

# **BMP** **LeukoChek™**

*Now available to replace  
BD Unopette™*

## Complete Test Kit for the Microscopic Counting of Leukocytes in Whole Blood

The **BMP LeukoChek™ Test Kit** for the microscopic counting of leukocytes and platelets in whole blood was developed to replace the discontinued Unopette from Becton, Dickinson and Company. Leukocyte and platelet count procedures are performed exactly the same as with the BD Unopette.

- Independently tested and confirmed to produce equivalent results to the discontinued BD Unopette
- Tested to CLIA guidelines
- Full Validation Study available
- Replaces BD Unopette numbers 365854/365855

Part Number	Description	Quantity
BMP-LUKCHK	Leukocyte Test Kit including reservoir and capillary assembly	100/pack



## Free Samples Available

For more information and/or Free LeukoChek samples e-mail: [sales@biomedicalpolymers.com](mailto:sales@biomedicalpolymers.com) or call 1-800/253-3684.



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# LeukoChek™ Validation Study–WBC & Platelets

The BMP LeukoChek is used to measure and dilute whole blood for manual counting of leukocytes (WBC) and platelets. A validation study was performed to compare WBC and platelet counts obtained with the LeukoChek and an automated hematology analyzer. Since automated hematology instruments are commonly used in clinical laboratories, the method comparison study used automation hematology counts as the reference method. Results were analyzed using existing performance limits for professional use according to CLIA regulations.

## Specifications

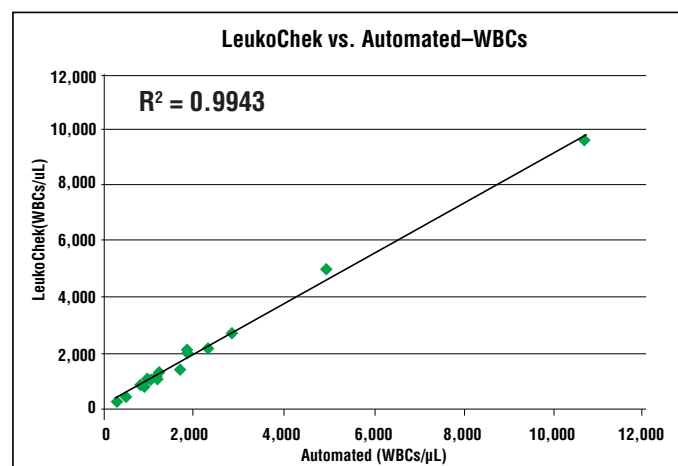
Method comparisons for clinical laboratory validation often use CLIA proficiency testing criteria in setting acceptance values. These values can be found in the Code of Federal Regulations (42 CFR Part 493). Listed acceptance criteria are 15% for WBCs and 25% for platelets. This means that the average of two manual readings on the hemocytometer must be within 15% of the average reading of the comparator method for WBC counts and within 25% for platelet counts for at least 95% of the test samples.

## Materials and Methods

Twenty-three (23) citrated whole blood samples collected for routine hematological testing were used for this study. Three samples were excluded from data analysis because they did not meet inclusion criteria, therefore a total of twenty (20) samples were included in the analysis. An attempt was made to include samples with low, normal, and high values for WBC and platelet counts.

Each sample was tested on a Sysmex XE 2100 automated hematology analyzer in duplicate and white blood cell (WBC) and platelet readings were recorded. Each sample was then prepared for testing using LeukoChek vials.

## Comparison and Index Plots for WBCs



## Calculations for WBC and Platelets

A WBC count is performed under 100x magnification. To obtain the number of WBCs per  $\mu\text{L}$ , all nine large squares of the hemocytometer counting chamber are used. An average of two raw counts is calculated and 10% is added to that number. The total number is then multiplied by 100.

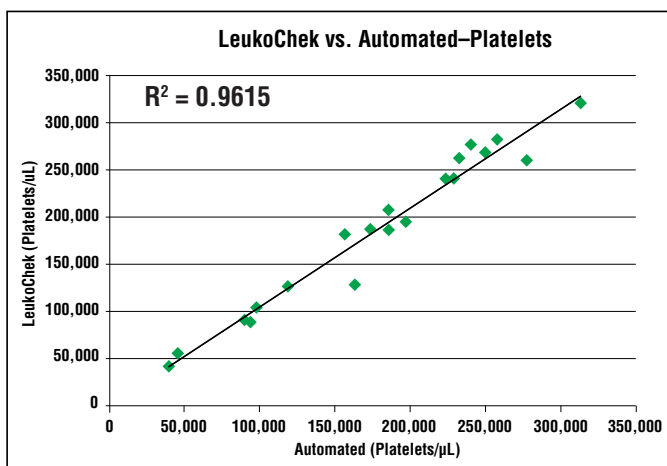
A platelet count is performed under 430x magnification. To obtain the number of platelets per  $\mu\text{L}$ , all 25 squares in the large centerpiece of the hemocytometer are counted. To get the total platelet count, the number counted is multiplied by 1000.

## Results

Twenty-three (23) total samples were evaluated in this study. Three (3) samples did not meet inclusion criteria; therefore twenty (20) samples were available. Total allowable error was calculated using acceptance criteria of 15% for WBCs and 25% for platelets. Samples included in the study represented high (10,720/ $\mu\text{L}$ ) and low (504/ $\mu\text{L}$ ) WBC counts and high (312,000/ $\mu\text{L}$ ) and low (39,500/ $\mu\text{L}$ ) platelet counts. The ATE range for WBCs was -0.70 to 0.94 and for platelets the ATE range was -0.83 to 0.97. All twenty (20) samples for both WBCs and platelets were within acceptable total error ranges.

The complete Validation Study is available at [www.biomedicalpolymers.com](http://www.biomedicalpolymers.com).

## Comparison and Index Plots for Platelets



## Conclusions

All 20 samples were within the allowable total error acceptance criteria of 15% for white blood cell counts and 25% for platelet counts when comparing the manual LeukoChek method to an automated hematology counter—the Sysmex.

An  $R^2$  value of 1 represents a perfect linear relationship between two variables. The  $R^2$  value for WBC is 99.4% and for platelets the  $R^2$  value is 96.1%. Both tests demonstrate a strong correlation between the LeukoChek and automated methods.