



MICRODIAGNOSTICS
PRIVATE CYTO/HISTOPATHOLOGY LAB

**WORK DIRECTIVE: SHIPPING OF BIOLOGICAL MATERIAL
SAMPLES**
CODE: OE.420.03
EDITION: 2
IN EFFECT SINCE: 20/10/2017
PAGES: 13

**“MICRODIAGNOSTICS I.D. HATZIBOUGIAS
Ltd”**

WORK DIRECTIVE

OE.420.01

SHIPPING OF BIOLOGICAL MATERIAL SAMPLES

COMPILED: 20.10.2017

APPROVED: 20.10.2017

Maintaining the integrity of the patient samples from the moment of collection until the time of completion for any examination is of paramount importance. Please follow the guidelines for collection, preparation and transportation that are required for every examination, taking care to always maintain the proper temperature.

1.1. General information

The Laboratory collaborates with private clinics as well as with external, privately operating doctors. All the required information (address, operation procedures, complaint registration processes, examination requirement, guidelines) are available at the Laboratory for use by all likely users of our its services.

The collection, labeling and transportation of biological samples for use in diagnostic examinations are carried out according to the relevant work directives of the laboratory. All the collaborating doctors are required to obtain these guidelines and sign a document which certifies that they have accustomed themselves with them. (**E.420-7: Declaration of Compliance with Collection & Transportation Guidelines for Biological Samples**).

The Laboratory “MICRODIAGNOSTICS I.D. CHATZIBOUGIAS LLP” doesn’t take part in the sample collection procedure itself.

The collection and transportation of biological samples (Pap test, biopsies of solid and hollow organs etc.) is not carried out by the staff of the Laboratory but by the relevant personnel of each collaborating doctor.

Patient sample preparation for transportation

The samples must be shipped to the Histopathology or Cytology department as soon as possible.

If immediate transportation is not possible, store the samples under refrigeration. **DO NOT FREEZE.**

YOU MUST complete an examination request form (referral) for every sample that you submit. In the request form, please include the following information:

- ❖ **Patient's name and surname**
- ❖ **Medical center code or other unique identifier**
- ❖ **Patient location**
- ❖ **Referring Doctor**
- ❖ **Name or initials of the person who collected the sample**
- ❖ **Date and time of sample collection**
- ❖ **Related clinical data, including medical history**

Every container that has a sample it must include the following information on its label:

- ❖ **Medical center code or other unique identifier**
- ❖ **Patient location**
- ❖ **Referring Doctor**
- ❖ **Name or initials of the person who collected the sample**
- ❖ **Date and time of sample collection**

Every sample must come with an examination request form. As such, if there are samples that must be transported at different temperatures from one another, separate examination requests are required. However, if only a single examination is requested, which requires samples transported at different temperatures to be carried out, provide a form only for one sample noting **CLEARLY** on it that the examination form accompanies one or more additional samples. For example, if the examination requires two samples, one under refrigeration and one which is frozen, place the form in the transportation bag of the sample under refrigeration and note that "a frozen sample has also been sent along". Store the samples under appropriate conditions in your facility until they are transported to the laboratory. In some areas a courier service can be provided. Pick-up times vary depending on the location. The courier will keep the samples during transport at the temperature indicated by the customer.

A lot of the samples require immediate coating and fixation by the personnel that performs the sample collection.

The materials that are used to coat the slides are placed in special paper pouches that protect them from damage.

Other samples in liquid/solid form are placed in special vials. These vials must be shipped according to the “Triple Packaging System” requirements as set by the World Health Organization in the WHO/EMC/97.3 document titled “Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens”.

Specifically:

- 1) The vials that contain the biologic material are sealed, wrapped in parafilm, and placed in special transportation tubes.
- 2) Afterwards they are placed in the sealed side of a “zip lock” bag marked with the “biohazard” sign. Seal properly to avoid any possible leakage.



3) The full set of containers is placed in the special biological material transportation bag of the "MICRODIAGNOSTICS I.D. HATZIBOUGIAS Ltd" Laboratory, to which they are sent for processing and diagnosis.

