PanCa Monitor

Test Report

CellMax Life

Test Report

PanCaMonitor

Patient Information

Requisition Number	
Patient Name	
ID Number	
Date of Birth	
Gender	
Patient Phone Number	
Patient E-mail	
Lab Phone Number	
Name of Physician	
Date of Collection	
Date of Report	

Test Report

PanCaMonitor

Patient Test Result

Current CTC Count	
Baseline Count (For Recurrence Monitoring Only)	
Current CTC Trend (Minimum 3 blood draws required after baseline to establish trend)	Current CTC Trend

Comments

Your current CTC trend is low. We recommend to continue assessing CTC counts every 3 months. Meanwhile, if your health condition deteriorates, it is advised you seek for a professional medical care at your local hospital or clinic.

Electronic Signatures

This test was developed and its performance characteristics determined by CellMax. Clinical decisions regarding care and treatment of patients should not be solely based on this test. Not all disease will be accurately detected. How this information is used to guide patient care is the responsibility of the physician.

Leon Chen

Leon Chen.

Manager, Clinical Laboratory

Date

Patient Medical History

Cancer Diagnosis	Tumor Type		Date of Diagnosis
	Pathological Diagnosis		
	Tumor Stage (TNM)	Metastasis Site	Date of Most Recent Treatment

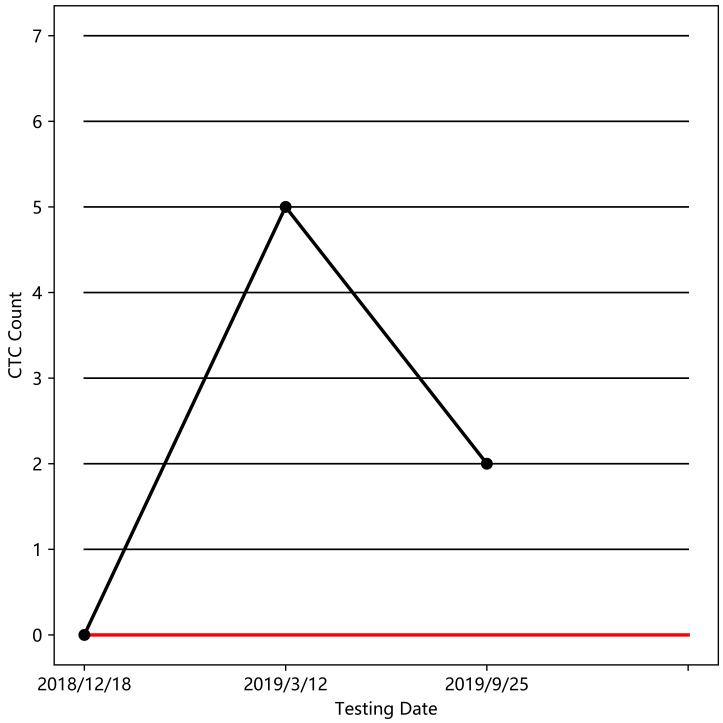
Testing History

Baseline

Test Date	CTC Counts

CTC Counts

Test Date	CTC Counts



About The Test

The CellMax Life PanCa Monitor test is intended for the isolation and enumeration of circulating tumor cells (CTCs) from whole blood. PanCa Monitor is an in-vitro test that uses the CellMax proprietary microfluidic chip device (CMx Platform™) coated with EpCAM antibodies, epithelial cell markers (CK8/18) and tissue specific markers (e.g. PSMA, Mammaglobin) to detect CTCs in the peripheral blood. PanCa Monitor can be used to accurately detect the presence and/or monitor recurrence for 16 different types of cancers. The list of cancers include: Breast, Colorectal, Lung, Prostate, Ovarian, Endometrial, Pancreatic, Liver, Thyroid, Small Intestine, Gastric, Bladder, Skin, Head and Neck, Hepatobiliary, and Esophagus. PanCa Monitor results are reported as number of CTCs identified in the blood and/or CTC trend is reported in case of recurrence monitoring after 3 consecutive measurements. Analytical sensitivity of PanCa Monitor is 1 CTC per sample. PanCa Monitor should be used in conjunction with other clinical methods for monitoring such as imaging, lab tests, physical examination, and a complete medical history review to assess patient prognosis through the course of treatment and/or disease.

Limitations of the test: PanCa Monitor is designed to detect circulating tumor cells (CTCs) of epithelial origin. The test utilizes tissue specific markers to identify origin of the cells derived from various tissue types. It has been demonstrated that CTC count can be affected by various types of treatment regimens including chemotherapy and radiation. To assess disease current status, it is recommended the test to be administered sufficiently before and after the treatment course.

Indications For Ordering

The PanCa Monitor test is appropriate for patients who have been previously diagnosed with any one of the cancers listed above, and cancer monitoring is warranted. The test is intended to be used as an ancillary tool for monitoring a patient’ s cancer status during the course of disease. Serial testing should be used in conjunction with other clinical monitoring methods such as laboratory test and imaging modalities. It is recommended that a patient is “therapy free” for at least 7 days at the time of blood draw.

Interpretations of Results

Results of the first blood draw from CellMax PanCa Monitor are for physician reference and is used to establish the baseline count. Each test administered will be reported in CTC numbers. Baseline (1-2) tests need to be administered before meaningful results can be obtained. CTC trend can only be reported after minimum of 3 consecutive measurements.

Important Notice

Clinical decisions regarding care and treatment of patients should not be solely based on this test. CellMax PanCa Monitor test results should be used in conjuction with all clinical information derived from diagnostic tests (e.g. imaging or laboratory tests), physicial examination, and complete patient medical history, in accordance with appropriate management procedures.

Utilization of the information provided is the sole responsibility of the treating physician. The test is not intended to replace any standard of care testing modalities, but rather to aid them for a better assessment of a patient’ s cancer during the disease course.

Disclaimer

This test was developed and its performance characteristics determined by CellMax Life, a clinical laboratory accredited by the College of American Pathologists (CAP) to perform testing. Clinical decisions regarding care and treatment of patients should not be solely based on this test. Not all disease will be accurately detected. How this information is used to guide patient care is the responsibility of the physician. This test is used for clinical purposes, and should not be regarded as investigational or for research. This test is not a diagnostic test and results of this test must be utilized in conjunction with other monitoring clinical tools.

The CellMax Life test is designed to assist health care practitioners in providing additional clinical information. The information therein should not be relied upon as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. Medical knowledge develops rapidly and new evidence may emerge between the time information is developed to when it is published or read.

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