



# Comparison of precision: integrated BD FACSDuet™ /BD FACSLyric™ Systems vs manual sample preparation using 6-color TBNK and 4-color IMK kits

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## Abstract

The BD FACSDuet™ Sample Preparation System integrated to the BD FACSLyric™ Flow Cytometer is an automated walk-away sample preparation system. For whole blood samples, the BD FACSDuet™ System performs Lyse-No-Wash sample staining and processing using 6C TBNK kit and 4C IMK kit. The BD FACSLyric™ System integrated to the BD FACSDuet™ System performs sample acquisition and analysis automatically to identify and enumerate lymphocyte subsets for human cells in suspension. The BD™ Multicheck controls are used on the BD FACSDuet™/BD FACSLyric™ System for daily process control and QC.

In this study, the precision of the BD FACSDuet™ /BD FACSLyric™ System for samples prepared with 6-color TBNK and 4-color IMK kits will be compared with the precision of manual sample preparation using the same reagents with analysis on the same BD FACSLyric™ System. The samples used to measure precision are from a production lot of Streck CD-Chex Plus™, the stabilized QC samples provided by Streck company. Two operators ran the study per study day with each operator assigned to a different method (manual vs automated). Daily measurements were obtained in two separate runs (AM and PM) for 5 days to evaluate the T, B, and NK-lymphocyte subset percentages and absolute counts.

On each day of the study, the BD FACSLyric™ System passed instrument performance QC (PQC) in BD FACSLyric™ Clinical Software, and a successful Assay Setup Report was generated using the BD™ Multicheck Normal and Low-Level controls as process controls.

## Results

Figure 1. Example dot plots of Lymphocyte subsets.

