# Evaluating Equivalency in High-Quality PPP Production: A Comparative Analysis of the DASH Coag and StatSpin® Express 3 Centrifuges

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# **Executive Summary**

**Background:** Blood sample preparation is essential for accurate diagnostic test results, which influence about 70% of medical decisions. Centrifugation is a key method for stabilizing blood samples, particularly for producing Platelet Poor Plasma (PPP), crucial for tests like coagulation profiles. This study compares the performance of two widely used centrifuges: the Drucker Diagnostics DASH Coag and the Beckman Coulter StatSpin® Express 3.

**Study Overview:** Sample Preparation: Blood samples from 24 volunteers were processed using both centrifuges. The resulting PPP was analyzed for platelet counts using a Sysmex XN-1000 Hematology Analyzer.

**Performance:** Both centrifuges produced consistent PPP with platelet counts under  $10 \times 10^3$  platelets/ $\mu$ L. Statistical analysis, including ANOVA (Analysis of Variance), confirmed no significant difference between the two centrifuges.

**Key Findings:** PPP Production: The DASH Coag and StatSpin® Express 3 are equivalent in producing high-quality PPP.

**Design Differences:** The DASH Coag has a larger capacity, while the StatSpin® Express 3 is more compact. Both are user-friendly and compliant with safety standards.

**Conclusion:** The Drucker Diagnostics DASH Coag and the Beckman Coulter StatSpin® Express 3 are both highly effective in preparing Platelet Poor Plasma, with no significant difference in their performance as demonstrated by this study. Laboratories can confidently choose either centrifuge based on specific needs such as capacity, size, and operational preferences, without compromising on the quality of PPP produced.

### Introduction

An estimated 2 billion blood samples are drawn annually in the United States, influencing approximately 70% of medical decisions<sup>1</sup>. Poor sample preparation, stabilization, handling, and quality control are leading factors contributing to inaccurate diagnostic test results, which can prevent or delay appropriate treatment<sup>2</sup>. The current practice for obtaining in vitro

diagnostic test results on blood samples begins with blood collection at various sites, including hospitals, blood draw centers, and physician offices.

Centrifugation is the simplest and most cost-effective method available for stabilizing pre-analytic blood samples, with many assays requiring stabilization within



2 hours of collection. Since serum or plasma is used in numerous diagnostic assays, achieving clean separation is crucial for producing reliable and repeatable results. For anticoagulated specimens, the goal of centrifugation is yielding platelet-poor plasma (PPP). It is essential that this process effectively removes the majority of platelets (PLT), from approximately 300  $x10^3$  platelets/ $\mu$ L to below 10  $x10^3$  platelets/ $\mu$ L to prevent interference with subsequent in-vitro diagnostic tests. The generally accepted definition of PPP is a prepared plasma sample with a PLT count of less than 10 x10<sup>3</sup> platelets/μL. Achieving this necessitates the use of precise and reliable equipment, as the choice of centrifuge can impact the quality of PPP and, consequently, the accuracy and reliability of diagnostic tests.

However, even with proper equipment, certain medical conditions may affect the creation of PPP due to their impact on blood composition, clotting factors, and the physical properties of blood components. Conditions that may influence PPP production include, but are not limited to, disorders that affect blood clotting, such as hemophilia or disseminated intravascular coagulation (DIC), which can cause irregular clot formation; hyperlipidemia, characterized by high lipid levels; thrombocytosis, an abnormally high platelet count; polycythemia, an elevated red blood cell count that increases blood viscosity; inflammatory conditions that

elevate fibrinogen and other acute-phase reactants; and anticoagulant therapy with drugs like heparin or warfarin, which may alter blood properties, thus impacting the separation process and leading to suboptimal platelet removal<sup>3,4,5,6</sup>. These conditions can pose challenges in achieving the proper balance needed to produce high-quality PPP using a centrifuge.

This study compares the DASH Coag and StatSpin® Express 3 centrifuges, two widely used devices in hospital laboratories for PPP preparation. Both centrifuges are designed to meet the rigorous demands of modern laboratories and are categorized as Class I medical devices by the FDA.

