and red blood cells aggregates in vitro cold environment). For such samples, the analyzer may not be able to detect the process of erythrocyte aggregation, and may produce wrong results. The analyzer will give an alarm and may shield the results. To ensure accurate ESR results of these samples, it is recommended to use the traditional Westphal method to measure such samples.
3. Other samples that may have rouleaux formation, blood coagulation, and abnormal erythrocyte morphology. The analyzer may give wrong results. Doctors should report based on the comprehensive judgment taking in consideration of analyzer-provided flags and prompts, as well as other clinical information of the patients.

Thanks!

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