

BE A
MATCH
SAVE
A LIFE



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Umbilical Cord Blood Transplantation: Understanding what are the critical quality attributes (CQAs) of a cord blood unit.

**Dr Andreea Iftimia-Mander, Daniel Gibson, Prof Alejandro Madrigal,
Dr Susana G Gomez**

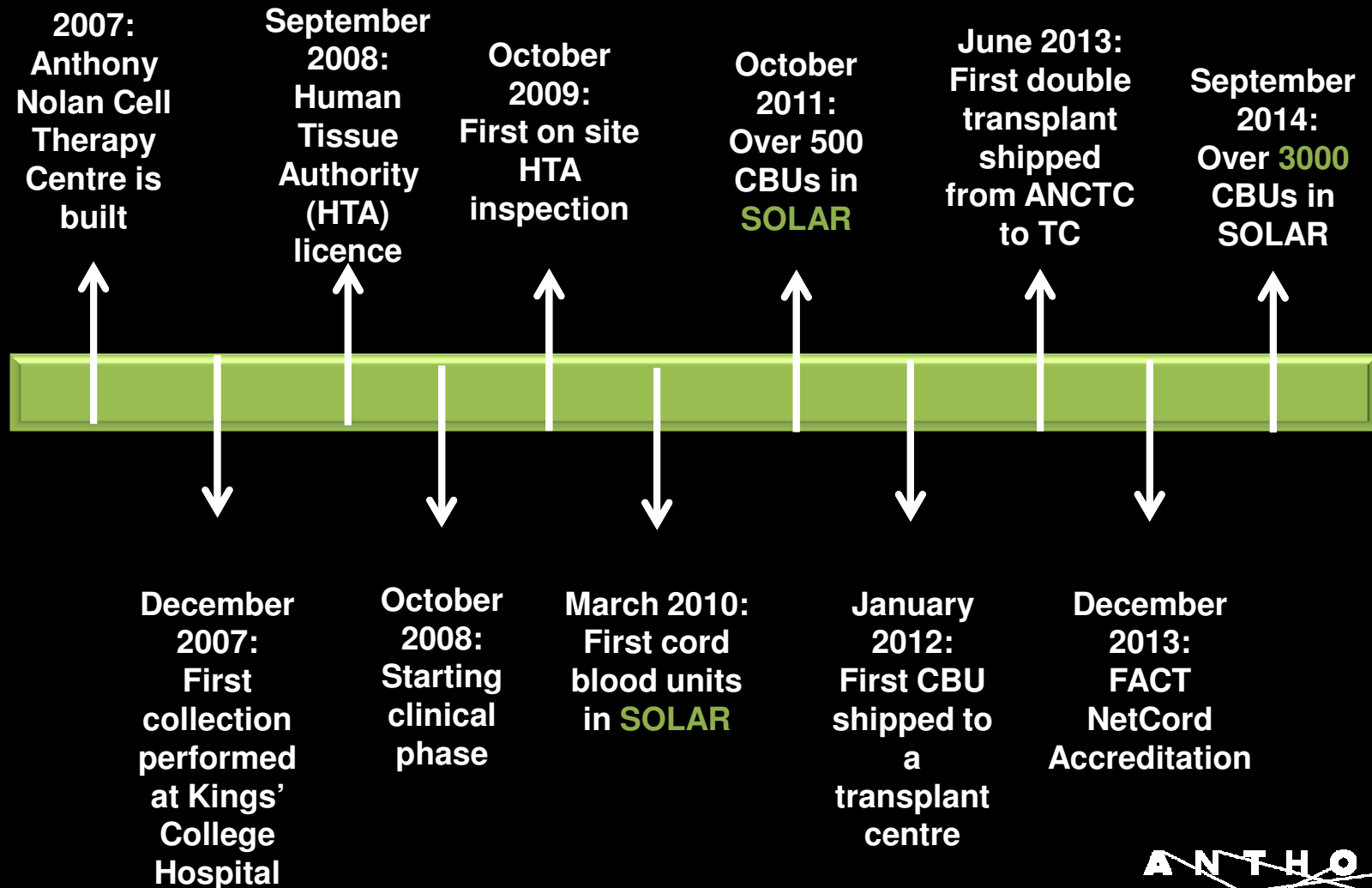
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ANTHONY NOLAN CELL THERAPY CENTRE