The goal of this study is to assist laboratory professionals and physicians in making informed decisions when selecting a centrifuge for PPP preparation by evaluating these centrifuges across numerous samples. This comparison will assess the specifications, features, and performance of each centrifuge in generating high-quality PPP.

Ultimately, the goal is to provide medical professionals with the necessary information to select the most suitable centrifuge for their specific needs, thereby enhancing the quality and reliability of PPP preparation in their laboratories.

# Methodology

The DASH Coag and StatSpin® Express 3 centrifuges are widely used in the preparation of PPP due to their specifications, performance capabilities, and extensive adoption in the industry. This study was designed to comprehensively evaluate and compare these centrifuges in terms of their ability to process PPP, utilizing a rigorous procedure encompassing sample collection, centrifugation, preparation, delivery, analysis, and statistical evaluation.

Blood samples were collected from 24 volunteer donors, each providing multiple lithium heparin plasma separator tubes (BD part number 367884). Each tube was labeled with an anonymized donor identifier and a single digit (1, or 2) indicating the order of collection. Within 5 minutes of phlebotomy, tubes from each donor were centrifuged, individually with a balance tube, in

either the DASH Coag or the StatSpin® Express 3 for three minutes at a force of 4,400 xg and marked according. To prevent any bias from the order of tube collection, the draw order was balanced across the two centrifuges, ensuring that each device processed an equal number of first and last-drawn tubes.

Upon completion of centrifugation, the tubes were removed, and the PPP was carefully pipetted from above the gel barrier and transferred into separate blood collection tubes (no additive Red Top Tube, BD part number 366703). The processed PPP samples were stored at room temperature until all samples were collected and processed. They were then packed in an insulated carrier with cold packs and shipped overnight to the laboratory for analysis.



Platelet (PLT) counts in the PPP samples were measured using a Sysmex XN-1000 Hematology Analyzer. Each sample was tested in duplicate using the fluorescence platelet method (PLT-f) provided by the Sysmex XN-1000, chosen for its clinically proven accuracy and reproducibility in low PLT samples<sup>7,8</sup>. The average value of the two PLT-f results from each sample were used for further statistical analysis with the average results shown in Table 1.

Data on PLT counts from each PPP sample were recorded and organized for statistical analysis, encompassing results from all 24 volunteers across both centrifuges. An ANOVA statistical analysis was

conducted to compare PLT counts between the two centrifuges. The analysis included a paired t-test to compare mean PLT counts, Bland-Altman analysis to assess agreement and identify any systematic differences, and the coefficient of variation (CV) to evaluate the consistency of results within each centrifuge group. The null hypothesis (H0) posited no significant difference in PLT counts between the two centrifuges, with a p-value of less than 0.05 in the paired t-test indicating rejection of the null hypothesis and thus no significant difference. Bland-Altman plots and CV values were further interpreted to determine the practical equivalency of the two centrifuges in a laboratory setting.

# **Comparative Analysis**

The comparative analysis indicated that the Drucker Diagnostics DASH Coag and the StatSpin® Express 3 centrifuges delivered statistically equivalent outcomes in preparing PPP. Both consistently achieved PPP with platelet counts below  $10 \times 10^3$  platelets/ $\mu$ L as illustrated in *Figure 1* and supported by the data in Table 1. Although four samples slightly exceeded  $10 \times 10^3$  platelets/ $\mu$ L, the results remained within a comparable range for each centrifuge. ANOVA results, shown in *Figure 2*, confirmed this equivalency, with the Sysmex PLT-f method yielding a p-value above 0.05, indicating

no significant difference in mean platelet counts between the two devices. This statistical finding suggests the means are effectively identical, confirming similar performance for PPP production.

Additional evaluations, including a paired t-test and a difference analysis shown in *Figure 3*, further corroborate that the mean values are statistically equivalent. Collectively, these findings indicate that both centrifuges are similarly effective in PPP preparation.

