



Design & Testing Services

Qualification Report
ThermoSafe® E38 Insulated Shipper-PUR
For Shipping Room-Temperature
Platelet Concentrate in Bags

Prepared for

Tegant Corporation, ThermoSafe Brands

Control # TEG 0709-1C

Tegant Corporation, ThermoSafe Brands

3930 N. Ventura Drive Suite 450, Arlington Heights, IL 60004

Phone: 847-398-0110 Fax: 847-632-9516



Qualification Report

ThermoSafe® E38 Insulated Shipper-PUR

For Shipping Room-Temperature Platelet Concentrate in Bags

Prepared for Tegrant Corporation, ThermoSafe Brands



Design & Testing Services

**Tegant Corporation, ThermoSafe Brands
ThermoSafe® E38 Insulated Shipper-PUR
For Shipping Room-Temperature
Platelet Concentrate in Bags**

Qualification Report

Control # TEG 0709-1C

**Miles Ducore
ISC Labs Project Engineer**

Miles Ducore 13 Sept 07

**Michelle Hunt
ISC Labs Quality Assurance Coordinator**

Michelle M. Hunt 10 Sept 07

**Scott Dyvig
ISC Labs Central U.S. Team Leader**

Scott Dyvig 13 Sept 07

Tegrant Corporation, ThermoSafe Brands
ThermoSafe® E38 Insulated Shipper-PUR
For Shipping Room-Temperature
Platelet Concentrate in Bags

Qualification Report

Table of Contents

I.	Summary	
	Overview.....	1
	Test Preparation.....	2
	Summary of Results	3
	Deviations	3
II.	Test Data	
	Graphs, Worksheets, and Data.....	5
III.	Procedures: Packout Diagrams	
	Figure 1: E38 Minimum Load	65
	Figure 2: E38 Maximum Load	66
	Packing Specifications.....	67
IV.	Calibration Data	
	Calibration Data.....	68
	Verification Data	77
V.	Appendix	
	Equipment Calibration Certificates	
	Thermal Qualification Protocol	

Tables and Diagrams

Table 1: Test Results Overview	1
Table 2: Summer Ambient Temperature Profile	2
Table 3: Winter Ambient Temperature Profile	2
Table 4: E38 Insulated Shipper Qualification Test Results	4
Figure 1: E38 Minimum Load Packout Diagram	65
Figure 2: E38 Maximum Load Packout Diagram.....	66



Design & Testing Services

Tegant Corporation, ThermoSafe Brands
ThermoSafe® E38 Insulated Shipper-PUR
For Shipping Room-Temperature
Platelet Concentrate in Bags
Qualification Report

OVERVIEW

Purpose

The purpose of this study was to demonstrate the ability of the ThermoSafe® E38 Insulated Shipper-PUR to maintain temperature of minimum and maximum loads of room-temperature platelet concentrate bags. Product temperatures must be maintained between 20°C and 24°C ($\pm 1^\circ\text{C}$) for 24 hours when exposed to simulated summer and winter ambient temperature profiles for 24 hours.

Test Results Overview

Test results indicate product temperatures were maintained between 20°C and 24°C ($\pm 1^\circ\text{C}$) for 24 hours during exposure to both summer and winter ambient profiles.

Product Load	Ambient	Product Temperature Range In 24 Hrs. (°C)
1 x 300 mL platelet concentrate bag, 45 mL fill	Summer	22.1 to 24.5
30 x 300 mL platelet concentrate bags, 65 mL fill		21.7 to 24.2
1 x 300 mL platelet concentrate bag, 45 mL fill	Winter	19.1 to 22.6
30 x 300 mL platelet concentrate bags, 65 mL fill		19.4 to 23.3

Table 1: Test Results Overview

TEST PREPARATION

Testing was prepared in accordance with Thermal Qualification Protocol Number 772388-0707-2692. The testing was performed using ThermoSafe® E38 Insulated Shippers–PUR and 48-oz Polar Pack® gels as manufactured by Tegrant Corporation, ThermoSafe Brands and product samples provided by ThermoSafe Brands.

Product Loads and Refrigerant Configurations

Minimum Load

- 1 x 300 mL platelet concentrate bag, 45 mL fill
- 4 x room-temperature 48-oz Polar Pack (PP48)

Maximum Load

- 30 x 300 mL platelet concentrate bags, 65 mL fill
- 4 x room-temperature 48-oz Polar Pack (PP48)

Ambient Profiles

Summer and winter ambient temperature profiles were used to simulate conditions encountered during transit. The product loads were tested for qualification (N=3), for a total of twelve (12) tests. See Tables 2 and 3 below for ambient profile details.

