The Golden Retriever Club of America, Inc.

OncoK9® by PetDx®
Information and Testing Considerations

The GRCA Health & Genetics Committee has been asked to provide information to assist owners in evaluating (with their veterinarians) whether OncoK9® is a suitable choice for their goals and circumstances. PetDx® suggests this test 1) for cancer screening in dogs not suspected to have cancer but who may be at higher risk by virtue of age or breed, and 2) as an aid-in-diagnosis for dogs suspected to have cancer. While we cannot make specific recommendations for individual situations, we will provide information that owners may find helpful in their decision process. Information in italics is quoted from a recently published (April, 2022) research paper[1]

A potential limitation of this study is its "case-control" design, wherein all subjects used to determine test performance had already been classified as either "cancer-diagnosed" or "presumably cancer-free" based on prior clinical evaluation. Most of the "cancer-diagnosed" subjects had initially presented for veterinary care due to clinical signs of disease, and subsequently received a definitive diagnosis of malignancy. Many subjects in a real-world screening setting would be expected to have sub-clinical disease; therefore, the sensitivity of the test (at a single point in time) for the screening use case is likely to be somewhat lower than the sensitivity reported here. The currently reported sensitivity is more likely to be reflective of real-world sensitivity in the aid-in-diagnosis use case, where patients receive the test because they are currently suspected of cancer based on observable clinical signs.

The research study included 351 dogs already diagnosed with cancer who were tested with OncoK9®. *In these subjects, the test returned a Cancer Signal Detected (positive) result for 192 subjects, for an overall sensitivity (detection rate) of 54.7%*

Of the 521 presumably cancer-free dogs tested, only 1.5% received false positive Cancer Signal Detected results. Thus, the overall specificity (not wrongly reporting cancer in dogs that don't have cancer) was 98.5%.

Data were further reported for several subsets of cancers. Again, these dogs had already been diagnosed by their veterinarian, so the results (as below) would not be considered "early detection."

Test performance in three of the most aggressive canine cancers: lymphoma, hemangiosarcoma, and osteosarcoma.

- Overall detection rate of 85.4% (117 of 137 dogs).

[1] Clinical validation of a next-generation sequencing-based multi-cancer early detection "liquid biopsy" blood test in over 1,000 dogs using an independent testing set: The CANcer Detection in Dogs (CANDiD) study. Published 4-26-22 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0266623

Test performance in eight of the most common canine cancers: (lymphoma, hemangiosarcoma, osteosarcoma, soft tissue sarcoma, mast cell tumor, mammary gland carcinoma, anal sac adenocarcinoma, and malignant melanoma)

- *The liquid biopsy test returned a positive result in 146 of these 236 subjects, resulting in an overall detection rate of 61.9%*

Test performance by extent of disease and tumor size

- Localized/regional, tumor less than or equal to 5 cm = 19.6%
- Localized/regional, tumor greater than 5 cm = 51.3%
- Disseminated/metastatic, tumor less than or equal to 5 cm = 82.9%
- Disseminated/metastatic, tumor greater than 5 cm = 87.5%

These findings have implications for the clinical utility of this type of testing in both the screening and the aid-in-diagnosis scenarios. For example, a smaller (.5 cm) lesion that is suspected to represent localized malignancy and is easily accessible by biopsy or fine needle aspiration (FNA) should likely be pursued with conventional tissue sampling rather than with liquid biopsy, given the lower sensitivity of the latter for smaller, localized cancers.

This utility may extend to certain disseminated/metastatic cases. Dogs may not show clinical signs until cancer has advanced to a stage where it is no longer curable at the time of diagnosis. In such situations, preclinical detection of disseminated/metastatic disease may nevertheless provide significant utility to the clinician and the pet owner. For example, it can help to shorten the path to diagnosis, or allow the diagnostic workup to take place without the time constraints that may exist when patients present with acute clinical signs–as, for example, in many hemangiosarcoma cases wherein cancer is detected after development of potentially life-threatening hemorrhage; it may also allow for palliative care to be initiated earlier, for improved quality of life; and it might give the family more time to make important medical management decisions for their pet

Although the OncoK9® Test Information page on the PetDx® website recommends testing "as an annual screening test for all dogs starting at 7 years of age and potentially starting at younger ages in certain breeds known to develop cancer earlier," aggressive cancers such as hemangiosarcoma, lymphoma, and osteosarcoma are generally considered to disseminate/metastasize very early and "early detection" may not extend the dog's life.

To explore this and other topics, PetDx® launched the "Cancer Lifetime Assessment Screening Study in Canines (CLASSiC)" in December 2021 to "follow over 1,000 initially cancer-free dogs, with semi-annual liquid biopsy testing and comprehensive documentation of cancer-related clinical outcomes, over many years."

OncoK9® is available only by prescription from a veterinarian, and PetDx® cautions that "important decisions about treatment or euthanasia should not be made based on the results of this test alone. Please discuss the results, and the most appropriate next steps, with your veterinarian."

Additional test information is available on the PetDx website at https://petdx.com/oncok9-test-information/

By Rhonda Hovan, Research Facilitator (June 2022)
On behalf of the GRCA Health & Genetics Committee