

Page on which the report for the examinee is printed	Site of printing	Contents
1/5	Upper frame	陰性です。今後も定期的な検診を受けましょう。 A negative finding was noted. Let's undergo regular examinations in the future.
		消化器がんの判定は陰性です。但し、他の検査項目を含めた総合的な診断結果については、担当医にご相談ください。 You are negative for gastrointestinal cancer. However, please consult a physician for comprehensive health checkup results including other examination items.
		精密検査をおすすめします。 We recommend you to undergo detailed examinaiton.
5/5	Primary evaluation	陰性 Negative
		境界域 Boundary zone
		陽性 Positive
1/5 4/5 5/5	Site evaluation	陰性 Negative
		胃・大腸 Stomach/large intestine
		膵臓 Pancreas
		胆道 Biliary tract
		特定不可 Impossible to identify
5/5	Results of final evaluation	陰性 Negative
		陽性 Positive

Date of collection

Sample ID

Name: \_\_\_\_\_

# Explanation of the results by microarray blood testing for digestive system cancers



## Microarray blood testing for gastrointestinal cancer, results of analysis

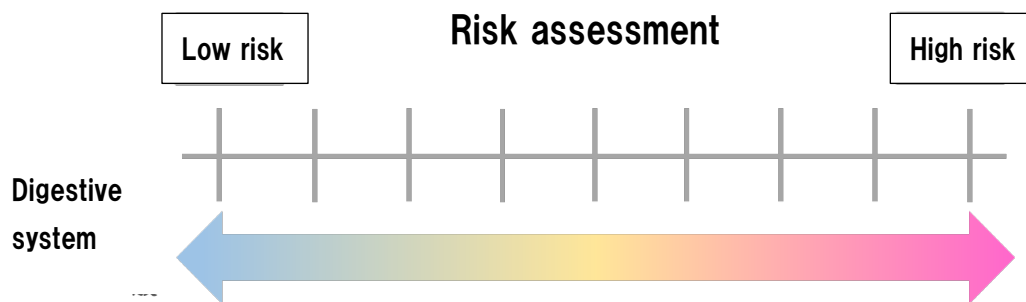
Hospital name:

Date of collection:

Sample ID:

Sex:

Age:



### Organs to be tested

Stomach/large intestine	( )
Pancreas	( )
Biliary trac	( )
Organ analysis	

This result is a type of reference data to check your health condition.

Your health condition will be comprehensively diagnosed in consideration with other examination items by the physician.

The risk is displayed with the circle's position. When the position is more adjacent to the left side (blue), the risk is lower. When it is more adjacent to the right side (red), the risk of "cancer is currently present" is higher. Risk assessment is comprehensively calculated based on statistical sieving, the number of RNAs that are changing, and discriminative assessment by pattern analysis (please confirm Pages 3 to 5).

Furthermore, the circle's position on risk assessment is adjacent to the center in some cases other than "positive". The RNA expression pattern sometimes becomes close to "positive" with immune responses, such as inflammation. In such cases, the risk is finally evaluated as "negative", but there is a possibility of "false-negative" or other diseases. Therefore, please consult the attending physician. If necessary, please consider detailed examination.

Microarray blood testing for gastrointestinal cancer is a test to measure the amount of “RNA\*” contained in blood using a method termed “microarray” and evaluate the possibility of cancer of the digestive system (stomach, large intestine, pancreas, biliary tract) based on the results of analysis.

