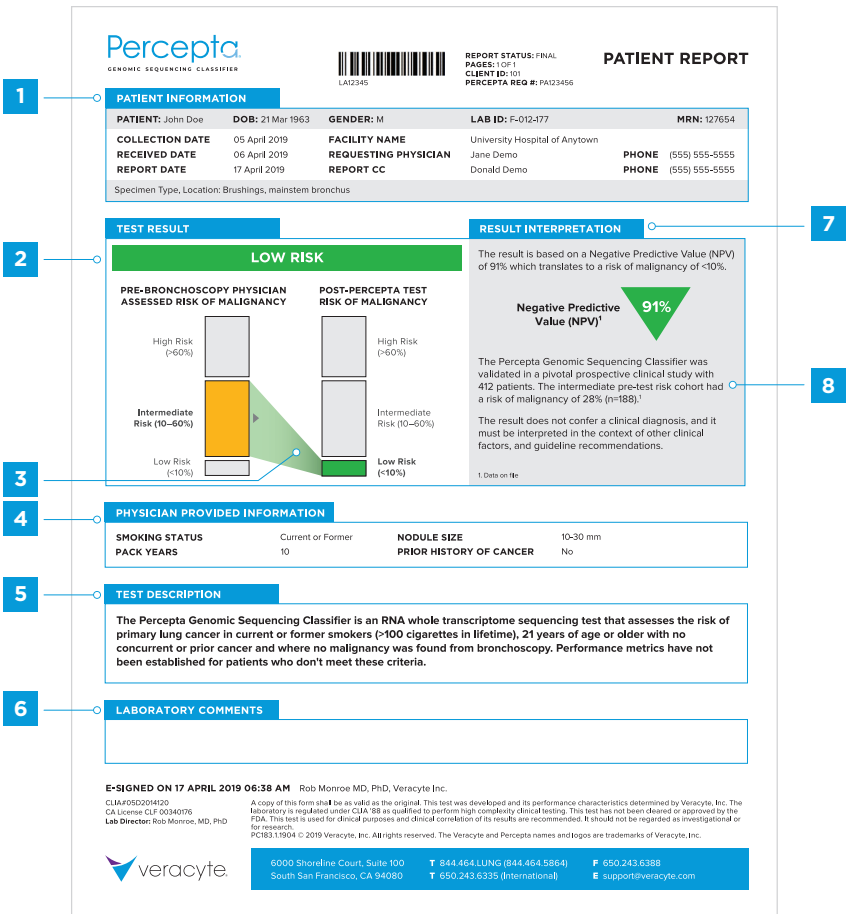
Percepta
GENOMIC SEQUENCING CLASSIFIER

Patient Report Interpretation Guide

The patient report interpretation guide will help you navigate the Percepta Genomic Classifier (GSC) patient reports. The FAQ section in the back will provide additional information and answers to the most common questions related to the patient reports.



1 **Patient information** provided by the physician in the test requisition form (TRF).

2 **Pre-bronchoscopy** physician assessed risk of malignancy (ROM). High (>60%), Intermediate (10%-60%), and Low (<10%). The pre-bronchoscopy ROM can be established based on physician's own assessment or by the use of available calculators.

3 **Post-Percepta test risk of malignancy** includes the possible results based on the pre-test risk group. For this example, an intermediate pre-test risk patient can have a post-Percepta ROM of high, intermediate or low.

4 **Physician provided information** from the bronchoscopy section of the TRF.

5 **Test description** inclusion criteria for patients in the validation study.

6 **Laboratory comments** includes the information on other types of results such as outside of indication test result, as well as other additional information provided by the physician in the TRF.

7 **The result interpretation** section highlights the key performance metrics Negative or Positive Predictive value (NPV or PPV). For this example, since the pre-test risk is down-classified, the performance metric is shown as the NPV with a green triangle facing down. When the pre-test risk is up-classified, the performance metric is shown as the PPV with a red triangle facing up.

8 **Clinical validation cohort** indicates the cancer prevalence observed for the specific pre-test risk group. The prevalence of cancer observed for intermediate pre-test risk patients was 28% (n=188) in the validation cohort. This prevalence is used in calculating the NPV.

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Frequently Asked Questions

1. What are all the possible results with Percepta Genomic Sequencing Classifier (GSC)?

Pre-Bronchoscopy Physician Assessed Risk of Malignancy (ROM)	Post-Percepta Test Risk of Malignancy (ROM)	Result Interpretation
Low (<10%)	Very Low (<1%)	▼ The pre-bronchoscopy ROM is down-classified
	Low (<10%)	ROM remains low
Intermediate (10–60%)	High (>60%)	▲ The pre-bronchoscopy ROM is up-classified
	Intermediate (10–60%)	ROM remains intermediate
	Low (<10%)	▼ The pre-bronchoscopy ROM is down-classified
High (>60%)	Very High (>90%)	▲ The pre-bronchoscopy ROM is up-classified
	High (>60%)	ROM remains high

2. How are the NPV and PPV calculated?

The NPV and PPV are calculated based on the prevalence of malignancy and the sensitivity and specificity of the Percepta classifier observed in the validation cohort for each pre-test risk group.

- NPV is the proportion of patients that are truly benign when the Percepta test down-classifies the patient's risk.
- PPV is the proportion of patients that are truly malignant when the Percepta test up-classifies the patient's risk.

3. What does it mean when the risk of malignancy remains the same after Percepta testing?

It means that there was no change in the risk of malignancy after testing with the Percepta classifier.

4. What does an "Outside of Indication" result mean?

The Percepta classifier result is outside of indication (OI) when the patient doesn't meet one of the indication criteria listed below:

- Current or former smokers (>100 cigarettes in a life time)
- No prior or concurrent cancer
- >21 years or older

The performance metrics have not been established for patients who do not meet these criteria.

5. What does a "No Result" mean"?

A Percepta GSC "No Result" is likely due to insufficient or degraded material in the RNAprotect® vial submitted to Veracyte. There could also be other reasons like a QC failure.

6. What does a "Test not performed" mean?

"Test not performed" is issued when the Percepta test has been canceled by the physician.

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