	MAYO UNIVERSITY HOSPITAL PATHOLOGY LABORATORY SPECIMEN RECEPTION		
Author	Leanne Mangan Senior Medical Scientist, Specimen Reception	**Document Identification**	PATH/PD/019
Authorised By	Dr Fadel Bennani, Laboratory Director Regina Creighton Laboratory Manager	**Edition Number**	2
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Pre-analytical Guidance for GPs/Service Users

Centrifugation, Storage & Transport of Samples

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1 Introduction

This document provides guidance for General Practitioners (GPs) and other service users on the proper centrifugation, storage and transportation of medical specimens intended for testing by medical laboratories from GP practices, nursing homes or other locations. The guidelines align with the ISO 15189:2022 standard for laboratory accreditation to ensure the integrity, safety, accuracy, and reliability of test results.

2 Documents

2.1 Test Directory A-Z (in-house and Referrals)

2.2 Mayo University Hospital Pathology Laboratory User Manual

3 Introduction to ISO 15189 and Its Relevance

ISO 15189 is an international standard that specifies requirements for quality and competence in medical laboratories. Accredited medical laboratories must adhere to these standards to provide reliable test results. A critical aspect of these standards involves the proper handling, storage, and transport of specimens from the point of collection to the laboratory. GPs play a crucial role in ensuring that specimens are stored and transported correctly to maintain their integrity.

4 Centrifugation Guidance

4.1 **Objective:** To prevent the deterioration of specimens if there is a delay in transport to the laboratory and to ensure the accuracy and reliability of test results.

****Note**: The laboratory would advise that samples should NOT be centrifuged off-site unless the practice utilises approved calibrated equipment that is compliant with regulations to assure the sample meets acceptable and safe criteria for testing.

Where a centrifuge is utilised off-site, the following **must be confirmed**:

- The centrifuge is calibrated – this calibration is confirmed at a minimum annually and by an ISO17025 accredited supplier for this service
- The spin speed and duration of centrifugation is compliant with the required centrifugation criteria as instructed by the laboratory (refer to section 4.1.4)

Please refer to the laboratory's A-Z Test Directory (refer to section 1.1) which clearly specifies for each test, the acceptable pre-analytical storage environment and timeframe to assure stability of the sample and reliability of test results.

4.1.1 All users should be **trained** prior to commencing use of the centrifuge.

4.1.2 **Placement and set up** (Note: when choosing a centrifuge make and model/ manufacturer, this should comply with the ISO 20658 standard as per below):

4.1.2.1 For non-floor models the centrifuge must be placed on a firm sturdy benchtop / desk that accommodates the entire width/breadth of the centrifuge. (The surface should not shake when the centrifuge is running.)

4.1.2.2 The Centrifuge must be secured by the supplier to the bench top.

4.1.2.3 Before use the supplier must provide the certificate of calibration on placement. This must be kept on file in the instruments book of life together with instruction manual, warranties etc.

4.1.2.4 Once the centrifuge has been placed and calibrated it must not be moved – if it is necessary that it be moved, the supplier must be contacted to move the centrifuge and recalibrate.

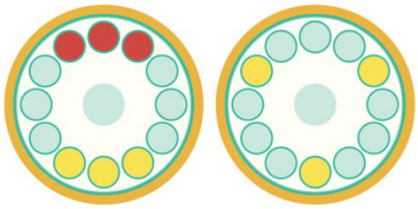
4.1.3 **Sample Type:** Only **Lithium Heparin and serum (SST)** samples can be centrifuged as per requirements for applicable tests stated in A-Z Test Directory.

4.1.3.1 **Prior to centrifugation, samples (SST) should sit for 20-30 minutes at room temperature** to allow for clotting and ideally **should be kept upright.** If adequate clotting does not occur, separation will be affected during centrifugation which may render the sample unsuitable for test analysis.

4.1.4 **Use of the Centrifuge**:

4.1.4.1 Always use the correct size tube that can be accommodated by the centrifuge.

4.1.4.2 Placement of tubes to ensure centrifuge is balanced must be done correctly. Keep a dummy tube with 3-5 ml of water inside to use as a balance tube if required (ensure that this tube is clearly marked BALANCE).



