

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



SAMPLE COLLECTION METHOD

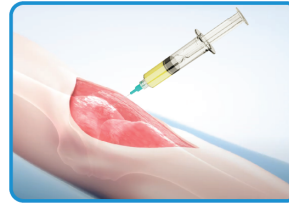
Optimal collection method for molecular testing

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 vial supplied in the OrthoKey Surgery kit. At least 2ml of synovial fluid is necessary to run all tests.

STEP 1a



STEP 1b



STEP 2: FLAT SWAB

After removal of modular components, use the CaptiGen Flat Swab to thoroughly wipe down implant surface as well as bone-implant interface. Pus may not provide viable microbial DNA and should be avoided when sampling.

After removal of modular components, use the first Flat Swab to wipe the surface of the implants, liner and exposed bone. Place the Flat Swab tip inside of the 50ml container. The tip can be detached by depressing the mechanism at the back of the Flat Swab handle.

STEP 2a



STEP 2b



STEP 3: SECOND FLAT SWAB

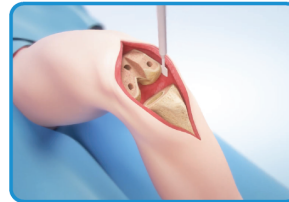
Use the second Flat Swab to **thoroughly wipe the medial and lateral gutters** including the posterior region of the joint maximizing tissue surface area.

Transfer the tip of the Flat Swab into the same specimen vial already containing the synovial fluid collected. The tip can be detached by depressing the mechanism at the back of the Flat Swab handle.

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.

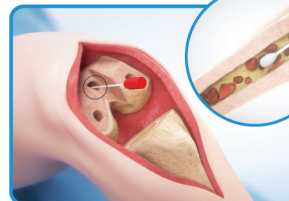
STEP 3a



STEP 3b



STEP 3c



STEP 3d



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 vial used in Steps 1 and 2.

STEP 3a



STEP 3b



Scan this code to view video sample collection instructions.

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.

21-0016-04

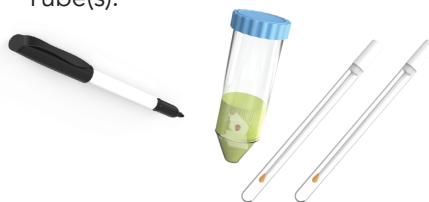


Correct packaging is vital to ensuring your sample is processed in a timely manner. Please follow the steps below.

PATIENT INFORMATION

1. MARK SAMPLE

Use a permanent marker to write patient name, date of birth and sample collection date on 50mL Collection Container 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.

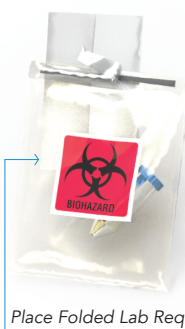
PACKING SAMPLES FOR SHIPMENT

1. Place the 50mL Collection Container 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 Prepaid FedEx Shipping Box.

NOTE: More than one Lab Bag can be placed in the Shipping Box



Place Sample in Center Pocket



Place Folded Lab Req in Short Pocket



SHIPPING

If shipping from a HOSPITAL, please follow your hospital's send out protocols.

If shipping from an outpatient SUREGEY 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.*