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ANTHONY NOLAN CORD BLOOD PROGRAMME



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ANTHONY NOLAN CORD BLOOD PROGRAMME - SOME FIGURES

- Capability to process **16 clinical units per day**
- **Over 3000 cord blood units** in the register **searchable** for transplant
- **41 cord blood units shipped** for a transplant (Nottingham City Hospital, Royal Marsden, Bristol, Leeds, King College Hospital, Manchester, Birmingham, Newcastle, Oxford, Netherlands, France, Canada, Australian Register and NMDP)
- Currently **8 collection sites** with over **70** members of staff
- Currently **24** members of staff at **processing facility**

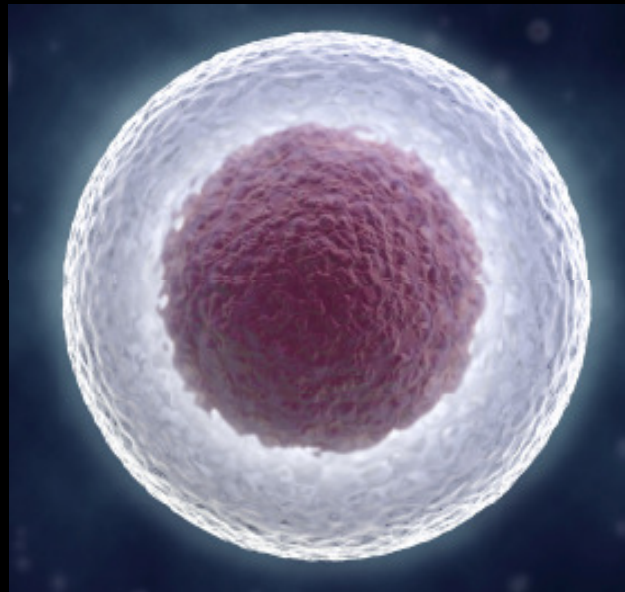
Jo, cord blood recipient



CORD BLOOD ADVANTAGES & CHALLENGES AS A STEM CELL SOURCE

Advantages

- Availability
- Long Storage
- Tested product ready for Immediate Use
- Tolerance for HLA mismatch
- Less GvHD
- Safe for Donor/ ethical
- Long term cost benefit



Challenges

- Delayed engraftment
- Cell dose
- Conditioning Regime
- Cost of building inventory
- Standardisation of Quality standards
- Confused perceptions of public vs. private banking

ANTHONY NOLAN CORD BLOOD PROGRAMME

QUALITY CONTROL : VALIDATION CRITERIA

- Final total nucleated cells (**TNC**) > 70×10^7
- **TNC yield** > 50%
- **Viability of CD45+** > 85% prior to cryopreservation (7AAD assay)
- **Final CD34+ cells** > 3×10^6
- Total Colony Forming Units (**CFU**) prior to cryopreservation > 10% of the CD34+ cell counts
- **Negative** for bacteriology tests (**aerobic, anaerobic & fungi**)
- **Negative for IDM tests** (HIV, HCV, HBV (HBsAg and HBc), Lues (antigen), HTLV I & 2, CMV and Toxoplasmosis)
- **Haemoglobinopathy testing** results not showing clinically significant abnormal haemoglobin
- **Tissue typing** for intermediate or high resolution for A, B, C, and DQB1, and allelic level for DRB1
- CBU must have at least **3 attached segments**

PROCESS CONTROL AND OPTIMIZATION IN CORD BLOOD BANKING

“Quality by design means designing and developing manufacturing processes during the product development stage to consistently ensure a predefined quality at the end of the manufacturing process.” (US Food and Drug Administration, 2006)