Examples of acceptable balancing

4.1.4.3 Inspect tubes to ensure caps are placed firmly on and there are no cracks before centrifuging.

4.1.4.4 Keep lid closed while rotor is moving. Only open once centrifuge has completed and stopped.

4.1.4.5 Centrifuge settings – this should be programmed by the supplier on installation:

- Primary program for serum yellow top tubes (5ml/7ml)
  - RCF 1800g (speed); time 10 minutes

Note the RCF (g) and rpm are not equivalent

To convert RPM to RCF (g) use the following formula:

$$RCF\ (g) = (1.118 \times 10^{-5}) \times radius\ of\ centrifuge) \times (RPM)^2$$

Or use the following link to calculator Centrifuge Calculator (omnicalculator.com)

4.1.5 **Maintenance**

4.1.5.1 It is important that the centrifuge is kept clean and free from dust and lint for optimum functioning. Use cleaning solutions (alcohol based for example) as recommended by the supplier. Use a soft cloth for rotors and accessories.

4.1.5.2 Daily cleaning should include the interior, rotor chamber, and any electronic components like touchscreens and keypads. A daily clean tick sheet should be incorporated as part of the centrifuge's routine use.

4.1.5.3 All spills should be cleaned up immediately before further use – using the allocated spill kit and in line with specifications regarding biological material.

4.1.5.4 Preventative maintenance including calibration /centrifuge speed checks should be done at a minimum annually, ideally 6 monthly. Calibration should be performed for all speed settings used routinely by an **ISO 17025 approved supplier**. Calibration records should be maintained and available for audit.

Note: This process is audited periodically by the laboratory, Mayo University Hospital to assure compliance with the ISO15189 standard to which our laboratory is accredited.

5 Storage Requirements

5.1 **Objective**: To prevent the deterioration of specimens prior to their transport to the laboratory.

5.1.1 Specimens should ideally be sent to the laboratory as soon as possible (via the next transport courier on the same day of sample collection).

5.1.2 After collecting specimens from patients, it is crucial to ensure that they are stored under appropriate conditions to prevent degradation. The specific requirements for storage conditions (such as temperature, light exposure, and humidity) vary depending on the type of specimen and the tests requested.

Follow the instructions provided in the laboratory's A-Z Test Directory for each type of specimen collected. Information located at: *Pathology Laboratory Department | Saolta University Health Care Group*

5.1.3 Samples should be stored in temperature-controlled environments and it is the responsibility of the external locations to ensure this is maintained until samples are transported.

5.1.4 Store blood, urine, and other biological specimens at the temperature conditions recommended for that specific type of sample and test, to prevent deterioration of the analyte and assure accuracy of test results.

5.1.5 For example, blood specimens might require special storage and processing requirements (example: spun and refrigerated at 2-8°C) if they cannot be transported to the laboratory within a certain time-period. Refer to storage and stability requirements for each individual test in the laboratory's A-Z Test Directory. Information located at: *Pathology Laboratory Department | Saolta University Health Care Group*

6 Transportation of Samples: Compliance Requirements

6.1 **Objective**: To ensure timely and safe transportation of samples from GP practices, nursing homes and external locations to the laboratory, following the specific requirements outlined in ISO 15189 and European Agreements.

6.1.1 **Compliance with ADR Regulations for Packaging of Samples**

6.1.1.1 The transport of specimens to the Laboratory must follow UN (UN 3373) regulations and guidelines in order to minimise the risk of infection to those who may come in contact with the specimens e.g. taxi drivers, couriers, postal workers, porters, laboratory staff etc.

