

PATHTEZT™ PROCESSOR OPERATING INSTRUCTIONS.

New Version: 5.0

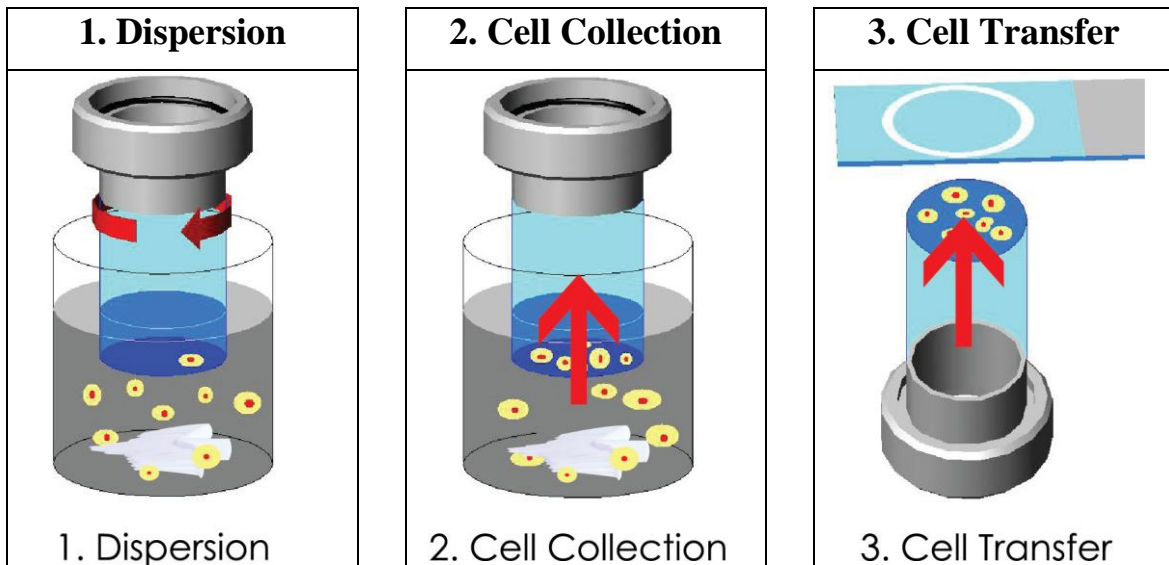


PRINCIPLE OF THE TEST.

To provide instructions on how to operate the PathTezt™ Processor, and how to prepare cytologic slides using the PathTezt™ Processor.

At the laboratory, the sample vial is placed into a PathTezt™ Processor and a gentle dispersion step breaks up blood, mucus, non-diagnostic debris, and thoroughly mixes the cell sample. The cells are then collected on a Filter specifically designed to collect diagnostic cells. The PathTezt™ Processor constantly monitors the rate of flow through the Filter during the collection process to prevent the cellular presentation from being too scant or too dense. A thin layer of cells is then transferred to a glass slide in a 20mm-diameter circle, and the slide is automatically deposited into a fixative solution.

Figure 1-1 The PathTezt™ Sample Preparation Process



(1) Dispersion:
The filter rotates within the sample vial, creating currents in the fluid that are strong enough to separate debris and disperse mucus, but gentle enough to have no adverse effect on cell appearance

(2) Cell collection:
A gentle vacuum is created within the filter, which collects cells on the exterior surface of the membrane. Cell collection is controlled by the **PathTezt™** Processor software that monitors the rate of flow through the Filter

(3) Cell Transfer:
After the cells are collected on the membrane filter, the Filter is inverted and gently pressed against the **PathTezt™** Microscope Slide. Natural attraction and slight positive air pressure cause the cells to adhere to the **PathTezt™** Microscope Slide resulting in an even distribution of cells in a defined circular area.

As with conventional Pap smears, slides prepared with the PathTezt™ Processor are examined in the context of the patient's clinical history and information provided by other diagnostic procedures such as colposcopy, biopsy, and human papillomavirus (HPV) testing, to determine patient management.

The PathTezt™ Processor is also marketed for non-gynecologic applications. This Operator's Manual is specific for the gynecologic use of the device.

LIMITATIONS

- Gynecologic samples collected for preparation using the **PathTezt™** Processor should be collected using a Cervical Brush collection device.
- Preparation of microscope slides using **PathTezt™** Processor should be performed only by personnel who have been trained by BIOCYTECH Corporation or by organizations or individuals designated by BIOCYTECH Corporation.
- Evaluation of microscope slides produced with the **PathTezt™** Processor should be performed only by technologists and pathologists who have been trained to evaluate **PathTezt™** prepared slides by BIOCYTECH Corporation or by organizations or individuals designated by BIOCYTECH Corporation.
- Supplies used in the **PathTezt™** Processor are those designed and supplied by BIOCYTECH Corporation specifically for the **PathTezt™** Processor. These include **Preserved Cell Solution, Gyn Filters, Non-Gyn Filters, UrineCell Filters and PathTezt™ Cyto-Slide**. These supplies are required for proper performance of the system and cannot be substituted. Product performance will be compromised if other supplies are used. After use, supplies should be disposed of in accordance with local, state, and federal regulations.
- A Filter must be used only once and cannot be reused.
- The **PathTezt™ Processor** is fused internally. No user accessible fuse is available.
- If this equipment is used in a manner not specified by the manufacturer, then the protection provided by the equipment may be impaired.

WARNINGS

WARNING: Moving Parts

The instrument contains moving parts. Keep hands, loose clothing, jewelry, etc., clear/

WARNING: Grounded Outlet

To ensure safe operation of the instrument, use a three-wire grounded outlet. Disconnection from the power supply source is by removal of the power cord.

WARNING: Glass

The instrument uses microscope slides, which have sharp edges. In addition, the slides may be broken in their storage packaging or on the instrument. Use caution when handling glass slides and cleaning the instrument.

WARNING: Flammable Liquid

Flammable liquid. Keep away from fire, heat, sparks, and flame. Evaporating alcohol could create a fire hazard.

WARNING: Poisonous Substance

Preserve Cell Solution contains Ethanol. Refer to Material Safety Data Sheet (MSDS) for safety and handling instructions. Solution should be stored and disposed of in accordance with local, state, and federal regulations. Wear protective laboratory gear.

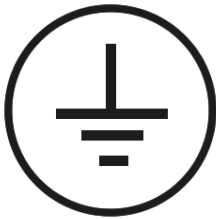
Symbol use on the Instrument



Warning: Biohazard



Attention, refer to accompany document



Protective Conductor Terminal (internal use only, not accessible to operators)

MATERIALS REQUIRED

SECTION A

MATERIALS PROVIDED

The PathTezt™ Processor consists of the following components:

- PathTezt™ Processor
- Power Cord
- 2 filter Caps
- Waste bottle system – includes bottle, bottle cap, tubing set, fitting
- 5 fixative vials
- 1 cleaning vial
- Pneumatic test control cylinder
- Operator's Manual

Items available as part of the PathTezt™ Pap Test:

- PathTezt™ Preserve Cell Solution Vial
- Cervical-brush Sampling Device
- PathTezt™ Gyn Filter for Gynecologic Applications
- PathTezt™ Cyto-Slide

MATERIALS REQUIRED BUT NOT PROVIDED

- Slide staining system and reagents
- Standard laboratory 95% fixative
- Cover slips and mounting media

STORAGE

The storage condition for Preserve Cell Solution without cytologic samples is up to 2 years from date manufacture at 15° to 30°C. The storage limit for Preserve Cell Solution with cytologic samples is 3 weeks at 4°C to 35°C.

