

Shelf life extension for: cfDNA Reference Standards

Dear Customer

We are pleased to inform you that we have extended the shelf-life of our cfDNA Reference Standards in buffer to 36 months from the date of manufacture (DOM). Previously, the shelf-life for these products were 12 months.

This study was conducted on an accelerated basis following Clinical Laboratory Standards Institute guidelines 'Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline' EP25-A (2009). A real time stability study at the recommended storage conditions of +4°C (2-8°C) is ongoing.

Method

HD780, the Multiplex I Cell Free DNA reference standard was used for this stability study.

The product was manufactured, and QC testing for DNA concentration, DNA integrity and variant allele frequency was performed. The product was then stored at 24°C and 37°C for up to 16 weeks and QC testing was performed again.

The two sets of results were compared. This data is shown in Figures 1-6 below.

The shelf-life of the samples was then calculated using the Arrhenius equation. We can confirm that cfDNA Reference Standards in buffer are stable for at least 36 months from the DOM when stored at the recommended conditions.

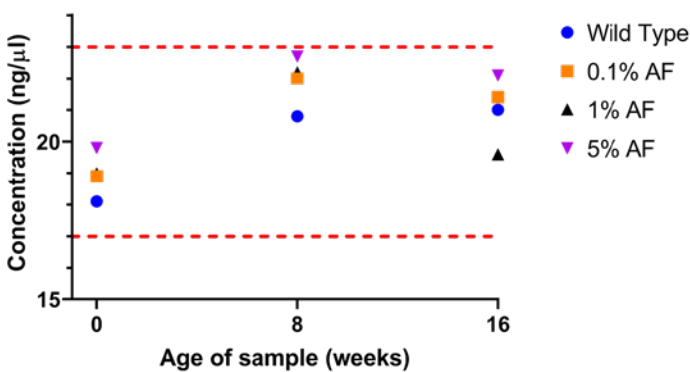


Figure 1. Average concentration measured by Qubit of HD780: Multiplex I cfDNA Reference Standard at time of manufacture (0 weeks), after storage at 24°C for 8 weeks and 16 weeks.

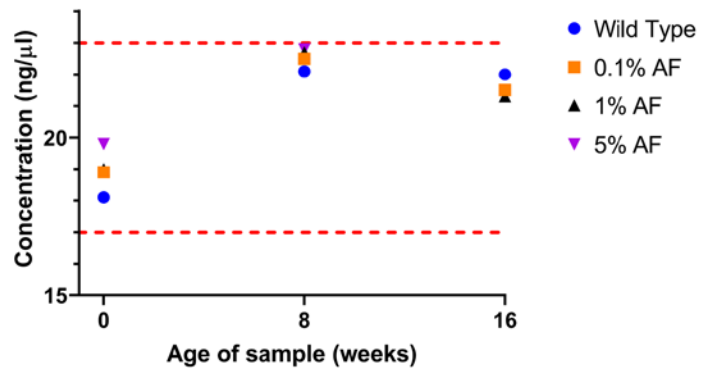


Figure 2. Average concentration measure by Qubit of HD780: Multiplex I cfDNA Reference Standard at time of manufacture (0 weeks), after storage at 37°C for 8 weeks and 16 weeks.

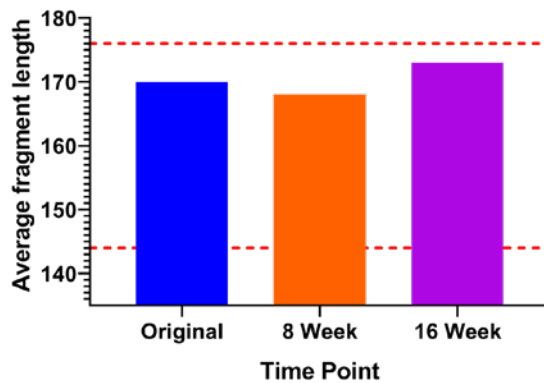


Figure 3. Average fragment length of HD780: Multiplex I cfDNA Reference Standard measured by TapeStation® at time of manufacture (0 weeks), or after storage at 24°C for 8 weeks and 16 weeks.