\*Blood-cell-derived messenger RNA

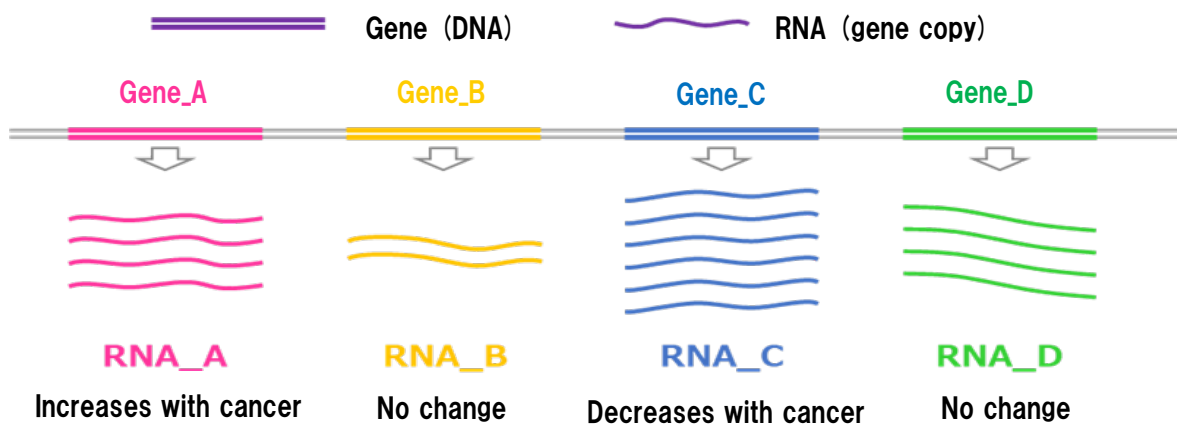
## Mechanism of this testing

In humans,  $\geq 20,000$  genes exist.

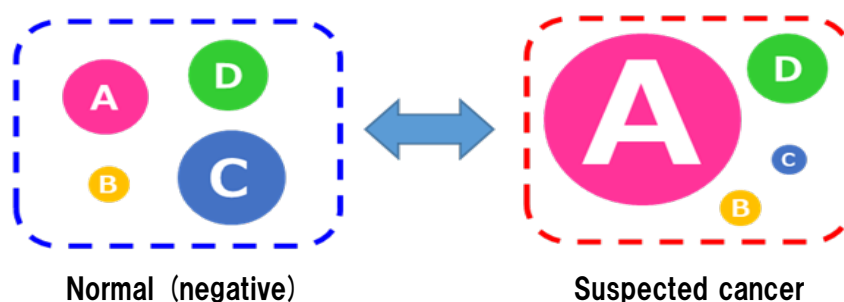
RNAs to be measured on this testing are transcripts (copies) of genetic information recorded in each gene (DNA). These substances exist in all cells of the body.

In a healthy state, the amount of each RNA is maintained in a specific range. However, the amounts of some RNAs may markedly change (increase or decrease) in the presence of a disease.

On this testing, the possibility of “cancer” is evaluated by investigating whether there are changes specific to patients with “cancer” in your blood RNAs.



The possibility of cancer is evaluated based on the pattern that your pattern resembles.



# Your test results, Details

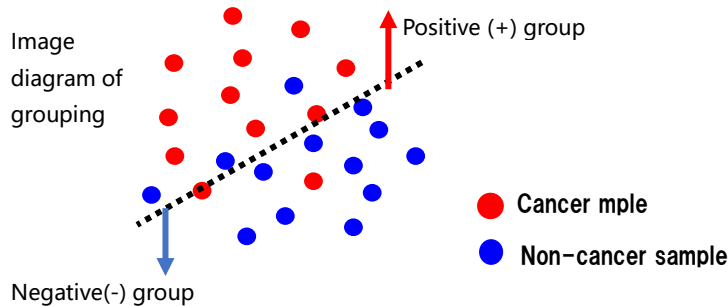
Hospital name :

Date of collection :

Sample ID :

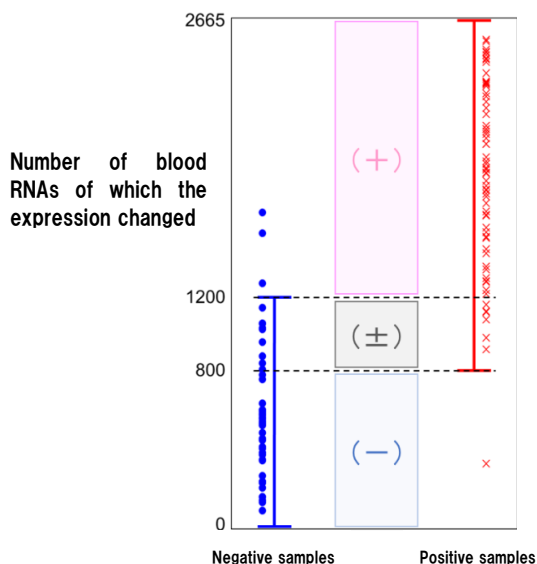
## 1. SVM

Using a statistical method, Support Vector Machine (SVM) method, the borderline to classify samples into positive and negative groups is calculated, and which group a test sample belongs to is investigated.



