COLVERA™

PATIENT TEST REPORT

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PATIENT INFORMATION	SPECIMEN	ORDERING PHYSICIAN
Last, First Name:	Specimen Type:	Name:
Date of Birth:	Specimen ID:	Address:
Gender:	Collection Date:	
Med Record #:	Report Date:	

TEST RESULT

	Reference Range
COLVERA: NEGATIVE (no methylation in *BCAT1* and/or *IZKF1* gene)	NEGATIVE
CEA: ng/mL	≤5ng/mL

COLVERA

INTERPRETATION

Colvera is intended for use as an aid in the monitoring of colorectal cancer patients for recurrent disease, by testing for the presence of circulating tumor DNA in the blood. The test qualitatively assays plasma for the presence of methylated *BCAT1* and/or *IKZF1*, which have been shown to be epigenetically silenced with colorectal cancer[1].

A NEGATIVE Colvera result does not exclude the presence of cancer, and should be interpreted in conjunction with all clinical findings.

Published performance data in a recurrence population of 122 patients showed Colvera detected 19/28 recurrent colorectal cancers (68% sensitivity, 95% CI=48%-84%; 87% specificity, 95% CI=79%-93%) compared to 9/28 with CEA[2] (32% sensitivity, 95% CI=16%-52%; 94% specificity, 95 CI=87%-98%). This trial population included 122 participants being monitored for colorectal cancer recurrence of varying stages. Applying a published Stage II & III colorectal cancer recurrence rate of 30%[3] yields an adjusted positive predictive value (PPV) of 70% and an adjusted negative predictive value (NPV) of 86%.

BACKGROUND

COLVERA METHODOLOGY

Total DNA is extracted from plasma and bisulfite converted to distinguish methylated and un-methylated products. Chemically converted DNA is then amplified by PCR, and methylation of *BCAT1* and *IKZF1* is determined. Detection of *ACTB* gene is used as a control.

OTHER CLINICAL DATA BACKGROUND

In a validation study of 2,105 participants undergoing colonoscopy or colonic surgery, including 129 cases of primary colorectal cancer, blinded testing with Colvera was positive in 66% (95% CI: 57-74%) of cancers (any stage) and 79% (95% CI= 66-88%) of late (III & IV) stage cancers. Colvera was 94% (95% CI=70-100%) sensitive for metastatic colorectal cancer (stage IV). In the subgroup of 450 participants with no evidence of colonic pathology at the time of colonoscopy, Colvera had a specificity of 95% (95% CI=92-97%)[4].

CEA

CEA METHODOLOGY

This laboratory uses a chemiluminescent method for the quantitative determination of Carcinoembryonic Antigen (CEA) in human plasma.

NOTE: The CEA test has been cleared by FDA. The COLVERA test was developed and its performance characteristics determined by Clinical Genomics Pathology Inc. Bridgewater, NJ 08807. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes and should not be regarded as investigational or for research use. Clinical Genomics Pathology Inc. is regulated under CLIA as qualified to perform high-complexity testing.

Lab Director: Robert Boorstein, M.D. Ph.D. CLIA License# 31D2122075

(1) Pedersen SK et al. A two-gene blood test for methylated DNA sensitive for colorectal cancer. PLoS ONE 2015;10:e0125041. (2) Young GP et al. A cross-sectional study comparing a blood test for methylated *BCAT1* and *IKZF1* DNA with CEA for detection of recurrent colorectal cancer. Cancer Medicine 2016; 5(10):2763-2772. (3) S. Pita-Fernández et al. Intensive follow-up strategies improve outcomes in nonmetastatic colorectal cancer patients after curative surgery: a systematic review and meta-analysis. Annals of Oncology 26: 644–656, 2015. (4) Pedersen SK et al. Evaluation of an assay for methylated *BCAT1* and *IKZF1* in plasma for detection of colorectal neoplasia. BMC Cancer 2015;15:654.