SECTION B

PRINCIPLES OF OPERATION

PathTezt™ Processor makes use of mechanical, pneumatic, and fluidic principles for cell dispersion, collection, and transfer. A rotary drive mechanism gently disperses samples. A pneumatic/fluidic system, controlled by a Program Logic Microcomputer, monitors cell collection. Electrochemical principles, the pneumatic and fluidic systems, the natural binding qualities of cells, and the qualities of the Filter are responsible for cell transfer.

Each **PathTezt™** Processor slide preparation processing sequence is optimized for the biological characteristics of the various logical specimens.

The **PathTezt™** Processor slide preparation process can be divided into the following phases:

- Sample preparation/Instrument loading
- Start of cycle
- Fluid level detection
- Dispersion
- Filter wetting
- Cell collection
- Waste clearing
- Bubble point
- Cell transfer
- Slide ejection
- Completion of cycle

The following sections describe the principles of each of these phases in detail:

In preparation for sample processing, the operator loads four essential items into the instrument: a Sample vial, a Filter attached to the filter cap, a **PathTezt™** Slide and fixative bath containing a standard laboratory 95% fixative. The processes of loading and operating a standard laboratory 95% fixative.

Start of Cycle

When the operator initiates a sequence, the **PathTezt™** Processor verifies installation of disposables, motor positions, and the positive and negative pressures in the pressure reservoirs.

After this the instrument processes the slide using the selected sequence.

Fluid Level Detection

The cap seal lowers to seal the filter assembly and the sample vial is raised towards the filter membrane. The sample vial stops when the filter membrane makes contact with the surface of fluid. If the fluid level is satisfactory, the instrument will continue the slide preparation process.

An error message and audible alarm indicate an unsatisfactory fluid level.

Dispersion

The cap seal lifts, and the dispersion system rotates the Filter assembly within the cell suspension, creating shear forces in the fluid that are strong enough to separate randomly joined material and disperse mucus, and are not known to have an adverse effect on the cellular architecture or on adhesive forces joining diagnostically relevant groups of cells.

Filter Wetting

The head seal lowers to seal the filter assembly. Negative pressure is briefly applied, drawing a small amount of fluid through the Filter to wet it. Following wetting, the system gently blows out the liquid in the Filter. This clears any cellular material from the filter surface.

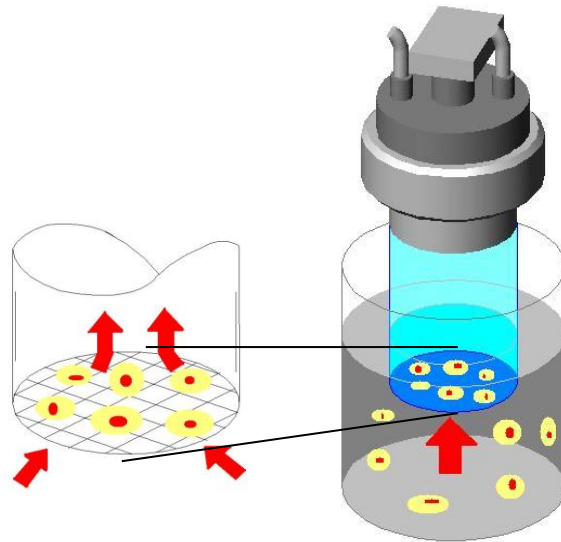
Cell Collection

The filter membrane is biologically neutral and is mounted at one end of the Filter cylinder. The membrane is a flat, smooth, porous surface that collects the cellular material on one plane.

The pneumatic system applies negative pressure to the filter in a series of pulses. These negative pressure pulses (sips) draw Solution through the filter membrane and collect suspended cellular material onto the outer membrane surface.

The collection process ceases when a target filter coverage, predetermined by the processor sequence, is attained. Cell collection is controlled by an embedded microprocessor that monitors the pressure in the Filter cylinder. After collection, the cells sit on a single plane over the pores, ready for transfer to the slide. Figure 1-3 illustrates cell collection.

Figure 1-2 Cell Collection



Waste Clearing

When collection ends, the Filter is withdrawn from the sample vial and the filtrate is aspirated into the waste bottle as the filter is inverted. The collected cells remain on the Filter due to the negative holding pressure.

Bubble Point

Bubble point removes excess fluid from the filter membrane prior to transferring cells onto the slide to enhance cell adhesion to the slide. Bubble point is performed after all of the fluid is evacuated. This is evident by the bubbling activity on the inside of the filter membrane. Cells do not air-dry during bubble point.

Cell Transfer

When bubble point is complete, the slide handler moves the slide into contact with the inverted Filter.

The natural adhesion properties of cells and the electrochemical charge of the glass slide are responsible for the transfer of cells from the filter membrane to the slide. The cells have a higher affinity for the glass slide than for the membrane; slight positive air pressure behind the filter membrane enhances cell transfer.