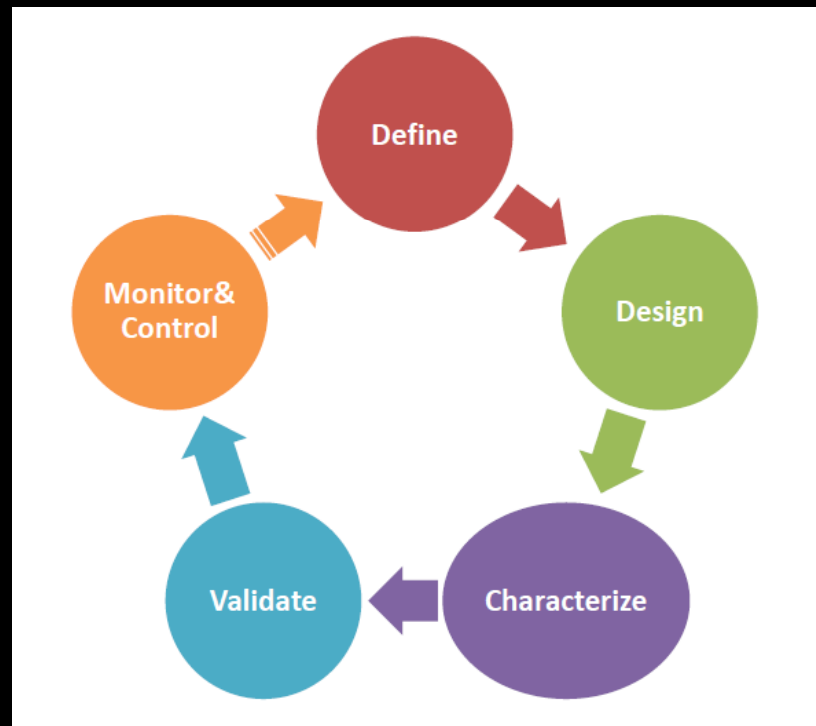
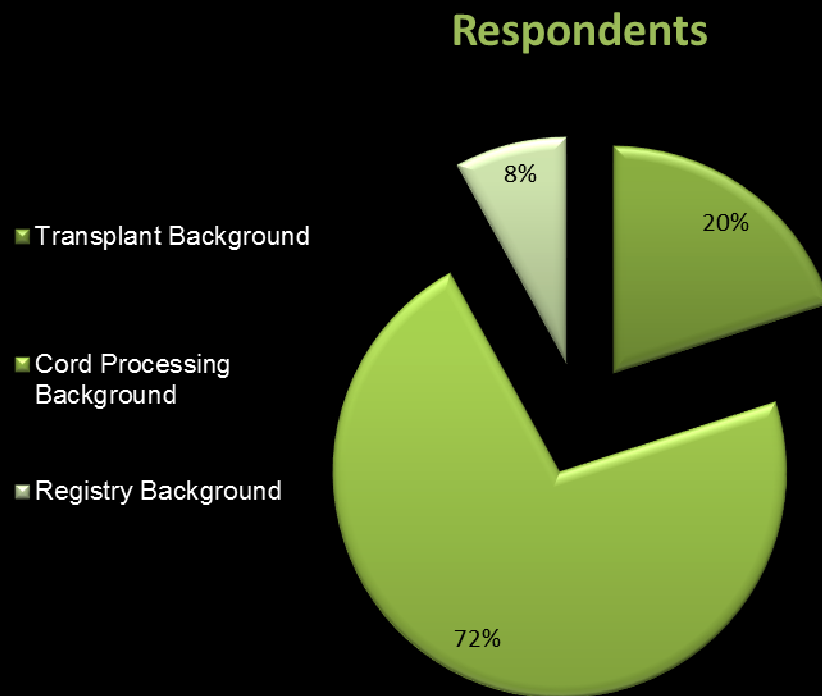


Fig. 1 Different phases during the life cycle of a pharmaceutical process. (Rathore AS, Winkle HN, 2009)

CRITICAL QUALITY ATTRIBUTES (CQAs) OF A CORD BLOOD UNIT (CBU)

WORLD MARROW DONOR ASSOCIATION (WMDA) Cord Blood Survey

The Survey) was sent out in the first quarter of 2013. Of all the WMDA members the survey was sent to, 50 responded. The breakdown of the respondents by background are detailed below



In the analysis of the responses, the groups of respondents have been broken down into two main groups: the **Cord Blood Providers (CBP)**, that have the CBUs processing background, and the **Cord Blood Selectors (CBS)**, that have the registry and transplant background.

Fig. 2 Graph shows the breakdown of respondents in accordance with their background expertise.

