A Stem Cell Potency and Release Criteria Assay Specifically Designed for Umbilical Cord Blood Transplantation that is Compliant with Regulatory Guidelines

Ivan N. Rich, Karen M. Hall and Holli Harper
HemoGenix®, Inc. Colorado Springs, CO,

**Measurement of Cord Blood Stem Cell Potency**

**Umbilical Cord Blood Stem Cell Potency, Release and Engraftment Study**
1. Performed in collaboration with the University of Colorado Cord Blood Bank (Chelakarina, Inc).
2. 26 Umbilical cord blood from donors for which engraftment was known.
4. All samples tested in triplicate.
5. Nightingale: cell count, viability by 7-AAD.
6. 24 Samples tested for CFC-GEMM and 22 samples tested for HPP-SP (5,500-7,500 or 10,000 cells/well, when sufficient cells were available.
7. All remaining samples tested at 5,000 cells/well.

**Characteristics of the Study Population**
- Time from thaw-freezing to transplantation: 91 days to 911 days
- Time from transplantation to ANC recovery: > 500 cells/mm³
- 1-14 days
- Time from transplantation to platelet recovery (>50 K/mm³): 2-27 days

**Cord Blood Characteristics**
- Pre-engraftment cord blood cell count: 8700-1780 x 10⁹
- Pre-engraftment cord blood cell count: 8700-1780 x 10⁹
- Pre-engraftment cord blood cell count: 8700-1780 x 10⁹
- Pre-engraftment cord blood cell count: 8700-1780 x 10⁹
- Pre-engraftment cord blood cell count: 8700-1780 x 10⁹

**Important Correlations (or lack of) with ATP Concentration and Stem Cell Potency**
- Correlation between intracellular ATP and the slope of the cell dose response
- Correlation between stem cell potency and release criteria

**Relationship between JATP, Release Criteria, Stem Cell Potency and Engraftment**

**CONCLUSIONS**
1. HALO®-96 is a rapid, reference-standard-based stem cell potency assay for umbilical cord blood that can help define acceptance limits for release criteria.
2. HALO®-96 is validated and fully compliant with FDA and EMEA regulations and guidelines.
3. Stem cell potency is determined by the cumulative stem cell proliferation potential.