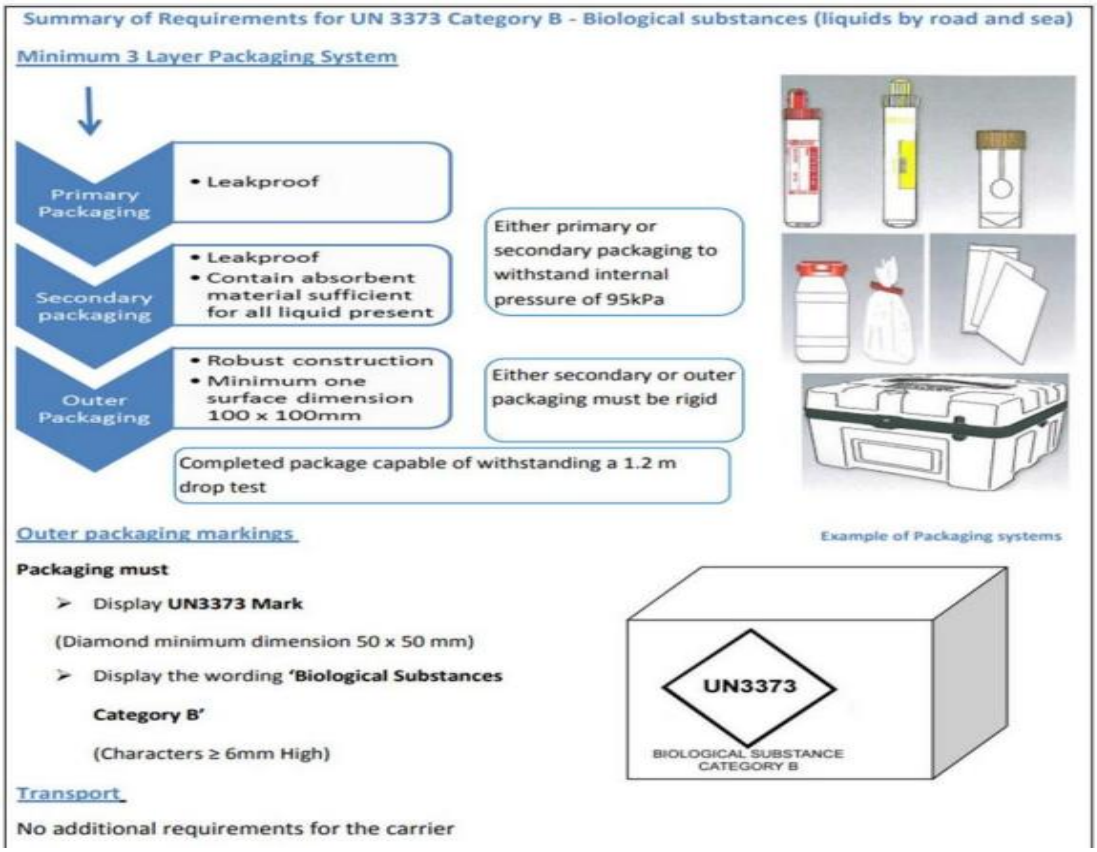
6.1.1.2 The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) regulates the packaging and transportation of specimens categorized as dangerous goods.

6.1.1.3 Consignors of specimens must ensure that packages are prepared in such a manner as to meet these requirements and in accordance with any special criteria as required by the laboratory at Mayo University Hospital.

6.1.1.4 Ensure all specimens are packaged in accordance with ADR regulations, which typically involves the use of triple packaging systems:
Primary Container: Leak-proof container holding the specimen.
Secondary Container: Sealed container to hold the primary container, providing an additional barrier.
Outer Packaging: Rigid container that protects both the primary and secondary containers during transport.

6.1.1.5 Label the packaging clearly with the necessary hazard and handling information.

6.1.1.6 The summary requirements within the guidance are shown below:



6.1.2 Ensuring **Appropriate Time between Collection and Receipt** in the Laboratory

6.1.2.1 The **time interval** between specimen collection and receipt in the laboratory is critical to maintain analyte stability. Certain tests have specific requirements for how quickly specimens must reach the laboratory to remain valid for testing.

6.1.2.2 Refer to the laboratory's A-Z Test Directory to determine the maximum allowable time for each type of specimen.

6.1.2.3 Plan specimen collection and courier schedules accordingly to meet these time constraints, especially for time-sensitive specimens like vitamins, metals or certain coagulation tests.

6.1.2.4 Prompt delivery is essential to maintain sample integrity and avoid rejection of samples.

6.1.2.5 Samples should be delivered to the Laboratory within the routine working hours (Monday to Friday 9-5pm). Delivery of samples outside of these hours can result in sample rejection.

6.1.3 **Maintaining Temperature Interval Specified** for Sample Collection and Handling

6.1.3.1 Many specimens require specific temperature ranges to maintain stability during transport.

6.1.3.2 Verify the temperature requirements for each type of specimen in the laboratory's A-Z Test Directory.

6.1.3.3 Use transport containers that maintain the required temperature (e.g., cool boxes with ice packs for refrigerated specimens or insulated bags for room-temperature specimens).

6.1.3.4 Monitor temperatures during transport using validated temperature monitoring devices.

*Note: The Laboratory periodically audits sample transport times and temperature to verify temperature conditions are met during transportation.

6.2 If **external locations are not using a compliant transport Logistics Company/ courier (such as patient/nurse/etc.)** please follow the instructions for the transport and delivery of samples to MUH Laboratory in appendix 1.

6.2.1 Arrangements made with individuals to deliver samples must include instruction that samples need to be packaged and transported in compliance with ADR regulations as above, and at the appropriate temperature conditions within an acceptable timeframe directly to the laboratory.

6.2.2 Samples should be delivered directly to the Laboratory within working hours (Monday to Friday 9-5pm) and should not be transported to the Laboratory outside of these routine hours.