CRITICAL QUALITY ATTRIBUTES (CQAs) OF A CORD BLOOD UNIT (CBU)

WMDA Cord Blood Survey

The Survey asked for the respondents to rate the following parameters out of 10 (1 being not at all important 10 being extremely important)

- Pre Freeze Total Nucleated Cells (TNC)
- Pre Freeze Mononuclear Cell (MNC)
- Pre Freeze CD34+
- Pre Freeze % Granulocyte
- Pre Freeze CD45+ viability
- Pre Freeze CD34+ viability
- Pre Freeze Haematocrit
- Pre Freeze potency (CFU)
- Post thaw Nucleated Cell (NC) yield
- Post thaw CD34+ yield
- Post thaw CD45+ viability
- Post that CD34+ viability
- Post thaw potency (CFU)

CRITICAL QUALITY ATTRIBUTES (CQAs) OF A CORD BLOOD UNIT (CBU)

WMDA Cord Blood Survey

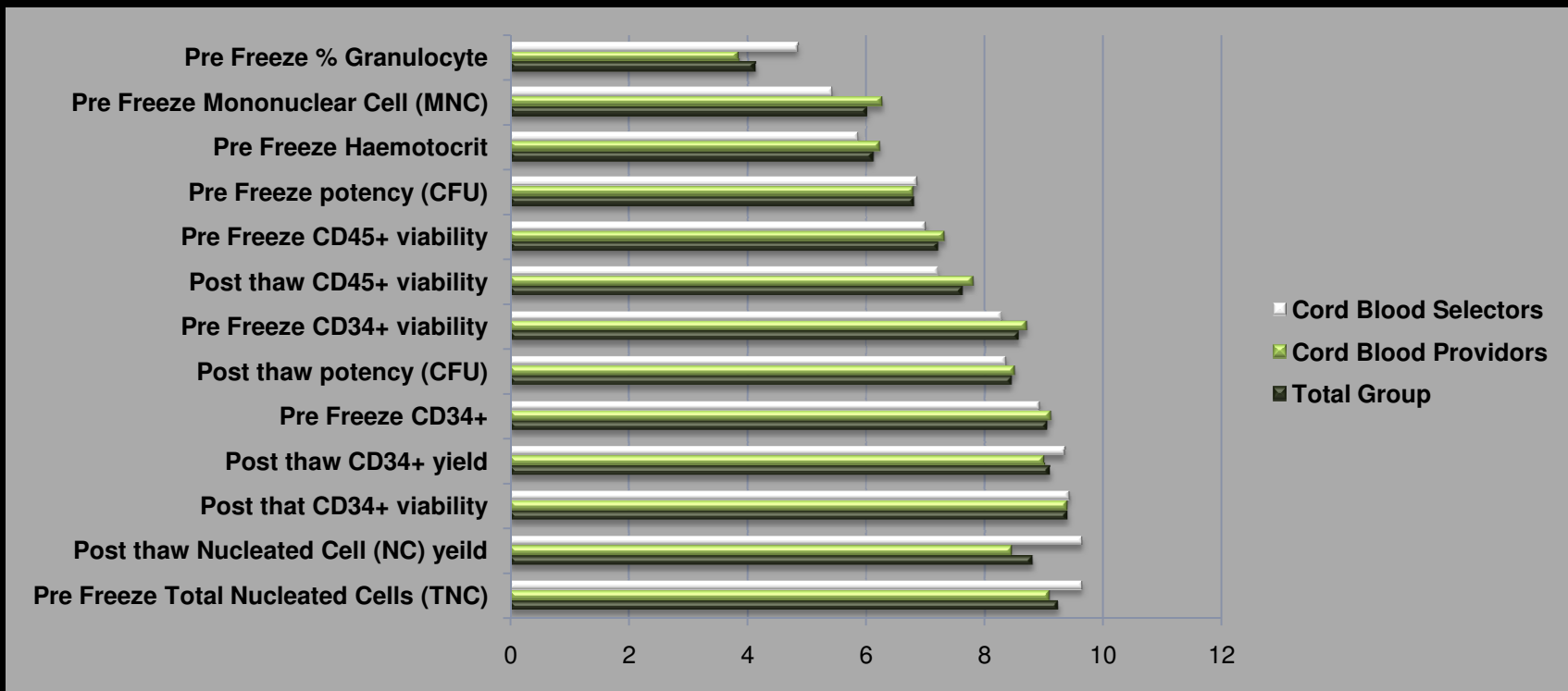


Fig. 3 The bars in the graph are average scores given for each parameter in the questionnaire by the two groups.

