OMI PathDx

OMI® PathDx™

Pathogenic Microorganism Sequencing (PMseq)

Sample Collection Guidance

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Contents

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
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1. Requirements of Sample

Type	Volume for PMseq	Volumn for PMseq Plus	Sample container	Storage condition	Transportation condition
Venous blood*	Adult: >3mL Children: >1.5mL	Adult: >3mL Children: >2mL	K tube or, equivalent tube for Cell-free DNA storage **(recommended)**	6-35℃	6-35℃ (In 96hrs)
			EDTA tube	Temporally, 4℃, plasma separated in 8 hours	4℃ in icebag
CSF	>1.2 mL	>2mL	Sterile, dry, clean cryotubes	**For DNA procedures:** -20℃ for 1 week; -80℃ for permanent storage; No freezing-thaw frequently **For RNA procedures:** -80℃ without freezing-thaw frequently	Drikold / ice box
BALF	>3mL	>3mL			
Sputum					
Sterile fluid (fester, joint, urine, pleuroperitoneal fluids, etc.)					
Fresh tissue	2-3 needles from puncture Green bean size from operation	>3-4 needles			
Swab (throat, fester)	2-3 swabs	>3 swabs			
Paraffin embedded tissue	>10-15 unstained slides	>10-15 unstained slides	Sterile, dry, clean cryotubes	Ambient	Ambient

Notes：

*For blood sample collection, Tube for cell free DNA is strongly recommended while EDTA tube (Purple cap) are acceptable in clinical sample collection. The transportation condition should be strictly kept for sample shipping.

2. Information for Sample Collection

2.1 The sample should be collected before anti-microbials are administered.

In clinical practice, doctor is suggested collecting the samples of infection suspects for identifying the infection agent at laboratory, and guiding the targeting treatment.

2.2 The sample from infected location is more valuable while the regular microbiome and colonized bacteria should be cleaned up.

The sample should be collected from sterile position as far as possible and try to avoid any contamination from regular microbiome in human body, such as lower respiratory tract, paranasal sinus and skin wound. The contaminated samples from infection position is not optimal for identifying the actual infection agent.

29A, Ptolemeon Thessaloniki, PC 54630 Greece
info@omibiomedics.com
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2.3 Keep aseptic operation in sample collection

Aseptic operation procedures should be kept in sample collection strictly to avoid any possible contamination. Local and surround skin should be disinfected. In case of disinfectant liquid used in skin, the sample should not be collected until the disinfectant liquid is dry on skin and kept in sterilized container.

2.4 Completeness of required information on test requisition form and informed consent.

The information for patients is as follows.

- Information of test requisition：*name of hospital or unit, *department, *Doctor;
- Patient information：*name; *sex, *age, *contact information, and so on;
- Clinical condition：*Symptoms, *laboratory test, * clinical diagnosis and history of anti-microbials administered;
- Product number; *required
- Sample information：*Type; *collection date;
- Suspected pathogens;
- Informed consent：*doctor signature; *signature of patient/guardian,*guardianship,*date;
- Sample identifier：*Stick the unique barcode on requisition form and informed consent.

Notes: Items with star(*) are required and incomplete or missing information will lead to rejecting the sample for the test.

3. Sample collection

3.1 Blood sample

Blood sample could be used to detect the infections in blood stream and other human body rapidly and correctly, which enable to improve the clinical treatment and prognosis.

3.1.1 Clinical indications for blood sample

3.1.1.1 Bacteriaemia

Bacteriaemia could be suspected when patient was in conditions of general infection, including fever(≥38℃) or hypothermia(≤36℃), chill, increased white cell count (>10.0×10^9/ L) and neutrophil count, or decreased white cell count (<3.0×10^9/L), hemorrhage in mucous or skin, or symptoms of comma, multiple organ failure and shock, and cannot be excluded from the bloodstream infection by bacteria and fungus, especially in the scenarios of hospital acquired pneumonia, more than 48 hours of vascular catheter with CVC and PICC at detention center or general infections of immunodeficient patients.