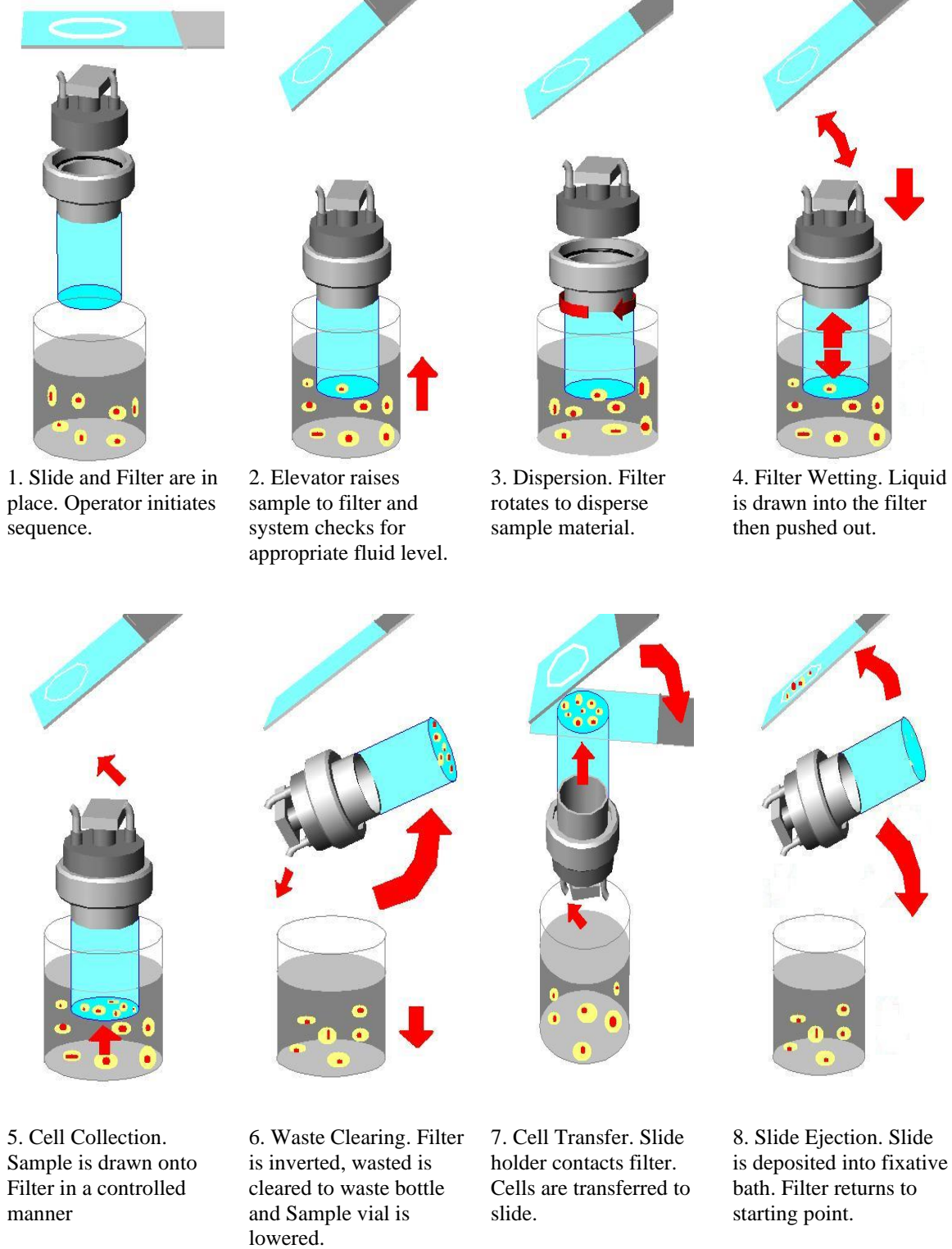
Slide Ejection

Once cell transfer is complete, the slide is removed from contact with the filter and automatically ejected into the fixative bath vial.

Cycle Completion

All the motorized mechanisms return to their initial positions and the display returns to the Main Menu. If the system detects an error during the process, a message will be displayed, and an audible alarm will sound.

Figure 1-3 PathTezt™ Processing



Installation And Specifications

Introduction

This section provides information for unpacking and installing your PathTezt™ Processor. Please completely follow the installation procedure, step by step, to ensure proper installation and system operation.

Before proceeding with the installation of the **PathTezt™ Processor**, compare the contents of the shipping container with the checklist below. If any items are missing or damaged, contact BIOCYTECH Corporation customer Service.

Checklist for contents of shipping container and accessory kit.

- PathTezt™ Processor
- Operator's Manual
- Power cord
- 2 filter caps
- Waste bottle assembly – includes bottle, bottle cap, tubing set, fittings
- 5 fixative vials
- 1 cleaning vial
- Pneumatic test sealed cylinder

Turning the power on before instructed to do so can damage the instrument and invalidate your warranty.

Location Selection Information

Locate the **PathTezt™ Processor** near a 3-prong grounded power outlet that is free of voltage fluctuations and power surges. As with most laboratory equipment, it may be necessary to install a line voltage stabilizer to eliminate power fluctuations and minimize interference from other systems. During operation the **PathTezt™ Processor** is sensitive to vibrations. It should be placed on a sturdy bench that can support the 25kg that the instrument weights. The bench should be away from centrifuges, vortexors, or any other equipment that may cause vibrations. If the location of the instrument must be in proximity to one of these devices, it should not be operating at the same time as any of these other devices.

PATHTEZT™ PROCESSOR SPECIFICATIONS

	PathTezt™ Processor	Waste Bottle
Dimensions	W = 18" / 46 cm H = 19.5" / 50 cm D = 12" / 30 cm	W = 6" / 15 cm H = 17" / 43 cm D = 6" / 15 cm
Weight	25kg (approx.)	
Clearance	Front = 0" / 0 cm Rear = 3" / 8 cm Side(ea) = 3" / 8cm Top = 3" / 8cm	Front = 1" / 3 cm Rear = 1" / 3cm Side(ea) = 1" / 3 cm Top = 0" / 0cm
Operating Temperature	15 - 32°C 59 - 90°F	
Operating Humidity	20% - 90% RH non-condensing	
Storage Temperature	-20~122°F -20C -50°C	
Storage Humidity	15%~95% RH Non-condensing	
Operation Air Pressure (Negative)	-0.22 ~ -0.18 psi	
Operation Air Pressure (Positive)	0.60 ~ 1.00 psi	
Electrical Voltage	AC 100 ~ 120V(2A) AC 220 ~240V(1A)	
Frequency Power	50/60 Hz Maximum 200 watts	
Transportation Temperature	- 10 - 50°C 14 – 122°F	
Transportation Humidity	15%~95% RH Non-condensing	

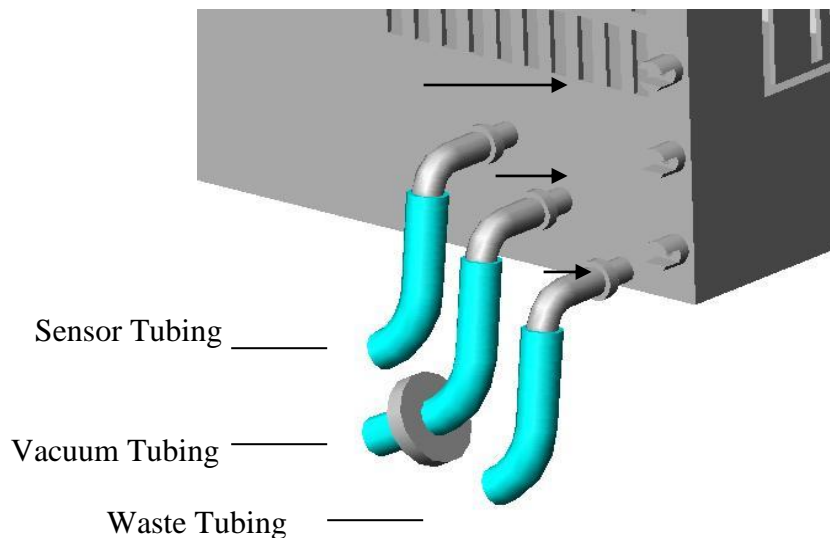
CONNECTING THE WASTE BOTTLE



At no time should bleach be present in the Waste Bottle while it is connected to the PathTezt™ Processor

1. The waste bottle should be placed at the same height or below the PathTezt™ Processor. Do not place the waste bottle above the instrument.
2. Ensure that the waste bottle cap is tightly secured. The waste bottle must rest in an upright position. Do not allow the waste bottle to lay on its side.
3. Locate the three waste bottle connections at the rear of the PathTezt™ Processor. Ensure that the bottoms of the connectors are in the down/inward position.

