Kode Veterinary Sciences Limited

Kv9 Clinical Trial Standard Operating Procedures – Sample Collection
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CONTROLLED DOCUMENT
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Index

Sample Collection

Fine Needle Aspiration (FNA) of Tumour Masses in Dogs

1. Purpose
To outline the standardized method for collecting fine needle aspirates (FNA) of tumour masses in canine cancer patients enrolled in the clinical trial, ensuring high-quality cytologic samples while minimizing patient stress, injury, and variability in technique.

2. Scope
This SOP applies to all veterinarians and trained veterinary technicians involved in tumour sampling for diagnostic, monitoring, or research purposes in eligible trial dogs.

3. Procedure
3.1 Patient Preparation

- Confirm dog identity, tumour site, and owner consent with owner of the dog.
- Position dog for minimal movement and optimal access to the mass.
- Sedation may be used for uncooperative or painful patients, per veterinarian's judgment.

3.2 Aspiration Technique
Option A: Suction Technique (most common)

- Attach a 22–25G needle to a 3 or 5 mL syringe.
- Insert needle into the central portion of the tumour mass.
- Apply negative pressure by retracting the plunger while moving the needle in and out within the lesion (4–6 times).
- Release the plunger before withdrawing the needle from the mass.

Option B: Non-Aspiration ("Woodpecker") Technique
Preferred for vascular or fragile tumours (e.g., lymphomas, melanomas)

- Use only a needle (no syringe).
- Insert the needle into the mass and move it rapidly in a pecking motion.
- Remove the needle and attach it to an air-filled syringe to express contents onto slides.

Ideally a minimum of two slides per aspiration, and two aspirations are performed – totally a minimum of four slides.

3.3 Slide Preparation

- Expel contents onto a clean slide using air pressure.
- Immediately make a smear using either:
    - Push technique (drag a second slide across to spread material)
    - Pull-apart technique (press two slides together and pull apart)
- Allow to air dry completely before staining or submission.

4. Sample Labelling and Documentation

- Label slides with dog's name and date.

- Complete laboratory request form.
- Record the procedure in the dog's clinical record

5. Post-Procedure

- Apply gentle pressure to the aspiration site for 30–60 seconds if bleeding occurs.
- Advise owner (if outpatient) to observe site for signs of infection or discomfort at home.

6. Needle Safety and Sharps Disposal

- Do not recap needles.
- Dispose of all used needles and syringes immediately into a puncture-proof sharps container.

If a needle stick injury occurs:

- Wash the area immediately.
- Report to the principal investigator or safety officer.
- Complete an incident report.

7. Sample Submission

Submit slides to SVS as per protocol.

Blood Collection in Dogs

1. Purpose
To establish standardized procedures for venous blood collection in canine clinical trial patients, ensuring safe handling, accurate sample collection, and proper specimen processing.

2. Scope
Applies to all veterinarians and veterinary technicians performing blood collection from eligible or enrolled trial dogs.

3. Procedure
3.1 Patient Preparation

- Confirm dog's identity.
- Restrain the dog gently, using minimal stress methods or sedation if required.

3.2 Collection Technique

- Prepare collection site with alcohol swab.
- Insert needle into vein bevel-up at 15–30° angle.
- Withdraw blood gently to avoid haemolysis.
- Collect correct volume required to fill red and/or purple top blood tubes (recommend 1.3mL tubes).
- Release pressure before withdrawing needle.
- Apply pressure to site with gauze for 30–60 seconds or until bleeding stops.
- Bandage if necessary.

3.3 Sample Handling and Processing
Gently invert tubes 5–10 times (do not shake).
Label each tube immediately with: Dog name and date

4. Sharps Safety and Disposal

- Do not recap needles.
- Place all sharps in a puncture-resistant sharps container immediately.
- Dispose of gauze in biohazard waste as needed.

In case of needle stick injury:

- Wash the wound immediately.
- Notify supervisor and document the incident.