CRITICAL QUALITY ATTRIBUTES (CQAs) OF A CORD BLOOD UNIT (CBU)

WMDA Cord Blood Survey

Reviewing this information, there are a few important things to note:

- Nothing scored lower than 4 by the total group. Although individuals scored lower, averagely the group or subgroup didn't consider any parameters to be of no importance suggesting that more information at selection is better.
- There was largely uniformity across the group with no significant difference observed between the subgroups with the exceptions of post thaw nucleated cell yield which the cord blood selectors considered to be more important than the cord blood providers did.
- The Cord blood selectors group appears more uniform with there answers showing considerably lower Standard deviations compared to the cord blood providers group. However this could also be an artefact of the smaller sample size.

CRITICAL QUALITY ATTRIBUTES (CQAs) OF A CORD BLOOD UNIT (CBU)

WMDA Cord Blood Survey

Table 1. List of the top 4 scoring parameters for each group; where 1 is has the highest and 4 has the lowest priority.

Cord Blood Providers	Cord Blood Selectors
1. Post thaw CD34+ viability	1. Pre Freeze Total Nucleated Cells (TNC)
2. Pre Freeze CD34+	2. Post thaw Nucleated Cell (NC) yield
3. Pre Freeze Total Nucleated Cells (TNC)	3. Post thaw CD34+ viability
4. Post thaw CD34+ yield	4. Post thaw CD34+ yield

CRITICAL QUALITY ATTRIBUTES (CQAs) OF A CORD BLOOD UNIT (CBU)

WMDA Cord Blood Survey

When asked to enumerate the parameters the following variations between the groups were noted:

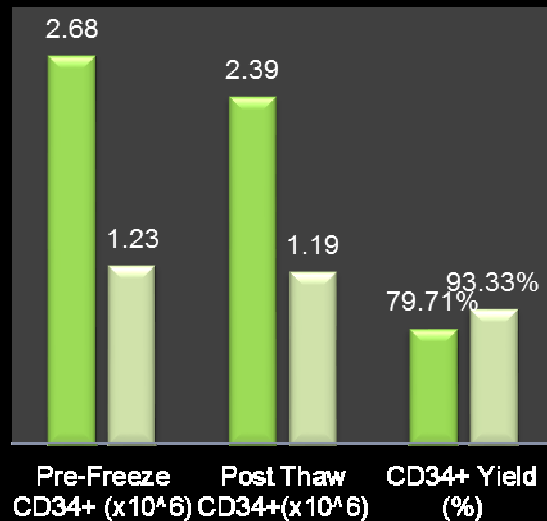


Fig. 4 A numerical representation of the TNC content and yield desired in the final product by each individual group.

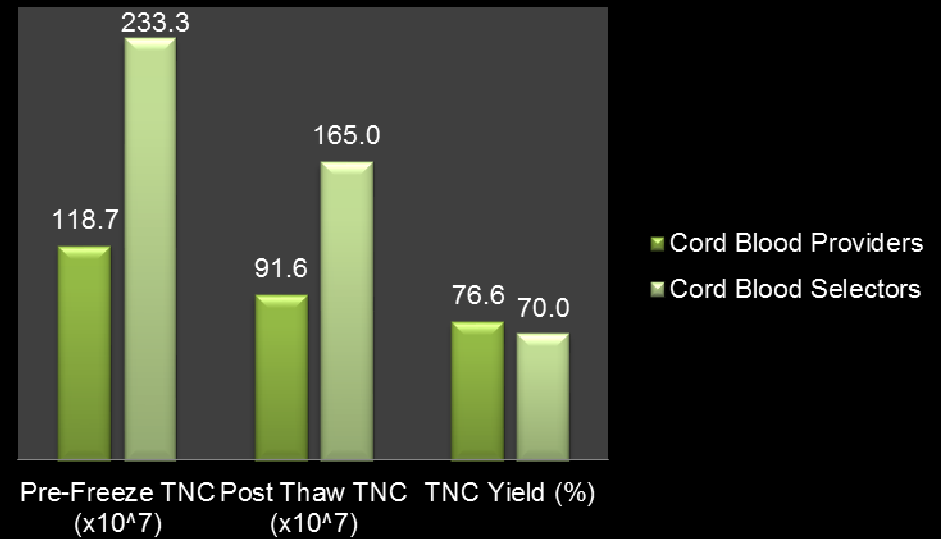


Fig. 5 A numerical representation of the CD34+ cells and yield desired in the final product by each individual group. Desired CD34+ observed by group.

