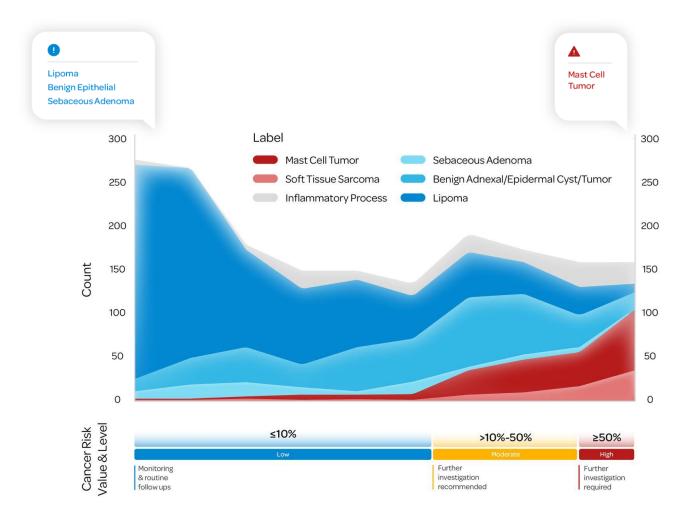


How to Interpret the HT Vista Cancer Screening Results

The HT Vista Primary Classifier (Screening Tool) displays the HDI results as **Cancer Risk**. This document provides key insights into the decision-making process that led to the formation of the three Cancer Risk Levels: **Low, Moderate, and High**.



General Explanation

The image above illustrates the distribution of Cancer Risk Values with corresponding diagnoses (cytology/histopathology) across the HT Vista database.

Key Points: General Graph appearance

- The X-axis represents the Malignancy Probability of the mass, which is translated into a Cancer Risk Value.
- Based on the Cancer Risk Value, each mass is classified into one of three Cancer Risk Levels: Low Risk; Moderate Risk; High Risk.
- The size of the Cancer Risk Bars reflects the prevalence of cases within each risk category: Low Risk: 60%; Moderate Risk: 34%; High Risk: 6%.
- The Y-axis represents the number of cases per Cancer Risk Value/Level

- Labels:
 - o Blue: Cases within the major benign group type.
 - Red: Cases within the major malignant group type.
 - Gray: Cases where the definitive diagnosis was either benign or malignant with inflammatory features.

Key Observations

- A high volume of benign cases is present in the low cancer risk group, with most of them being Lipomas.
- A very low volume of malignant cases is observed in the low cancer risk group, demonstrating a very low false-negative rate.
- The number of malignant cases begins to increase in the moderate risk group and rises significantly in the high cancer risk group.
- Inflammatory cases are observed throughout, but they occur in very low numbers.
- The moderate risk group includes a mix of benign, malignant, and inflamed cases.
- When the cancer risk value exceeds 10%, the recommendation shifts from monitoring (low risk) to requiring further investigation (moderate & high risk).
- In the high cancer risk group, the cancer risk value surpasses 50%, making investigations critical. At this stage, a malignant diagnosis is more likely than a benign one.

Sub-Classifiers and Diagnostic Alerts

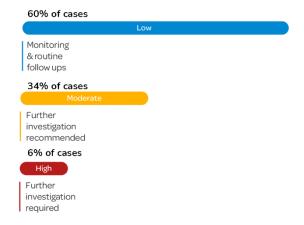
The sub-classifiers provide diagnostic alerts when the specificity is 90% or higher. This occurs when the cancer risk is either very high or very low. Under these conditions, the current product can provide diagnostic alerts for the following cancer types:

- Benign: Lipoma; Benign Epithelial Tumor; Sebaceous Adenoma
- Malignant: Mast Cell Tumor

Recommendation Guidelines

If all masses are scanned without discretion (assuming a disease prevalence of benign:malignant = 85:15), the expected distribution of risk classifications is:

- 60% of masses will receive a low cancer risk classification.
- 34% of cases will receive a moderate cancer risk classification.
- 6% of cases will receive a high cancer risk classification.



Key Recommendation

- Cancer can be ruled out when the cancer risk value (malignancy probability) is 10% or lower.
- Any case with a cancer risk value greater than 10% should undergo further investigation.
- The diagnostic alert can be used to guide next steps, based on the nature of the process identified.

Stat Made Easy

- **Sensitivity** is about detecting disease correctly in those who have it (avoiding false negative).
- NPV is about ruling out disease correctly in those who test negative.
- Specificity is about detecting true negatives correctly (avoiding false positives).
- **PPV** is about how trustworthy a positive test result is.

	Feature	Sensitivity	Negative Predictive Value (NPV)
Screening Tool	What it measures	Ability to detect true positives	Probability that a negative test is correct
	Formula	TP / (TP + FN)	TN / (TN + FN)
	Population Focus	Only among actual diseased individuals	Among all individuals who test negative
	Affected by Prevalence?	No	Yes (higher prevalence \rightarrow lower NPV)
	Feature	Specificity	Positive Predictive Value (PPV)
Diagnostic Tool	What it measures	Ability to correctly identify true	Probability that a positive test is
		negatives	actually correct
	Formula	TN / (TN + FP)	TP / (TP + FP)
	Population Focus	Only among actual non-diseased individuals	Among all individuals who test positive
			Yes (higher prevalence → higher

When assessing a screening tool, we prioritize sensitivity and NPV to ensure that disease cases are not missed (i.e., minimizing false negatives). A highly sensitive test is crucial for early detection, and a high NPV ensures that negative results are reliable.

When evaluating a diagnostic tool, we focus on **specificity** and **PPV** to confirm true disease cases (i.e., minimizing false positives). High specificity ensures that healthy individuals are not misdiagnosed, and a high PPV means that a positive result strongly indicates the presence of disease.

Summary

For screening tools, we emphasize sensitivity and NPV to effectively rule out disease in those who test negative and minimize missed cases.

For diagnostic tools, we prioritize specificity and PPV to accurately confirm disease presence and avoid unnecessary treatments or interventions.

HT Vista's Performance

	Primary Classifier	Subclassifiers	
		Lipoma	MCT
Sensitivity	90%	69%	44%
NPV	98%	40%	78%
Specificity	70%	90%	90%
PPV	42%	99%	77%