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# Design Qualification Report for the MaxPlus Donor Tube Shipper

Intended for 24-hour transport of donor tubes cooling toward 2-8°C OR maintained at 2-8°C in transit



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## 1. Scope:

The scope of this Design Qualification (DQ) report is to summarize the components and thermal performance of the MaxPlus Donor Tube Shipper (SKU#U17DT24). The report addresses basic system requirements, components breakdown, packing methods, and temperature compliance data for the U17DT24 to transport donor tubes cooling towards 2-8°C OR maintained at 2-8°C for a minimum of 24 hours.

## 2. Requirements Summary:

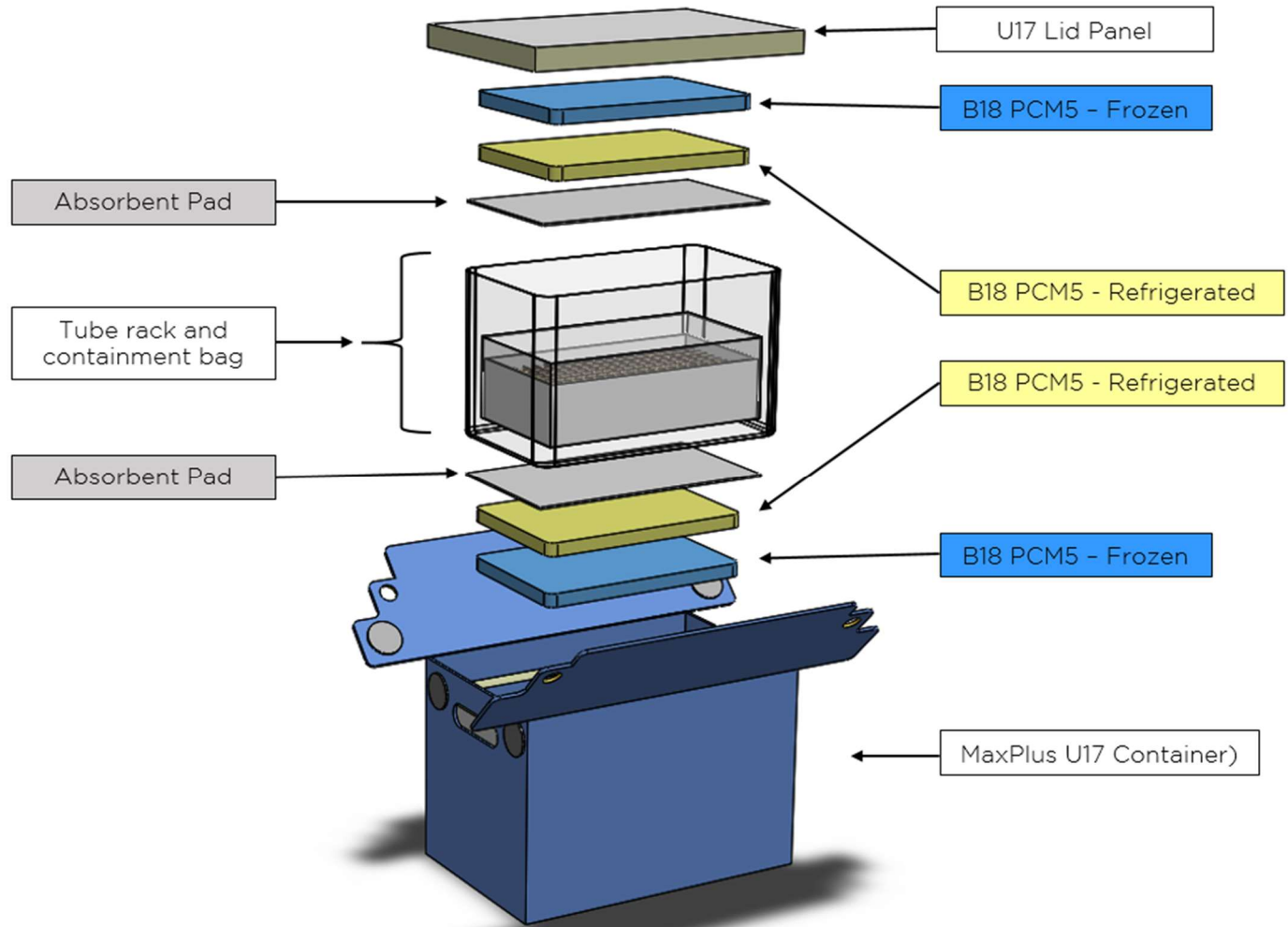
Payload type	Room temperature donor tubes OR refrigerated donor tubes
Payload form factor	6mL Vacutainer tubes
Payload volume	6mL per unit
Payload capacity	1-190 tubes using the tube rack configuration OR up to 250 tubes in a bundled configuration.
Payload temperature	Cooling towards 2-8°C OR maintained at 2-8°C
Validation	24 hours against ISTA 7D standards