3.1.1.2 Infective endocarditis

Patients were in conditions of unknown fever more than 1 week with cardiac souffle or neoplasma by cardiac ultrasonography, or with underlying cardiac disease, or implanted heart valve prosthesis.

3.1.1.3 Catheter related Infections of bloodstream

Patients in conditions of fever (>38℃), chills or hypotension after carrying with Endovascular catheter more than 1 day or removing it no more than 48 hours while cannot exclude catheter as the causes of infection.

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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3.1.2 Important information for blood collection

3.1.2.1 Bacteriaemia

- As far as possible to collect blood before the onset of chills and 30-60 minutes before the fever peak.
- As far as possible to collect blood before the antibacterial drug administered. Otherwise, collect blood just before the next drug administer.
- Venous blood should be collected at median cubital or cephalic vein of arm while not at the point of intravenous drip of anti-microbial drug. Blood should not be collected from Indwelling Venous Catheter or arterial duct for the colonized bacteria except of CRI.
- The skin should be disinfected and kept dry to avoiding contamination from colonized bacteria and any potential false positive.
- Avoid to collect blood at joint of the Indwelling Venous Catheter preventing from contamination.

3.1.2.2 Infective endocarditis

- Collect the blood in 30 minutes before the anti-microbial drug administered empirically.
- Arterial blood could improve the positive of endocarditis in left heart

3.1.2.3 CRI：

- Blood collected from the peripheral vein and indwelling venous catheter separately and tested simultaneously.

3.1.3 Blood processing after collection

3.1.3.1 Tube (cell-free DNA, recommended) for venous blood

- Unused tubes kept at 18-25℃.
- Prepare the vacutainer blood collection tube and collect venous blood from adult about ≥3mL and infant about ≥1.5mL. Avoid the hemolysis in blood drawing.
- Slowly and gently, invert the tube 8-10 times as figure below to avoid clotting and hemolysis. Inadequate and delayed mixing will lead to incorrect test results.

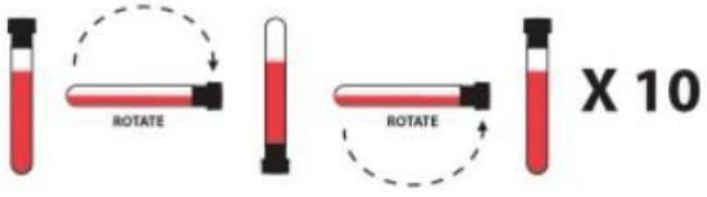

Figure1. Diagram for inverting tube

- Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.

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Thessaloniki, PC 54630
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- Blood can be stored and shipped at 6-35℃. Plasma should be centrifuged in 96 hours.

3.1.3.2 EDTA-tube (purple cap) for venous blood

- Prepare EDTA tube for collecting venous blood in adult about ≥3mL and infant about≥1.5mL. Avoid the hemolysis in blood drawing as far as possible.
- Slowly and gently, invert the tube for about 8-10 times to allow mixing of the anticoagulant and avoid the hemolysis. Keep the whole blood at 4℃ and centrifuge plasma in 8 hours at 4℃ and 1600g for about 10 minutes.
- Prepare sterile, dry and clean 2ml EP tube and write the patient information such as name clearly on the tuber wall using permanent marker.
- Suck up the supernatant(plasma) to EP tube and avoid any Red and white blood cell. Strew the tube cap tightly to ensure no leakage and correctness of patient information. Seal the tube using film.
- Sample can be stored in refrigerator at -20℃ for testing soon while at -80℃ for permanent storage.

3.2 Sample from respiratory tract

Respiratory tract is composed of upper and lower respiratory tract. The pathogens for infection at upper respiratory tract are always virus while causative pathogen for infection at lower respiratory tract is diverse. Therefore, appropriate sample is important for infection determination at respiratory track, which is subject to be contaminated by microbiome at mouth and incorrect laboratory results.

