STAGE ZERO LIFE SCIENCES

Aristotle® Multi-Cancer Panel
LABORATORY RESULTS

Patient

Name:			Patient ID #:
June Partick Doe			T01-000-000
Gender	Birthdate:	Age:	Phone #:
FEMALE	11/06/1966	55	

Specimen

Collection Time:	Specimen ID:
09:15	A123456789
Collection Date:	Report Type:
10/06/2020	COMPLETE
Received Date:	Report Date:
10/07/2020	10/07/2020 16:32

Provider

Requesting Provider
PHYSICIAN, TEST, MD
Test Practice
8751 Park Central Drive, Suite 200
Richmond, VA 23227

Client ID:
09999

Test Results

Aristotle Multi-Cancer Molecular Signature Detection Panel			
Bladder Cancer	Molecular Signature Not Detected	*Endometrial Cancer*	Molecular Signature Not Detected
Breast Cancer	Molecular Signature Not Detected	*Liver Cancer*	Molecular Signature Not Detected
Cervical Cancer	Molecular Signature Not Detected	*Ovarian Cancer*	Molecular Signature Not Detected
Colorectal Cancer	Molecular Signature Detected	*Stomach Cancer*	Molecular Signature Not Detected

Test Description

The Aristotle Multi-Cancer Molecular Signature Detection Panel is a laboratory developed test (LDT) that analyzes the gene expression profile from human peripheral blood tissue. The gene expression profile generated by the test is analyzed to determine if it has significant similarity to any of the gene expression signatures identified in each of the cancers that comprise the test panel.[1-3]

Intended Use

The Aristotle test is a qualitative test intended to determine if the gene expression profile, or signature, captured from a peripheral blood sample is similar to the gene expression signature from any of the cancer types, diagnosed according to current clinical and pathological best practices, that comprise the test panel. This is accomplished by calculating a numerical value, or score, from the gene expression signature corresponding to each of the different cancer types and assessing if the outcome is above a pre-determined threshold and thus, a positive or negative indication of similarity (i.e. detected or not detected) to any of the previously defined cancer gene expression signatures.

The Aristotle test is ordered by prescription only and must be evaluated by a qualified health professional in the context of the patient's clinical history and other diagnostic test results. This test was validated, and its performance characteristics determined, in a population, both male and female, with a mean age of 60 ± 26 years (mean ± 2SD), age range 26-97.

Limitations

The Aristotle test is not intended to diagnose the presence of any cancer or pre-cancerous condition that cannot be diagnosed according to current clinical or pathological best practices. The test is not intended to re-classify or modify any diagnoses by current clinical or pathological best practices, nor to predict disease course, patient survival, treatment efficacy and/or help determine optimal therapy. The Aristotle test has been validated only for the molecular signatures of the cancers reported. A "Molecular Signature Detected" result requires a confirmatory diagnostic evaluation. False-positive and false-negative results may occur with Aristotle.

Dr. Leroy D. Mell, Jr. | Laboratory Director | CLIA No. 49D2059683 | NPI No. 1437710415

Rpt ver: SZLS 1.0
Ref ver: 2.0
Source:

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Clinicial Recommendations

If the results indicate "Molecular Signature Detected", the patient should be referred for further diagnostic evaluation.

References

1. Liew C-C, Ma J, Tang H-C, et al. The peripheral blood transcriptome dynamically reflects system wide biology: a potential diagnostic tool. J Lab Clin Med 2006; 147: 126-32.
2. Mohr S, Liew C-C. The peripheral-blood transcriptome: new insights into disease and risk assessment. Trends Mol Med 2007; 13: 422-432.
3. Chao S, Cheng C, Liew C-C. Mining the Dynamic Genome: A Method for Identifying Multiple Disease Signatures Using Quantitative RNA Expression Analysis of a Single Blood Sample. Microarrays 2015; 4: 671-689.
4. Dempsey A, Chao S, Burakoff, R et al. Aristotle: A single blood test for pan-cancer screening. Journal of Clinical Oncology 2020 38:15_suppl, e15037-e15037

Disclaimers

The Aristotle test was developed, and its clinical performance determined, by StageZero Life Sciences. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). This test is for clinical purposes and it should not be regarded as investigational or for research use. The StageZero Life Sciences laboratory is certified under CLIA to perform high complexity clinical laboratory testing.

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LABORATORY RESULTS

Patient

Name:			Patient ID #:
Jacob Testpatient			T01-000-000
Gender	Birthdate:	Age:	Phone #:
MALE	11/06/1960	61	

Specimen

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Test Results

Aristotle Multi-Cancer Molecular Signature Detection Panel

Bladder Cancer	Molecular Signature Not Detected	*Stomach Cancer*	Molecular Signature Not Detected
Colorectal Cancer	Molecular Signature Detected		
Liver Cancer	Molecular Signature Not Detected		
Prostate Cancer	Molecular Signature Not Detected		

Test Description

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