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PRODUCT DATA

Shelf life extension for:
Myeloid gDNA reference standard HD829

Summary

The stability of our Myeloid gDNA reference standard (HD829) was tested via a real-time stability study. Samples were kept under routine storage of 4°C (2-8°C) for up to 27 months and quality tested at the end of the period. As our Myeloid gDNA product is supplied at a concentration of 25 ng/ul, its shelf life has been determined independently from our 50 ng/ul gDNA products.

DNA yield, integrity, and allelic frequency were analysed in representative samples and compared to the values established during the initial QC.

All batches of gDNA used during the study fall within quality control criteria required for product release and sale.

Experiment Details

HD829 was manufactured following our standard processes and stored at standard storage conditions of 4°C (2-8°C) for 27 months.

DNA concentration was assessed using NanoDrop. Analysis of DNA integrity was performed using gel electrophoresis, while allelic frequency was determined using Droplet Digital™ PCR.

The results of DNA yield, integrity, and allelic frequency analysis all fell within standard acceptance criteria when tested at 27 months post manufacture.

Conclusion

In conclusion, Myeloid gDNA stored at 4 °C (2-8 °C) for the duration of the study met quality control criteria for product release and sale.

The expiry date for this material can therefore be extended to 27 months from date of manufacture with a storage specification of 4 °C (2-8 °C).

DNA Concentration

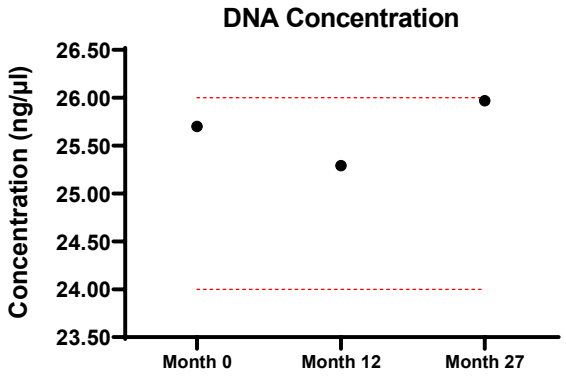

Figure 1. Concentration determined by NanoDrop at 0, 12 and 27-month when stored at standard storage conditions 4 °C (2-8 °C). The red dotted line shows the minimum and maximum yield acceptance criteria. All observed concentrations were within specification.

DNA Integrity

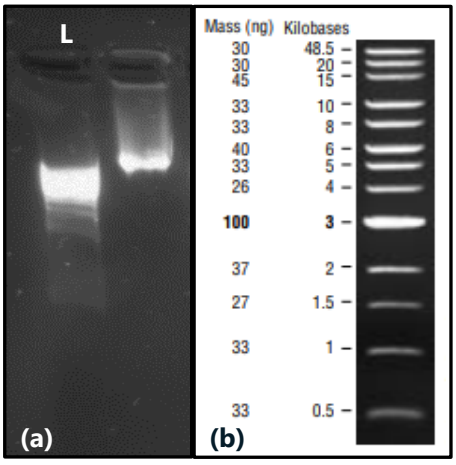

Figure 2. The DNA integrity of samples at the 27-month time point on agarose gel. (a) DNA ladder (L) in Lane 1 for QC of the DNA sizing and integrity with sample. A high molecular weight band is evident showing intact gDNA. Lane 2. (b) Quick-load 1kb extend DNA ladder used in the gel that shows the size of the DNA bands for reference.

Allele Frequency

For the allele frequencies measured in HD829, please see the results in Appendix 1: Allelic Frequency Results at 0, 12 and 27-Month Time Points. All product specifications fell within acceptance criteria at all time points tested.

Appendix 1: Allelic Frequency Results at 0, 12 and 27-Month Time Points.

