

Validation of va-Q-tec Small Blood Component Transport Containers

Supplied by NHSBT for Hospital Use

28th October 2021

Background

The va-Q-tec Small Blood Component Transport Containers are supplied to hospitals for internal use to move blood components.

This document provides a summary of the recent re-validation tests performed to determine the time the containers will hold blood components at the standard storage temperature specification when packed in accordance with NHSBT datasheet DAT48, published on the NHSBT hospitals website.

<https://hospital.blood.co.uk/components/transport-containers/>

The containers had previously been validated in March 2015 and the results obtained in the 2021 validation represent a decrease in the validated times for red cell and platelet components.

Testing

The re-validation testing was carried out at two NHSBT sites, Tooting and Cambridge, in September and October 2021. Both sites have test cabinets where the required environmental testing temperature can be controlled at +35°C and -5°C.

The tests were determined in advance to a series of validation protocols. These detail the packing of the containers and the layout of the temperature monitoring probes. The temperature monitoring probes are also certified as accurate. Copies of the validation protocols are available on request, (NHSBT controlled document numbers VAL1273, VAL1274 and VAL1275).

The boxes were tested with minimum and maximum loads of each component, including a single low volume (neo-natal component).

Each box was packed in a specific manner and the container placed in the test cabinet at either +35°C or -5°C. The time taken for the controlled temperature conditions for each component to be breached at either the upper or lower limit, was recorded.

The shortest time across all tests for each component informs DAT48 for the minimum time blood components are outside of controlled storage conditions and in the container for the purposes of delivery. The shortest time is used for operational simplicity in that the containers can be used consistently at a temperature range of external temperatures -5°C and +35°C throughout the year.

Results

Red Cells

The container was validated to maintain red cell components at a temperature between 2°C and 6°C for **5.5 hours** when subjected to external temperatures of -5°C and +35°C.

This represents a reduction of 1.5 hours from the value attained at the last validation in March 2015.

Platelets

The container was validated to maintain platelet components at a temperature between 20°C and 24°C for **7 hours** when subjected external temperatures of -5°C and +35°C.

This represents a reduction of 1.0 hours from the value attained at the last validation in March 2015.

Frozen Products

The container was validated to maintain frozen components at a temperature below -30° for 17.5 hours when subjected to external temperatures of -5°C and +35°C.

For operational reasons, the current limit of 11 hours will continue to be used. This is no change from the value attained at the last validation in March 2015.

Conclusions

The re-validation of the va-Q-tec Small Blood Component Transport Container has resulted in a reduction in the validated minimum time that red cell and platelet components can be out of controlled storage and in the container. However, this exercise has highlighted the importance of re-validation of transport container systems.

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28th October 2021