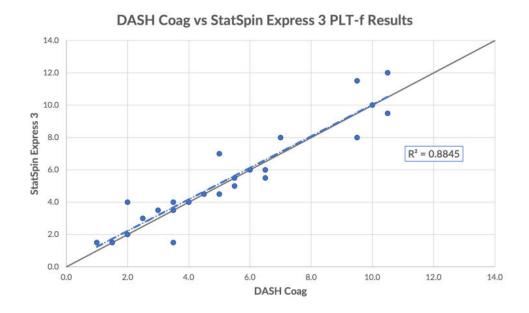


Figure 1 - PLT-f Test Results (x103 platelets/ $\mu$ L)



# One-way ANOVA: PLT-f versus Centrifuge

# Method

Null hypothesis All means are equal
Alternative hypothesis Not all means are equal
Significance level  $\alpha = 0.05$ 

Equal variances were assumed for the analysis.

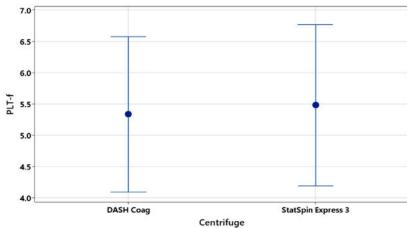
### **Factor Information**

Factor	Levels	Values
Centrifuge	2	DASH Coag, StatSpin Express 3

### **Analysis of Variance**

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Centrifuge	1	0.255	0.2552	0.03	0.867
Error	46	411.073	8.9364		
Total	47	411.328			

### Interval Plot of PLT-f 95% CI for the Mean



Individual standard deviations are used to calculate the intervals.

Figure 2 - PLT-f One-way ANOVA Results

Paired T-Test and CI						
Sample	N	Mean	StDev	SE Mean		
DASH COAG	24	5.33	2.93	0.599		
StatSpin Express2	24	5.48	3.04	0.662		

Estimation for Paired Difference					
Mean	StDev SE Mean 95% CI				
-0.15	1.04	0.212	0.292	-0.584	
Difference is population mean of DASH - StatSpin					

Т	T-Test (1 sided)	T-Test (2 sided)
-0.674	0.249	0.498

# **Bland-Altman**

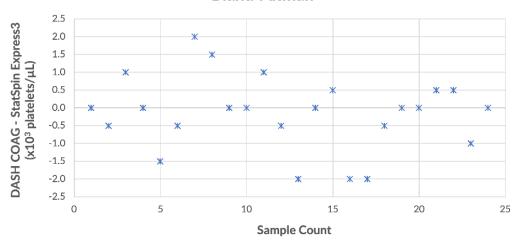


Figure 3 - Paired T-Test, Difference Analysis, and Bland Altman Plot

# **Unit Comparison**

The Drucker Diagnostics DASH Coag and the Beckman Coulter StatSpin® Express 3 are both compact centrifuges designed for the efficient preparation of PPP in laboratory settings. Below is a detailed comparison of their features and specifications:

# 1. Design and Build:

DASH Coag: The DASH Coag is a compact and lightweight unit with a footprint of 12.0(W) x 13.8(D) x 9.1(H) inches (30 x 36 x 23 cm) and weighs 12.0 lbs. (5.4 kg). It is designed to minimize turnaround time by eliminating queuing in accessioning. The unit can accommodate 12 tubes up to 100 mm long (i.e.10 mL tubes), using adapters for smaller tube sizes, and features a fixed-angle rotor that maintains a 45° angle, which is optimal for PPP formation, as shown in Figure 4. The DASH Coag is built with a clear shatter-proof lid for safe sample observation and optical speed checks.

StatSpin® Express 3: The StatSpin® Express 3 is also compact and lightweight, measuring 10.5(W) x 10.0(D) x 7.1(H) inches (26.7 x 25.4 x 18.0 cm) and weighing 9.5 lbs. (4.3 kg). It is designed to enhance laboratory productivity through quicker processing times. The StatSpin® Express 3 can spin 8 tubes ranging from 1.5 to 10 mL using adapters, as shown in Figure 5.