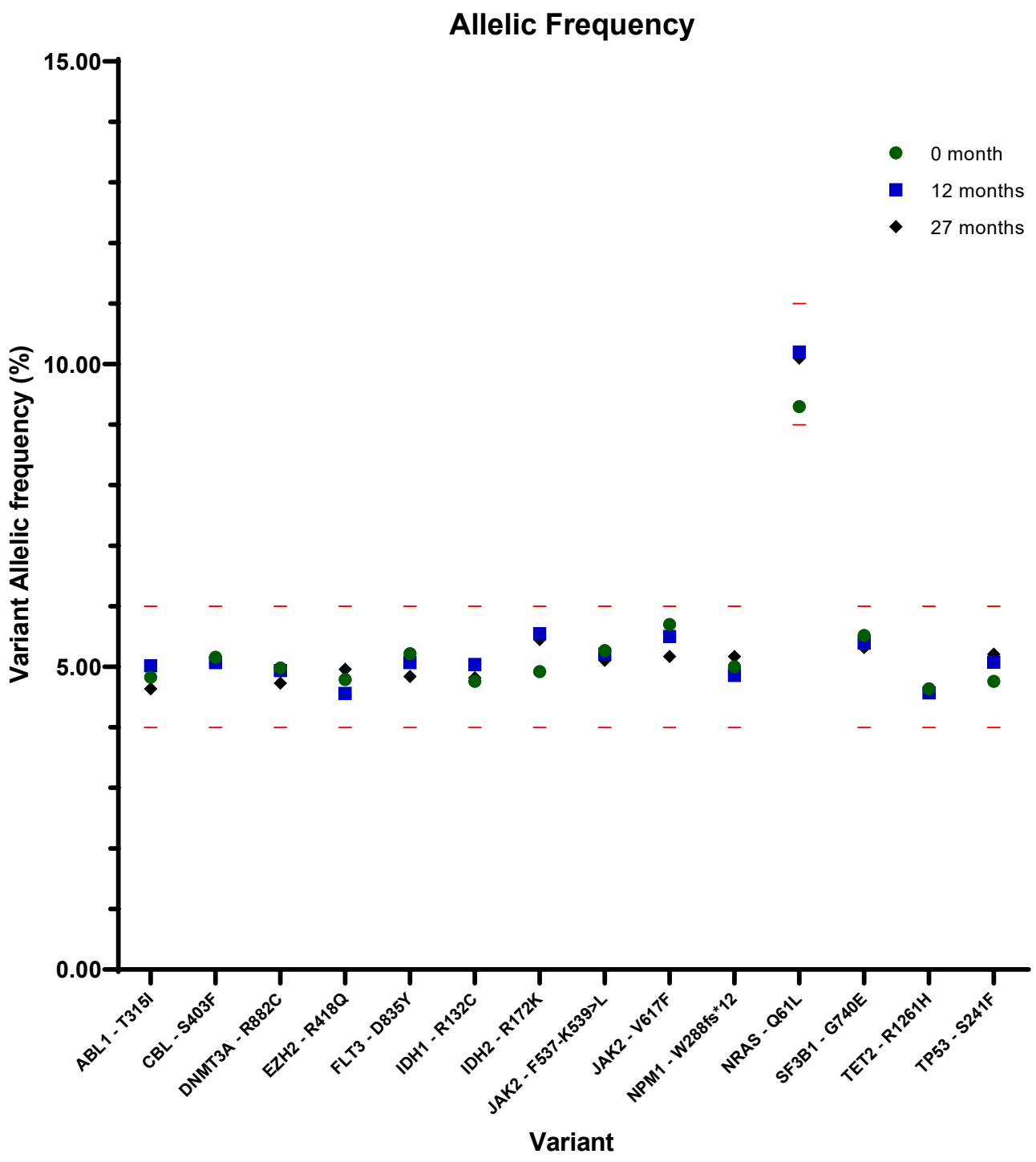

Figure 3. Allelic frequencies of the Myeloid product variants when tested at 0, 12, and 27 months. The red dotted line shows the minimum and maximum yield acceptance criteria. At all timepoints tested the product was within specification.

For more information

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