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Design Qualification Report for the MaxPlus Donor Tube Shipper

Intended for 40+ hours transport of donor tubes 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#DT10V48). The report addresses basic system requirements, components breakdown, packing methods, and temperature compliance data for the DT10V48 to transport donor tubes maintained at 2-8°C for a minimum of 40 hours.

2. Requirements Summary:

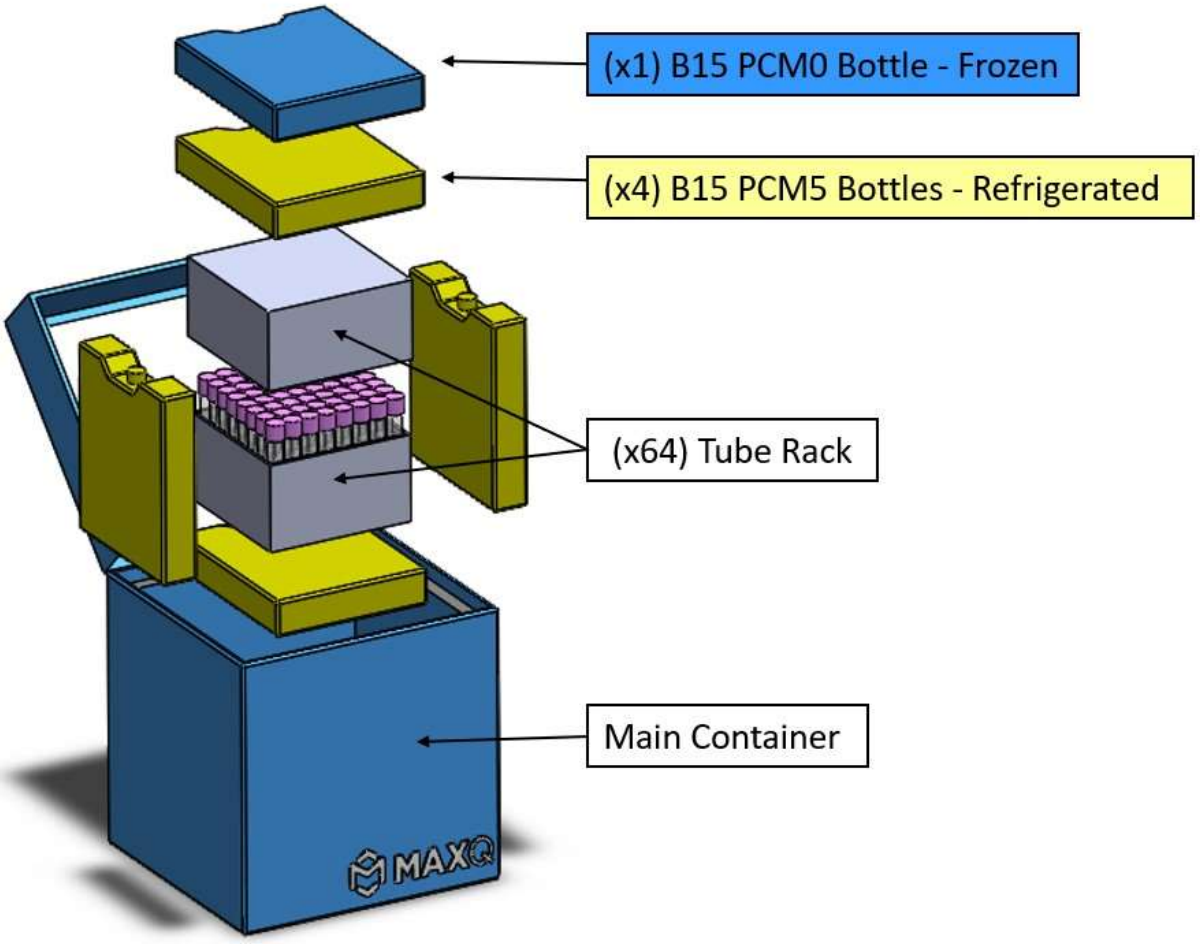
Payload type	Refrigerated donor tubes
Payload form factor	6mL Vacutainer tubes
Payload volume	6mL per unit
Payload capacity	1-64 tubes using the provided tube rack
Payload temperature	Maintained at 2-8°C
Validation	48 hours against ISTA 7E standards

3. Product Summary and Components:

- Outer Shell Material: Corrugated plastic, highly reusable
- Outer Dimensions: 11in x 10in x 10in (LWH)
- Inner Dimensions: 8in x 7.5in x 8in (LWH)
- System Weight (excluding payload): 9 lbs.
- Coolant Bottles: Yellow B15 PCM5 bottles (x4), Blue B15 PCM0 bottles (x1)
- Accessories: Tube rack (x1)

4. Packing Methods

4.1 DT10V48 Packout Schematic:



4.2 DT10V48 Coolant Conditioning Procedure:

- Charge (x1) B15 PCM0 coolant bottle (blue) inside a freezer (below -20°C) for a minimum of 24 hours.
- Charge four (x4) B15 PCM5 coolant bottles (yellow) inside a refrigerator (2-6°C) for a minimum of 24 hours.