Your results	
SVM	Evaluation
	( )

## 2. Number of blood RNAs of which the expression changed



There are changes (increases/decreases) in the amounts of some blood RNAs in persons with cancer in comparison with those without cancer.

How many RNAs are changing among RNAs (2,665 RNAs) that change in the presence of cancer is evaluated.

In persons with cancer, the values are higher than non-cancer. The number of RNAs with changes in expression may also change with chronic inflammatory responses or modulation of the immune system.

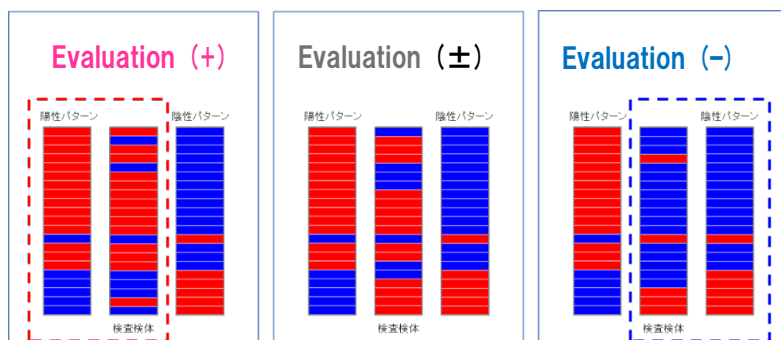
Your results	
Number of RNAs that are changing	Evaluation
	( )

## 3. 21 genes expression profile analysis on pattern

21 RNAs of which the amount markedly changes with the presence or absence of cancer are investigated.

Changes in each RNA are color-coded and compared.

Results are evaluated based on the color scheme of the test sample, that is, positive or negative patterns.



Your results	
Pattern analysis of 21 genes	Evaluation
	( )

Hospital name :

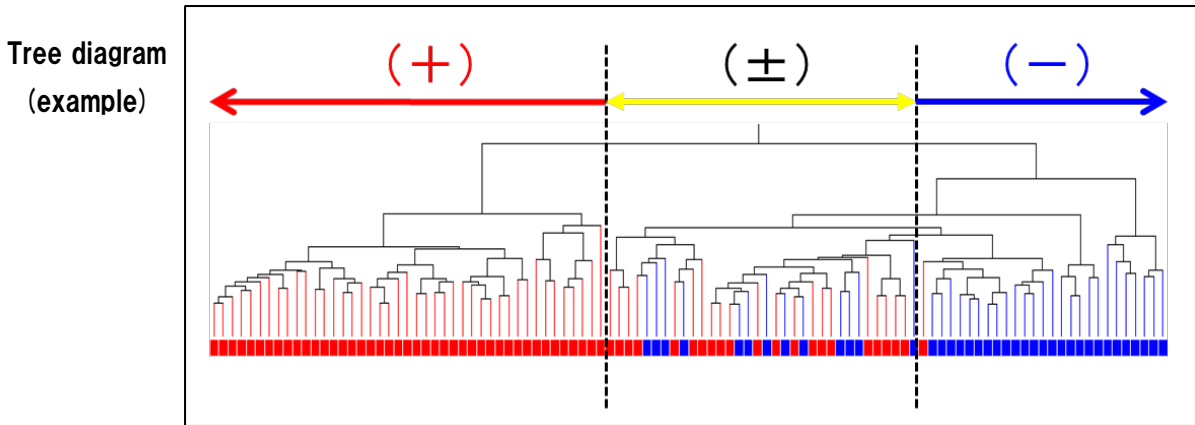
Date of collection :

Sample ID :

### 4. Clustering analysis

The following tree diagram was prepared to consider with similar gene expression profiles characteristics might be placed at adjacent cases.