4. **CAUTION – the referrals should be placed in the special waterproof pouch which is always found inside the transportation bag.**



The isothermal biological material transportation bag UN3373 of "MICRODIAGNOSTICS I.D. HATZIBOUGIAS Ltd" has been designed and fabricated with high attention to detail and in collaboration with the English Institution NHS Trusts/VERSAPAK in order for it to fully comply with the regulations concerning the transportation of diagnostic samples. The bags have been tested by the PIRA independent institution to certify their compliance with the PI650 packaging instruction. The isothermal transportation bag has an insulation system made by the material "Thinsulate" which allows it to keep the temperature of its contents steady for up to 6 hours. It also has integrated inflexible protective lining against impacts and additional wadding on the inside. Particular care has been placed on security, as it possesses a safety zipper which shows if it has been tampered with. It possesses a number of "windows" to easily facilitate the change of address for both recipient and sender addresses (with an optical reminder system). Specifically, there are 2 A5-sized windows on its two sides.

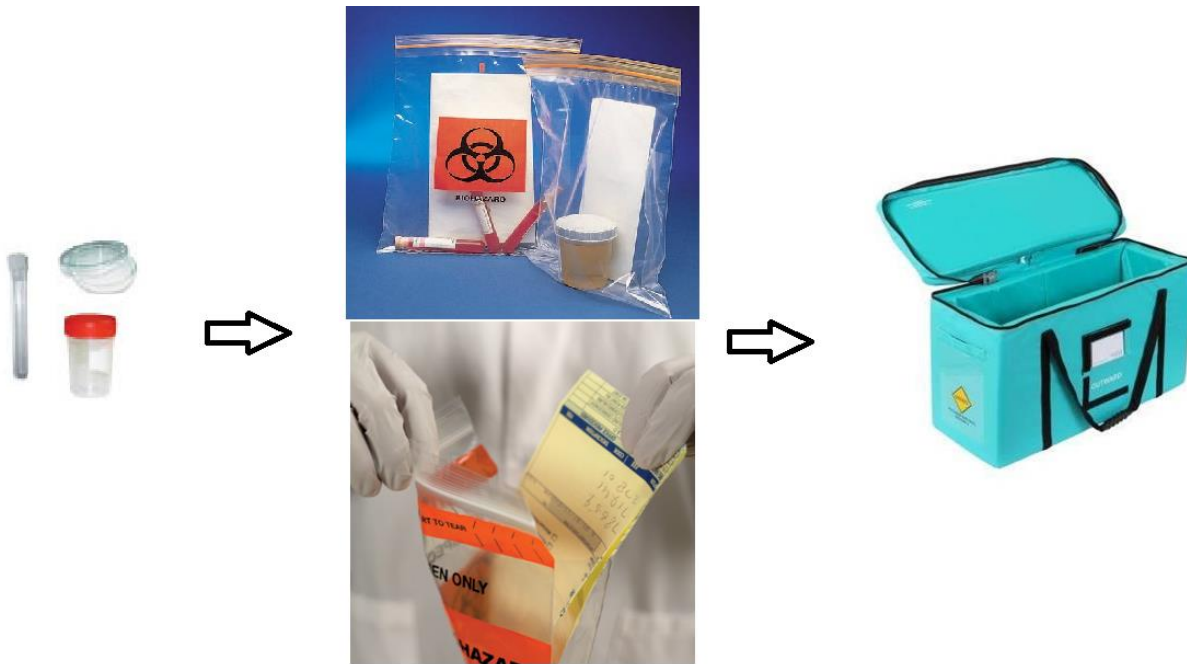
COMPILED: 20.10.2017



APPROVED: 20.10.2017



CONSIDE DIAGRAMM OF TRANSPORTATION PROCEDURE



COMPILED: 20.10.2017

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APPROVED: 20.10.2017

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The transportation of biological samples per the aforementioned procedures & guidelines set out by WHO ensures the integrity of the sample and the safety of the transporter, of the public in general and of the receiving Laboratory, in compliance with the existing requirements.

Our partner drivers are trained in the particularities that the transportation of biohazard materials present as per the UN 3373 "Category B' Infectious Substances, Class 6.2" regulation and take particular care to:

- ❖ Ensure the integrity and proper preservation of the biological material under transport.
- ❖ Respect the Health and Safety requirements to safeguard the Public Health and the Environment, as the materials that are being transporting are both infectious as well as possibly infectious (diagnostically)
- ❖ Apply the regulations and special requirements for the safe transportation of biological material, governed by the good practice rules (GMOs), the Cold Chain requirements of the World Health Organization (W.H.O) and the requirements of other International Institutions (DGR, ADR/road transportation, IATA/flight transportation, Code IMDG/sea transportation).
- ❖ Make sure that their vehicles are climate-controlled and regularly cleaned/disinfected according to the guidelines for the management of biological material.

