

## Oncology Controls

Elevate your standard of  
care in oncology

**ZeptoMetrix oncology controls and reagents for liquid biopsies provide consistent and accurate results for use in the development, validation, and implementation of molecular assays (NGS and PCR). Human DNA-depleted plasma and cfDNA controls and associated reagents are available.**

- Off-the-shelf quality controls, reference materials, and reagents
- Reliable control material for validation, lot-to-lot testing, and periodic QC
- Accuracy and quality you can trust
- Customizable to meet the needs of your laboratory

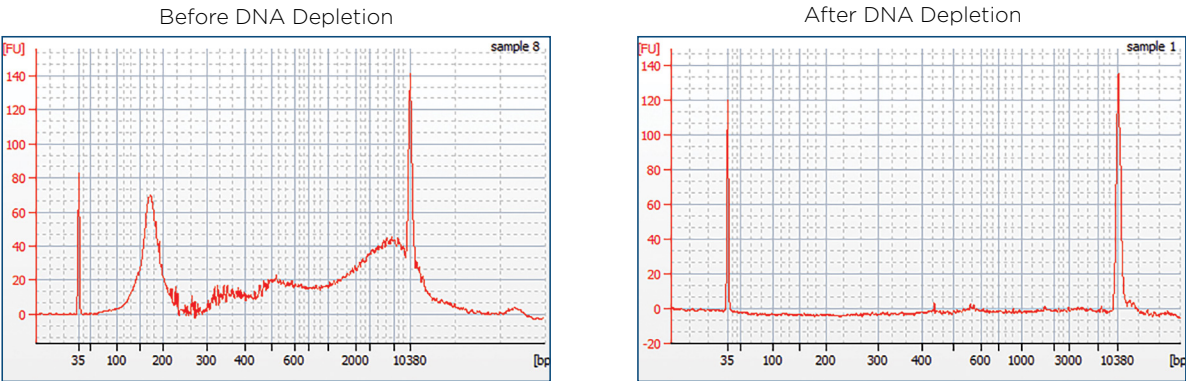


## Human DNA-Depleted Plasma

Build your own controls using your high-positive samples to save time. With our human DNA-depleted plasma (DNA-free plasma) as a matrix, you can produce reference materials specific to your time-sensitive needs while retaining the natural components of the sample.

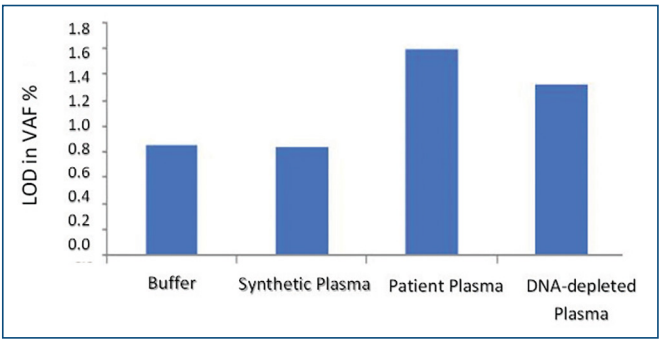
### Why use ZeptoMetrix human DNA-depleted plasma?

- Proprietary DNA depletion process allows for DNA levels less than 4 pg/mL
- The depletion process decreases background DNA noise in plasma while keeping everything else consistent
- Using a patient-like matrix for quality control and assay valuation can result in a more accurate assay



### Why is human DNA-depleted plasma better than buffer as a reference material matrix?

- Plasma matrix is a better representation of a real patient sample because the natural interfering proteins are retained
- Risk of underestimation of assay Limit of Detection (LOD) when buffer or synthetic plasma were used as sample matrix
- The higher imprecision in both untreated patient plasma and DNA-depleted plasma is associated with higher, more accurate, Limit of Blank (LOB) and LOD for AF% determination



Compared to buffer or synthetic plasma, using the human DNA-depleted plasma matrix provides a better representation of the real patient sample because the natural interfering proteins are retained.

### Human DNA-Depleted Plasma

Part Number	Product Description
0860007-5	Human DNA-depleted EDTA plasma base matrix (1 x 5 mL)
0860007-50	Human DNA-depleted EDTA plasma base matrix (1 x 50 mL)
0860007-100	Human DNA-depleted EDTA plasma base matrix (1 x 100 mL)
0860007-500	Human DNA-depleted EDTA plasma base matrix (1 x 500 mL)
0860007-1000	Human DNA-depleted EDTA plasma base matrix (1 x 1,000 mL)

## Cell-Free DNA (cfDNA) Controls

cfDNA controls or reference standards are highly characterized, biologically relevant materials used to assess the performance of assays that detect somatic mutations in cfDNA via PCR, Next Generation Sequencing (NGS), or other novel readout methods.

Part Number	Product Description		
ESR1 Control Kit			
0860016	16 ESR1 mutations in TE buffer, 1% VAF		
ESR1 Mutations			
Vial 1	Vial 2	Vial 3	Vial 4
S463P	E380Q	S463C	S463F
L536H	P535H	L536R	V534E
Y537S	L536P	Y537N	L536Q
D538G	Y537C	K303R	V422del

### Key Features

- Run control for PCR- and NGS-based ESR1 mutation assays
- Verification/Validation control
- Reference material for ESR1 assay development
- ESR1 spike-in experiments

### Why use cfDNA controls and reagents?

- ZeptoMetrix controls help ensure the accuracy of the highly sensitive assays needed for the detection of cfDNA in plasma
- Nucleosomal fragmentation results in a range of cfDNA fragment sizes that mimic patient samples
- Available as concentrated DNA in TE buffer or blended into DNA-depleted plasma as a ready-to-use, full-process control
- Highly customizable product configuration

Part Number	Product Description
<b>Multiplexed ctDNA fragments (~150 bp) mixed with nucleosomally fragmented wildtype cfDNA background</b>	
0860001	1 µg in TE buffer, 3% AF
0860003	125 ng in 5 mL plasma, 3% AF
<b>Normal female cfDNA standards</b>	
0860005	1 µg in TE buffer
0860006	250 ng spiked in 5 mL plasma, wildtype background

The 40+ variants below are included in the off-the-shelf products. Additional variants can be added for a custom product.

#### Cell-Derived and Synthetic Variants

<b>Cell-Derived Variants – Formulated for amplicon- and capture-based methods</b>			
APC Q1429	EGFR E746-A750del	KRAS G12C	PTEN R130G
APC R1450	EGFR L858R	KRAS G12D	TP53 R175H
BRAF V600E	EGFR T790M	KRAS G12V	TP53 R248Q
CTNNB1 T41A	FGFR3 S249C	NRAS Q61R	
EGFR C797S	IDH1 R132H	PIK3CA E545K	
EGFR D770_N771insG	KIT D816V	PIK3CA H1047R	
<b>Synthetic Variants – Formulated for amplicon-based methods</b>			
AKT1 E17K	HRAS Q61R	NOTCH1 H1601L	EML4-ALK v1 fusion
ATM R337C	KIT W557_K558del	PDGFRA D842V	ETV6-NTRK3 fusion
CDKN2A R80	MAP2K1 P124S	POLE P286R	K1F5B-BICC1 fusion
DDR2 R709	MDM2 R189H	SMARCA4 T910M	KIF5B-RET fusion
EGFR G719A	MDM4 Q118L	STK11 F354L	SLC34A2-ROS1 fusion
ERBB2 S310F	MED12 G44D	TP53 R273H	
ERBB4 R711C	MET Y1253D	CCDC6-RET fusion	
ESR1 D538G	NF1 I679Dfs 21	CD74-ROS1 fusion	



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