Ambient °C	Hours
22	6
Ramp to 45	2
45	2
Ramp to 30	2
30	12

Total of 24 hours

Table 2: Summer Ambient Temperature Profile

Ambient °C	Hours
22	6
Ramp to -20	2
-20	2
Ramp to 15	2
15	12

Total of 24 hours

Table 3: Winter Ambient Temperature Profile

Note: The tolerance for ambient temperatures is within $\pm 3^{\circ}\text{C}$ of set point temperatures

Pre-Testing Conditions

- The product was conditioned at $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ (lab environment) for a minimum of 24 hours prior to testing.
- The Polar Pack gels were conditioned at $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ (lab environment) for a minimum of 24 hours prior to testing.
- The ThermoSafe® E38 Insulated Shippers were conditioned at $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ (lab environment) for a minimum of 24 hours prior to testing.
- All other components were conditioned at $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ (lab environment) for a minimum of 24 hours prior to testing.

Thermocouple Configurations

Prior to testing, the necessary thermocouple probes were calibrated in accordance with the ISC Labs Standard Calibration Procedures¹. For more detail concerning thermocouple probe locations, refer to the test worksheets included with the test data (Section II of this report) or included in the protocol (Appendix).

- ❑ Each minimum load utilized one (1) thermocouple probe inserted into the filled platelet concentrate bag to monitor the product temperature during testing.
- ❑ Each maximum load utilized three (3) thermocouple probes, each probe inserted into a filled platelet concentrate bag, to monitor the product temperatures during testing.
- ❑ Two (2) thermocouple probes were placed outside the E38 Insulated Shippers to record the ambient temperature experienced during testing.

The shippers were packed as diagrammed², closed, and placed into an environmental chamber, which was programmed to run the ambient profiles in Tables 2 and 3. All temperature readings were recorded in 15-minute intervals. Upon completion of testing, all thermocouple probes used in testing were verified in accordance with ISC Labs Standard Verification Procedures³.

Test Acceptance Criteria

Product temperatures must be maintained between 20°C and 24°C ($\pm 1^\circ\text{C}$) for 24 hours of testing when exposed to simulated summer and winter ambient temperatures for 24 hours.

Tegant Corporation, ThermoSafe Brands will review all test results to determine acceptability and applicability of the packaging system performance.

SUMMARY OF RESULTS

A detailed summary of the E38 Insulated Shipper-PUR qualification test results is contained in Table 4.

DEVIATIONS

- ❑ No deviations were observed during this study.

¹ Procedures on file at ISC Labs

² Refer to exploded packing diagrams in the Procedures section for packing instructions.

³ Procedures on file at ISC Labs

Tegant Corporation, ThermoSafe Brands
 ThermoSafe[®] E38 Insulated Shipper-PUR
 For Shipping Room-Temperature Platelet Concentrate in Bags

Qualification Results

Product Load	Ambient	Min/Max Product Temperature (°C) in 24 Hours	Product Temperature Range at Hour (°C)			Test Number
			0.0 to 8.0	8.25 to 16.0	16.25 to 24.0	
1 x 300 mL platelet concentrate bag, 45 mL fill	Summer	22.1 to 24.5	22.1 to 22.4	22.2 to 23.6	23.6 to 24.5	08242007.1C
		22.1 to 24.5	22.1 to 22.4	22.2 to 23.6	23.7 to 24.5	08242007.2C
		22.1 to 24.3	22.1 to 22.2	22.1 to 23.6	23.6 to 24.3	08242007.3C
30 x 300 mL platelet concentrate bags, 65 mL fill	Summer	21.7 to 24.1	21.7 to 22.2	21.8 to 23.3	23.2 to 24.1	08242007.4C
		21.7 to 24.2	21.7 to 22.2	21.8 to 23.4	23.3 to 24.2	08242007.5C
		21.7 to 24.0	21.7 to 22.1	21.9 to 23.4	23.3 to 24.0	08242007.6C
1 x 300 mL platelet concentrate bag, 45 mL fill	Winter	19.1 to 22.5	22.1 to 22.5	19.8 to 22.1	19.1 to 19.8	08212007.1C
		19.1 to 22.6	22.1 to 22.6	19.9 to 22.1	19.1 to 19.9	08212007.2C
		19.1 to 22.4	21.9 to 22.4	19.8 to 22.1	19.1 to 19.9	08212007.3C
30 x 300 mL platelet concentrate bags, 65 mL fill	Winter	19.5 to 23.1	22.2 to 23.1	20.2 to 22.5	19.5 to 20.5	08212007.4C
		19.4 to 23.3	22.1 to 23.3	20.0 to 22.5	19.4 to 20.7	08212007.5C
		19.4 to 23.1	22.2 to 23.1	19.9 to 22.5	19.4 to 20.3	08212007.6C

Table 4: E38 Insulated Shipper-PUR Qualification Test Results