Avantect | OVARIAN CANCER TEST

CLIA LAB ID: 05D2249973

1. PATIENT INFORMATION

Patient Name_____

Date of Birth_____ MRN/Other Patient ID_____ Sex at Birth_____

2. ORDERING PROVIDER

Name_____

Institution/Account Name_____

3. SPECIMEN INFORMATION

Collection Date_____

Specimen Received Date_____

Specimen ID_____

Specimen Type_____

Report Date_____

RESULTS

DETECTED

An ABNORMAL epigenomic signal was DETECTED.

- This signal in circulating cell free DNA has been associated with the presence of ovarian cancer.
- It could also indicate benign ovarian conditions, including the presence of non-cancerous masses.
- Consultation with a physician or licensed genetic professional is recommended.
- Further clinical assessment and imaging is recommended with biopsy serving as the definitive method for establishing a diagnosis.

ABOUT THE TEST

- Avantect is intended to evaluate the presence or absence of a signal in circulating cell-free DNA (cfDNA) associated with cancer by assessing epigenomic and genomic signals derived by next generation sequencing (NGS) of 5-hydroxymethylation (5hmC) enriched cfDNA and total cfDNA[1,2].
- Based on a case-control validation study involving ovarian cancer and non-cancer subjects, the Avantect test demonstrates a sensitivity of 78.2% (95% CI: 65.0% - 88.2%) for ovarian cancer detection, along with a specificity of 94.0% (95% CI: 90.2% - 96.6%). Additional test performance information is available upon request.
- The Avantect Ovarian Cancer Test has been specifically designed for the early detection of ovarian cancer in patients at higher risk of developing the disease. Various factors contribute to an increased risk of developing ovarian cancer, including family history and genetic predisposition[3].
- We recommend that test results and clinical information be discussed with the treating physician to fully understand the implications and appropriate course of action.

LIMITATIONS AND REGULATORY

Avantect does not establish a diagnosis of ovarian cancer, and results should be considered in the context of other clinical criteria. Definitive diagnosis typically requires imaging scans, blood tests, and biopsy. Not all patients with ovarian cancer will be classified as "signal detected," and some patients without ovarian cancer will have a "signal detected" result. The test is not intended to look for cancers other than ovarian cancer or for hereditary genetic conditions associated with cancer. Avantect is intended for clinical use and should not be regarded as investigational or for research. The test has been developed, and the performance characteristics determined, by the ClearNote Health Clinical Laboratory, which is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing. The Avantect Ovarian Cancer Test has not been cleared or approved by the U.S. Food and Drug Administration.

References: **1.**Guler GD, Ning Y, Ku CJ, Detection of early stage pancreatic cancer using 5-hydroxymethylcytosine signatures in circulating cell free DNA. Nat Commun. 2020 Oct 19;11(1):5270. **2.**Haan D, Bergamaschi A, Friedl V, et al. Epigenomic Blood-Based Early Detection of Pancreatic Cancer Employing Cell-Free DNA. Clin Gastroenterol Hepatol. 2023 Mar 24:S1542-3565(23)00224-0. **3.**Daly MB, Pal T, Maxwell KN, Churpek J et al. NCCN Guidelines Insights: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic, Version 2.2024. J Natl Compr Canc Netw. 2023 Oct;21(10):1000-1010. doi: 10.6004/jnccn.2023.0051. PMID: 37856201.

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ClearNote™ HEALTH

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3. SPECIMEN INFORMATION

Collection Date_____

Specimen Received Date_____

Specimen ID_____

Specimen Type_____

Report Date_____

RESULTS

NOT DETECTED

An ABNORMAL epigenomic signal was NOT DETECTED. This does not exclude the presence of ovarian cancer. If signs or symptoms appear and are suggestive of cancer, please consult your physician.

ABOUT THE TEST

- Avantect is intended to evaluate the presence or absence of a signal in circulating cell-free DNA (cfDNA) associated with cancer by assessing epigenomic and genomic signals derived by next generation sequencing (NGS) of 5-hydroxymethylation (5hmC) enriched cfDNA and total cfDNA[1,2].
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RESULTS

QUANTITY NOT SUFFICIENT (QNS)

The quality metrics for this sample did not meet the laboratory defined thresholds. Repeat testing also yielded a QNS result.
Please recollect a blood sample for this patient.

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Amended Report

CLIA LAB ID: 05D2249973

1. PATIENT INFORMATION

Patient Name_____

Date of Birth_____ MRN/Other Patient ID_____ Sex at Birth_____

2. ORDERING PROVIDER

Name_____

Institution/Account Name_____

3. SPECIMEN INFORMATION

Collection Date_____

Specimen Received Date_____

Specimen ID_____

Specimen Type_____

Report Date_____

RESULTS

Amended Result (1/13/2022):

The result for this patient has been updated to **Not Detected**. The original result (12/10/2021) was Detected.

NOT DETECTED

An ABNORMAL epigenomic signal was NOT DETECTED. This does not exclude the presence of ovarian cancer. If signs or symptoms appear and are suggestive of cancer, please consult your physician.

ABOUT THE TEST

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Corrected Report

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Name_____

Institution/Account Name_____

3. SPECIMEN INFORMATION

Collection Date_____

Specimen Received Date_____

Specimen ID_____

Specimen Type_____

Report Date_____

RESULTS

Date (1/11/2022): This report was updated to correct the spelling of the physician's name. The results of the testing are unchanged from the original report.

NOT DETECTED

An ABNORMAL epigenomic signal was NOT DETECTED. This does not exclude the presence of ovarian cancer.
If signs or symptoms appear and are suggestive of cancer, please consult your physician.

ABOUT THE TEST

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