The red color represents cancer samples (gastric cancer, colorectal cancer, pancreatic cancer, biliary tract cancer). The blue color represents non-cancer samples. Results are evaluated based on the group in which the test sample is allocated.

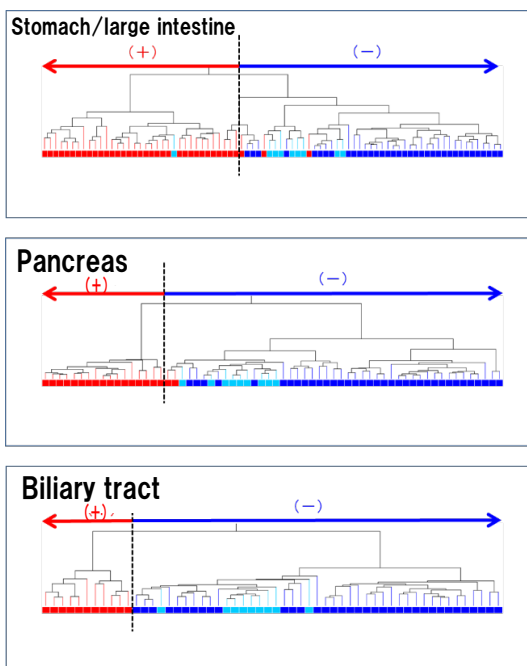


The above tree diagram is an example.

Your results	
Clustering analysis	Evaluation
	( )

### 5. Organ evaluation (Clustering analysis with respect to organs)

Tree diagram (example)



The light blue color represents false positive cases. The above tree diagram is an example.

Using the same method as described above, the presence or absence of gastric/colorectal, pancreatic or biliary tract cancer is evaluated.

The red color represents cancer samples at each site. The blue color represents non-cancer samples. Results are evaluated based on the group in which the test sample is allocated.

Your results	
Site	Evaluation
Stomach/large intestine	( )
Pancreas	( )
Biliary tract	( )
<b>Organ evaluation</b>	

## Results of primary evaluation

On primary evaluation, the results are evaluated from the following 4 test items.

1. SVM
2. Number of RNAs that are changing
3. 21 genes expression profile analysis on pattern
4. Clustering analysis

Test items	Test results
1. SVM	( )
2. Number of RNAs that are changing	( )
3. 21 genes expression profile analysis on pattern	( )
4. Clustering analysis	( )
Results of primary evaluation	

## Final evaluation

The results of the above primary evaluation and 5. Site evaluation are finally evaluated.

Site	Evaluation
Stomach/large intestine	( )
Pancreas	( )
Biliary tract	( )
Organ evaluation	

Final evaluation	
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Even when the result is finally evaluated as “negative”, it does not completely rule out the possibility that digestive system cancer (target gastric/colon/pancreas/biliary tract) may be present. We recommend that you receive regular screening in the future.

In cases in which the result is finally evaluated as “negative” despite that of the primary evaluation: “boundary zone” or “positive”, the following diseases or drugs may have influenced the result.

The case of treated with adrenal corticosteroids (excluding inhalants), immunosuppressive drugs, anticancer drugs, or biological preparations (interferon, vaccines, blood preparations, infliximab)

The case of diagnosed with cancer other than gastrointestinal cancer, those receiving treatment under a diagnosis of cancer, or those who previously received cancer treatment

The case of colon/gastric polyps, or those with an interval of <2 years from resection

The case of treatment under a diagnosis of an autoimmune disease (ulcerative colitis, systemic lupus erythematosus, autoimmune hepatitis, rheumatoid arthritis)

The case with liver disease related to hepatitis B/C virus

The case for diagnosed with liver cysts, renal cysts, or adenomyomatosis of the gallbladder

– (Only females) Those with uterine fibroids, pregnant women, or those who may be pregnant

Even when the result is finally evaluated as “positive”, it does not mean a definitive diagnosis of gastrointestinal cancer (target: stomach/large intestine/pancreas/biliary tract). We recommend that you should undergo detailed examination after consulting physician.