## 3. Product Summary and Components:

- Outer Shell Material: Corrugated plastic, highly reusable
- Outer Dimensions: 17.25in x 11in x 11.5in (LWH)
- Inner Dimensions: 14in x 8in x 8in (LWH)
- System Weight (excluding payload): 14 lbs.
- Phase Change Coolant: B18 PCM5 coolant bottle (x4)
- Accessories: Tube rack (x1), containment bag (x1) and absorbent pads (x2)

## 4. Packing Methods

### 4.1 U17DT24 Packout Schematic:



#### 4.2 U17DT24 Coolant Conditioning Procedure:

- Charge two B18 PCM5 coolants (blue) inside a freezer (below -20°C) for a minimum of 24 hours.
- Charge two B18 PCM5 coolants (yellow) inside a refrigerator (1-6°C) for a minimum of 24 hours.

#### 4.3 U17DT24 Packing Instructions:

- 1) Place one frozen B18 PCM5 coolant (blue) in the bottom of the container.
- 2) Place one refrigerated B18 PCM5 coolant (yellow) on top of the bottom coolant.
- 3) Place one absorbent pad on top of the yellow B18 PCM5 coolant.
- 4) Prepare tube rack with up to 190 tubes OR if packing over 190 tubes then bundle up to 250 tubes and place them in the containment bag and load inside the container (**Note:** Example shown in the photos below).



**Figure 1.** Tube rack scenario used for 1 to 190 tube capacity. The photo above was taken with the lid of the tube rack removed for clarity. The lid was placed on the tube rack for thermal validation testing.



**Figure 2.** Bundled tube scenario used for 191-250 tube capacity. The photo above was taken prior to a thermal validation test and shows 250 tubes bundled in sets of five with data loggers attached.

- 5) Place the second absorbent pad on top of either the tube rack or bundled tubes.
- 6) Place the remaining refrigerated yellow B18 PCM5 coolant on top of the absorbent sheet.
- 7) Set the remaining frozen blue B18 PCM5 coolant on top of the yellow coolant.

- 8) Place the lid back on the cooler (**Note:** Black gasket side facing down)
- 9) Equip the proper tamper evidence solution to the left and right-side grommets and Velcro the flaps down.
- 10) The container is now ready for transport. No packaging tape required.

## 5. Design Qualification Test Methods and Results:

**5.1 Test Methods:** The presented U17DT24 Donor Tube Shipper with B18 PCM5 coolant bottles (x4) is designed to maintain donor tubes cooling towards 2-8°C OR within 2-8°C for a minimum of 24 hours. Four different test cases were conducted to demonstrate the shipper's ability to meet the extreme ambient requirements. All test cases were conducted using the critical test scenario of tubes starting out refrigerated within the 2-8°C window and maintained at that 2-8°C throughout the tested duration. Thermal chambers with NIST traceable calibration were programmed with a 24-hour summer and winter ISTA-7D ambient profiles for testing. Data logger (NIST traceable calibration) with probes were submerged in simulant sample tubes to measure sample temperature during test runs. The shippers were prepared and packed following the methods listed in Section 4 and placed inside a chamber for 24 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

**5.2 Pass and Failure Criteria:** The below criteria were used to determine the pass or failure of each test case.

**Pass Criteria:** Payload temperature maintained 2-8°C ( $\pm 0.5^\circ\text{C}$ ) during the 24 hours of test duration.