Specialized guidelines according to the type of biological material:

- ❖ **Liquid-based cytology Test PAP**
 - ✓ Using a brush «Rovers Cervix-Brush», insert the core fibers of the brush in the endometrial canal.
 - ✓ Maintaining steady and light pressure, turn the brush clockwise five times.
 - ✓ Insert the brush in the liquid-based cytology vial. Remove the brush handle. Reseal the vial.
 - ✓ Clearly fill out the label on the vessel so that the patient identification is possible.

❖ **Conventional cytology PAP test**

- ✓ The patient should not use vaginal medication or vaginal lavages for 24 hours before taking the sample.
- ✓ The name of the patient should be marked with a black pencil on the rough side of the tile where the sample is to be placed.
- ✓ Insert the endoscope without using lubricant gel and collect the sample
- ✓ Any use of lubricant of any kind may render the sample useless.
- ✓ Using suitable spatulas and an endometrial brush, collect samples from the entire endo / exometrial surface. A number of suitable tools are now available to collect adequate endometrial specimens. Spatulae are sufficient for vaginal, ectopic, and endometrial specimens.
- ✓ Quickly smear the collected material across the entire glass surface of the tile.

❖ **Body cavity fluids**

- ✓ May include: pleural, ascetic, cystic, or spinal fluids.
- ✓ Liquids that may coagulate must undergo anticoagulation (heparinization) before they are submitted.
- ✓ Liquids can be transported to the laboratory in any suitable container with the relevant, complete, and legible marking. Keep refrigerated until shipment.

❖ **Nipple secretions**

- ✓ The few first drops of secretions should not be collected, as they mainly contain cellular debris.
- ✓ Using a tile in which the necessary marking has already been completed, slide it along the nipple to achieve a uniform spread.
- ✓ Fix immediately with cytology fixative in sprayable form.
- ✓ Repeat the procedure until the secretions stop.
- ✓ Aspiration of cystic fluid.
- ✓ Drain the liquid into a syringe and submit it to our lab, with the name of the patient on a label.

- ✓ Until they are shipped to the laboratory, samples should be kept refrigerated.

- ❖ **Solid mass aspiration**
 - ✓ Absorb the sample with a syringe
 - ✓ Label the syringe with the name of the patient
 - ✓ Submit it to our laboratory or store under refrigeration until you submit it.

- ❖ **Sample collection with a protected bronchial brush – PBB**
 - ✓ Samples that have been collected using a protected bronchial brush can be submitted in two different ways:
 1. Place the brush in a test tube with a screw cap filled with saline and submit it to our laboratory immediately.
 2. Apply the sample from the brush to a glass tile in which you have previously filled the label (use pencil). Ensure that the entire sample is spread evenly on the tile.

- ❖ **BrochoAlveolar Lavage – BAL**
 - ✓ The samples should be sent inside a clean, airtight, and securely sealed tube or container.
 - ✓ The samples should be transported to the laboratory as soon as possible in a container with a fully filled out and legible label. If immediate transfer is not feasible, store the specimen under cooling or place it in a bowl filled with "CytoRich Red" to avoid spoilage of the sample cells.

- ❖ **Sputum samples**
 - ✓ The only acceptable samples are those produced from expectoration after deep coughing. Saliva and samples infected with nasal discharge or food are not acceptable.
 - ✓ Advise the patient to collect the sample in the morning, before anything else. Ask him to take a deep breath and spit out the mucus that will be caused by the deep cough in a suitable pot that you will have provided him.