CRITICAL QUALITY ATTRIBUTES (CQAs) OF A CORD BLOOD UNIT (CBU)

WMDA Cord Blood Survey

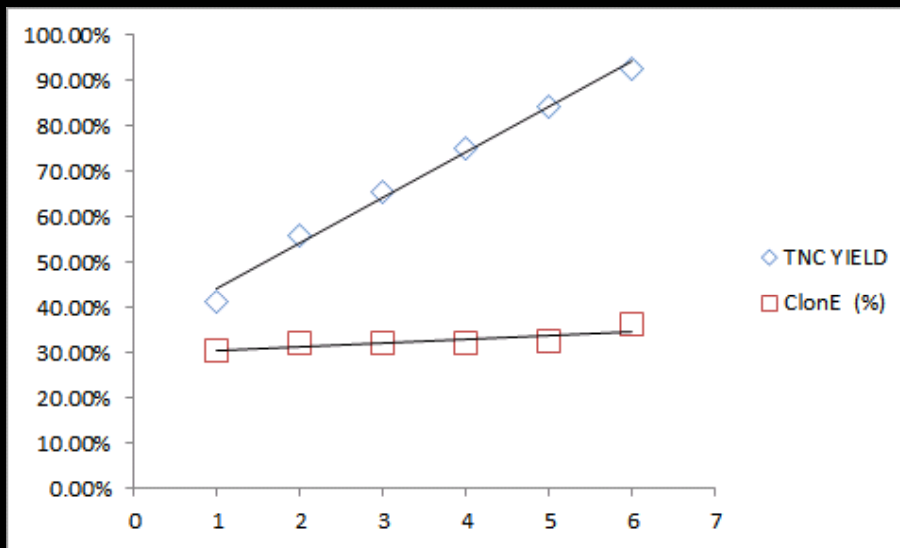


Fig. 6 Correlation between TNC yield and ClonE yield post processing.

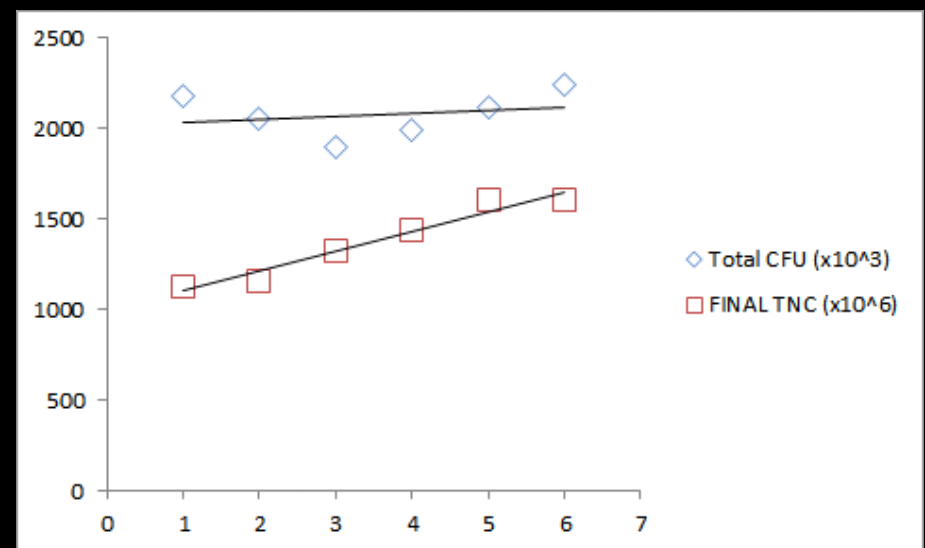


Fig. 7 Correlation between TNC and CFU content post processing.

QUESTION TIME

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