AM Multiplexed ctDNA Standard

NAME AND INTENDED USE

The AM Multiplexed ctDNA Standard is intended for use with molecular diagnostic assays that are designed to identify somatic mutations in DNA from human samples. The assays can be either amplicon- or capture-based. The control is intended to provide a true-human plasma-based standard for validation of the assay, assessing day-to-day test variation and may help in identifying increases in random or systematic error, such as reagent lot changes, operator-based deviations, and instrument malfunction. This product is for Research Use Only.

CATALOG NUMBER

60100103, Multiplexed ctDNA 3% AF Standard (300ng in TE).

60100104, Multiplexed ctDNA 3% AF Standard (25ng/ml, 5ml, in Plasma).

SUMMARY

The AM Multiplexed ctDNA Standard contains well defined wildtype genomic DNA (gDNA) nucleosomally fragmented to around 145 bp. It carries 23 mutations formulated at around 3% allele frequency. It also contains heterozygous mutations, BRCA1 (P871L) and BRCA2 (N372H). The mixture of DNA is spiked either in DNA-depleted human plasma or in TE-based buffer. Please refer to the product Certificate of Analysis for the exact DNA concentration.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures. CAUTION: Handle the plasma sample as though it is capable of transmitting infectious agents.

SAFETY PRECAUTIONS

Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

STORAGE INSTRUCTIONS

Store AM Multiplexed ctDNA Standard can be stored for up to 30 days at 2-8°C. For longer term storage, please keep it frozen at -20 °C or colder. Shelf life when stored under these conditions is three years from date of manufacture.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

AM Multiplexed ctDNA Standard is a mixture of human genomic DNA. In plasma matrix, it should appear as a yellowish or brownish liquid. In TE buffer, it should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

HANDLING PRECAUTIONS

Do not use the product beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

INSTRUCTION FOR USE

For plasma samples, after thawing, 0.5 to 5 ml of the plasma-based AM Multiplexed ctDNA Standard is extracted with a cfDNA extraction method before library preparation or direct assay. For buffer samples, the DNA may be diluted to an appropriate concentration for library preparation or direct quantitation, refer to your assay procedures in order to determine the amount of material to use.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

In-house quantitation results were provided in the Certificate of Analysis (CoA). Each laboratory must establish an assay-specific expected value. When results for the product significantly deviate from values on the CoA, it may indicate unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, etc.

MUTATIONS INCLUDED

Variant Name	Cosmic ID
KRAS G12C	COSV55497469
KRAS G12D	COSV55497369
KRAS G12V	COSV55497419
TP53 R248Q	COSV52661580
PIK3CA E545K	COSV55873239
PIK3CA H1047R	COSV55873195
EGFR T790M	COSV51765492
EGFR C797S	COSV51766493
EGFR D770_N771insG	COSV51769298
EGFR L858R	COSV51765161
BRAF V600E	COSV56056643
NRAS Q61R	COSV54736340
PTEN R130G	COSV64288384
TP53 R175H	COSV52661038
IDH1 R132H	COSV61615239
CTNNB1 T41A	COSV62687862
CTNNB1 S33C	COSV62687839
FGFR3 S249C	COSV53390026
APC Q1429*	COSV57322632
APC R1450*	COSV57321313
EGFR E746-A750del v1	COSV51765119
EGFR E746-A750del v2	COSV51765066
KIT D816V	COSV55386424

1.Note BRCA1 (P871L) and BRCA2 (N372H) are present as heterozygous (50% AF) mutations.