Instructions for Use
CytoPath® Discs

CATALOG NUMBER	DESCRIPTION	UNIT OF MEASUREMENT
CPD06	CytoPath® Disc 6 mm	20 disc matrices/cs
CPD12	CytoPath® Disc 12 mm	20 disc matrices/cs

INTENDED USE
The CytoPath® Disc is a single-use, non-sterile in vitro diagnostic device intended for clinical laboratory use in the collection, transfer, and preparation of cell block material from cytological specimens. The device is used with specimens that have already been collected according to established procedures for the specific sample type. Prepared cell block material may then be used in routine anatomical pathology workflows, including histology, immunohistochemistry (IHC), and molecular testing applications.

The device is compatible with commercially available cytology fixatives and is supplied ready for use.

CytoPath Disc is intended for use by trained and qualified laboratory personnel using manual laboratory procedures. The device consists of 6 mm or 12 mm circular polymetric disc and is used with common laboratory consumables and equipment, including Falcon tubes, microcentrifuge tubes, pipettes, centrifuges, tissue processors, embedding stations, microtomes, and stainers.

The device is designed to collect and support the cytological pellet after separation and removal of the supernatant according to laboratory's standard procedures. The collected material can then be processed to prepare a cell block for further pathological evaluation.

The device does not come into direct contact with the patient. It is used only during laboratory specimen preparation as an aid in the diagnostic workflow.

The device does not generate analytical or diagnostic results on its own. It is intended to assist in specimen preparation prior to downstream testing evaluation.

APPLICATIONS
Used as part of the cell block preparation workflow. Supports subsequent tissue processing, embedding, sectioning, staining, and ancillary testing.

MATERIALS REQUIRED BUT NOT PROVIDED
- Consumables and instruments required for cytological sampling and centrifugation.
- Loops, pipettes, or tweezers to retrieve the disc matrix once the cytological material has been absorbed.
- Consumables and tools required for cell block processing, embedding, cutting, staining, and mounting.
- Necessary instrumentation and kits for subsequent molecular, immunohistochemistry, or immunocytochemistry analyses.

STORAGE AND STABILITY
Storage: Room temperature of 15 - 30°C and relative humidity of 20-80%
Refer to SDS for details

WARNINGS AND LIMITATIONS
For professional use only.
Single-use device.
Non-sterile.
Does not contact the patient directly.
Used to aid in diagnosis.

SPECIMEN PREPARATION
Collect and fix cytology specimens according to established laboratory SOPs for the specimen type.

DEVICE USAGE INDICATIONS
- CytoPath Disc 6 mm
  - Maximum capacity: 60-70 µL
  - Suitable for samples with low cellular volume
- CytoPath Disc 12 mm
  - Maximum capacity: up to 230-350 µL
  - Suitable for samples with larger pellet availability

Size selection must be made according to cytological pellet volume obtained after centrifugation to ensure proper absorption, avoid device overload, and optimize the cell block yield.

PROCEDURE METHOD 1 - HIGH CELLULARITY SAMPLES

1 Place cytology sample into falcon or Eppendorf tube.
2 Centrifuge at 1200 RPM for 10 minutes.
3 Remove supernatant with a pipette or other method, leaving pellet at the base of the container.
4 Add one drop of fixative and vortex quickly to resuspend.
5 Insert CytoPath Disc so that it settles on the conical bottom of the tube to come into direct contact with the cell pellet.
6 Close tube and let absorb for 10 minutes.
7 Remove CytoPath Disc with plastic Pasteur pipette or similar device, place in biopsy bag or paper for added security during processing, and then into properly labeled cassette.
8 Fix in formalin and process specimen according to your laboratory protocols.
9 Embed, cut, and stain specimen according to your laboratory protocols.

PROCEDURE METHOD 2 - LOW CELLULARITY SAMPLES

1 Collect cytology sample with pipette or syringe so that it can be aspirated and easily expelled.
2 Place CytoPath disc on a clean surface.
3 Deposit the sample directly onto the disc synthetic matrix slowly so that the matrix can absorb all of the material.
4 Allow absorption time of 10 minutes.
5 Insert CytoPath Disc into a biopsy bag or paper for added security during processing, and then into properly labeled cassette.
6 Fix in formalin and process specimen according to your laboratory protocols.
7 Embed, cut, and stain specimen according to your laboratory protocols.

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GYNECOLOGICAL SAMPLES
For alcohol-fixed gynecological specimens, select the appropriate CytoPath Disc size based on pellet volume and device capacity. Prepare the cell block and apply the CytoPath Disc using Method 1 or Method 2.

NON-GYNECOLOGICAL SAMPLES
Samples may arrive fresh or already fixed in fixative or mucolytic/hemolytic solution.

Fine Needle Aspiration Samples (FNA)
Recommended procedure: Collect the specimen directly into a mucolytic/hemolytic solution and wash as needed.

Mucoid Samples
- Use a mucolytic/hemolytic solution whenever possible.
- For fresh specimens, add the mucolytic/hemolytic solution promptly after collection.
- For specimen volumes greater than 20 mL, concentrate the specimen before treatment.

Fluid Samples
- Recommended procedure: concentrate the fresh specimen before adding a mucolytic/hemolytic solution.
- If concentration is not possible, collect and transport the specimen directly in a mucolytic/hemolytic solution.
- Fluids with high protein content may precipitate.
- Specimen volumes may vary widely (<1 mL to >1000 mL).
- Multiple pellets obtained after centrifugation may be combined.

Brushings/Scrapings
For specimens collected in fixative or mucolytic/hemolytic solution, determine whether washing is required, concentrate the specimen, and prepare according to the applicable procedure.

CONCENTRATION BY CENTRIFUGATION
600 g for 10 minutes; check the correct rpm setting for the centrifuge based on its rotor size.

REMOVAL OF THE SUPERNATANT AND RESUSPENSION
- Gently invert the tube by 180 degrees (check the pellet during the process to prevent any leakage).
- Remove the supernatant completely.
- Return the tube to an upright position.

Caution: Incomplete removal of the supernatant may result in sample dilution.

Resuspension of the pellets
Vortex for 10 seconds OR pipette repeatedly using a plastic pipette until a homogeneous cell suspension is obtained.

SAMPLE WASHING
Add lysis solution to the sample to wash. The lysis solution preserves cellular morphology while providing the following benefits:
- Lyses red blood cells
- Breaks down mucus
- Reduces protein precipitation

Washing procedure
- Add 30 mL of lysis solution to the bloody/mucoid cellular precipitate.
- Mechanically agitate.
- Concentrate by centrifugation: 600 g x 10 minutes.
- Remove supernatant and vortex to resuspend cellular precipitate.

One wash is generally sufficient for most non-gynecological samples. Samples containing excessive blood or mucous may require additional washing steps.

FINAL EVALUATION OF CELLULAR PRECIPITATE
White, pale pink, light brown, or transparent: Proceed with CytoPath Disc preparation according to the selected procedure and sample quantity.
Red or brown (presence of blood): Wash with mucolytic/hemolytic solution: add 30 mL solution, centrifuge to concentrate, remove supernatant, vortex to resuspend pellet.
Mucoid (non-liquid): Wash with mucolytic solution: add 30 mL solution, centrifuge to concentrate, remove supernatant, vortex to resuspend pellet.

Store any remaining sample according to established laboratory SOPs.

Please contact productsupport@statlab.com with any additional questions.

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