Evaluating the Stability and Consistency of Stabilized Cellular Controls Versus Whole Blood for Monitoring Flow Cytometry Assay Performance

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INTRODUCTION

Reliable flow cytometry performance depends on consistent quality control (QC); however, whole blood, a commonly used QC material, is limited by biological variability and rapid degradation that can introduce assay instability. Stabilized cellular controls (SCCs) provide an alternative by preserving antigen expression and minimizing variability over time. In this study, the stability and reproducibility of a commercial SCC, CD-Chex™ Daily (Streck), was evaluated relative to whole blood collected into EDTA across multiple immunophenotyping markers to assess its suitability for routine QC applications.

METHODS

Twelve lots of CD-Chex Daily were evaluated at assay, mid-dating, and expiration, while EDTA whole blood from three to five donors was assessed over 14 days (Days 0, 3, 7, and 14). Samples were stained using a standard stain lyse wash protocol and acquired on a BD® FACSCanto® II cytometer. Median fluorescence intensity (MFI) and percentage of gated events were measured for TBNK markers and additional immunophenotyping targets. Standardized gating was applied across all time points in Kaluza, and longitudinal changes were assessed using percent difference, coefficient of variation, and paired t-test analysis.

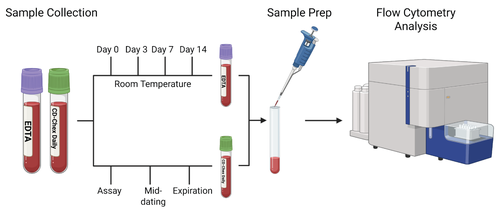

Figure 1. Study design demonstrates parallel evaluation of SCC and whole blood across defined timepoints, enabling direct comparison of longitudinal stability and variability. Created with BioRender.com

CONCLUSION

CD-Chex Daily demonstrated superior stability, reduced variability, and more consistent marker expression compared to whole blood, which showed rapid signal degradation and high donor-dependent variability. By minimizing biological noise and preserving fluorescence signal over time, stabilized cellular controls provide a more reliable and reproducible QC material for flow cytometry, supporting improved assay monitoring and standardization.

CD-Chex Daily is For Research Use Only. Not for use in diagnostic procedures.

CD-Chex Daily has superior longitudinal stability compared to whole blood samples

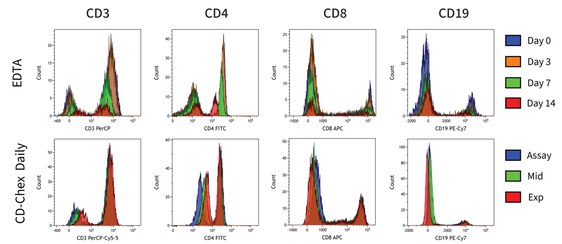

Figure 2. CD-Chex Daily maintains consistent MFI across product dating, whereas whole blood exhibits substantial fluorescence signal loss over time.

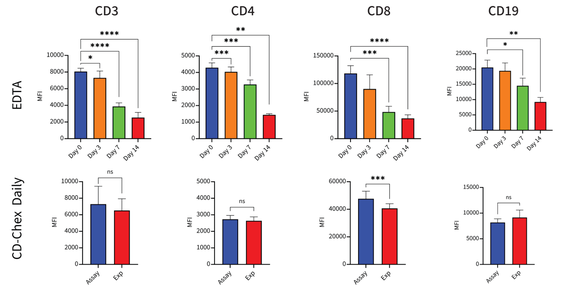

Figure 3. Statistical analysis confirms significant longitudinal MFI decline in whole blood, and minimal or no significant change in CD-Chex Daily. Paired t-tests were performed for each donor or lot across the testing timeframe. Significance is denoted as NS (no significance), * (p<0.05), ** (p<0.01), *** (p<0.001), or **** (p<0.0001) as indicated.

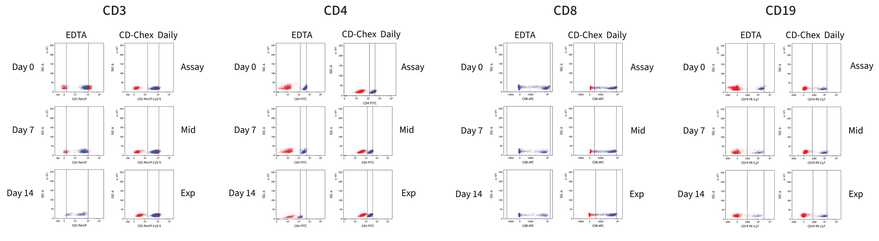

Figure 4. Whole blood displays wide 2SD distributions and decreased separation from negative populations, whereas CD-Chex Daily maintains tight, well defined populations throughout dating.

CD-Chex Daily displays strong lot-to-lot reproducibility for core lineage markers and beyond

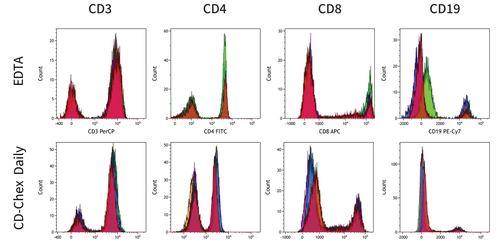

Figure 5. Overlay analysis demonstrates strong lot-to-lot reproducibility of CD-Chex Daily compared to substantial donor-to-donor variability in whole blood. Representative overlays of data acquired using identical instrument settings and gating strategies. Each color in the overlay represents a unique donor or manufacturing lot.

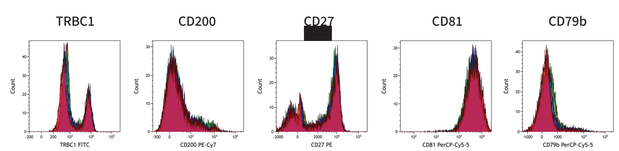

Figure 6. Extended immunophenotyping and clonality markers show consistent expression across CD-Chex Daily lots. Representative overlays of data acquired using identical instrument settings and gating strategies. Each color in the overlay represents a unique manufacturing lot.

KEY TAKEAWAYS

- **CD-Chex Daily provides superior longitudinal stability compared to whole blood**, maintaining consistent MFI and population distributions across assay, mid-dating, and expiration, while whole blood shows rapid signal degradation (≈55–69% MFI loss over 14 days).
- **Biological variability is a major limitation of whole blood QC**, with high donor-to-donor variability leading to broad distributions, unstable gating, and reduced reproducibility.
- **CD-Chex Daily demonstrates strong lot-to-lot reproducibility**, with tight overlays and low coefficients of variation, enabling reliable cross run and longitudinal assay monitoring.
- **Stabilized controls improve QC reliability for clinical flow cytometry**, enabling clearer differentiation between true analytical shifts and expected assay performance, supporting consistent immunophenotyping and assay standardization.

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