

Correct collection process is vital to receiving the most accurate NGS diagnostic results. Please follow the steps below.



SAMPLE COLLECTION METHOD

Optimal collection method for molecular testing

IMPORTANT: Prior to taking sample, do not administer marcaine, lidocaine, or any local anesthetics.

STEP 1: COLLECTING A FLUID SAMPLE

Make incision - Prior to arthrotomy, aspirate the joint and transfer the synovial fluid into the sterile 50mL Screw Cap Vial labeled "Synovial Fluid Only" supplied in the OrthoKEY PJI OR/Surgery Kit. At least 2mL of synovial fluid is necessary to run all tests. Securley close the cap on this vial and place inside the bio bag.

STEP 2: ALPHA FLAT SWAB & 2X2 GAUZE

After removal of modular components, use a surgical instrument to grasp a 2x2 piece of gauze to thoroughly wipe down the implant surface as well as the bone-implant surface. Using a surgical instrument will decrease the chance of contamination. You can also use the Alpha Flat swab in place of gauze or in conjunction. For best sample quality use both the gauze and Alpha Flat Swab. Pus may not provide viable microbial DNA and should be avoided when sampling. Place the gauze inside of the second 50mL Screw Cap Vial. **Do not place the gauze inside the 50mL vial that already contains synovial fluid.** Break off or cut (with a sterile instrument) the swab head of the Alpha Flat swab enough to fit into the same 50mL screw cap vial.

STEP 3: SECOND ALPHA FLAT SWAB

Use the second Alpha Flat swab to thoroughly wipe the medial and lateral gutters including the posterior region of the joint maximizing tissue surface area. Break off or cut (with sterile instrument) the swab head of the Alpha Flat Swab into the 50mL screw cap vial. The second piece of 2x2 gauze may also be used to wipe the medial and lateral gutters. Place into the same 50mL Screw Cap Vial, that contains the other 2x2 gauze and/or Alpha Flat Swab heads.

NOTE:

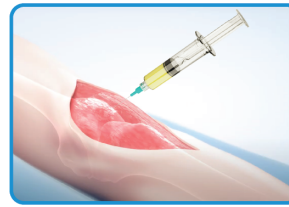
If implants are removed and the intramedullary canal is exposed...

Use a round tipped swab provided in the kit to sample the canal. A rotating motion in the intramedullary region is preferable. Use a different round swab to sample if more than one intramedullary canal is exposed. The round tipped swabs can be placed into their tubing and included in the kit. They do not need to be added to the 50ml vial.

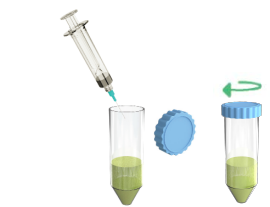
STEP 4: COLLECTING A TISSUE SAMPLE

Using a clean rongeur or appropriate surgical instrument, remove a pea sized amount of tissue from regions of the joint where infection is suspected. Deposit into the same 50mL Screw Cap Vial used in Steps 2 & 3.

STEP 1a



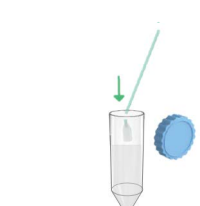
STEP 1b



STEP 2a



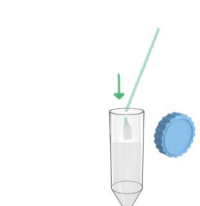
STEP 2b



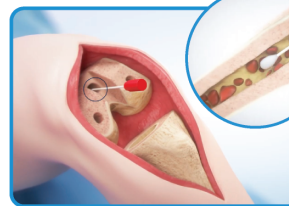
STEP 3a



STEP 3b



STEP 3c



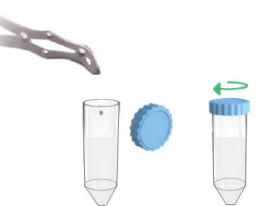
STEP 3d



STEP 4a



STEP 4b



PLEASE NOTE: If taking parallel samples for both traditional culture and MicroGenDX, please take the MicroGenDX samples first, followed by your tissue sample to the culture lab.



Scan this code to view video sample collection instructions.

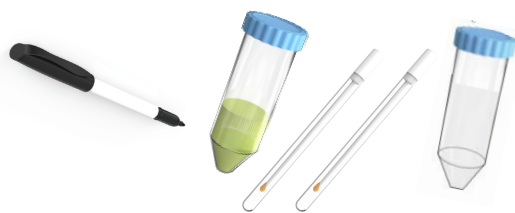


Correct packaging is vital to ensuring your sample is processed in a timely manner. Please follow the steps below.

PATIENT INFORMATION

1. MARK SAMPLE

Use a permanent marker to write patient name, date of birth and sample collection date on 50mL Screw Cap Vials and Swab Tube(s).



2. FILL OUT LAB REQ

Please fill out lab requisition form completely.



3. INSURANCE INFORMATION

If this procedure is taking place in an outpatient surgery center, patient insurance can be billed. The lab requisition will have fields allowing for the gathering of the patient's insurance information. If the lab requisition does not have insurance fields skip this step.

PACKING SAMPLES FOR SHIPMENT

1. Place both 50mL Screw Cap Vials and Swab Tube(s) into the center/sealable pocket of the Biohazard Lab Bag.
2. Place folded Lab Requisition Form into the short pocket of the Lab Bag.
3. **IMPORTANT:** Place only one Sample and one Lab Requisition in each Lab Bag.
4. Peel strip off Lab Bag to expose adhesive backing and follow instructions printed on Bag to create a continuous, airtight seal.
5. Place the sealed Lab Bag into the MicroGenDX Shipping Box (shipping label already attached to bottom of box).
6. Close the MicroGenDX Shipping Box and seal with the clear sealing sticker or a piece of tape.
7. You can add multiple completed lab bags into the MicroGenDX Shipping Box.



Place Sample in Center Pocket



Place Folded Lab Req in Short Pocket



SHIPPING

If shipping from a HOSPITAL, please follow your hospitals send out protocols.

If shipping from an outpatient SURGERY CENTER, here are 3 convenient FedEx shipping Methods:

1. Drop into FedEx Dropbox including Kinkos FedEx locations
2. For Physician Offices Only: Call for pick up 1-800-GoFedEx (1-800-463-3339). Say "agent" twice to speak to agent. Let them know it's prepaid pick up.
3. For Physician Offices Only: Use our online "schedule a pick up" page at MicroGenDX.com. *Make sure to retain your tracking number.*

