

ColoScape™ Test

A highly sensitive test for precancerous lesions



Physician brochure

Colorectal cancer is the second leading cause of cancer death in the US when women and men are combined. It is estimated that 50,630 deaths (27,390 men and 23,240 women) will be attributed to Colorectal cancer this year.

<https://www.cancer.net/cancertypes/colorectal-cancer/statist>

According to the American Cancer Society, the guideline for colorectal screening is to start the colorectal cancer screening at age 45. However, among the 98 million Americans aged 50 to 84, one-third of them are not screened for colorectal cancer for different reasons.

Source: American Cancer Society



ColoScape™ Test is a novel highly sensitive diagnostic test that uses qPCR-based multigene panel for the qualitative detection of colorectal cancer-associated gene mutations and methylation markers in liquid biopsy samples. The test panel targets 61 mutations in 8 genes and 7 methylation markers mostly associated with colorectal cancer. The test utilizes DiaCarta's proprietary XNA technology which leverages a sequence-specific clamp made by xeno-nucleic acid (XNA) to clamp the wild type sequences.

Test configuration of ColoScape™

| | | | | | |
|-------------|---------------------------------|--------------|-------------------------|-----------------|-----------------|
| Mutation | APC (E1309, Q1367, R1450, R876) | BRAF V600 | CTNNB1 (S5, T41) | KRAS (G12, G13) | NRAS (G12, G13) |
| | PIK3CA (E545) | SMAD4 (R361) | TP53 (R175, R248, R273) | | |
| Methylation | C9orf50 | KCNQ5 | MYO1G | | |
| | CLIP4 | FLI1 | TWIST1 | ZNF132 | |

| TEST | DESCRIPTION | SENSITIVITY | | SPECIFICITY |
|------------|---|-------------------|-------------------|-------------|
| | | COLORECTAL CANCER | ADVANCED ADENOMAS | |
| ColoScape™ | ColoScape™ is a novel qPCR-based multi-biomarker assay for qualitative detection of colorectal cancer (CRC) associated genetic and epigenetic markers (61 mutations in 8 genes and 7 methylation markers) that are highly associated with colorectal neoplasia (including cancer and advanced adenomas). | 92.2% | 62.5% | 95.2%-100% |
| Shield™ | Uses a multimodal approach, integrating genomics, epigenomics and proteomics, to detect colorectal cancer signals in the bloodstream | 91% | 20% | 92% |
| ColoGuard® | ColoGuard® is an FDA approved test (2014) for colorectal cancer by checking gene mutations and methylations from stool DNA it detects two DNA methylation markers [NDRG4, BMP3], mutations on K-ras gene, and fecal hemoglobin https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5108981/# | 92% | 42% | 87% |

ColoScape™ has been validated as a Lab Developed Test in the DiaCarta CLIA certified reference laboratory. It has not been approved by the US FDA.

References:

<https://pubmed.ncbi.nlm.nih.gov/34610014/>

<https://pubmed.ncbi.nlm.nih.gov/30315134/>