**Fail Criteria:** Payload temperature went above 8°C ( $\pm 0.5^\circ\text{C}$ ) or below 2°C ( $\pm 0.5^\circ\text{C}$ ) during the 24 hours of test duration.

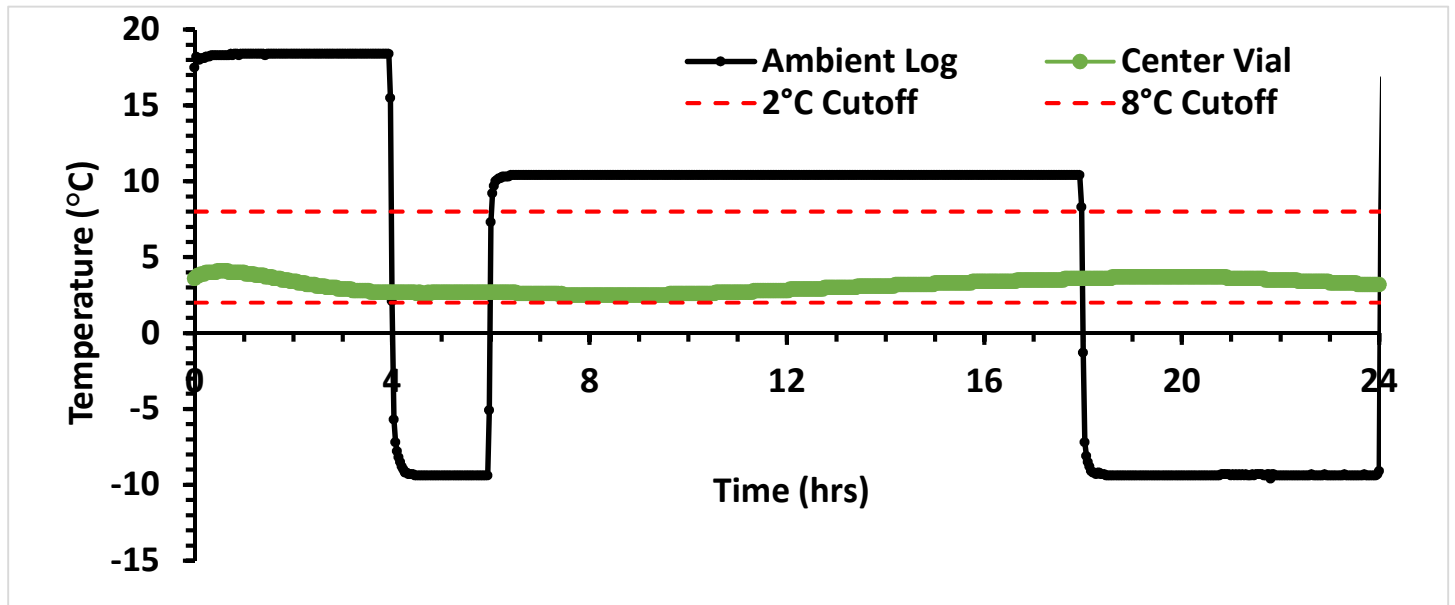
**5.3 Test Results:**

**5.3.1 Minimum Payload Configuration | Diagnostic tube samples maintained at 2-8°C | Winter Ambient**

Test setup:

Test payload	15 x 6mL Vacutainer simulant tubes kept in the center of a tube rack at 2-8°C 12 hours
Ambient temperature	Winter Ambient
Test duration	24 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

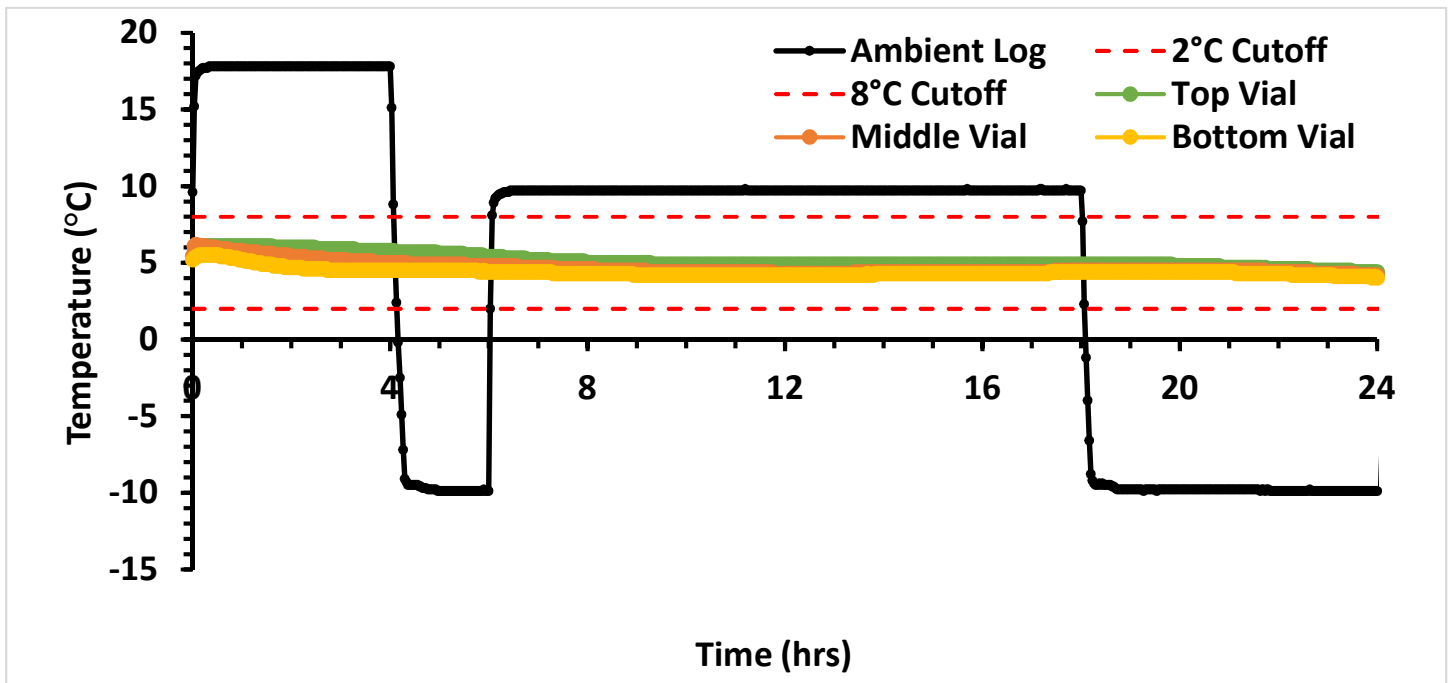
Total time (hours) payload-maintained 2-8°C	Minimum payload temperature during tested duration
24	2.5°C @ 7.4 hours

5.3.2 Maximum Payload Configuration | Diagnostic tube samples maintained at 2-8°C | [Winter Ambient](#)

Test setup:

Test payload	250 x 6mL Vacutainer simulant tubes bundled and kept at 2-8°C 12 hours
Ambient temperature	<a href="#">Winter Ambient</a>
Test duration	24 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 2-8°C			Minimum payload temperature during tested duration (°C)		
Top	Middle	Bottom	Top	Middle	Bottom
24	24	24	4.4°C @ 24 hours	4.2°C @ 24 hours	4.0°C @ 24 hours

