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What To Expect When You Request Post-Thaw Segment QC Testing On A Cord Blood Unit?

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INTRODUCTION

The selection process of cord blood units (CBU) requires post-thaw quality control (QC) testing to verify the quality and potency of stored cells. CBU are manufactured with attached segments that can be cut from the CBU without compromising the bag, allowing for testing without having to thaw the whole CBU.

Heterogeneity of data between labs can make the interpretation of QC results difficult for transplant centers.

Here we present the post-thaw segment QC results for 2,249 consecutive segments cut at our institution, in order to create a benchmark of what is to be expected when interpreting segment testing.

METHODS

During the period 4/2016 – 2/2023, **1,828 clinical CBU** from the National Cord Blood Program had a segment cut for confirmatory HLA typing and QC testing. Of those, 421 were split into two bags. A total of **2,249 segments** were analyzed.

The following QC parameters were measured:

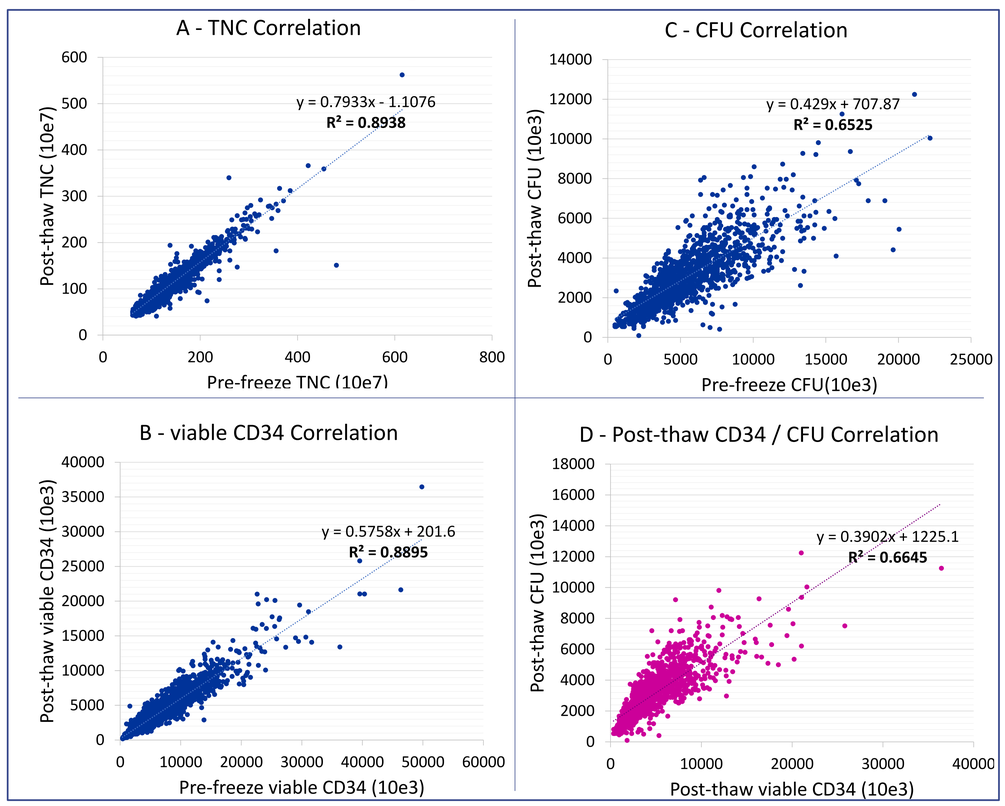
- Total nucleated cells (TNC), using a Sysmex XE-2100 analyzer;
- Viable CD34 cells (vCD34), by flow cytometry (single platform flow cytometry using ISHAGE strategy and 7-AAD for viability);
- Colony forming units (CFU).

Cell concentrations from the segment were extrapolated to reflect the expected content of the full CBU.

Recoveries were calculated using pre-freeze and post-thaw results and expressed as percentages.

Confirmed date of infusion and engraftment data were obtained from CIBMTR.

Figure 2 Correlations



RESULTS

Mean **recoveries** for TNC, viable CD34 and CFU on the segments were 78.4%, 61.85% and 58.99%, respectively (Table 1).

Mean CD34 **viability** was 94.33% (Table 1 and Figure 1). Two segments (0.1%) had a CD34 viability lower than 70% (below FACT requirement); both were found to be testing issues (one segment opened during thaw; for the second, another segment from the CBU was tested with good results).

Correlation between pre-freeze and post-thaw TNC, viable CD34 and CFU was excellent (Figure 2-A B C). Post thaw viable CD34 and CFU were also strongly correlated (Figure 2-D).