Figure Waste Tubing Connections



4. Connect the waste tubing connectors to the corresponding connectors located in the rear of the **PathTezt™** Processor. When the proper connection has been established, the buttons on the connectors pop up/ outward with a click sound. It may be necessary to push the button in before placing the waste tubing connector into the instrument connector.



Do not attempt to mismatch tubing connection. This may result in damage to your processor.



Always empty the waste bottle before it reaches the maximum liquid level line.

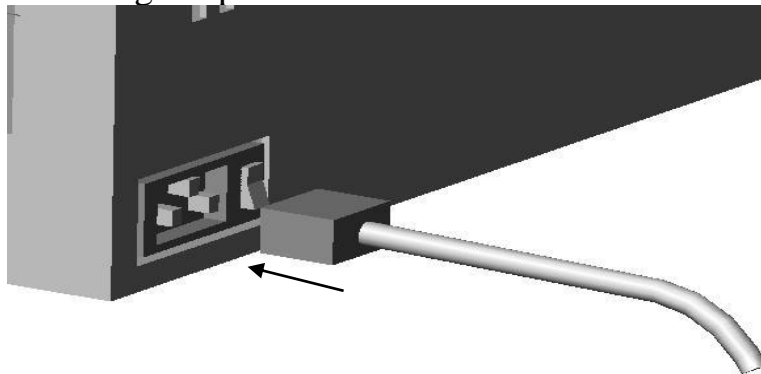
CONNECTING THE POWER CORD



Turning the power on before instructed to do so can damage the instrument and invalidate your warranty.

1. Ensure that the power switch, located on the rear of the **PathTezt™** Processor, is in the “O” (Off) position. For “Off”, the top half of the toggle power switch is in the “out” position (protrudes).
2. Insert the power cord into the power receptacle located on the rear of the **PathTezt™** Processor next to the power witch. Refer to Figure 2-7.
3. Connect the power cord to a 3-prong grounded outlet.

Figure 2-7 Connecting the power cord



4. The **PathTezt™** Processor is designed with a manually switching the system line voltage setting to meet your specific requirements. The instrument wills manually set the line voltage between 100-120VAC and 220-240VAC at the power supply.



The PathTezt™ Processor is fused internally. No user accessible fuse is available.

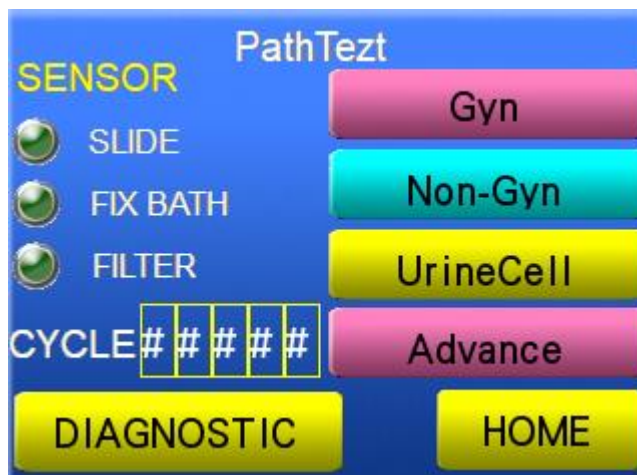
TURNING ON YOUR PATHTEZT™ PROCESSOR

1. **CAUTION!** Confirm that the internal securements have been removed from the instrument before proceeding with this procedure. With the door to the PathTezt™ Processor closed, turn the toggle power switch, located on the right rear of the PathTezt™ Processor, to the “1” (ON) position. For “On”, the top half of the toggle power switch is in the “in” position.
2. As the power is applied to the instrument, the touch screen control panel will display the following sequence of messages. If a different message appears in the display, follow the instructions on the touch screen display or refer to Chapter 4, Troubleshooting, of this manual.

This message will appear for approximately ten to twenty seconds. At this point the system initializes all mechanisms while displaying this message. At the same time, the system also calibrates all pressure sensors while displaying this message.



If the system initialization and calibration were successful, the touch screen display will read:



SPECIMEN REQUIRED.

Gynecologic and non-gynecologic cytology specimens.

REAGENTS, INSTRUMENTATION.

1. The required materials: Operator's manual. Gloves. Preserve Cell Solution. Fixative bath vial. Gyn/Non-Gyn Filter. PathTezt™ slide. Filter cap. Staining rack and 95% Alcohol bath.
2. The Preserve Cell Solution vial is a plastic vial that contains an alcohol-based preservative solution that preserves cells from all body sites for up to three to four weeks at room temperature.
3. The Gyn/Non-Gyn Filter is a disposable plastic cylinder that is open at one end and has a Special design filter membrane bonded onto the other end. The filter membrane has a flat, smooth, porous surface.
4. The filter cap is a white plastic color cap, that fits into the open end of the Gyn/Non-Gyn Filter and mounts the Gyn/Non-Gyn Filter into the processor.
5. The fixative bath vial is a plastic vial, that should be filled with standard laboratory 95% fixative alcohol. After the PathTezt™ Processor transfers cells onto the glass-slide, it automatically ejects the slide into the fixative bath vial.
6. The PathTezt™ Slide is a high-adhesive special coating function, pre-cleaned glass microscopic slide, with a defined screening area, and a larger labeling area. The slide is specifically designed for use with the PathTezt™ Processor.
7. Supplies used in the PathTezt™ Processor are those designed and supplied by BIOCYTECH Corporation, specifically for the PathTezt™ Processor. These include Preserve Cell Solution vials, Cervical-brush, Gyn/Non-Gyn filters, and PathTezt™ Microscopic Slides. The supplies are required for proper performance of the system and cannot be substituted for gynecologic use. Product performance will be compromised if other supplies are used. After use, supplies should be disposed of in accordance with local, state, and federal regulations.
8. The PathTezt™ Processor Operator's Manual contains detailed information about the PathTezt™ Processor, such as principles of operation, operating instructions, specifications, and maintenance information. The manual also contains information on the solutions and materials to prepare gynecologic slides with the PathTezt™ Processor.
9. Disposable laboratory gloves: non-powdered gloves are recommended.
10. Alcohol bath with slide staining rack and standard laboratory fixative alcohol. (95% Ethanol)

PRE-OPERATION CHECKLIST.

The following conditions should be checked before preparing a slide on the PathTezt™ Processor.

- Waste Bottle.** Make sure that the fluid level of the waste bottle is below the **MAX** fill line of the bottle.
- Main Menu mode.** Confirm that the PathTezt™ Processor is powered on and in Main Menu mode. If the Main Menu is not displayed, then follow the instructions on the display until the Main Menu appears.
- Filter Cap-seal O-rings.** Make sure that the two O-rings at the base of the filter cap are not dry, cracked, or in need of lubrication.
- Disposable Laboratory Gloves.** Always wear disposable laboratory gloves and other laboratory safety garments (lab coat, protective eyewear), when operating the PathTezt™ processor.
- Once** a sample has been added to a Preserve Cell Solution vial, the vial is then designated as a Preserve Cell Sample vial.