3.2.1 Sputum

Although sputum could only be used for diagnosing the infection at lower respiratory tract, such as pulmonary infection, Bronchoalveolar Lavage Fluid (BALF) and cultured isolates from endotracheal aspirates are more optimal in term of correctness in diagnosis. The patient should be assessed capability of deep breathing for sputum and coached to collect sputum correctly in direct observation of doctor/nurse avoiding the potential cross contamination from mouth microbiota.

3.2.1.1 Clinical indication for sputum collection

- Persistent cough with fever and purulent sputum and new or expansive infiltration presented in lung imaging examination.
- Purulent or blood sputum in patient experiencing tracheotomy;
- Suspected infection at lower respiratory tract.

3.2.1.2 Sputum collection methods

- Have the patient rinse their mouth with plain water or normal saline. Remove patient's dentures if they have them. Deep breath and bring the thick secretions from the lungs rather than expectorating saliva or the thin secretions from the mouth and Nasopharynx.
- Expectorating the sputum into sterile, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the sputum in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

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Thessaloniki, PC 54630
Greece
info@omibiomedics.com
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3.2.2 Bronchoalveolar Lavage Fluid (BALF)

BALF could be used to detect pulmonary infection improving the positive and reducing false positive due to the cross-contamination from microbiota of oropharynx.

3.2.2.1 Clinical indication for BALF collection

If tracheoscopy is operated for suspected pulmonary infection, BALF should be collected for further laboratory test, especially for those not geting sputum through deep breathing.

3.2.2.2 Sample collection methods

- Sampling location selection: localized lesion or middle lobe of right lung or upper lobe of left lung in case of diffuse lesion.
- Local anesthesia: Local anesthesia can be given 1-2 ml of 2% lidocaine (or similar) to lavage the planned pulmonary segment via the puncture site, which can also be performed for those with strong reaction of airway in total Intravenous anesthesia .
- Normal saline (at room temperature) is instilled through the bronchoscope, with a total volume between 60 and 120 ml and divided into three to five aliquots(20-50mL/aliquot).
- Vacuum aspiration: After the instillation of each aliquot, instilled saline is generally retrieved using a negative suction pressure less than 100 mm Hg. The optimal total sampling retrieves should be greater than 30% of the instilled volume.
- BALF: The retrieves might include substances in excretions from the terminal bronchioles and alveolus pulmonis about 10 mL; discard the first part of them potentially contaminated and collect the other remainings about 3 ml for test.
- Collect the retrieved fluid in sterile, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the BALF in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

Notes: In case for testing RNA in sputum and BALF, the sample should be kept in refrigerator at -80℃ or in drikold avoiding freezing-thawing.

3.2.3 Sample from airway suction

3.2.3.1 Clinical indicatives for sampling through airway suction

Patients experiencing artificial airway through operations of trachea cannula and tracheotomy cannot conduct deep breathing for sputum by himself, sample can be suctioned through artificial airway.

3.2.3.2 Sample collection methods

- Push the disposable sterilized suction catheter into respiratory tract through trachea cannula and start to pump once any resistance in the track. About 3mL of sample is needed for the test.

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Thessaloniki, PC 54630
Greece
info@omibiomedics.com
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- Collect the fluid in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the fluid in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.2.4 Sample from throat swab

Sample from throat swab can be used for diagnosing the infections at upper respiratory tract.

3.2.4.1 Clinical indications for throat swab collection

Will be collected in clinical conditions including unexpected pharyngalgia, antiadoncus, score of lymph nodes at submaxillary and neck with fever while without cough and rhinorrhea.

3.2.4.2 Sample collection methods

- Ask patient to speak out “a~” aloud to expose his throat completely, using tongue depressor if necessary. Carefully take out the swab from package and quickly rotate it around two sides of fauces, throat and tonsil a few times applying pressure to collect as much secretions as possible. In case that there are pus points in tonsil, they should be squeezed out for collecting the purulence material. 2-3 swabs are better for testing.
- Put the swab into the specimen tube. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the sample in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.3 Cerebrospinal fluid (CSF)

CSF is the prime sample for detecting infection in **central nervous system**.

