Use of blood-based methylated DNA biomarkers for screening of cancer and other diseases is growing. For example, screening for Septin 9 (SEPT9) methylated DNA in blood plasma facilitates the detection of colorectal cancer, since specific cytosine residues in SEPT9 are methylated in cancerous tissue but not in normal colon tissue. Accurately assessing methylation levels for methylated DNA biomarkers, however, requires a robust positive control. Typical screening assays rely on completely methylated genomic DNA from cell line sources that fail to represent naturally occurring patterns of methylated DNA accurately. This novel biomarker assay uses the pooled plasma of pregnant women as a positive control substrate for SEPT9 biomarker assays. Pooled plasma of pregnant women can also potentially be used as a positive control substrate for other methylated oncofetal biomarkers.

- Provides a better, more relevant biological control compared to artificial alternatives.
- Offers a readily available source of SEPT9 methylated DNA for use in commercially available kits.
- Holds potential for use in disease or treatment monitoring.

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