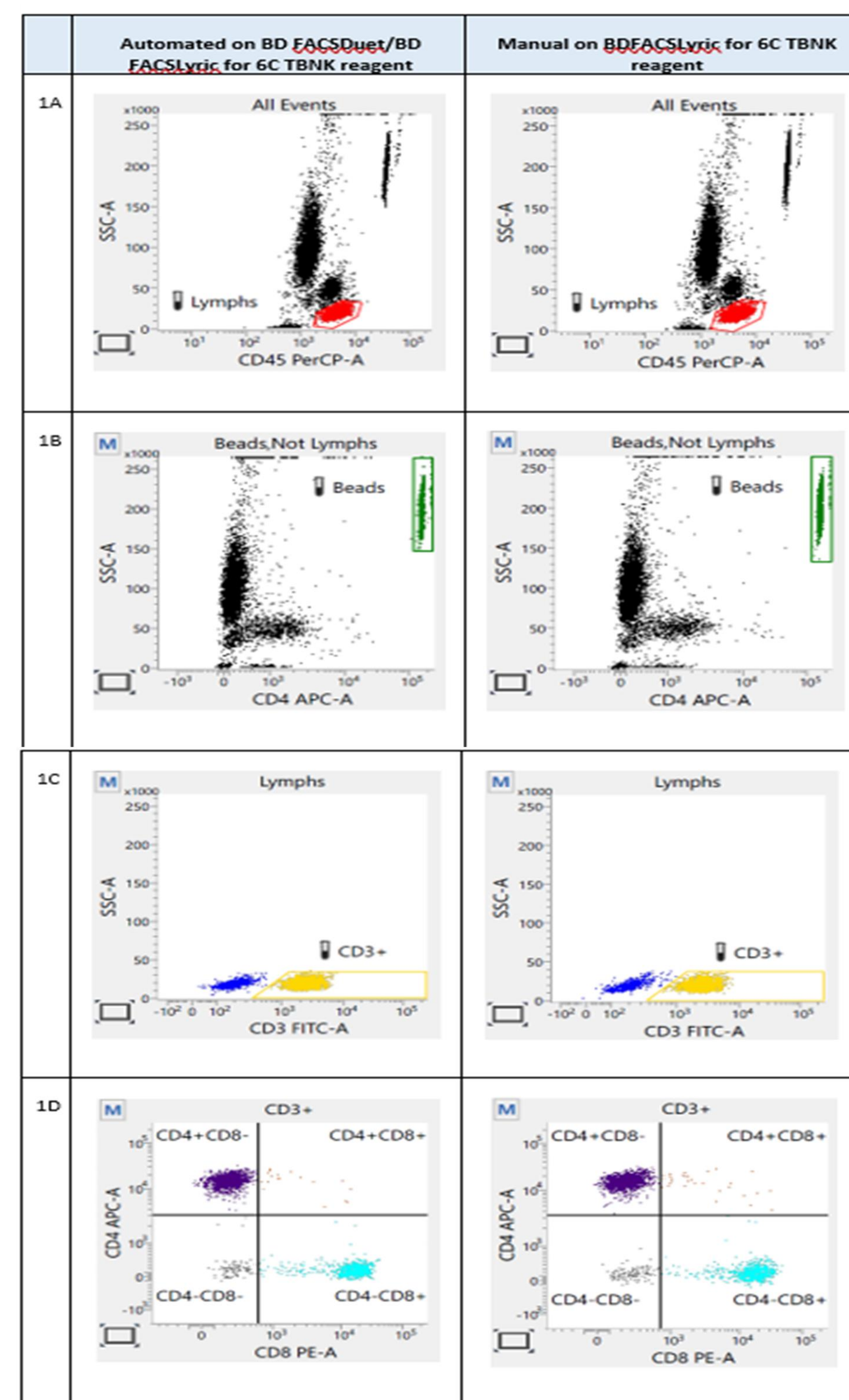
