

Intended Use

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.

Test Procedure

SAMPLE INSTRUCTIONS

Do not discard or compromise the integrity of the Sample Collection Kit, as it will be used to return the filled blood tubes to PetDx® for sample processing.

- Open the OncoK9 box and assemble your sample collection kit.
 - Select 21 gauge Vacuette® straight needle or 21 gauge butterfly Vacutainer® Safety-Lok Blood Collection Kit and attach to Vacutainer Needle Holder.
- Prepare your patient for the blood draw.
- Puncture the vein with the needle.
 - If using the straight needle, there will be no flash.
 - If using the butterfly, confirm flash of blood through visual inspection at the needle hub.
- Place the Roche® cell-free DNA (cfDNA) tube inside the needle holder and push tube firmly to connect it to the needle.
 - Only connect the tube to the needle once the needle is in the vein, otherwise the tube will lose its vacuum.
- Allow the blood tube to fill completely. The tube must be filled to above the minimum (lower) fill line printed on the label, corresponding to 7mL, to be eligible for processing. Filling to the upper (maximum) fill line, corresponding to 8.5mL, is preferred.



- Once full, disconnect the tube from the needle holder and invert the tube gently 8-10 times to mix the blood with the sample preservative.



- Repeat steps 4 - 6 with the second Roche cfDNA tube.
- If the minimum volume is not achieved for each tube, use a 21 gauge or larger bore needle and regular syringe to obtain the remaining required blood.
 - Remove needle and deposit blood from syringe into the uncapped cfDNA tube.
 - Replace cap and mix sample thoroughly by inverting 8-10 times.
 - The tube must be filled within 15 minutes from initial tube puncture.
- Remove needle and apply pressure to the venipuncture site. Dispose of sharps appropriately.
- Label the blood collection tubes with the Pet Name and Requisition ID from the test submission form (see following section).
- Store the filled tubes at ambient temperature and away from direct sunlight. Do not freeze or refrigerate the sample at any time.

USE OF CELL-FREE DNA BLOOD COLLECTION TUBES

- Avoid contact with contents of the tube with skin and mucous membranes. In case of eye contact, rinse thoroughly with plenty of water for at least 15 minutes. In case of skin contact, wash off with soap and plenty of water.
- Do not use the cfDNA collection tube if the contents are cloudy or if foreign matter is present.
- Do not use the cfDNA collection tube for collection of materials intended for injection.
- Ensure the cfDNA collection tube is filled to at least the minimum fill line, corresponding to 7mL. Under-filling of one or both tubes will result in the entire sample being rejected and a request for redraw being issued.
- Do not fill the cfDNA collection tube above the maximum fill line. Over-filling may cause incorrect blood to additive ratio and may lead to inaccurate analysis or poor product performance.
- Store the kit and its components at room temperature (65-77°F/18-25°C).

REGISTERING A SAMPLE USING THE PETDX VETERINARY PORTAL

These instructions pertain to clinics that use the PetDx Veterinary Portal to order tests. In cases where a system integration connecting the clinic's medical record system with PetDx has been implemented, orders should be completed via your practice management software instead.

- From a desktop computer, access vet.petdx.com.
- Log in to your clinic's account.
- Click "New OncoK9 Test".
 - If the patient has been previously tested with OncoK9, select "Returning Patient". Choose the patient from the list, and verify their information is correct in the subsequent prompts.
- Follow the on-screen prompts to complete the fields.
- Verify information and submit the form.
- A Test Submission Form will appear as a printable PDF.
 - Ensure the Requisition ID (under the barcode) and patient name is written on the blood tubes.
- Print the document to be shipped with the patient's sample.

PACKAGING & SHIPPING INSTRUCTIONS

- Place each filled and labeled Roche cfDNA tube in the absorbent pouch with one tube in each sleeve.
- Place the sleeved tubes in the bubble wrap bag and seal.
- Place the bubble wrap bag in the biohazard bag and seal the bag.
- Fold and place the test submission form in the external document pouch of the biohazard bag.
- Place the sealed biohazard bag back in the OncoK9 box and tape shut.
- Place box(es) in provided FedEx® Clinical Pak and seal. Then apply the FedEx® Billable Stamp.





