

Product performance for VACUETTE® Blood Collection Tubes

We Greiner BIO-ONE hereby inform,

regarding the product performance of following VACUETTE® Products

VACUETTE® Blood Collection Tubes

In course of internal performance test spp1029 the impact of transport to the functionality in regards to draw volume was tested. In a worst case approach the heaviest item (14.95kg per carton with 1200 tubes) was selected. The test is in accordance to ASTM 04169. The weight of the carton defines a drop height of 533mm. The carton is dropped on 12 different positions (see Figure 1; no. 12 from doubled height: 1066mm). In a double worst case approach the tubes were repacked into a new carton after the first test was completed to repeat the dropping sequence.

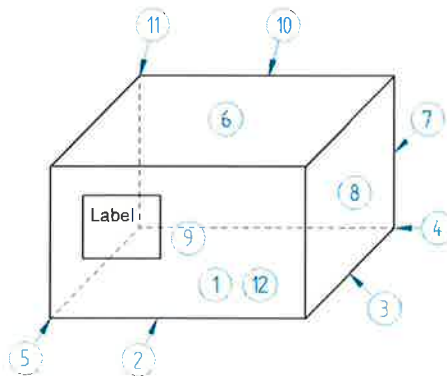


Figure 1: dropping sequence with positions (edges, corners, areas)

After simulated transport tubes from worst case regions of the carton (e.g. positions 3, 4 and 5) were tested regarding draw volume and compared to tubes from less critical positions (e.g. middle of the carton).

Results

We hereby confirm that the draw volume results showed functionality of all tubes after dropping the shipping carton 24 times. None of the tested tubes showed a reduced draw volume value. In comparison to tubes from non-critical positions no deviations or significant differences were found.

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(Moritz Wiesbauer – Team Leader Physical Testing and Change Control)

Date & Signature