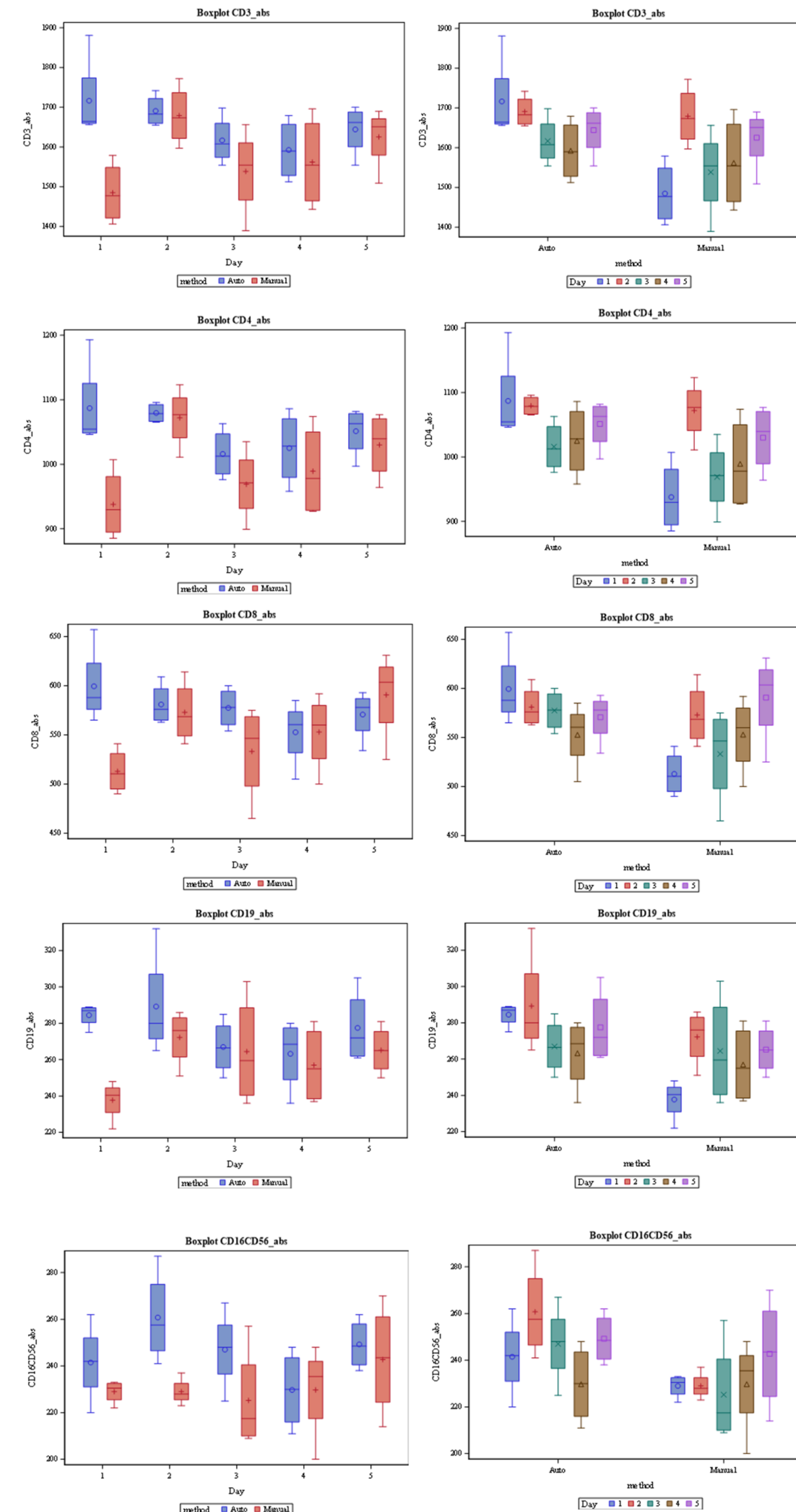