Figure 4 - DASH COAG and Adapters





- SV02 10.25 x 64 mm
- SV05 1.5-2.0 mL microtubes, 10.25 x 47 mm, and BD Microtainers
- SV06 16 x 75 mm
- SV08 13 x 75 mm BD tubes
- SV09 13 x 100 mm
- SV10 13 x 75 mm Greiner tubes
- SV11 13 x 100 mm BD RST tubes

Figure 5 - StatSpin® Express3 with Adapters

### 2. Performance:

DASH Coag: The DASH Coag reaches a maximum Relative Centrifugal Force (RCF) of 4,400 xg and a maximum speed of 6,600 RPM. It offers three preset cycles: 2 minutes at 6,600 RPM/4,400 xg, 3 minutes at 6,600 RPM/4,400 xg, and 5 minutes at 5,165 RPM/2,685 xg. This centrifuge is equipped with a brushless DC motor, which requires no routine maintenance, ensuring reliable operation under heavy workloads. Additionally, it features a convection-based cooling system that maintains cool operation.

**StatSpin® Express 3:** The StatSpin® Express 3 also has a maximum RCF of 4,400 xg but at a higher speed of 7,200 RPM due to a smaller rotor radius. It provides similar preset cycles: 2 minutes at 7,200 RPM/4,400 xg, 3 minutes at 7,200 RPM/4,400 xg, and 5 minutes at 5,600 RPM/2,685 xg. This centrifuge is also equipped with a brushless DC motor for reliable operation under heavy workloads.

# 3. User Interface and Operation:

**DASH Coag:** The DASH Coag features a simple twobutton interface for cycle selection, making it userfriendly. It also includes an LED lid lighting system that, along with audible beeps, indicates cycle status and completion. The centrifuge is equipped with a set-andlock function for single or customized settings, providing flexibility and ease of use.

**StatSpin® Express 3:** The StatSpin® Express 3 offers a straightforward operation with selectable 2-, 3-, or 5-minute cycles. Like the DASH Coag, it also emits audible beeps upon cycle completion, ensuring the user is promptly notified when the process is done.

# 4. Safety and Compliance:

DASH Coag: This centrifuge complies with US, Canadian, and European safety regulations and standards°. It includes an automatic lid lock for safety and is designed with a clear, shatterproof lid. The DASH Coag operates on a universal power input (100-240V, 50/60 Hz, 3 amp) and is supported by a two-year warranty with a lifetime warranty on the rotor.

**StatSpin® Express 3:** The StatSpin® Express 3 is UL and CE marked, ensuring compliance with essential safety standards. It also operates on universal power input (100-240V, 50/60 Hz, 3 amp) and comes with a two-year warranty.

### 5. Summary:

Both the DASH Coag and StatSpin® Express 3 centrifuges are well-suited for PPP preparation, offering reliable performance with slight variations in design and features. The DASH Coag is slightly larger and heavier, with a focus on reducing queuing in high-throughput settings, while the StatSpin® Express 3 emphasizes speed and compactness, making it ideal for fast-paced laboratories. Both units offer similar safety features, compliance certifications, and user-friendly operations, ensuring they meet the rigorous demands of modern laboratory environments.



# **Conclusion**

Proper blood sample preparation is crucial for generating accurate and reliable test results, which performs a vital role in influencing medical decisions. Centrifugation is the most straightforward and costeffective method for stabilizing pre-analytic blood samples, especially since serum or plasma is required for many high-volume diagnostic tests, including coagulation profiles. For coagulation testing, it is essential that the centrifugation process effectively removes the majority of platelets (PLTs) from the plasma to prevent interference with subsequent in vitro diagnostic tests.

The results of this study demonstrate that both the Drucker Diagnostics DASH Coag and the Beckman Coulter StatSpin® Express 3 produce equivalent Platelet Poor Plasma (PPP). Both centrifuges are well-suited for PPP preparation, delivering reliable performance with only slight differences in design and features. These findings confirm that either centrifuge can be confidently used in clinical settings where high-quality PPP is required.