3.3.1 Clinical indications for sampling CSF :

Clinical symptoms with unknown cause, including headache, fever, positive in meningeal irritation sign (nuchal rigidity, kernig sign and Brudzinski’s sign), Neuropathologic signs, hydrocephalus and centrogenic hyponatremia, etc. will indicate infection of central nervous system and CSF will be optimal sample for detecting and determining the causative pathogen.

3.3.2 Methods of CSF collection

- In case of suspected bacterial meningitis, CSF should be collected immediately to determine the infection prior to administering the anti-microbial drug. If infection by mycobacterium cryptococcus or chronical meningitis was suspected, CSF might be collected several times. In scenario of increased intracranial pression, cranial CT should be conducted and Dehydration treatment be implemented prior to puncture.
- Specimen should be collected by trained and qualified clinical staff in line with local or international clinical standard operation procedure. Lumbar puncture (spinal tap) is the most common method. Sterile technique should always be STRICTLY used to reduce the risk of infection. Lumbar puncture is always performed in lumbar vertebrae L3/L4 or L4/L5 region under local anesthesia using a sterile technique. A hypodermic needle is used to

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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access the subarachnoid space and fluid collected. To avoid cross contamination, the CSF collected from the 2nd vial are suggested for testing. Total volume of CSF should not be less than 1.2 ml.

- Collect CSF in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the CSF in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.4 Hydrothorax

Hydrothorax was usually caused by bacterial pleuritis, or in some situation of inflammation of lower diaphragm, pneumonia and tuberculosis. Hydrothorax can occasionally presented in neoplastic disease or hypoproteinemia.

3.4.1 Clinical indications for hydrothorax collection

Auscultation and imaging examination could indicate hydrothorax. Thoracocentesis was performed to get serous, blood, chyle or pus fluid from pleural cavity, suggesting infections such as mycobacterium, pneumonia and pleurtitis and test for further determination.

3.4.2 Methods to collect hydrothorax

- Collect the sample prior to antibiotics administered as far as possible. Specimen must be collected by trained and qualified clinical staff through percutaneous puncture or surgical operation. Sterile technique is always STRICTLY used to reduce the risk of infection. In a thoracentesis, a needle is inserted through the back of the chest wall into the pleural space under the guidance of ultrasound and percussion. 3-10 ml fluid will be collected for testing.
- Collect the fluid in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the fluid in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.5 Hydroperitoneum

Hydroperitoneum can be exudative or transudative. The most common causes of exudative effusions are infected by bacteria, mycobacterium and anaerobe.

3.5.1 Clinical indications of sampling

Patients will present some symptoms but not limited to fever, abdominal distention and pain, or pressing pain and jumping pain with imaging evidence of fluid in peritoneal cavity.

3.5.2 Methods of sample collection

- Collect the sample prior to antibiotics administered as far as possible. Specimen should be collected by trained and qualified clinical staff through percutaneous puncture or surgical operation. Sterile technique is always STRICTLY used to reduce the risk of infection. In puncture, a needle is inserted into the peritoneal cavity under the guidance of ultrasound. 3-10 ml fluid will be collected for testing.
- Collect the fluid in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the fluid in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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3.6 Joint fluid

Synovitis is always caused by infection of bacteria, or occasionally by virus, fungus and mycobacterium.

3.6.1 Clinical indication for joint fluid

Infectious Arthritis should be suspected for testing when Artheroedema is found by imaging examination accompanying by arthrocele, joint pain and LOM with unknown cause and ineffective treatment.