- ✓ If patients cannot produce any sputum out of their lungs, consider whether the sputum induction process is possible in the first place.
- ✓ The samples should be transported to the laboratory as soon as possible in a container with a fully filled out and legible label. If immediate transfer is not feasible, store the specimen under cooling or place it in a bowl filled with "CytoRich Red" to avoid spoilage of the sample cells.
- ❖ For small amounts of liquid (1
Thyroid gland liquid sample collection
- ✓ Για -2ml), you can smear the sample on a glass laboratory tile. Place a second tile on the first and remove it to create a uniform spread. Spray immediately with a fixative.
- ✓ For Wright stain tiles: Repeat the staining procedures for one or two tiles and allow to dry in the air. Please indicate on the tile that it has dried in the air.
- ✓ For larger quantities of liquid: Send the sample to a sealed syringe for processing. Refrigerate the sample if immediate shipment is not possible.
- ❖ **Tzanck stain collection procedure (for herpes)**
- ✓ Open the rash from which the sample will be collected with a sterile blade or biology needle.
- ✓ Scrape the base of the rash with a tongue depressor, a spatula, or a sterile blade. If there is liquid, you can collect it with a biology needle.
- ✓ Immediately smear the specimen onto a glass tile on which you have already marked the patient's name using a pencil.
- ✓ Spray the tile immediately with a cytology fixative. If you do not, then the sample will air-dry, and the diagnosis will not be possible.
- ✓ Place the samples in a plastic container used for Pap tests. Send it to the lab.
- ❖ **Urine**
- ✓ Samples not coming from the first morning urine are preferable

- ✓ Minimum sample volume: 5ml. 50 to 100 ml are preferable.
- ✓ Samples collected by catheter or from the first morning urine should be transferred to a clean container with a legible and completely filled-out label.
- ✓ All specimens should be transported as soon as possible to the laboratory or, if that is not possible, stored under refrigeration to avoid cellular degeneration. Samples from a 24-hour collection are not accepted.

Patient sample Transportation

Maintaining the integrity of the samples from the time of collection until the time of completion for any and all required examinations is of paramount importance.

As such, the compliance of the doctors with the guidelines provided by the laboratory concerning the collection, preparation and transportation of the samples following the requirements of each requested examination, including the maintenance of the appropriate temperature throughout the whole procedure, is deemed necessary.

Delivering samples in person

When the samples are delivered to the laboratory in person, they need to be placed in the sealed side of a resealable "Ziploc" bag with the biohazard label on it. Make sure that the bag is sealed properly to avoid any leakage.

Place the accompanying documents in the appropriate pouch that you will find on the outside of the resealable bag.

Every sample must come with an examination request form. As such, if there are samples that must be transported at different temperatures from one another, separate examination requests are required. However, if only a single examination is requested, which requires samples transported at different

temperatures to be carried out, provide a form only for one sample noting CLEARLY on it that the examination form accompanies one or more additional samples. For example, if the examination requires two samples, one under refrigeration and one which is frozen, place the form in the transportation bag of the sample under refrigeration and note that “a frozen sample has also been sent along”.

Store the samples under appropriate conditions in your facility until they are transported to the laboratory.

In some areas a courier service can be provided. Pick-up times vary depending on the location. The courier will keep the samples during transport at the temperature indicated by the customer.

3.6. Shipping of samples

The samples are transported to the laboratory of anatomic pathology and cytology **Microdiagnostics Ltd** by courier and the containers need to be packaged as described below in order to conform to the specifications set out for the transportation of biological samples and elements.

❖ **Sample containers:**

- ✓ The samples need to be placed in a closed, securely sealed, and leak-proof primary container.
- ✓ Plastic tubes with tight screwcaps are deemed acceptable as primary containers/
- ✓ The primary containers need to be waterproof and leakproof.

Transportation procedure

COMPILED:20.10.2017



APPROVED: 20.10.2017



Place the primary container inside a durable, waterproof secondary container.

Place enough absorbing material inside, in a compact form (no pellets or powder), to allow for the absorption of the entire content of the primary container in case of a leak.

Plastic bags with absorbent gauze padding is considered an acceptable secondary container.

More than one primary containers can be placed inside the secondary container as long as there is enough absorbent material for all their contents.

The secondary container must be placed in a transportation crate made out of ply-wood, carton, wood, or other material of equal strength.

Mailing tubes made from carton and insulating crates of polystyrene in carton could also be used as transportation crates.

Polystyrene crates can be used as secondary transportation crates as long as they can withstand pressure greater than 90gk.

Simple mailing bags or folders can't be used as secondary containers.

The external container or crate must be marked with a biohazard label along with the full address of the referred laboratory.



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