Figure 2. 6-color TBNK assay



Figures 2 and 3: Cell absolute counts of lymphocyte subsets plotted against testing days or auto vs manual method

Figure 3. 4-color IMK assay

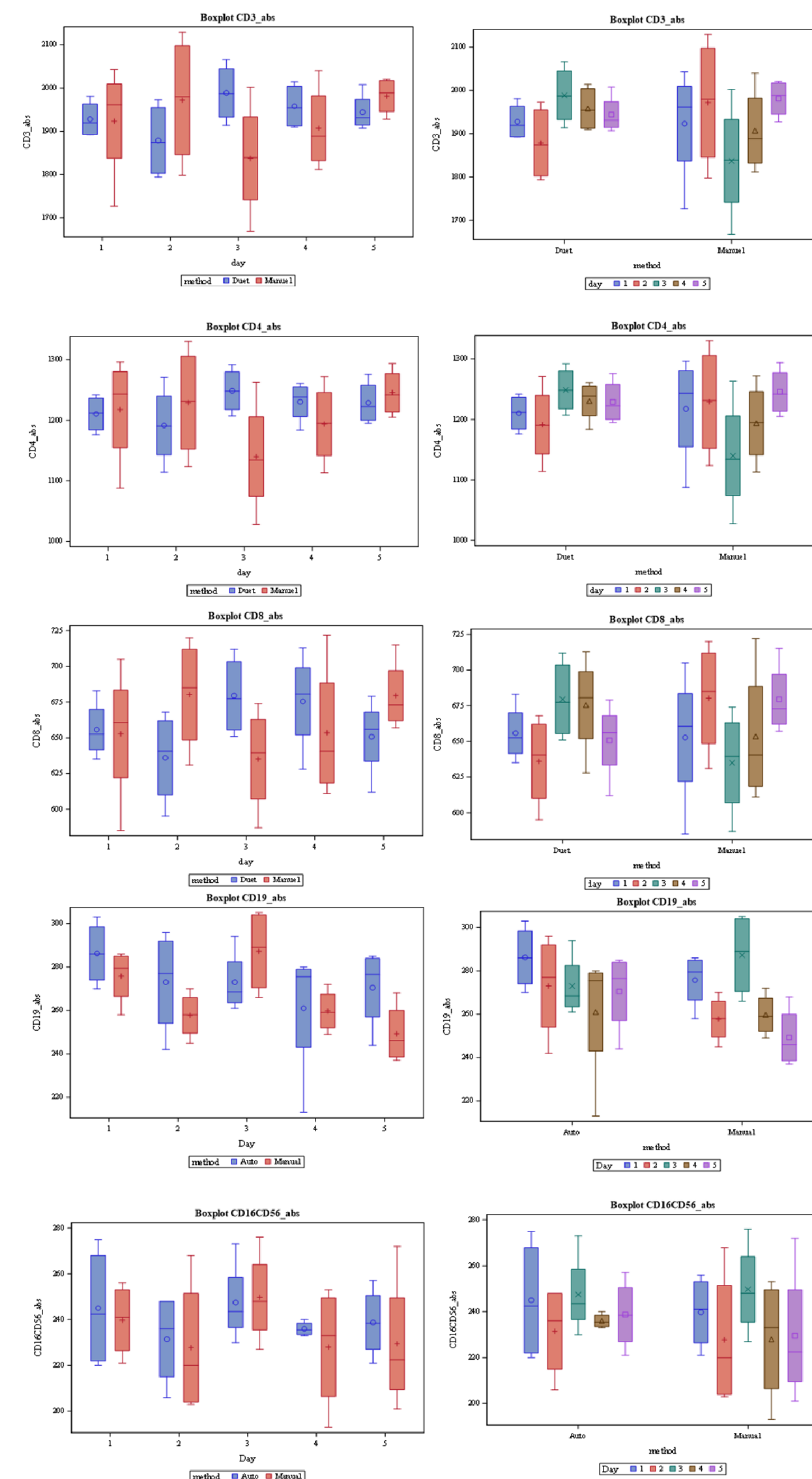
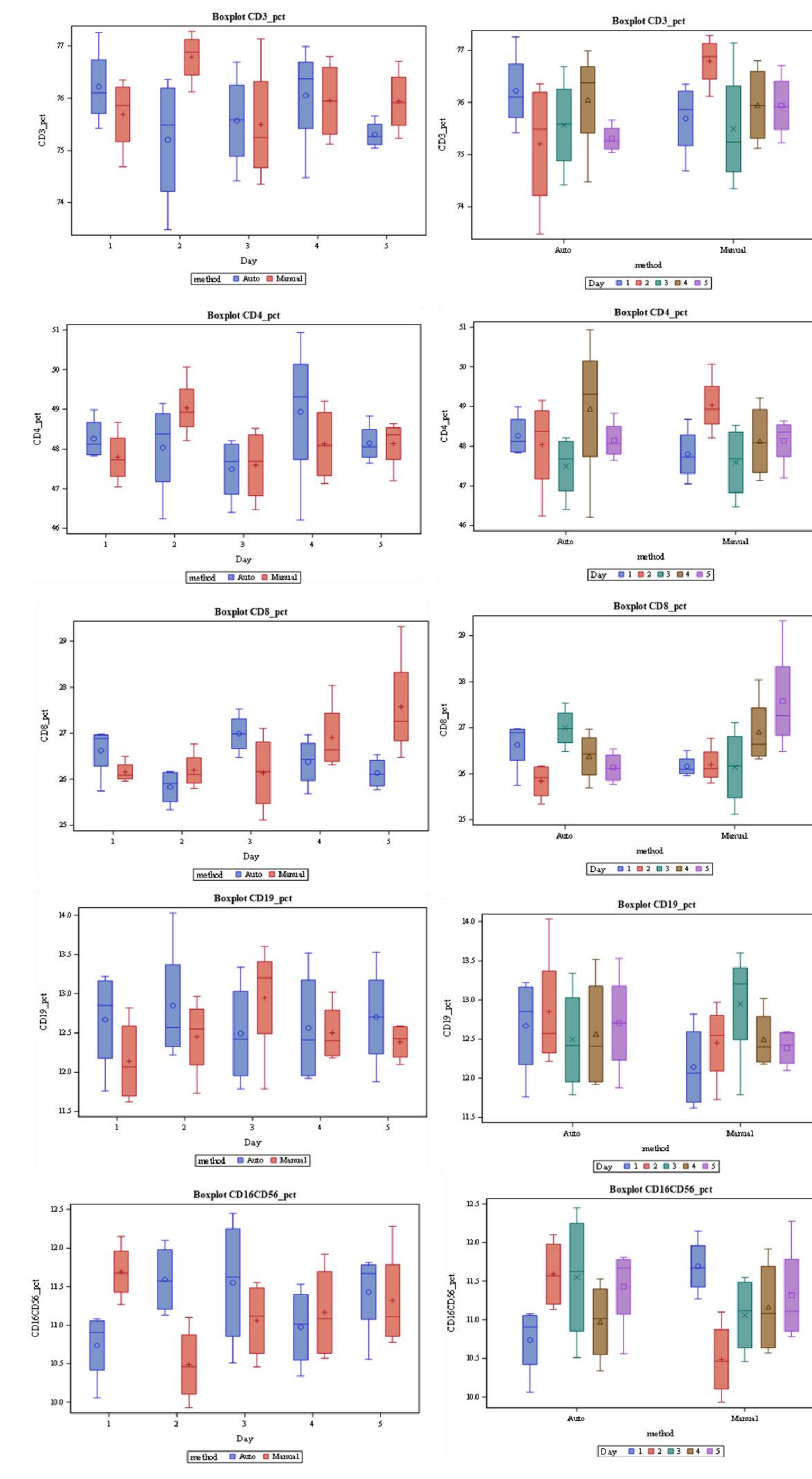
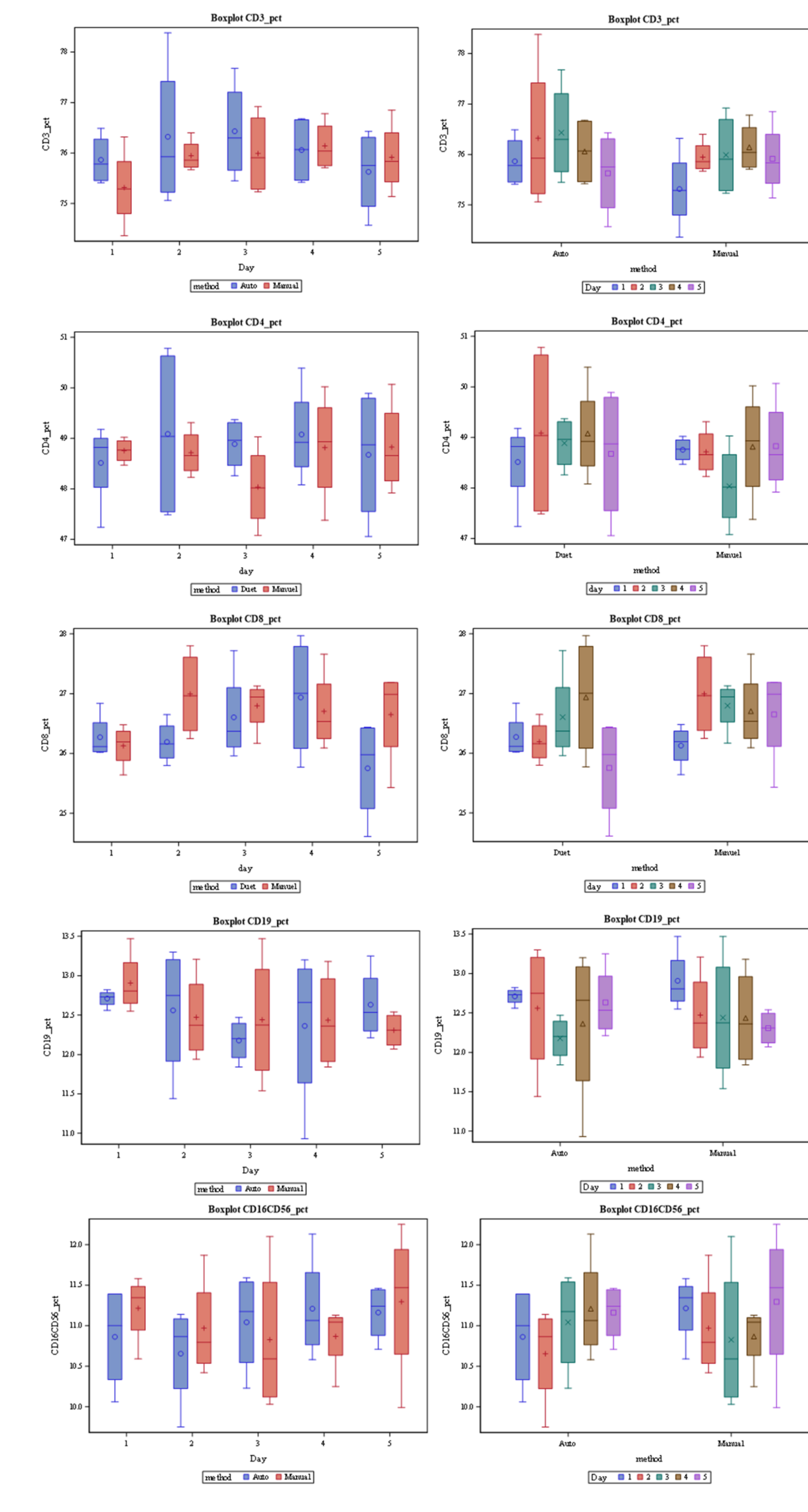