OVERVIEW OF LOADING PROCESSOR.

The next four sections describe in detail the methods for loading the PathTezt™ Processor. The following supplies must be loaded into the processor before initiating a sample run.

PathTezt™ Processor loaded with supplies.

- Preserve Cell Solution Vial.
- Gyn/Non-Gyn Filter.
- PathTezt™ Cyto-Slide.
- Fixative Bath Vial.

LOADING THE PRESERVE CELL SAMPLE VIAL.

Figure Loading the Preserve Cell Sample Vial.

- 1. Open the PathTezt™ Processor swing door.
- 2. Confirm that the sample holder, fixative bath vial holder, and slide handler are empty.
- 3. Remove the cap from the Preserve Cell Sample Vial.
- 4. Gently place the Preserve Cell Sample Vial into the sample holder, until the bottom of the vial rests on the sample holder base.
- 5. The vial will remain loose in the sample holder, until the process begins. The system will automatically grasp the vial during processing.



>>>



LOADING THE GYN/NON-GYN FILTER.

1. Remove a new Gyn/Non-Gyn Filter from the storage tray by grasping the slides of the cylinder.

Never touch the filter membrane of the Gyn/Non-Gyn Filter.

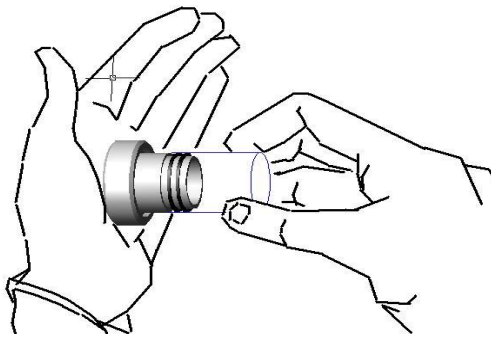
2. There are two different techniques for mating the Gyn/Non-Gyn Filter and the filter cap. This configuration of the two parts is called a filter assembly.

Method A. Hold the filter cap in the palm of one hand and the Gyn/Non-Gyn Filter in the other hand, as shown in below the Figure. Insert the Gyn/Non-Gyn filter.

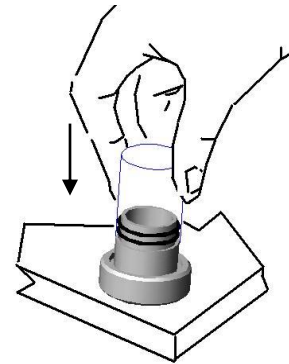
Method B. Place the filter cap on the bench and hold the Gyn/Non-Gyn Filter in one hand. Insert the Gyn/Non-Gyn Filter.

Using a slight twisting motion may be helpful with either technique. The filter seal O-rings should be lightly greased.

Figure Assembling the filter cap and filter



Method A

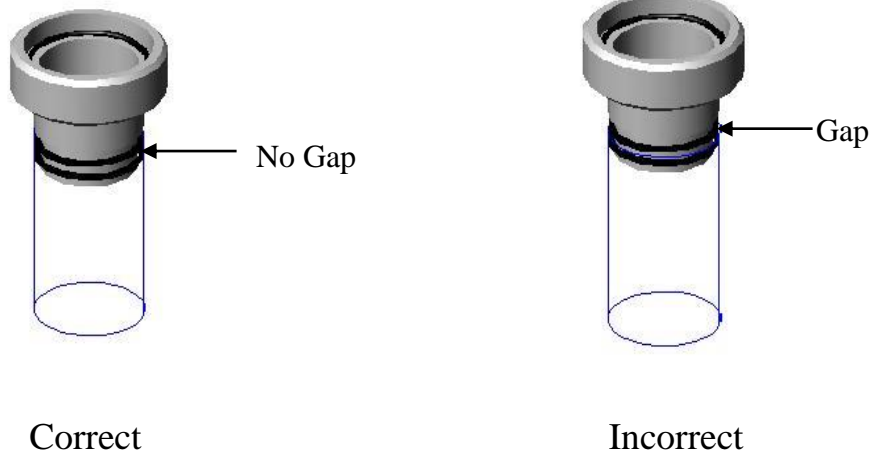


Method B

Figure A. Assembling the filter cap and Gyn/Non-Gyn filter.

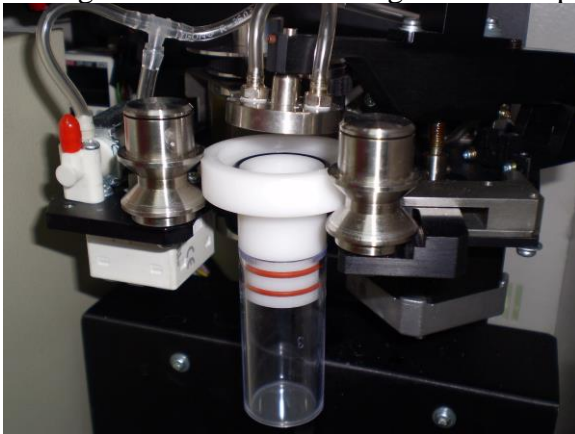
3. Ensure that there is no visible gap between the Gyn/Non-Gyn Filter and the Filter Cap, as shown in Figure B. The Gyn/Non-Gyn Filter must seat against the filter cap lip.

Figure B Correct filter cap-to-filter assembly



4. Insert the filter assembly into the instrument. Hold the filter assembly by the Gyn/Non-Gyn Filter cylinder and place the angled edges of the filter cap against the two front bobbins as shown in Figure **Correct**.

Figure **Correct** Positioning the filter cap in the bobbins.



5. Keeping the filter assembly level, push it straight into the instrument. The right bobbin will move to the right, as the filter assembly is inserted. The filter assembly is completely seated when the right bobbin moves back to the left, and the two front bobbins hold the filter assembly in the processor.

When properly loaded, the filter cap is level inside the instrument, and the filter cylinder is above the Preserve Cell Sample Vial, and slightly to the left. If the positioning of the Filter Assembly does not correspond to this description, remove it and try again. The Filter Assembly will easily rotate in the bobbins, when properly seated.

Loading the Filter Assembly.



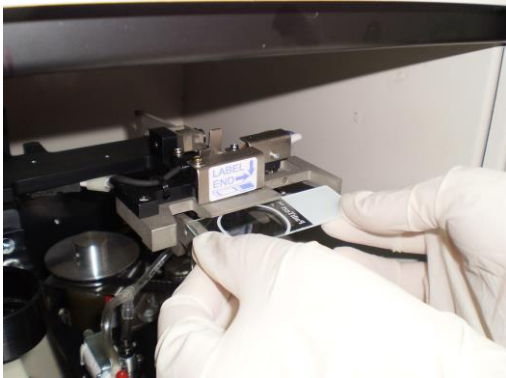
LOADING THE PATHTEZT SLIDE.