5. Documentation
Record in the patients clinical history blood tubes collected.

Preserving Surgical Tumour Tissue Samples

1. Purpose
To establish standardized procedures for preserving surgically removed tumour tissue samples in canine clinical trial patients, ensuring safe handling, accurate sample collection, and proper specimen processing.

2. Scope
This SOP applies to all veterinarians, veterinary technicians, and personnel involved in the collection, handling, preservation, and documentation of tumour tissue samples from eligible or enrolled dogs in clinical trials.

3. Procedure
3.1 Sample Collection

- Tumour tissue must be collected with appropriate surgical techniques by a veterinarian.
    - A suture knot can be placed on one edge of the sample to assist with orientation.
    - Handle the tissue sample gently to avoid mechanical damage and preserve histological quality.
- Immediately place the tissue in a leak-proof container that is at least 10 times the volume of the sample to allow sufficient fixative coverage.
- Add **10% neutral buffered formalin** at a **10:1 fixative-to-tissue ratio** (e.g., 10 mL of formalin per 1 mL of tissue).
- Seal the container tightly and label it clearly with:
    - Patient name and ID
    - Date of collection
    - Orientation of knot if used

4. Formalin Safety and Disposal
4.1 Handling Safety

- Always handle formalin in a well-ventilated area or under a certified fume hood.
- Personnel must wear appropriate personal protective equipment (PPE), including:
    - Nitrile gloves
    - Eye protection (safety goggles or face shield)
    - Surgical or N95 mask
- Avoid inhalation, ingestion, and skin or eye contact. Formalin is toxic and a known carcinogen.

4.2 Spill Response

- In case of a small spill (<100 mL), absorb with formalin-specific spill absorbent or inert material (e.g., vermiculite), and dispose of in a sealed chemical waste bag.
- For large spills, evacuate the area and notify the designated safety officer or supervisor immediately.

- Use spill kits and follow institutional hazardous chemical response protocols.

4.3 Disposal

- Do not pour formalin down the sink or drain.
- Collect all used or excess formalin in approved hazardous waste containers with proper labelling.
- Dispose of through your institution's licensed hazardous waste disposal service in compliance with local and national environmental regulations.

5. Documentation

Record in the patients clinical history the sample collected, orientation of any suture knots placed and any additional relevant details.

Submitting Laboratory Samples

1. Purpose
To establish standardized procedures for submitting laboratory samples from canine clinical trial patients. This ensures proper handling, labelling, transportation, and documentation of samples.

2. Scope
Applies to all veterinarians, veterinary technicians and any personnel involved in submitting laboratory samples from eligible or enrolled trial dogs.

3. Procedure
3.1 Samples

- **Blood samples**: Ensure tubes are properly sealed and protected, and placed in a leak-proof transport container or bagged twice.
- **Microscopic Slides**: Slides should be placed in slide holders to prevent damage during transport.
- **Preserved Formalin Samples**: Ensure the container is properly sealed and protected, and placed in a leak-proof transport container or bagged twice.

3.2 SVS Laboratory Form

- Complete the KVS provided SVS Laboratory Submission Form for each sample being submitted.
- Ensure all required fields are filled out accurately, including:
    - Date of sample collection
    - Animal name and ID
    - Brief history
    - Ticked which tests are requested from the below list:
        - Pre-Op/ Health Check
        - CBC
        - Smear Cytology Site(s)
        - Histology Single Tissue
- Include the form with the submission package.

3.3 Posting

- Samples should be transported to the laboratory in a timely manner.
- Use SVS provided courier bags where possible.
    - If you have run out of bags then contact the clinical trial co-ordinator to arrange for more.

3.4 Communication

- Please ensure that KVS has received a referral submission before or at the same time as submitting the laboratory samples.

4. Documentation and Records

- Maintain a record of what patients samples were submitted and courier/ shipping information.
- Record any deviations or issues encountered.

5. Deviations

Any deviation from this SOP must be reported to the trial co-ordinator immediately and documented.