3.6.2 Methods of collection

- Collect the sample prior to antibiotics administered as far as possible. Specimen should be collected by trained and qualified clinical staff through puncturing articular cavity. Sterile technique is always STRICTLY used to reduce the risk of infection. 3ml fluid will be collected for testing.
- Collect the fluid in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the fluid in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.7 Urine

Urinary tract infection is diagnosed mainly based on laboratory confirmation via urinalysis and microbiological test of urine as simple, complicated or urosepsis in terms of symptoms and seriousness. Escherichia coli is the single most common microorganism accounted for 90% of UTI outpatient and 50% inpatient, followed by Candida Albicans and other bacteria, to cause urinary tract infection.

Urine is always sterile or sometimes with few colonized bacteria. Cross-contamination should be avoid from the urethra in process of sample collection.

3.7.1 Clinical indications of sample collection

- The most common symptoms are burning with urination and having to urinate frequently (or an urge to urinate) in the absence of vaginal discharge and significant pain. Some people may experience flank pain, fever, and increased white blood cell count in urinalysis. UTI will be suspected.
- Routine urinalysis indicates UTI.
- Fever in patients with indwelling catheter.

3.7.2 Methods of urine collection

3.7.2.1 Clean-catch midstream urine

A clean-catch urine specimen is a sample for testing the cause of an infection in urinary tract. A clean- catch specimen is a way of collecting urine that does not contain a lot of bacteria from the skin or mucosa. Patient should collect the urine by him/herself with training from doctor on the practical methods, such as morning urine or before the anti-biotics administered.

Please refer to following for the detailed procedures.

3.7.2.1.1 Female: please clean and disinfect the urethral orifice before urine collection

- Keep two legs separated;
- Clean the urethral orifice using warm soapy water, or disinfect the orifice using iodine or

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Thessaloniki, PC 54630
Greece
info@omibiomedics.com
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Iodine tincture

- Hold the urine container, taking care not to touch the inside of the cap or the inside of the container. Begin urinating into the toilet and bring the specimen container into the urine stream to collect a “midstream” specimen. Stop when the container is approximately half full.
- Tightly screw the cap on the container and ensure no leakage.

3.7.2.1.2 Male: clean the urethral orifice before urine collection

- Retract foreskin (if present) to expose the Balanus completely.
- Clean the Balanus and urethral orifice using warm soapy water;
- Hold the urine container, taking care not to touch the inside of the cap or the inside of the container. Begin urinating into the toilet and bring the specimen container into the urine stream to collect a “midstream” specimen. Stop when the container is approximately half full.

3.7.2.2 Catheter specimen of urine

Catheter specimen of urine could increase the risk of Catheter-associated urinary tract infection (CAUTI). Samples should not be collected from the drainage bag tap as the urine specimen may be contaminated.

A fresh sample of urine is required for a CSU and should be obtained from the sampling port on the catheter bag or in the case of a catheter valve, directly from the valve. The sampling ports are designed to be accessed directly using a syringe and do not require a needle, therefore removing the risk of sharps injury. The follows were for information：

- Clamp the catheter tube no more than 30 minutes;
- Clean the sampling port with an alcohol-impregnated swab according to local policy and allow to dry;
- Insert the syringe tip into the sampling port and aspirate at least 10ml of urine. Withdraw the syringe.

3.7.2.3 Suprapubic aspiration

It is typically used as a method to collect urine in child less than 2 years of age who is not yet toilet trained in an effort to diagnose a urinary tract infection or in suspected anaerobic infection.

- The area about 1-2 centimeters above the pubic symphysis is cleansed with antiseptic solution, such as betadine or alcohol;
- Local anesthesia of the planned puncture site can be given either as an infiltration of lidocaine (or similar), or application of topical anesthesia.
- Insert the needle into the bladder in the center line between public bone and belly button;
- A thin needle (similar in gauge to one used for routine vein puncture) with a syringe is advanced until urine is withdrawn.

3.7.3 Sample storage

- Collect the urine in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the urine in refrigerator at -20℃ and deliver it for testing as soon as possible while in

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Thessaloniki, PC 54630
Greece
info@omibiomedics.com
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refrigerator at -80℃ for permanent storage.

