

## PATIENT

DOG: Daisy Goodrich  
 OWNER: Patricia Goodrich  
 AGE: 8y  
 WEIGHT: 60lb/27kg  
 SEX: FS  
 BREED(S): Golden Retriever

## SPECIMEN

PETDX REQUISITION ID: B32MND9  
 ANTECH ACCESSION ID: CHBE12105954  
 SPECIMEN TYPE: Blood  
 DATE COLLECTED: May 18, 2022  
 DATE RECEIVED: May 19, 2022

## CANCER HISTORY &amp; CURRENT PRESENTATION

As reported by the ordering clinician at the time of sample submission, **this patient has not been previously diagnosed with cancer.**

As reported by the ordering clinician at the time of sample submission, **this patient is not currently suspected of having cancer.**

## Test Result

**Cancer Signal Detected**

Cancer-associated genomic alterations were detected in the DNA from *Daisy's* blood sample.

## CANCER SIGNAL



- A *Cancer Signal Detected* result significantly increases the likelihood that cancer is present, but does not confirm the presence of cancer. **This result should not be used as the sole basis for making important decisions such as treatment or euthanasia.**
- A confirmatory cancer evaluation should be performed to establish a definitive diagnosis.

To learn more about this result and how to interpret it for this patient, please consult the [OncoK9 Test Interpretation Guide](#).

**Recommended Next Steps**

A *Cancer Signal Detected* result does not establish a diagnosis of cancer. A confirmatory cancer evaluation is required to establish a definitive diagnosis. The following confirmatory measures should be considered: thorough clinical history and physical exam (including an oral and rectal exam), complete bloodwork and urinalysis, routine imaging (such as thoracic radiographs and abdominal ultrasound), tissue sampling of any detected masses for pathological analysis, and, if indicated, advanced imaging such as CT and/or MRI. If the confirmatory cancer evaluation does not result in a cancer diagnosis, this could mean that the selected confirmatory measures did not identify the cancer, or that the test result was a false positive. Further evaluation and/or monitoring of this patient should be considered.

## Test Information

### About Cancer

Cancer is a disease caused by the accumulation of genomic alterations (mutations) in DNA over time. Cancer cells release DNA fragments containing genomic alterations into the blood, which may be detected by this test.

### About the Test

**OncoK9** is a multi-cancer early detection (MCED) test for the detection and characterization of cancer-associated genomic alterations in DNA isolated from canine whole blood samples, using next-generation sequencing (NGS) technology. **OncoK9** is intended for use in dogs who are at higher risk of cancer. It is recommended as an annual screening test for all dogs starting at 7 years of age and potentially at younger ages for dogs belonging to breeds that are predisposed to cancer. It is also recommended as an aid-in-diagnosis for dogs in which cancer is suspected based on clinical signs or other clinical findings. As with any laboratory test, **OncoK9** results should be interpreted by a veterinarian in the context of each patient's medical history and clinical presentation. The test is available by prescription only.

**The OncoK9 test does not provide a definitive cancer diagnosis, and should never be used as the sole basis for making important decisions such as treatment or euthanasia.** As with any laboratory test, the primary risk associated with the **OncoK9** test is a false test result (i.e., a false positive or a false negative result). A *Cancer Signal Detected* result significantly increases the likelihood that cancer is present, but does not confirm the presence of cancer; a confirmatory cancer evaluation must be performed to establish a definitive diagnosis. If the confirmatory cancer evaluation does not result in a cancer diagnosis, this could mean that the selected confirmatory measures did not identify the cancer, or that the test result was a false positive; further evaluation and/or monitoring of this patient should be considered. A *Cancer Signal Not Detected* result significantly reduces the likelihood that cancer is present, but does not rule out the presence of cancer or the possibility of cancer developing in the future; if cancer is still clinically suspected, a general cancer evaluation should be performed. Patients should continue to participate in any other cancer screening programs recommended by their veterinarian.

This test does not detect all cancers, and not all cancers are detectable from a blood sample. The result only indicates the detection or non-detection of cancer-associated genomic alterations in the patient's blood at the time of sample collection; it does not provide information about a patient's genetic risk for developing cancer or other clinical conditions in the future. Biological confounders such as genetic mosaicism, pregnancy, stem cell therapy, solid organ and bone marrow transplant, or recent whole blood transfusion may lead to an incorrect test result. The test may not detect genomic alterations present in the sample below the test's limit of detection, or genomic alterations that are not interrogated by the test. Future versions of the test, including future enhancements to the bioinformatics pipeline, may reveal new cancer-specific genomic alterations in the sample, or may otherwise modify the interpretation of genomic findings in the sample; in such instances, the updated information may or may not be communicated to the ordering veterinarian. In rare cases, the test may yield a *Non-Reportable* result, for reasons that include but are not limited to: sample receipt more than 7 days after collection; insufficient DNA quantity or quality; and technical noise and/or artifacts. The **OncoK9** test has not yet been validated for detection of minimal residual disease; for detection of cancer recurrence; for personalized treatment selection; or for monitoring treatment response. Additional detailed information regarding the uses and limitations of the **OncoK9** test are provided in the [OncoK9 Product Insert](#) and other resources at [www.petdx.com](http://www.petdx.com).

Note: **PetDx** developed the **OncoK9** test and determined its performance characteristics.

**Test Information (Continued)**

**Test Performance**

The clinical performance characteristics of the **OncoK9** test have been validated in over 1,000 dogs, with and without a diagnosis of cancer, as part of the CANDiD (CANcer Detection in Dogs) study. The validated performance of the test in predefined cohorts of 3 of the most aggressive canine cancers and 8 of the most common canine cancers, and in an all-comers cohort of cancer-diagnosed subjects, is summarized below. The [CANDiD Study Publication](#) provides more information.

CANCER TYPE	SENSITIVITY	SPECIFICITY
Three Aggressive Cancers	85%	
Eight Common Cancers	62%	<b>98.5%</b>
All-comers Cohort	55%	

**Sensitivity**

The percentage of cancer-diagnosed dogs who receive a *Cancer Signal Detected* result; also known as the “detection rate”.

**Specificity**

The percentage of cancer-free dogs who receive a *Cancer Signal Not Detected* result. A specificity of 98.5% corresponds to a false positive rate of 1.5%.

**Three of the Most Aggressive Canine Cancers**

Lymphoma, Hemangiosarcoma, Osteosarcoma

**Eight of the Most Common Canine Cancers**

Lymphoma, Hemangiosarcoma, Osteosarcoma, Soft Tissue Sarcoma, Mast Cell Tumor, Mammary Gland Carcinoma, Anal Sac Adenocarcinoma, Malignant Melanoma

**Cancer Types Detected by OncoK9**

The current version of the **OncoK9** test has been proven to detect cancer signal in 30 distinct cancer types. The [OncoK9 MCED List](#) provides more details.