

Quality guidance: mobile and/or sample collection service

Quality management

The service develops and implements written quality and operational policies, processes and procedures, ensuring that all policies, processes and procedures are followed.

- It is highly recommended to follow the same procedures as the referral laboratory regarding patient identification, labelling, specimen collection and procurement
- It is essential to comply with any instructions in the referral laboratory's test directory

The service employs adequate, trained, qualified and competent professional and technical personnel. The personnel employed must be appropriate and adequate for the workload, range and complexity of the procedures that are performed.

The service ensures adequate training and orientation of staff and has developed policies, processes and procedures to support orientation and training. Evidence of training records on employee files must also be maintained.

The service ensures ongoing competency of staff at defined intervals and has policies, processes and procedures to support a competency program.

The service ensures that current authorized documents are readily available for active use at relevant locations (e.g., safety manuals, collection procedures).

There is a process for the resolution of complaints by patients or referral laboratories.

There are policies, processes and procedures for the risk management, identification and control of non-conformances, near misses and adverse events (e.g., clerical errors, wrong sample tubes collected, patient misidentification and patient or staff injury).

There are processes and procedures for the care of patients who experience adverse reactions during the phlebotomy process (e.g., fainting, excess bleeding).

The service has a process to ensure the timely, appropriate and safe transportation of samples to the laboratory that also includes any special sample transport requirements (e.g., on ice, ambient temp, protection from light).

Sample collection

Samples are collected in a setting that provides safety, privacy and confidentiality for patients, including accommodation for patients with disabilities.

There are clear instructions for patients providing urine samples.

There are processes and procedures regarding when informed consent is required from patients. This should include information on dealing with minors and incompetent adults.

There are developed processes and procedures for the proper positive identification of patients before collection, including those with communication challenges.

There are comprehensive sample collection instructions readily available for those responsible for primary sample collection:

- Sample collection instructions should include:
 - Copies/examples of consent forms, where applicable
 - Positive patient identification requirements
 - Requisition requirements
 - Order of draw
 - Information and instructions provided to patients in relation to their own preparation before primary sample collection
 - Patient preparation and procedures for caregivers and phlebotomists
 - Patient assessment procedures (preparation requirements met, age-specific conditions that might influence collection approach, appropriate collection site, contraindications, hazards, potential complications)
 - Type and amount of the primary sample to be collected
 - Special timing of collection, if required
 - Sample identification requirements
 - Sample labelling requirements
 - Any special handling needs between the time of collection and time received by the laboratory (e.g., transport requirements, refrigeration, warming, immediate delivery, protection from light)
 - Sample collection procedures (e.g., phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the sample containers and any necessary additives
 - Instructions for the collection of complex test requirements such as for transfusion medicine and/or microbiology
 - Specific guidelines regarding blood collection for neonates and young children (e.g., site to be used, number of punctures allowable, minimum/maximum draw volumes, allowable age for venipuncture vs. micro collection)
 - Instructions for recording the identity of the person collecting the primary sample

Equipment

Management ensures adequate equipment, instruments, reference materials, consumables and reagents for the provision of services.

There are procedures and criteria for the receipt, inspection, acceptance/rejection and storage of consumable materials. This includes a process for ensuring that collection tubes or other materials are not expired.

The service ensures that adequate storage capabilities are maintained so that items do not deteriorate or become compromised.

If centrifuges or other equipment is used, there are procedures for preventative maintenance and evidence that it is being performed regularly as per the manufacturer's instructions.

Any reusable equipment that comes into contact with patients is cleaned and disinfected or sterilized before each use, in accordance with the manufacturer's instructions.

There are procedures for safe disposal of materials used in the collection (e.g., disposal of single-use equipment).

Safety

The service has a comprehensive written safety plan.

- This includes risk/hazard assessments for employees entering the patient's home, including action to be taken to mitigate risk (aggressive patients, verbal abuse).

There are comprehensive safety policies, processes and procedures that include all of the following where applicable to the scope of service:

- General requirements and policies
- Infectious hazards and standard precautions
- Hand hygiene protocols
- Incidents and injury procedures, including procedures for follow-up of any exposure to blood-borne pathogens (e.g., needle stick exposure)
- First aid program
- Biological spills procedures, including spill kit usage for blood tube breakage
- Training on Canada's Transport of Dangerous Goods Regulations

There are comprehensive policies, processes and procedures for the use of personal protective equipment (PPE) and mandated requirements when dealing with patients.

There are policies, processes and procedures to prevent contamination of workers, patients, or the environment during the transport of samples, cultures and other biological materials. This includes ensuring transport and shipping containers are leak-proof, safe and secure, as well as appropriately labelled.