

Instructions for Use

cfDNA Reference Standard

Revision A

RUO

REF 100479



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Overview

The cfDNA Reference Standard contains mononuclear DNA (mnDNA) containing the KRAS G12V mutation and the TP53 Arg158Leu, which is an established standard¹ for spike-and-recovery extraction analysis for cfDNA. The expected mnDNA size is 150 bp. mnDNA is obtained from the NCI-H441 lung cancer cell line. Dinucleosomes and trinucleosomes may also be observed at the given multiples of 340 bp and 560 bp.

The cfDNA Reference Standard contains 5 single-use tubes containing 1 mL at a 1 ng/ μ l concentration in TE Buffer. Comparing the spike-in amount to the recovery amount, the percent recovery is determined.

For Research Use Only. Not for use in diagnostic procedures.

Instructions for Use

1. Remove one tube of cfDNA Reference Standard from the ≤ -20 °C freezer
2. Place the tube of cfDNA Reference Standard on ice.
3. Leave the cfDNA Reference Standard to thaw on ice for one hour.
4. If the cfDNA Reference Standard is not thawed, keep on ice and check at 15-minute intervals. Remove the tube(s) from ice once completely thawed.

NOTE: *Each tube is designed for single use upon thawing. Thawed cfDNA Reference Standard should be disposed of properly once used and not refrozen and reused. freeze/thaw cycles may adversely affect results.*

5. Vortex the cfDNA Reference Standard tube at speed 8 (Vortex-Genie setting, or about 2200 rpm) for 10 seconds.
6. Pulse spin (1 second) the cfDNA Reference Standard tube(s) in a benchtop centrifuge to bring down any volume in the cap.
7. The cfDNA Reference Standard is now ready to be added to the sample to be extracted.
8. The recommended final concentration of the cfDNA Reference Standard mnDNA in the sample is 20 ng/mL.

¹ Lampignano R, et al. Multicenter Evaluation of Circulating Cell-Free DNA Extraction and Downstream Analyses for the Development of Standardized (Pre)analytical Work Flows. Clin Chem. 2020 Jan 1;66(1):149-160. doi: 10.1373/clinchem.2019.306837. PMID: 31628139