3.8 Skin and soft tissue infections (SSTIs)

Skin and soft tissue infections (SSTIs) are clinical entities of variable presentation, etiology and severity that involve microbial invasion of the layers of the skin and underlying soft tissues. SSTIs range from mild infections, such as burn wound infection, infection of incisional wound of post operation, pyoderma, Acute cellulitis, to serious life-threatening infections, such as necrotizing fasciitis. When specimen collection in in open wound, the wound should be cleansed and specimen should be collected from the deep layer or center and edge of the wound in aseptic condition.

3.8.1 Burn wound infection

Specimen should be collected before local antibiotics are commenced. The wound should be cleansed completely.

3.8.1.1 Clinical indications for sampling

No bacteria are on the surface of wound in first 12 hours after burn. Specimen collection should be implemented 12 hours later after burn in patients with fever and worsening wound.

3.8.1.2 Methods of specimen collection

Before the specimen collection, the wound should be cleansed using sterile saline solution or Water for Injection.

- Swab: Roll the swab over entire surface area of the wound applying pressure as it moves across the wound. Get as much material on the swab as possible to ensure a conclusive sample. Insert swab into specimen tube and seal tightly;
- Scrape down debris under slough. Collect samples from all areas of the wound, when possible, to ensure a full and accurate sample, about 0.3-0.5g;
- Anaerobic bacteria: Aspirate the specimen in deep wound or its edge using syringe.

3.8.1.3 Specimen storage

- Store the specimen in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the specimen in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.8.2 Abscess specimen

Specimen is collected before anti-biotics is commenced. For those with fever, chills and other general infection symptoms, Abscess specimen should be tested in addition to blood sample.

3.8.2.1 Clinical indications for specimen collection

- Locally appear inflamed, swell, fever and pain caused by abscess on skin or subcutaneous layer
- Localized Pain and hypalgesia with fever and anorexia suggested deep abscess.
- Wound of trauma and operation infected.

3.8.2.2 Methods of collecting specimen：

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Greece
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- Closed Abscess: Cleanse the wound margins and superficial area thoroughly with sterile saline. Get the exudates from deep wound or ulcer using swabs; or cut the deep biopsy or margin of the lesion for testing.
- Open abscess: Cleanse the wound margins and superficial area thoroughly with sterile saline. Aspirate the fester using syringe or cut the abscess using with a scalpel to Collect a biopsy or curette sample from the base or advancing margin of the lesion for testing.
- Pus from fistula or sinus tract: Aspirate the deepest portion of the lesion or exudate with a syringe and needle.

3.8.2.3 Storage

- Store the specimen in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the specimen in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.8.2.4 Precaution in Abscess specimen collection

- **Heparinate containing tube** should not be used in sampling for blood and other specimen.
- Dispensing the specimen should be conducted in sterile condition in super clean bench or BSC to avoid any cross contamination from environment.
- Optimal time for sampling is the day of hospitalization or before commencing the antibiotics.
- Sputum from deep breath is better.
- Virus can be DNA or RNA (Appendix table 1&2). RNA detection procedure should be highlighted in the test requisition form when RNA virus is suspected for the infection.

3.9 Fresh tissue and paraffin slides

3.9.1 Fresh tissue

- Operation: Mung bean like size or gram size.
- Puncture：2-3 needles.
- Store the tissue in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the specimen in refrigerator at -20℃ and deliver it for testing as soon as possible while in refrigerator at -80℃ for permanent storage.

3.9.2 Paraffin embedded tissue

- Find the causative pathogen by microscopy and section the tissue with centralized pathogens.
- Section 10-15 unstained paraffin slides, about 10μm **for bacteria,** 20μm for fungus in **Thickness**. The thickness for parasite should be justified based on the size of body, egg, larva and metacercaria.
- Store the tissue in sterilized, dry and clean plastic Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film. Use a permanent marker to write clearly on the tube wall the patient information, such as name, identifier.
- Keep the specimen in ambient temperature for storage and transportation.