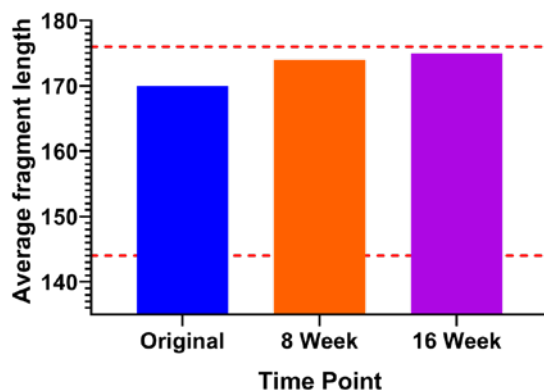


Figure 4. Average fragment length of HD780: Multiplex I cfDNA Reference Standard measured by TapeStation® at time of manufacture (0 weeks), or after storage at 37°C for 8 weeks and 16 weeks.

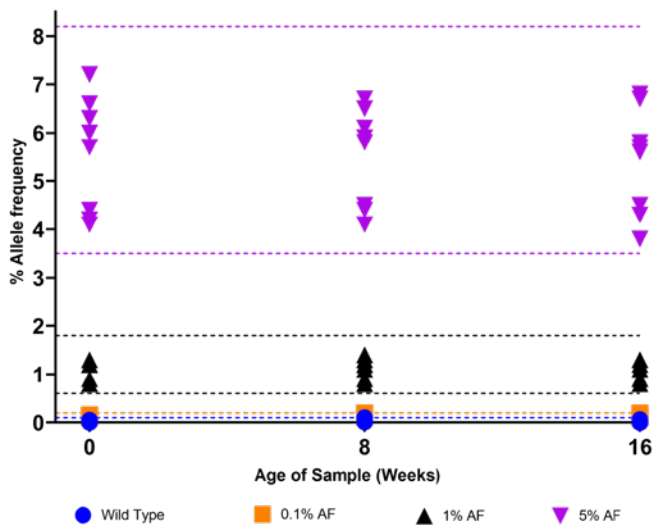


Figure 5. ddPCR results for HD780: Multiplex I cfDNA Reference Standard for each allele frequency with acceptance criteria as dotted lines. Data shown is at time of manufacture (0 weeks), or after storage at 24°C for 8 weeks and 16 weeks.

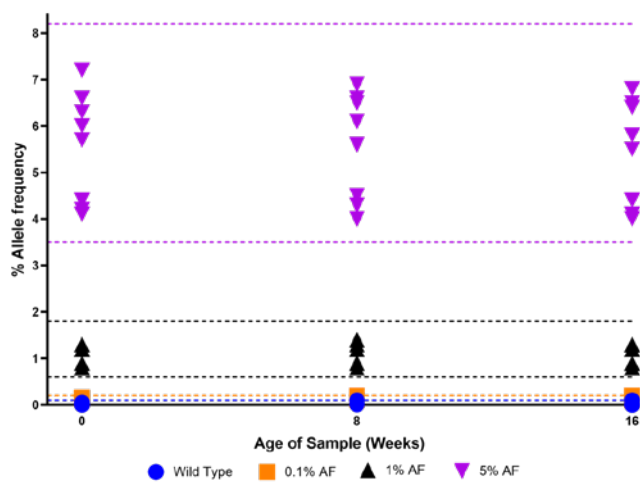


Figure 6. ddPCR results for HD780: Multiplex I cfDNA Reference Standard for each allele frequency with acceptance criteria as dotted lines. Data shown is at time of manufacture (0 weeks), or after storage at 37°C for 8 weeks and 16 weeks.

For more information

To find the contact information in your country for your technology of interest, please visit us at horizondiscovery.com/contact-us

Horizon Discovery, 8100 Cambridge Research Park, Waterbeach, Cambridge, CB25 9TL, United Kingdom

©2020 The Horizon logo and other trademarks are the property of Horizon Discovery Limited, unless otherwise stated. DHARMACON is a trademark of Dharmacon Inc.