# **Appendix**

### Table 1 Comparison Data Results

*^	DI	T f	1.1	$\Omega$ 3	nlate	late /	٠١

Donor	Centrifuge	Draw Order	Avg. PLT-f*
1	DASH Coag	2nd Tube Drawn	3.5
2	DASH Coag	2nd Tube Drawn	3.5
3	DASH Coag	2nd Tube Drawn	10.5
4	DASH Coag	2nd Tube Drawn	5.5
5	DASH Coag	2nd Tube Drawn	10.5
6	DASH Coag	2nd Tube Drawn	2.5
7	DASH Coag	2nd Tube Drawn	3.5
8	DASH Coag	2nd Tube Drawn	9.5
9	DASH Coag	2nd Tube Drawn	4.0
10	DASH Coag	2nd Tube Drawn	6.0
11	DASH Coag	2nd Tube Drawn	6.5
12	DASH Coag	1st Tube Drawn	3.0
13	DASH Coag	1st Tube Drawn	5.0
14	DASH Coag	1st Tube Drawn	2.0
15	DASH Coag	1st Tube Drawn	5.0
16	DASH Coag	1st Tube Drawn	9.5
17	DASH Coag	1st Tube Drawn	2.0
18	DASH Coag	1st Tube Drawn	1.0
19	DASH Coag	1st Tube Drawn	1.5
20	DASH Coag	1st Tube Drawn	4.5
21	DASH Coag	1st Tube Drawn	5.5
22	DASH Coag	1st Tube Drawn	6.5
23	DASH Coag	1st Tube Drawn	7.0
24	DASH Coag	2nd Tube Drawn	10.0

Donor	Centrifuge	Draw Order	Avg. PLT-f*
1	StatSpin Express 3	1st Tube Drawn	3.5
2	StatSpin Express 3	1st Tube Drawn	4.0
3	StatSpin Express 3	1st Tube Drawn	9.5
4	StatSpin Express 3	1st Tube Drawn	5.5
5	StatSpin Express 3	1st Tube Drawn	12.0
6	StatSpin Express 3	1st Tube Drawn	3.0
7	StatSpin Express 3	1st Tube Drawn	1.5
8	StatSpin Express 3	1st Tube Drawn	8.0
9	StatSpin Express 3	1st Tube Drawn	4.0
10	StatSpin Express 3	1st Tube Drawn	6.0
11	StatSpin Express 3	1st Tube Drawn	5.5
12	StatSpin Express 3	2nd Tube Drawn	3.5
13	StatSpin Express 3	2nd Tube Drawn	7.0
14	StatSpin Express 3	2nd Tube Drawn	2.0
15	StatSpin Express 3	2nd Tube Drawn	4.5
16	StatSpin Express 3	2nd Tube Drawn	11.5
1,7	StatSpin Express 3	2nd Tube Drawn	4.0
18	StatSpin Express 3	2nd Tube Drawn	1.5
19	StatSpin Express 3	2nd Tube Drawn	1.5
20	StatSpin Express 3	2nd Tube Drawn	4.5
21	StatSpin Express 3	2nd Tube Drawn	5.0
22	StatSpin Express 3	2nd Tube Drawn	6.0
23	StatSpin Express 3	2nd Tube Drawn	8.0
24	StatSpin Express 3	1st Tube Drawn	10.0



# Resources

- <sup>1</sup> https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html
- <sup>2</sup> Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine; Balogh EP, Miller BT, Ball JR, editors. Improving Diagnosis in Health Care. Washington (DC): National Academies Press (US); 2015 Dec 29. 3, Overview of Diagnostic Error in Health Care. Available from: https://www.ncbi.nlm.nih.gov/books/NBK338594/
- <sup>3</sup> Lippi G, Favaloro EJ. "Pre-analytical variables in coagulation testing associated with diagnostic errors in hemostasis." *Laboratory Medicine*. 2009.
- <sup>4</sup> Gelinas RJ, Wallach H, Blum A. "Evaluation of Pre-analytic Variables Affecting Plasma Preparation and Coagulation Factor Levels." Journal of Clinical Pathology. 2013.
- <sup>5</sup> Kitchens CS, Kessler CM, Konkle BA. "Consultative Hemostasis and Thrombosis." Elsevier Health Sciences. 2013.
- 6 Souto JC, Almasy L, Borrell M, et al. "Genetic Determinants of Thrombophilia." Circulation. 2000.
- <sup>7</sup> https://pubmed.ncbi.nlm.nih.gov/24045545/
- 8 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4619826/
- <sup>9</sup>Complies with UL61010-1/CSA C22.2 No. 61010-1 and IEC61010-2-020



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