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
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3.10 Feces specimen

Feces was the primal specimen for intestinal infection.

3.10.1 Clinical indications for collecting feces

When patients was in conditions of stomachache and diarrhea of watery or bloody stool with fever, feces should be collected for further laboratory test in case of abnormity found through routine feces microscopy.

3.10.2 Methods of specimen collection

- Roll the swab over middle of the feces in toilet bowl to transfer some faces to specimen tube and seal tightly.
- For infant in difficult defecation, wash the anus using warm soapy water and insert a swab processed by sterile saline solution into the anus about 4-5cm (infant 2-3cm). Rotate the swab lightly to scrub the rectum mucus for feces.
- Feces specimen should be testes as soon as possible. Otherwise, it should be stored in refrigerator at 4℃ no more than 3 days.

4. Specimen packing

4.1 Blood collection tube

- Stick the bar code label along the length of the tube to ensure the Alphabet to direction of tube mouth. Otherwise, circling the label round the tube will prevent looking into the tube. (Figure 2). Specimen identifier and type should be agreed.” B” was used for Whole blood-B and “P” for Plasma in the label.

Figure 2. Stick the bar code label on the tube (bar code upward and along the tube length).

- Requisition form and blood collection tub should packed using self-seal bag individually by specimen. Then, the specimen should be packed using bubble and other cushion packaging and banded using rubber string (figure 3).

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Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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Figure 3. Packing blood collection tube

- Transportation of tube at ambient temperature in case of higher than 35℃ in summer or lower than 6℃ in winter. The package for transportation should be prepared as follows.

  Pack the ice bag completely using bubble packing and put it into the foam box with the packaged specimen while they should be separated completely by papers or bubble packing and fixed by packing tap to avoid direct contact. The extra space in the foam box should be stuffed using waster papers or bubble wrap to ensure the required temperature for transportation (Figure 4).

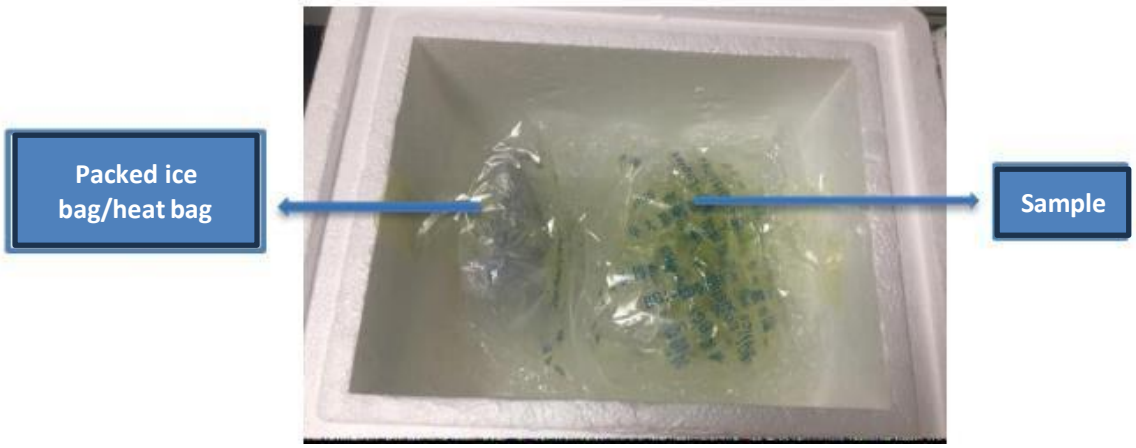

Figure 4: Packing K/G tube at extreme temperature condition

- Specimen in EDTA tube should be temporally stored at 4℃ and put them vertically in the foam box with biological Ice bags for transportation. The requisition form should be packed in self-seal bag and shipped in the same box with specimen. The foam box should be kept upright in the shipment. Plasma should be centrifuged in 8 hours after blood was collected.