Analyzed CBU were collected between 1999 and 2022. Post-thaw CD34 viability was found to be similar across all **collection dates** (Figure 3).

Of the 1,828 CBU tested, 323 were **transplanted**. Engraftment information was available for 81 of them. Two patients failed to engraft (2%), and 4 patients died too early for engraftment to be evaluated. The rest were successfully transplanted (Figure 4).

Table 1 Post-thaw segment QC results

Criteria	NCBP results
CD34 viability (n=2249) (a)	94.33% (58.45 – 100)
TNC recovery (n=1579) (b)	78.40 % (31.46 – 140.58)
viable CD34 recovery (n=1823) (c)	61.85 % (20.87 – 305.20)
CFU recovery (n=1281) (d)	58.99 % (4.23 – 408.38)

(a) 2,249 segments were assessed for CD34 viability (421 CBU were preserved into 2 bags, 1,407 CBU into one bag)
(b) 1,579 CBU were assessed for TNC recovery (test became available after August 2017)
(c) 1,823 CBU were assessed for CD34 recovery (5 CBU didn't have pre-freeze CD34, collected 1999 – 2000)
(d) 1,281 CBU were assessed for CFU recovery (547 CBU had not post-processing CFU testing)

Figure 1 Segment post-thaw CD34 viability

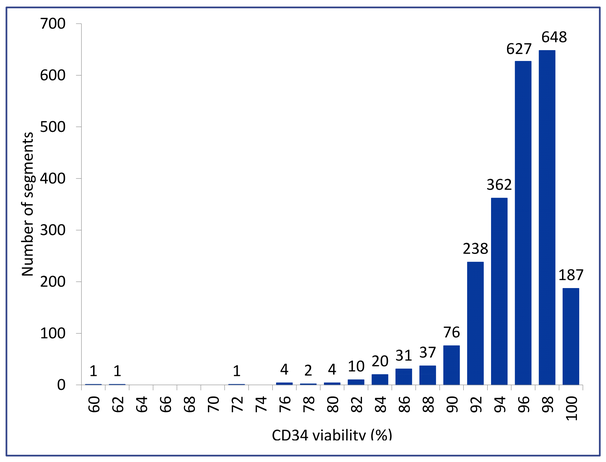


Figure 3 CD34 viability by collection year

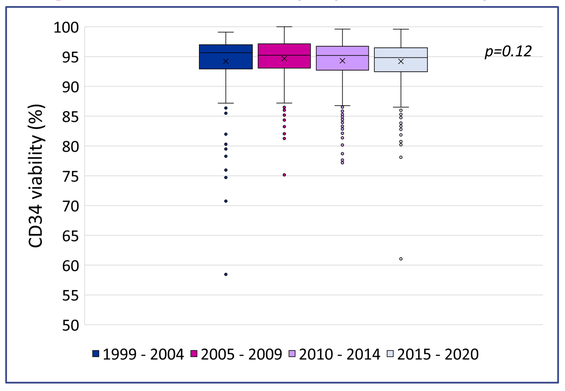
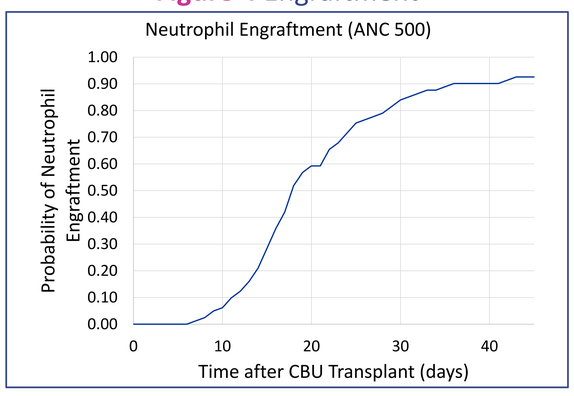


Figure 4 Engraftment



CONCLUSIONS

This analysis confirms that segment QC testing continues to be a **reliable indicator of CBU quality** for the transplant centers, with strong correlation between pre-freeze and segment post-thaw values.

Our data also demonstrates that post-thaw viable CD34 and CFU are significantly correlated; segment viable CD34 is a **reliable predictor of CFU growth** and as such, can be used as an indicator of CBU quality before infusion when CFU results are not yet available.

Our results on a large number of segments, from CBU collected over a 20-year period, provide transplant centers with a range of expected recoveries that can be used as a reference to predict the ability of the CBU to be successfully transplanted.

No relationships to disclose.

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