Figure 4. 6-color TBNK assay



Figures 4 and 5: Cell subset percentages relative to total lymphocytes plotted against testing days or auto vs manual method

Figure 5. 4-color IMK assay



## Methods

Reagents were 6-color kit –catalog# 662967 and 4-color IMK kit –catalog# 662965. Instruments and software were BD FACSDuet™ Sample Preparation System with BD FACSDuet™ Software Version 1.0 integrated to a BD FACSLyric™ 10-color (4-Blue 3-Red 3-Violet) with BD FACSuite™ Clinical software version 1.3. **BD FACSLyric™ Setup:** The performance QC was run with BD® CS&T Beads (Cat#6565054). The Assay/Tube Settings Setup was run for 6C TBNK and 4C IMK assays. The BD™ Multicheck Controls (High and Low) were run as process controls to pass manufacturer specified ranges and were stained and acquired by the integrated BD FACSDuet™/BD FACSLyric™ System. For **Sample Processing and acquisition** of the manual method, CD-Chex Plus™ samples from Streck were stained manually and acquired on the BD FACSLyric™ with BD FACSuite™ Clinical Software. For the automated method, the BD FACSDuet™/BD FACSLyric™ Integrated system was used to stain and acquire the same CD-Chex Plus™ samples automatically. Samples were processed and analyzed in duplicate. For each 50 µL sample, 20 µL of each reagent (6C TBNK reagent, IMK B cell CD3/CD16+CD56/CD45/CD19 or IMK T cell CD3/CD8/CD45/CD4) was used for staining, followed by lysis with 450 µL of 1X BD FACSLyse™ Solution. Samples were analyzed automatically on the BD FACSLyric™ using BD FACSuite™ clinical software version 1.3.

## Results

Precision of cell absolute counts by 6-color TBNK assay				Precision of cell percentages by 6-color TBNK assay			
Cells	Method	CV%	Upper_CV%	Cells	Method	CV%	Upper_CV%
CD3	Auto	4.97	7.26	CD3%	Auto	1.23	1.80
CD3	Manual	7.05	10.30	CD3%	Manual	1.12	1.63
CD4	Auto	4.96	7.25	CD4%	Auto	2.36	3.44
CD4	Manual	7.21	10.53	CD4%	Manual	1.85	2.71
CD8	Auto	5.28	7.71	CD8%	Auto	2.29	3.34
CD8	Manual	8.26	12.07	CD8%	Manual	3.49	5.10
CD19	Auto	7.36	10.75	CD19%	Auto	5.17	7.55
CD19	Manual	8.31	12.14	CD19%	Manual	4.40	6.43
CD16+CD56	Auto	7.45	10.88	CD16+CD56%	Auto	5.73	8.38
CD16+CD56	Manual	7.32	10.69	CD16+CD56%	Manual	5.81	8.49

## Conclusion

Study results demonstrated that the precision of the automated integrated BD FACSDuet™ and BD FACSLyric™ System is equivalent to the precision of the manual sample preparation followed by FACSLyric™ acquisition and analysis using 6-color TBNK assay and 4-color IMK assay.

The BD FACSDuet™ Sample Preparation System is a Class 1 Laser Product. The BD FACSDuet™ Sample Preparation System is for In Vitro Diagnostic Use. Sample preparation for user-defined protocols and cocktail functions are for Research Use Only, not for use in diagnostic or therapeutic procedures.

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