6.2.3 If the GP requires an urgent/out of hour's request, they must make contact with the Scientist on-call via the MUH switch-board.

7 Confidentiality, Data Protection (GDPR), and Responsibility in the Transport of Patient Specimens

7.1 All patient specimens and associated documentation must be handled in accordance with applicable data protection legislation, including the General Data Protection Regulation (GDPR) and national data protection laws.

7.2 Patient confidentiality must be maintained at all times throughout the pre-examination, transport, and handover processes.

7.3 Specimen containers and accompanying request forms must be securely packaged to prevent accidental disclosure of patient information and loss or misplacement of documentation.

7.4 Where possible, the use of sealed, opaque transport bags or containers is required to ensure that patient details are not visible during transit.

7.5 Verbal disclosure of patient information during transport must be avoided unless clinically necessary and conducted in a secure and appropriate setting.

7.6 Chain of custody should be maintained where applicable, ensuring traceability from collection to laboratory receipt.

7.7 The requesting clinician retains overall responsibility for ensuring that specimens are safely and securely transferred to the laboratory.

7.8 Where specimens are transported by a third party (e.g., courier, healthcare staff, or other designated individual), the requesting clinician must provide clear guidance on maintaining patient confidentiality and GDPR compliance.

7.9 Any breach of confidentiality, loss of specimens, or data protection incident must be reported in accordance with local incident reporting procedures and data protection policies.

8 Demand Management

8.1 The laboratory, as instructed by the laboratory medical consultants, periodically review test requests and current guidelines to assure that the testing service is appropriately utilised.

8.2 Managing demand efficiently ensures that laboratory resources are utilised effectively, critical tests are prioritised and delays are minimised. This enhances patient care by delivering timely and accurate test results essential for diagnosis and treatment.

8.3 All users will be advised and informed of testing protocols and changes prior to implementation.

9 References

9.1 Current Version of ISO 15189 Standard for Medical Laboratories - Requirements for Quality and Competence PATH/EXT/372

9.2 Current Version ISO 20658 Medical laboratories — Requirements for the collection and transport of samples for medical laboratory examinations PATH/EXT/375

9.3 Test Directory A-Z (in-house and Referrals) PATH/PD/014

9.4 Mayo University Hospital Pathology Laboratory User Manual PATH/PD/001

Appendix 1

Instructions for transport & delivery of samples to MUH Laboratory

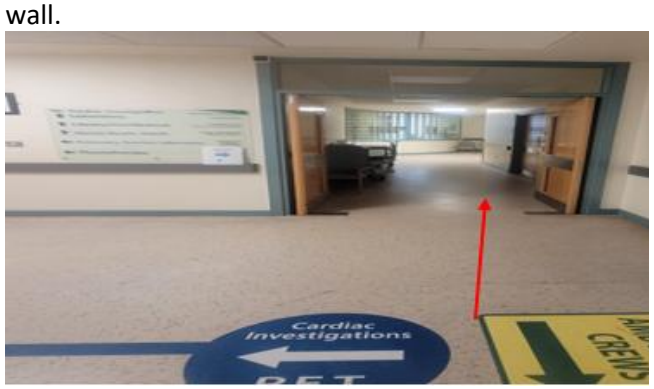
1. Ensure samples are accompanied with a sample request form and all relevant details are complete (e.g. 24 Hour urines, Stool etc.)
2. **Prompt delivery** to MUH Laboratory is essential to maintain sample integrity. It is key to ensure there are no delays which may result in tests not being processed.
   a. Samples should be delivered directly to Specimen Reception at the Laboratory. See directions to the Laboratory below.
   b. Do not leave samples at Hospital Reception. Hospital staff will not accept these samples.
   c. Samples should be delivered within the routine working hours (Monday to Friday 9-5pm). In the case of an emergency, GPs can contact the Laboratory for samples to be delivered out of routine hours.
3. Samples should be transported to the Laboratory in environments which do not compromise sample integrity.
   a. Do not store in areas where temperature is too high or too cold:
      i. Heating units in cars
      ii. Boot of car
      iii. Outside

Directions to the Laboratory

1. Walk through the main entrance to Mayo University Hospital

2. **TURN RIGHT** at main entrance (shop on your right) and continue straight to follow the orange and blue floor signs to Day Services corridor.

3. Walk down to the end of the corridor and continue through the double doors and pass by the glass ball wall.



4. The Laboratory will be on your left, shortly after the glass ball wall. Specimen Reception staff are to the left of the double doors. Ring the doorbell if no one is in attendance.

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