1. Label the PathTezt™ slide with patient's identification information. Use the frosted area of the slide. When using an adhesive label, ensure that the label is completely adhered to the slide, and that there are no overhanging edges.

2. Using two hands, hold the slide by the two front corners, with your index fingers and thumbs, as shown in Figure Be sure not to touch the slide within the defined screening area. Place the label-end to the right and facing down.

3. Insert the slide. Using the slide to push the spring-loaded clamps down, insert the slide halfway under the upper guide block, and over the spring-loaded clamps, then release the slide. Refer to Figure

Inserting the slide onto the clamps.



4. The slide should now rest **on top of** the two clamps, and **under** the upper guide block, as shown in Figure

Figure Correct/Incorrect slide insertion.

5. To fully insert the slide, place your index fingers against the exposed edge of the slide, and push the slide in until it does not go any further, as shown in below Figure. The slide handler clamps grasp the slide, when the slide is seated correctly, and the slide moves up slightly, behind the upper guide block.

Inserting the slide fully.



Note: To remove a slide, press down on the front edge of the slide. Gently pull the slide toward you.

LOADING THE FIXATIVE BATH VIAL.

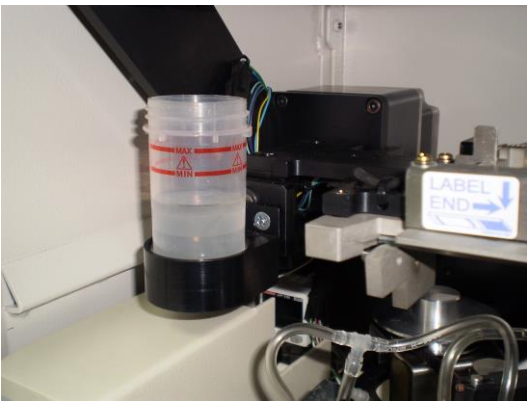
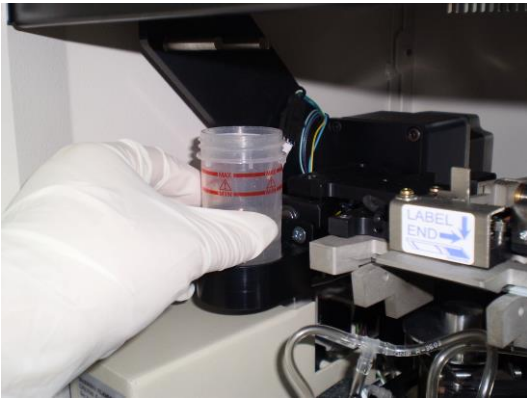
1. Fill a fixative bath vial with standard laboratory fixative alcohol, until the fluid level is between the **MIN** and **MAX** marks on the vial.

If the staining protocol requires alternative fixation methods, then leave the fixative bath vial empty, or else fill it with the appropriate fixative solution.

Change the contents of the fixative bath vial at least every 100 slides or daily, whichever occurs first.

2. Place the fixative bath vial into the fixative bath holder, until the bottom of the vial rests on the base of the holder. Refer to Figure. Ensure that the fixative bath vial is completely seated.

Figure. Loading the fixative bath vial.



CLOSING THE DOOR.

To close the door, grasp the door tab, as swing it completely to the left. **Do not open the door during processing! Depending upon where a sequence is interrupted, cells may be lost or air-dried during recovery.**

Door opening and closing. (Swing left and right)



SELECTING AND INITIATING A SEQUENCE.

The PathTezt™ Processor has several program modes in its program. There are Four primary types of modes:

1.2.3.4. Sample processing sequences. **Gyn, Non-Gyn, UrineCell & Advance (Gyn+B)**

5. DIAGNOSTIC

6. HOME



The sample processing sequences are used to process different kinds of specimens. The diagnostic modes are used to display the status of the instrument, or to perform maintenance procedures. The Main Menu, shown below, is displayed whenever the instrument is in its idle state.

Main Menu: Select

1. GYN

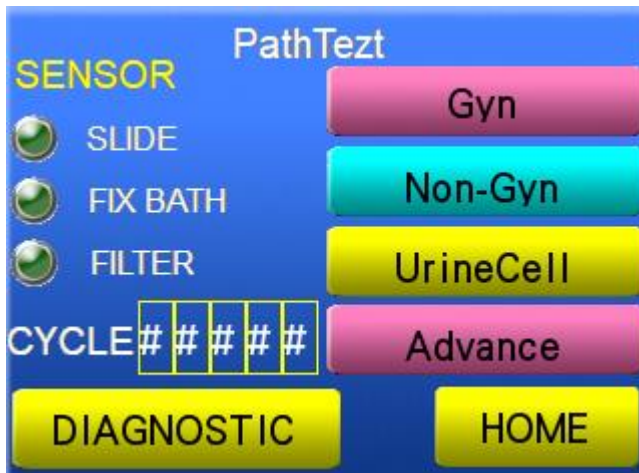
2. NON-GYN

- FLU/FNA
- SUPER
- MUCOID

3. UrineCell

4. Advance: Gyn+B (Pathteszt processor is improvement new version 2016 software, Advance function "Gyn+B". Detach the brush inside the Pathteszt preservative vial, the vial can directly to processing in Pathteszt processor.)

Do not open the door during processing! Depending upon where a sequence is interrupted, cells may be lost or air-dried during recovery.



Completely to installation the SLIDE, FIX BATH, FILTER, and Sample Vial, then press the button to processing. To install the SLIDE, FIX BATH, FILTER, the display will presence the light sensor (green color).

Process Completed, the screen will show below the page message: Sample too dense, Process completed, Sample is dilute.



SAMPLE IS DILUTE

Bloody or Proteinaceous Specimens

A. Did the “Sample is dilute” message appear during processing?

Yes!

1. Check to see if cellularity is adequate. If not, use more of the pellet if available. Prepare a slide using Sequence 2.

B. Does the slide have an obvious “halo” of cellular material and/or white blood cells?

Yes!

1. Dilute the sample 20:1 Use a calibrated pipette to add 1ml of sample to a new Preserve Cell Solution vial. Prepare slide again.

C. Is the slide sparse and does it contain blood, protein, or non-cellular debris?

Yes!

1. Processing Sequence 2.

Sequence 2

1. Pour the contents of the Patient sample into a centrifuge tube.
2. Concentrate by centrifugation – 800 X 10 min.
3. Pour Off Supernatant and Vortex to Resuspend Cell Pellet.
4. If the sample contains blood or non-cellular debris:
Mix a solution of 9 parts Cytolysis Solution to 1-part Glacial acetic acid. Add 30ml of this solution to the sample centrifuge tube.
If the sample contains protein:
Add 30ml of Saline to the sample centrifuge tube.
5. Concentrate by centrifugation – 800g X 10 min.
6. Pour Off Supernatant and Vortex to Resuspend Cell Pellet.
7. Evaluate Cell Pellet Appearance.
If pellet contains blood or protein, repeat steps 4-6
8. Add Specimen to new Preserve Cell Solution vial. Allow to stand in solution 15mins.
9. Run on PathTezt™ Processor again.
- 10.If the new slide is sparse, call BIOCYTECH Technical Service.

