

**VERIFICATION REPORT ON THE ABSTRACT REVISION
OF THE PHD THESIS**

- **Research Title:** Research on the Stability of Human Red Blood Cell, Simulated White Blood Cell and Platelet Count in the Quality Control of Hematology Tests
- Field of Study: Biotechnology
- Code: 9420201
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CONTENT:

The objectives of thesis:

- The production of hematological reference samples, which measure the number of red blood cells, white blood cells, and platelets, helps laboratories proactively secure a sample supply.

Contribution of this thesis:

- Preservation solution for human red blood cells, pseudo-leucocytes from goose blood, and pseudo-platelets from goat blood has homogeneity and stability for 100 days. The results of the red blood cells durability survey showed that fixed red blood cells exhibited higher durability compared to unfixed cells.
- Screening results by Plackett-Burman matrix showed that serum, neomycin sulfate, and glycerol were the three most influential factors on the number of red blood cells, white blood cells, and platelets. These three factors were subsequently optimized by RSM-CCD method at 3 levels of red blood cells, white blood cells, and platelets. At normal concentrations the optimal values of serum, neomycin sulfate and glycerol are 45,00 %; 0,30 g/l; 3,00%, respectively. At low concentrations, the optimal serum values of neomycin sulfate and

glycerol are 45,00 %; 0,30 g/l; 3,00%, respectively. At high concentrations the optimal serum values of neomycin sulfate and glycerol are 45,00 %; 1,00 g/l; 1,00%, respectively. After optimization, the experimental model exhibited excellent agreement with theoretical predictions, exceeding 95% concordance across all three concentration levels. The optimized samples demonstrated high homogeneity and stability, with a shelf life of 95 days for normal concentrations and 100 days for both low and high concentrations when stored at 2-8°C under both laboratory and shipping conditions. The morphology of the hematological specimens closely resembled that of commercial human blood cells.

- Defined assigned values of hematological reference samples on five different hematology analyzers (ABX Micros 60, Abbott CD 1700, Mindray BC 3000, CD 3200, CD Ruby). The results showed good agreement between laboratories for the impedance-based analyzers (Celldyn 1700, ABX Micros 60, Mindray BC 3000) across different concentration levels. However, for the photometric analyzers (CD 3200, CD Ruby), while white blood cell and red blood cell counts were comparable, platelet counts showed significant variation.
- Hematological reference samples were employed in a 2022 pilot external quality assessment (EQA) program to assess laboratories grouped based on their specific methodologies and instrumentation for more targeted performance evaluation.
- Hematological reference samples demonstrated comparable performance to commercial controls in internal quality control, and can be used to detect errors during routine testing of laboratories.