

**CTC (Circulating Tumor Cells) Test  
Microfluidic Device (Microfluidic Chip) Method  
Letter of Consent**

1) Purpose of Test

This is the test to detect Circulating Tumor Cells (CTC) in blood.

2) What is Circulating Tumor Cells(CTC) ?

CTC is abbreviation of “Circulating Tumor Cells” (hereafter called “CTC”) and it is regarded as the cells which are freed from primary tumor tissues or metastatic tumor tissues and invaded into blood.

This CTC exists in peripheral blood of solid cancer patients in minute amounts and it is considered that it contains cells that have capability to metastasize to other parts of the body.

3) Limitation of Test and Interpretation of Test Results ※ Explanation of Most Important Points

- **CTC Test will not really detect cancer for 100%.**
- **There is no guaranty of non-existence of cancer or its metastasis even if CTC is not detected.**

Results of this test do not make any commitment that the test subject will neither be determined as being affected with cancer nor will be affected by cancer in the future.

Even if the test results were negative, it does not testify that the test subject is not affected with cancer.

Please consult with your doctor in attendance as the doctor will make a thorough study of CTC test taking into consideration of imaging test such as CT scanning and determination results of tumor markers.

4) Microfluidic Device (Microfluidic Chip) Method

It has made possible to obtain higher detection sensitivity of CTC than ever and high specificity by Microfluidic Circuit Chip Technology by Celsee, Inc., and it is designed not to cause damage to the cells as much as possible. It is the new method to automate preparation of samples until imaging and to measure circulation tumor cells in blood by enriching them. It has made possible to obtain high sensitivity and high specificity by innovative detection technology of circulation tumor cells by Celsee, Inc.

5) Handling of Patient Samples (Protection of personal information)

Blood samples used for this test will be administered in the form of coded numbers which cannot be identified as individual person and shall be controlled strictly so that the personal information of clients should not be leaked out to the exterior. Patient samples shall be transported to NGRL and after the tests are completed, they will be discarded after appropriate destruction process has been made to the samples so that nobody can identify whose they are.

6) Disclosure of Test Results and Protection of Privacy

The results obtained by this test may be publicized in academic conferences or medical journals however privacy of the clients shall be protected. It shall never be publicized such as history of disease, test results, contents of medical treatment, medical examination and test results after medical treatment has been completed. Risky information from which individual person can be identified such as clients’ address, names so forth are strictly administered and we will pay utmost attention to prevent leakage of such information to the exterior.

7) Disclaimer

In case the test could not be performed due to weather, natural disaster, transportation condition (including the case that the patient samples have become unsuitable to the test due to damage and change of properties ), please be reminded that concerned parties of this test including test organizations will not assume any responsibility to the clients. If the test could not be performed due to these cases and not be made the report of results, the clients will not be charged.

In case you can agree with the above-mentioned Explanation of Important Points, please submit the prescribed Letter of Consent to the doctor in attendance with your name and date of consent.

**【I have received an explanation on the above-mentioned contents and understood well and agree with the above-mentioned Explanation, I hereby agree to undergo the test by my own accord. I also received copies of Explanation of Important Points and signed Letter of Consent. 】**

<b>&lt;Selective Matters&gt;</b>			
(Be sure to mark <input type="radio"/> for either of the following options. No disadvantages will be caused to you even if either of two options is selected.)			
Results of CTC Tests can be used for research purpose, do you agree to use them for research purpose?			
<input type="checkbox"/> I agree		<input type="checkbox"/> I disagree	
Date of Consent		Client name	(signature)
Address of Clients			
Elucidator of Important Points	(Doctor in attendance)		