4.3 DT10V48 Packing Instructions:

1) Place a refrigerated PCM5 (yellow) coolant bottle in the bottom of the container (**Note:** Situate the bottle with the cap facing the rear wall).
2) Place two refrigerated PCM5 (yellow) coolant bottles on the left and right sides of the bottom bottle (**Note:** Situate the bottles with the caps facing up as shown in the diagram above.)
3) Load the tube rack to the desired capacity (up to x64 tubes) and place the rack inside the container on top of the bottom PCM5 (yellow) coolant bottle.
4) Lay the remaining refrigerated PCM5 (yellow) coolant bottle on top of the tube rack.
5) Remove the frozen PCM0 (blue) coolant bottle from the freezer and place on top of the PCM5 (yellow) bottle.
6) Close the lid and tighten the buckle on the front of the container.
7) The packout process is complete and the container is ready for shipment. (**Note:** No packaging tape required)

5. Design Qualification Test Methods and Results:

5.1 Test Methods: The presented DT10V48 Donor Tube Shipper with (x4) B15 PCM5 (yellow) coolant bottles and (x1) B15 PCM0 (blue) coolant bottle is designed to maintain donor tubes within 2-8°C for a minimum of 40 hours. Two minimum capacity test cases were conducted to demonstrate the shipper's ability to meet the extreme ambient requirements. These 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. A total of (x15) tubes were used in testing and configured in the following orientation: (x14) tubes located in the center slots and single tube located in the front left corner slot. Thermal chambers with NIST traceable calibration were programmed with a 48-hour summer and winter ISTA ambient profiles for testing. Data logger (NIST traceable calibration) with probes were submerged in a center and edge tubes to measure critical sample temperature during test runs. The shippers were prepared and packed following the methods listed in Section 4 and placed inside a chamber for 48 hours. At the end of the each 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 (±0.5°C) for a minimum of 40 hours of during the whole test duration.

Fail Criteria: Payload temperature went above 8°C (±0.5°C) or below 2°C (±0.5°C) before 40 hours.

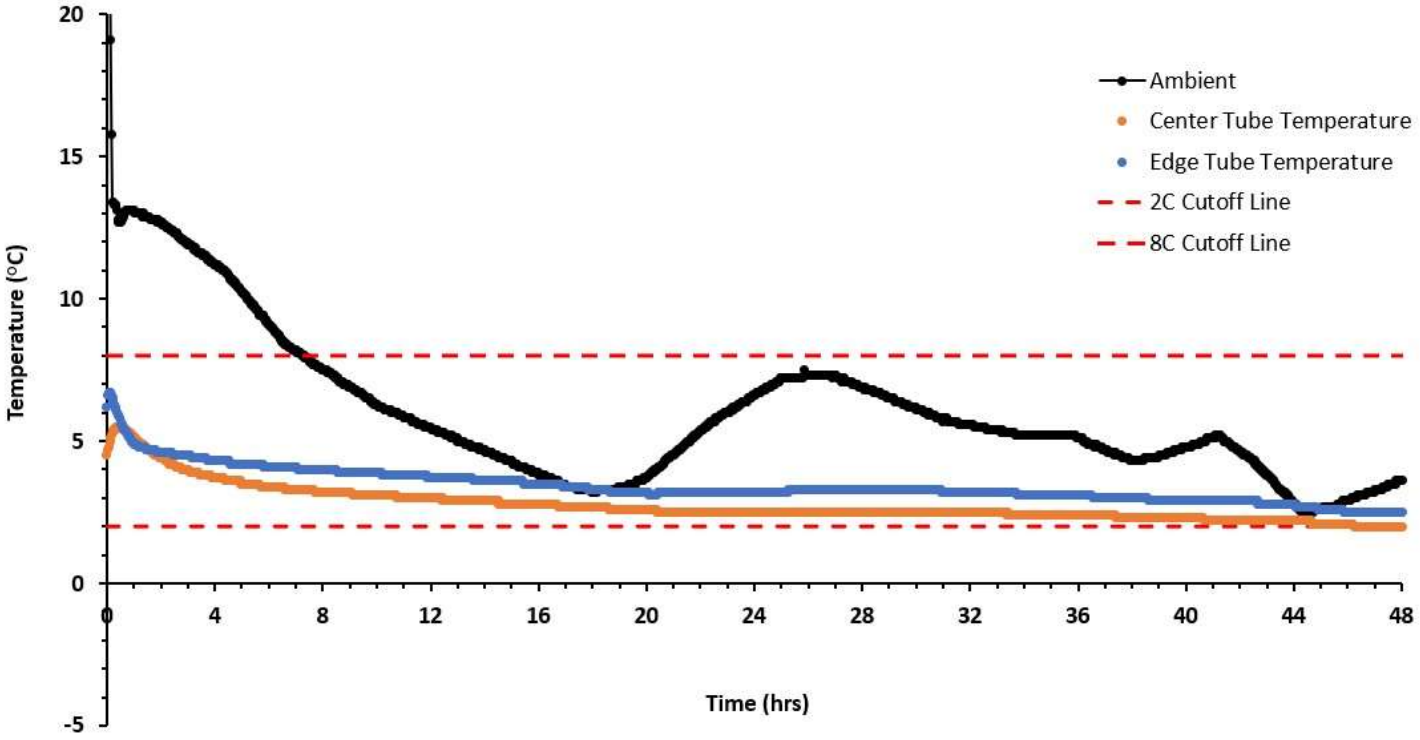
5.3 Test Results:

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 conditioned at 2-8°C 12 hours
Ambient temperature	Winter Ambient
Test duration	48 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

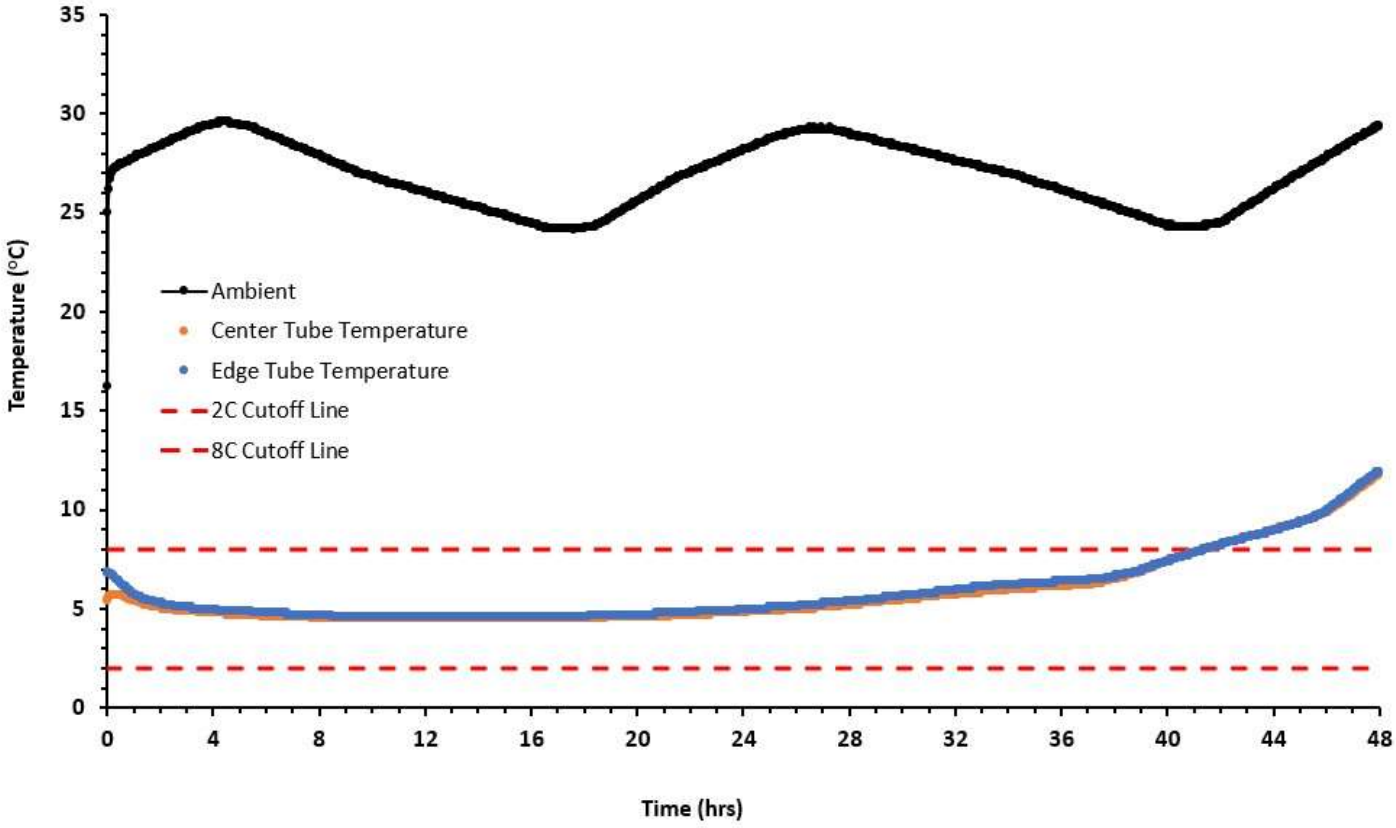
Total time (hours) payload-maintained 2-8°C	**Maximum payload temperature after 48 hours (°C)**	
48	Center Tube 2.0°C @ 48 hours	Edge Tube 2.5°C @ 48 hours

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 conditioned at 2-8°C 12 hours
Ambient temperature	Summer Ambient
Test duration	48 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 2-8°C	**Maximum payload temperature after 48 hours (°C)**	
41.5	Center Tube 11.5°C @ 48 hours	Edge Tube 11.7°C @ 48 hours