4.2 Sampling tube/Cryotube

5 ml sampling tubes or cryotubes be used in specimen collection, crew the cap tightly and seal it using film. The bar code label of specimen should be sticked along the length of the tuber. Ensure the specimen identifier and type agreed (type of tissues and others is S). Specimen was sealed in the bag and kept in another bigger self-seal bag with the packed requisition form

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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for transportation. Drikold and Ice box should be packed to meet the temperature requirement.

Figure5. packing the sampling tube

【Comments】

- Operate the packing in line with the protocol strictly to ensure the specimen in freezing when arrive at laboratory.
- In case that the specimen is not met the requirements, it will be rejected for testing, leading to delayed testing for recollection of specimen and test failure.

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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5. Specimen rejection for testing

The specimen in following situation will be rejected for testing.

- Specimen shipment: The specimen was not transported in required temperature. For instance, the specimen should be shipped in foam box with Drikold while the drikold has evaporated or the specimen thawed when they arrive at laboratory.
- Specimen collection: wrong blood collection tube is used.
- Appearance of the specimen: specimen leaked and contaminated due to broken tube or uncap.
- Volume of specimen: small in volume.
- Quality: specimen clotted, contaminated and hemolyzed.
- incomplete Information of specimen: mandatory information in requisition form and formed consent are incomplete.

【Revision history for the guidance】

Version	Revision history	Revision date
DOC-PMP- 11 V1.2	Translated into English version for the purpose of using in international market	2019-10-11
DOC-PMP- 11 V1.3	Removed G-tube from sample collection requirement since G tube for blood collection was removed due to potential contamination, domestically released by Product center. Clarified K tube in sample collection requirements for blood collection as Cell- free tube. Equivalent tube for cell-free DNA storage is applicable. Deleted all information related to G-tube in whole context.	2023-10-26

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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Appendix 1 DNA viridae

Viridae	Profile	Virus list
（*Poxvirudae*)	dsDNA, enveloped	Smallpox, vaccinia, poxvirus, Molluscum conagiosum virus
（*Herpesviridae*）	dsDNA, enveloped	Herpes simplex virus Ⅰ/Ⅱ, chicken pox- herpes zoster virus, EB virus, Cytomegalovirus and Human herpes virus 6/7/8
（*Adenoviridae*）	dsDNA, enveloped	Adenovirus
（*Hepadnaviridae*）	DNA, revert transcription in replication	Hepatitis B virus
（*Papovaviridae*）	dsDNA, circle, no-enveloped	Papilloma virus
（*Parvoviridae*）	ssDNA, no-enveloped	Adeno-associated virus, Parvovirus B19

Appendix 2 RNA viridae

Viridae	Profile	Virus list
（*Paramyxovirudae*)	ssRNA, not segmented, enveloped	Para-influenza virus, Sendai virus, measle virus, Mumps virus, respiratory syncytial virus and Metapneumovirus
（*Orthomyxoviridae*）	ssRNA, segmented, enveloped	Influenza virus A/B/C
（*Retroviridae*）	duplicated ssRNA, not segmented, enveloped	HIV, HTLV（T）
（*Picornaviridae*）	ssRNA, not segmented, enveloped	Poliovirus, ECHOV, Coxsackievirus
（*Coronaviridae*）	ssRNA, not segmented, enveloped	Coronavirus
（*Parvoviridae*）	ssRNA, segmented, enveloped	Lassa fever, Machupo virus, Lymphocytic choriomeningitis
（*Rhabdoviridae*）	ssRNA, not segmented, enveloped	irus, Vesicular stomatitis virus
（*Filoviridae*）	ssRNA, not segmented, enveloped	Ebola virus, Marburg virus
(*Flaviviridae*）	SSRNA, outer enveloped	Epidemic encephalitis B virus

29A, Ptolemeon
Thessaloniki, PC 54630
Greece
info@omibiomedics.com
www.omibiomedics.com
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