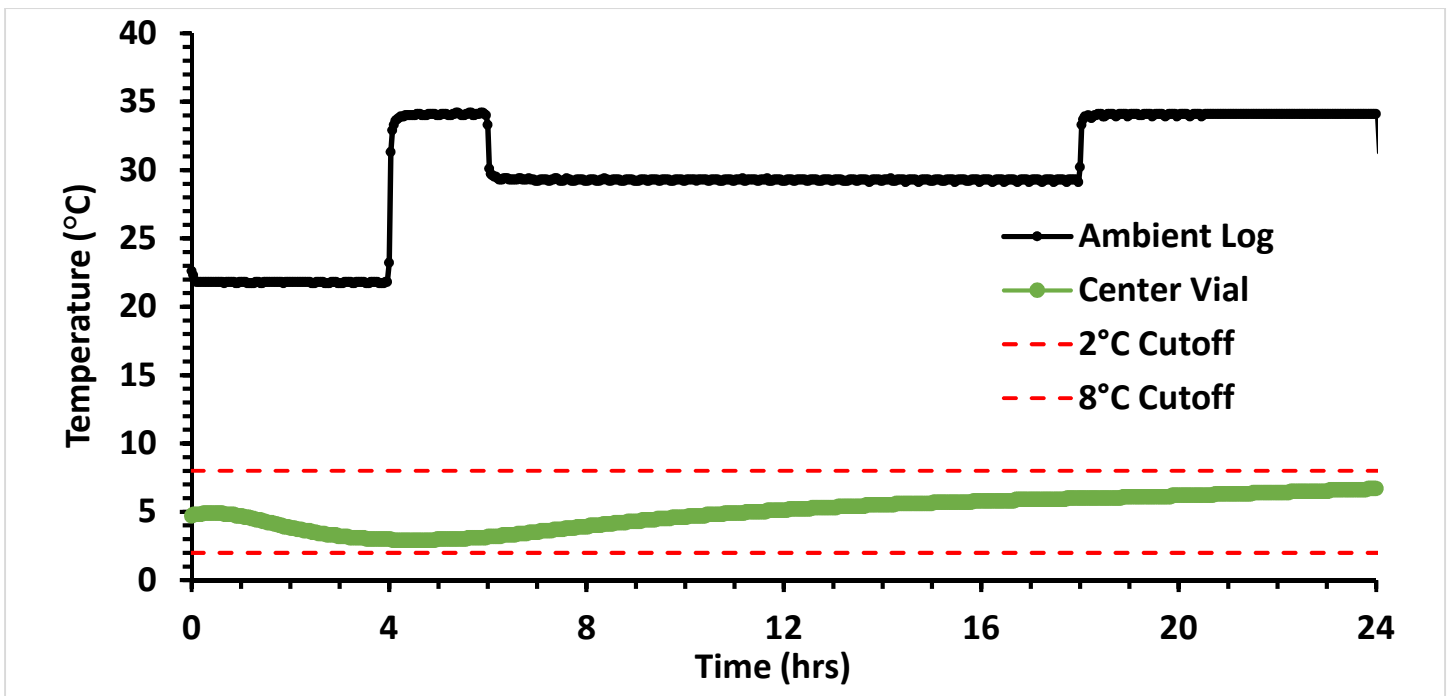


**5.3.3 Minimum Payload Configuration | Diagnostic tube samples maintained at 2-8°C | Summer Ambient**

Test setup:

Test payload	15 x 6mL Vacutainer simulant tubes kept in a tube rack at 2-8°C 12 hours
Ambient temperature	Summer Ambient
Test duration	24 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