Mucus Specimens

A. Did the “Sample is dilute” message appear during processing?

Yes!

1. Check to see if cellularity is adequate. If not, use more of the pellet if available. Prepare a slide using Sequence 2.

B. Does the slide have an obvious “halo” of cellular material and/or white blood cells?

Yes!

1. Dilute the sample 20:1 Use a calibrated pipette to add 1ml of sample to a new Preserve Cell Solution vial. Prepare slide again.

C. Is the slide sparse and does it contain mucus?

Yes!

1. Processing Sequence 2 or 3

Sequence 2

Note: Large specimens (greater than 20ml) should be concentrated before addition of Cytolysis solution to the sample.

If DTT is being used with respiratory mucoid samples, add stock before agitation. See below for preparation instructions.

The use of Dithiothreitol (DTT) has shown to reduce the amount of mucus present in transpiratory samples. To use DTT with the PathTezt™ system, prepare a stock solution by adding 2.5g DTT to 30ml of Cytolysis solution. This solution is suitable for use for 1 week when stored at room temperature (15-30° C). Add 1ml of stock solution to the sample.

1. Pour the contents of the Patient sample into a centrifuge tube.
2. Vortex for a minimum of 5 minutes in "hands-free" vortexor.
3. Concentrate by centrifugation – 800 X 10 min.
4. Pour Off Supernatant and Vortex to Resuspend Cell Pellet.
5. Evaluate Cell Pellet Appearance.

Confirm the cell pellet is in liquid form.

If the cell pellet is not in liquid form, add 30ml Cytolysis solution and repeat steps 2 and 4.

6. Add Specimen to new Preserve Cell Solution vial. Allow to Stand in Solution for 15mins.
7. Run on PathTezt™ Processor again.
8. If the new slide is sparse, call BIOCYTECH Technical Service.

OR

Sequence 3

Prefilter Protocol



Step 1 Write down the Patient I.D to Prefilter Vial.



Step 2 Pour the contents of the Patient sample into a Prefilter.



Step 3 After the prefilter put back into the empty Pathtext preservative vial.



Step 4 Run on PathText™ Processor.

UNLOADING THE PATHTEZT™ PROCESSOR.

1. Open the door by swinging it to the right.

2. Remove the fixative bath vial containing the prepared slide from its holder. It is necessary to remove the fixative bath vial from the holder after each slide is processed.

The fixative bath vial must be removed. Evaporating alcohol could create a fire hazard.

3. Remove the prepared slide from the fixative bath vial and deposit the slide into a staining rack in a bath containing standard laboratory fixative.

Refer to Chapter 6, Fixation and Staining, for more information about slide fixation and staining.

4. Using the cross-contamination precautions listed below, remove the filter assembly, and separated the Gyn/Non-gyn Filter from the filter cap (a slight twisting motion may be helpful).

To reduce the possibility of cross-contamination, use one of the following methods to remove the Gyn/Non-gyn Filter from the filter cap:

Method A: Place a lint-free wipe around the Gyn/Non-gyn Filter to prevent contamination of your gloves, while removing the Gyn/Non-gyn Filter assembly from the instrument, and while separating the Gyn/Non-gyn Filter from the filter cap. Dispose of the lint-free wipe with the Gyn/Non-gyn Filter.

Method B: Remove the Gyn/Non-gyn Filter from the filter cap and wipe off your gloves with lint-free wipe to remove any liquid or change your gloves after each slide preparation cycle.

5. Dispose of the used Gyn/Non-gyn Filter cylinder, using appropriate laboratory procedures.

6. Remove the Preserve Cell Solution Sample Vial from the instrument and recap it firmly. Be sure to line up the torque line on the cap with the torque line on the vial. Refer to Figure 3-13.

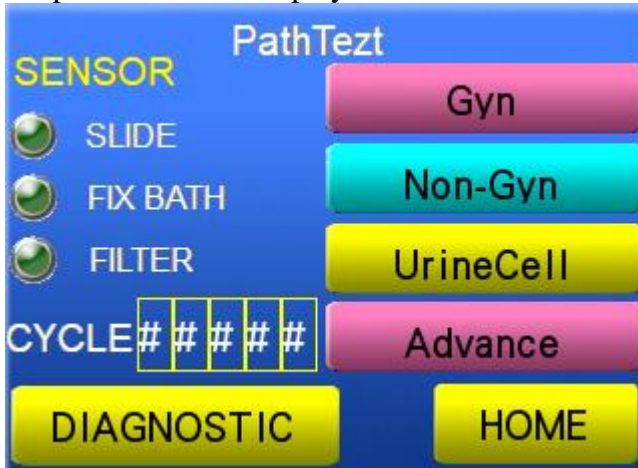
Figure 3-13. Capping the Preserve Cell Solution Sample Vial.

7. Do not discard the sample vial, until it has been determined that no additional slides are needed. Refer to Chapter 7, Biocytch Solutions, for information regarding solution disposal and sample storage.

INTERRUPTING THE SLIDE PREPARATION PROCESS.

INTERRUPTING THE SLIDE PREPARATION PROCESS.

1. **(IMMEDIATE)** switch OFF the power switch, and wait a few seconds then switch ON the power until the display show:



2. When the ERROR or FATAL ERROR to show the display reads: Press the **ENTER** key to stop the ERROR alarm, and to return to the Main Menu.



3. Call Biocytch technical.

The Main Menu contains the other two sequences for processing.

The DIAGNOSTIC and HOME modes:

Main Menu: Select **DIAGNOSTIC**

DIAGNOSTIC

HOME

To Select **DIAGNOSTIC** modes from the Main Menu, and the Diagnostic page will be displayed.

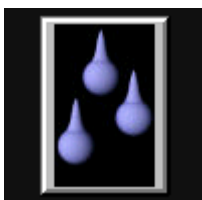
DIAGNOSTIC PAGE



DIAGNOSTIC

The purpose of this section is to describe the function of Status:

- 1. Cleaning**
- 2. Pneumatic Test**
- 3. Services**
- 4. Waste System**
- 5. Alarm Error History.**



- 1 Cleaning: this logo to cleaning the waste system tubing to protect accuracy sample test.



- 2 Pneumatic tests: this logo to QC the pneumatic system.
-



3 Services: Biocytch technical services.



4 Waste system: this logo to clean up the waste and open the waste bottle cap.



5 Error: this logo to record the error memory.

To initiate a sample processing sequence, simply press the key corresponding to the desired sequence. The sequence will begin immediately after the key is pressed. At the end of the sequence, the display will return to the Main Menu.

