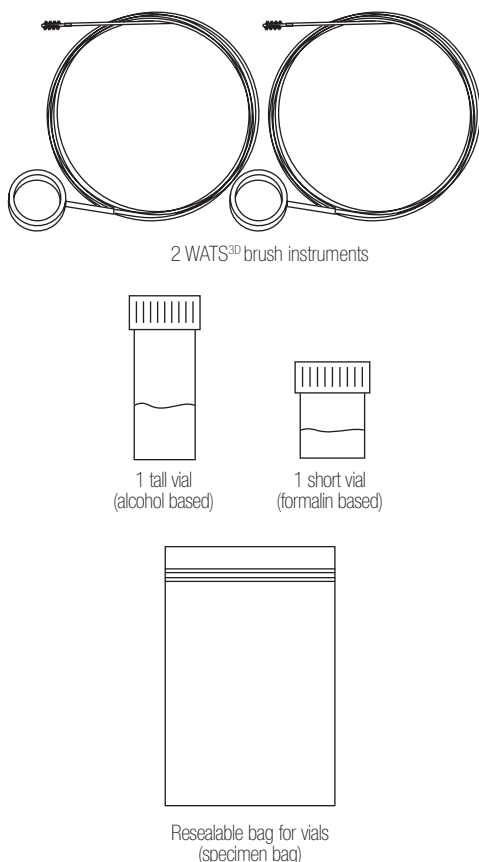


WATS^{3D} TESTING COMPONENTS

Includes Test Requisition Form



WATS^{3D} consists of a brush biopsy instrument that is used to collect a Wide Area Transepithelial Tissue Sample for Computer-Assisted Analysis.

IMPORTANT TO NOTE

- Per New York State regulations, each specimen (both vials) submitted to the laboratory for processing must be marked with 2 patient identifiers that match the information provided on the Test Requisition Form. Examples of identifiers include patient name, date of birth, or medical record number.
- For patients with long-segment Barrett's esophagus, a separate kit should be utilized for every 5 cm.
- It is important to retract the brush tip into the surrounding sheath before inserting it into and removing it from the scope. Allowing the brush tip to remain exposed can compromise the specimen.
- To prevent leakage, ensure that all specimens are tightly closed and sealed before being placed into the specimen bag.
- The WATS^{3D} sampling device is designed to collect a full thickness epithelial sample. Risks associated with upper endoscopy and WATS^{3D} are similar to those associated with upper endoscopy and standard forceps biopsy. Specifically, these risks are those related to sedation for the procedure (allergic reaction, respiratory depression), and endoscopy with biopsy (small amounts of bleeding or infection). Rare side effects include significant bleeding and perforation of the esophagus.
- Patients with persistent clinical signs or symptoms of esophageal disease should be re-evaluated.

UTILIZATION OF WATS^{3D} BRUSHES

Each kit contains 2 sterile WATS^{3D} brushes, 1 tall vial (alcohol based) and 1 short vial (formalin based), and a Test Requisition Form.

Brush 1: Obtain specimen ► Clip brush tip into tall vial (cytology specimen)*

Brush 2: Obtain specimen ► Clip brush tip into short vial (cell block specimen)*

Do not place two brush tips into one vial. While not required, we recommend placing the first brush into the tall vial and the second brush into the short vial.

*Wire cutters are needed for clipping off the brush tips

WATS^{3D} PROCEDURE

1. Preparation

Open the test kit and lay out the WATS^{3D} testing components. Open brushes and uncoil. Activate handle several times to be sure the brush retracts and deploys properly

2. Intubate esophagus and visualize mucosa - Retract first brush into sheath and pass through channel of scope

3. Brushing (brush #1)

- With the brush still inside the sheath, extend the sheath slightly beyond the scope's distal tip
- Advance the brush and place bristles against surface mucosa
- While maintaining firm pressure, rotate and repeatedly pass back and forth over the intended biopsy site until pinpoint bleeding is observed
- Retract brush into sheath
- Remove brush from endoscope

4. Clipping (brush #1)

Clip Brush #1 into tall vial (alcohol based for cytology component)

- With the tip of the brush slightly inserted into the taller vial, use wire cutters to clip off the bristle portion of the brush and submerge in vial
- Replace vial cap and twist it closed until the black line on the cap passes the black line on vial
- Discard remaining cable

5. Brushing (brush #2)

Extract second brush into sheath and repeat brushing as mentioned above

6. Clipping (brush #2)

Clip Brush #2 into short vial (formalin based for cell block component)

- With the tip of the brush slightly inserted into the smaller vial, use wire cutters to clip off the bristle portion of the brush and submerge in vial
- Replace vial cap and twist it closed until an audible click is heard
- Discard remaining cable

7. Ensure all specimens (both vials) are labeled with 2 forms of patient ID to match Test Requisition Form

8. Place both vials into the specimen bag

9. Complete the Test Requisition Form and insert form and all relevant kit paperwork into outer pouch of specimen bag

10. Place WATS^{3D} specimen bag into return mailer, close and seal mailer and return to CDx Diagnostics in pre-labeled mailer

Completed WATS^{3D} kit bag should contain:

- Completed Test Requisition Form/kit paperwork
- Specimen bag with 2 WATS^{3D} vials with 1 brush tip in each

*The WATS^{3D} brush instrument should not be forced through the endoscope channel. If resistance is met, it may be necessary to relax the angle of the endoscope to allow passage of the brush.

**Questions regarding technique or testing?
Call 845-777-7000**