- Ship the sample to PetDx promptly, ideally within 12 to 24 hours after collection but not later than 48 hours following sampling. The postage is prepaid.
 - Give to your FedEx carrier during their normal rounds, or
 - Take the Clinical Pak to a FedEx-owned Express-eligible location: Express Drop Boxes, Express Stations (Ship Centers), and FedEx Offices, or
 - Call FedEx at 1-800-463-3339 and say “schedule a pickup” to arrange a weekday pickup for the package.
 - Note: Clinical Paks are not accepted at 3rd party locations that partner with FedEx (e.g., Walgreens®, Postal Annex®).
 - DO NOT REFRIGERATE OR FREEZE SAMPLES.**
- Failure to follow the procedures as outlined may result in erroneous results or significant reduction in sample quality.
 - Check venipuncture collection system and cfDNA blood collection tubes before use. Do not use any kit components beyond their stated expiration date or if they appear damaged.
 - Use of 21 gauge or larger needle is required to reduce sample hemolysis.
 - Gentle inversion of each filled blood tube 8-10 times is required to properly mix the sample with the preservative.
 - Each tube must be filled to the minimum fill line, though preferably to the maximum fill line, to ensure the appropriate volume of blood is collected.
 - Clotted samples cannot be analyzed.
 - Do not add any additives to the tube.
 - Collected blood specimens must remain at ambient temperature (59-86°F/15-30°C) at all times.
 - Samples should not be centrifuged.
 - Samples must arrive at PetDx in the shortest time possible, and in no case later than 7 days after collection.
 - DO NOT REFRIGERATE OR FREEZE SAMPLES.**
 - Ensure that collected specimens are packaged and labeled following all requirements for transportation of “Exempt Animal Specimen”.
 - The OncoK9 Summary of Safety and Effectiveness Data and the Roche cfDNA Collection Tube Safety Data Sheet are available on the PetDx support website (support.petdx.com).

Kit Storage & Sample Shipping/Handling Considerations

- Prior to blood collection, a cfDNA collection tube is stable through the expiration date when stored between 65-77°F/18-25°C.
- Blood specimens collected in a cfDNA collection tube are stable for 7 days when stored or shipped between 65-77°F/18-25°C, with transient excursions of up to 16 hours to 60-86°F/15-30°C.
- The sample should not be refrigerated or frozen.
- The sample should not be centrifuged.

Precautions and Warnings

- This test does not provide a definitive cancer diagnosis, and it should never be used as the sole basis for making important decisions such as treatment or euthanasia. A full clinical evaluation should be performed to establish a definitive diagnosis.
- This test does not provide information about a patient’s genetic risk for developing cancer or other clinical conditions in the future. The result only indicates the detection or non-detection of cancer signal in the patient’s blood at the present time.
- The primary risk associated with the OncoK9 test is a false test result (i.e., a false positive or a false negative result). All *Cancer Signal Detected* results should be followed up with confirmatory diagnostic testing to establish a definitive diagnosis of cancer. In the case of *Cancer Signal Not Detected* results, if cancer is still clinically suspected, a full diagnostic evaluation should be performed.
- This test does not detect all cancers, and not all cancers are detectable from a blood sample. A *Cancer Signal Not Detected* result does not rule out the presence of cancer or the possibility of cancer developing in the future.
- Early-stage disease may not provide sufficient detectable signal for the OncoK9 test. If cancer is suspected and the OncoK9 test result is *Cancer Signal Not Detected*, consider re-testing if cancer remains high on the differential diagnosis list, as advancing disease generally provides a higher cancer signal.
- The classification and interpretation of all genomic alterations identified reflects the current state of scientific understanding at the time the result report is issued. In some instances, the classification and interpretation of genomic alterations may change as new scientific information becomes available.
- 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.

Contraindications

Based on the possibility of confounding results or risk to the patient, the OncoK9 test should not be used in the following cases:

- Non-domestic canids and hybrids
- Any species other than domesticated canids (pet dogs)
- Dogs smaller than 3.5lb/1.6kg
- Dogs that cannot safely have 14-17mL of blood taken without fluid resuscitation
- Severely anemic dogs (Hct <18-22%) weighing less than 7.3lb/3.3kg
- Dogs that have had trauma or surgery within the previous 7 days
- Dogs that have received an allogeneic (donor-derived) bone marrow transplant at any time
- Dogs that have received allogeneic (donor-derived) stem cell therapy at any time
- Dogs that have received an organ transplant at any time
- Dogs that have received a whole blood transfusion containing white blood cells within the past 3 months
- Pregnant dogs
- Dogs known to be a chimera or mosaic (which arise from irregularities in embryonic development resulting in the presence of more than one genetic profile)

Kit Components

(2) Roche® Cell-Free DNA Collection Tubes - Single-use blood collection tube with K3EDTA + cell preservative

(1) Vacuette® Needle - 1” 21 gauge straight blood collection needle

(1) Butterfly Vacutainer® Safety-Lok Blood Collection Kit - ¾” 21 gauge butterfly needle with 12” extension and multi-sample Luer adapter

Other components: Tube Holder, Biohazard Bag, Absorbent Pouch, Bubble Wrap, FedEx® Clinical Pak, FedEx® Billable Stamp



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