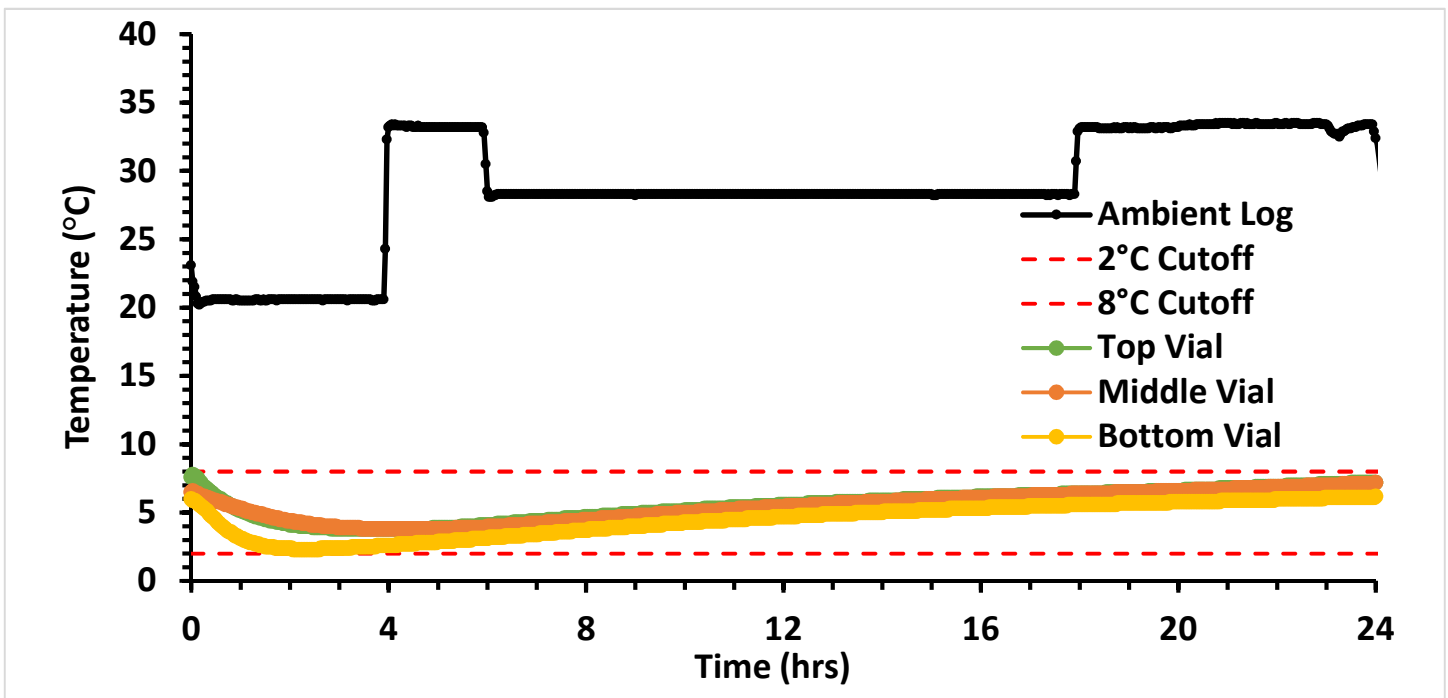
Total time (hours) payload-maintained 2-8°C	Maximum payload temperature during tested duration (°C)
24	6.7°C @ 24 hours

5.3.4 Maximum Payload Configuration | Diagnostic tube samples maintained at 2-8°C | **Summer Ambient**

Test setup:

Test payload	250 x 6mL Vacutainer simulant tubes bundled and kept at 2-8°C 12 hours
Ambient temperature	<b>Summer Ambient</b>
Test duration	24 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 2-8°C			Minimum payload temperature during tested duration (°C)		
Top	Middle	Bottom	Top	Middle	Bottom
24	24	24	7.2°C @ 24 hours	7.2°C @ 24 hours	6.2°C @ 24 hours