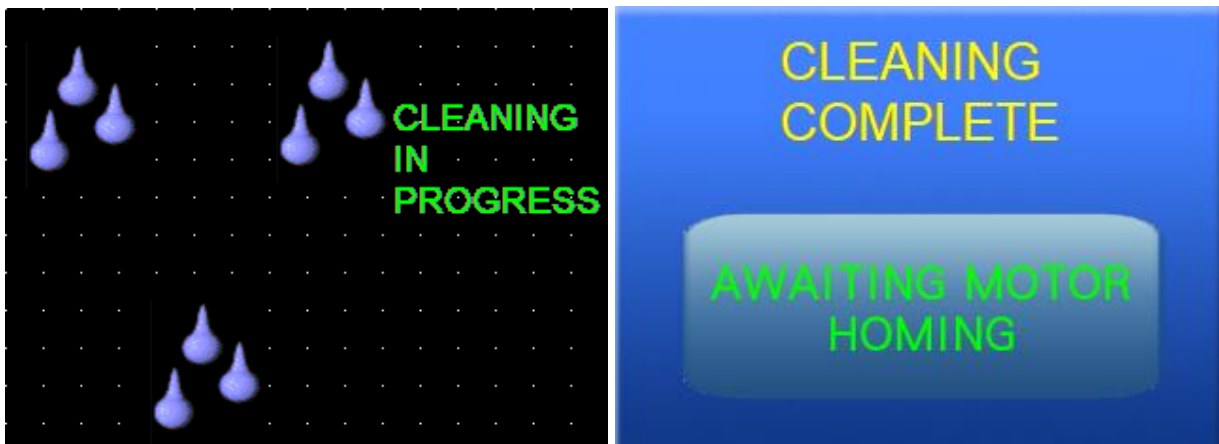
By pressing the Cleanser key, the following appears:

1. Cleanser: **LOADING THE CLEANSER VIAL.**



1. Fill a Cleanser vial with standard laboratory 95% Ethanol alcohol, until the fluid level is between the **MIN** and **MAX** marks on the vial.

Pressing **Cleanser** fill in Filter to the cap seal into the instrument. Press the **ENTER** key, the test will automatically end, then the test will end with a message that indicates a **CLEANING COMPLETE**.



* The Cleanser Filter can reuse a more time until the filter membrane to broken then to change a new one. *

2. **Pneumatic Test:** This test is used to confirm the proper operation of the entire pneumatic system. This is Biocyttech technical use only.



Pressing **Pneumatic Test** prompts the user to load the QC sealed cylinder into the instrument. Press the **ENTER** key, to initiate the test. The test will automatically end if any errors occur, and the operator will be notified of the area of concern. Once the problem has been addressed, it is necessary to run the test again, to ensure proper operation. If no errors occur, then the test will end with a message that indicates a successful test.

ERRORS:

- CAP SEAL LEAK
- WASTE PRESSURE FAILURE
- ATM VALVE LEAK
- QTO VALVE LEAK
- POSITIVE PRESSURE FAILURE
- NEGATIVE PRESSURE FAILURE
- WASTE LINE CLOGGED
- TANK LINE CLOGGED
- + TANK LINE CLOGGED
- QTO LINE CLOGGED

ACTION:

- Clean Filter Cap and Cap Seal.
- Follow troubleshooting for Waste Pressure Failure
- Call Biocyttech Technical Service.
- Call Biocyttech Technical Service.
- Call Biocyttech Technical Service.
- Call Biocyttech Technical Service.
- Call Biocyttech Technical Service.
- Call Biocyttech Technical Service.
- Call Biocyttech Technical Service.
- Call Biocyttech Technical Service.



Pneumatic Test successful will be show this page, after press enter back to the main menu.

3. Service Mode: Pressing **SERVICE LOGO** initiates the Service Mode screen. This Service Mode is for Biocytch use only. Technical Service may ask you to access this screen, during troubleshooting. To return to the Main Menu, press the **BACK** key.



4. Waste System: Pressing **WASTE SYSTEM LOGO** initiates the waste system maintenance mode. It is critical to remove the fixative bath vial, filter, slide, and sample vial, before continuing. After pressing the **ENTER** key to continue, three things occur:



Waste Bottle Vacuum vents to atmosphere. The waste bottle bleeds off, to allow the operator to remove the cap more easily off the waste bottle for emptying its contents.

Rotator plate in processor inverts. The rotating plate inverts, to allow the operator to clean the underside of the cap seal more easily.

Sample Vial Holder rises. The Sample Vial Holder rises, to allow the operator to more easily clean under the holder.

When the maintenance operation is complete, the operator must press the **ENTER** key, with the door closed, to return to the Main Menu.

5. Alarm Error History Screen.



The system will store the last 50 error messages that occurred on the processor. Technical Service may ask you to access this screen during troubleshooting.

Maintenance

SECTION 1

Introduction

This chapter describes routine maintenance procedures for the **PathTezt™** Processor. This chapter includes the following sections:

- SECTION 2: Emptying Waste Bottle
- SECTION 3: Filter Cap Cleaning
- SECTION 4: Filter Cap O-ring Lubrication
- SECTION 5: Filter Seal O-ring Replacement
- SECTION 6: Cap Seal Cleaning
- SECTION 7: General Cleaning
- SECTION 8: Waste Tubing Replacement
- SECTION 9: Waste Filter Replacement
- SECTION 10: Moving the Pathtezt™ Processor
- SECTION 11: Maintenance Schedule

Note: Any procedure not described in this section requires specially trained personnel. Contact BIOCYTECH Technical Service for more information.

Please Contact Biocytech Technical Services Team at:

Biocytech Corporation Sdn. Bhd. (854649-T)

820, Simpang Empat, Jalan Lahat,
31450 Menglembu,
Ipoh, Perak D.R. Malaysia.
Hotline: 0060125199098
Fax: 0062828891
Email: biocytech@gmail.com ; info@biocytech.com
www.biocytech.com
www.pathtezt.com

SECTION 2

EMPTYING WASTE BOTTLE

Check the waste bottle on a daily or message to show “WASTE BOTTLE FULL PLEASE CLEAN IT” to display and empty it before the fluid level reaches the “MAX” marking on the bottle.

Appear this warning message, every CYCLE time 150, 300, 450, 600, 750, 900, etc...

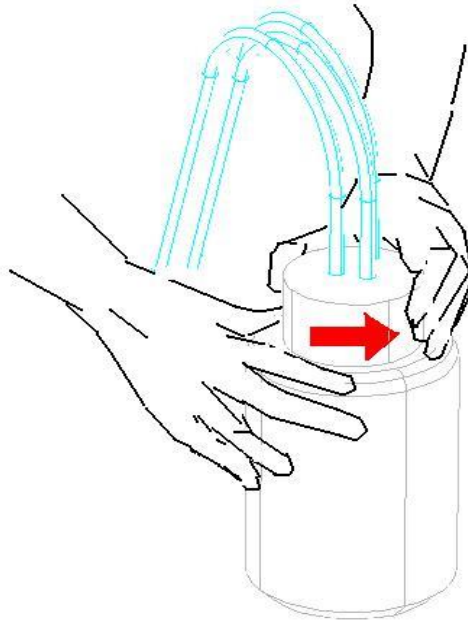


1. **Disable the waste system –**
 - From the Test Menu, press the “DIAGNOSTIC” button
 - Press “WASTE SYSTEM” button at Diagnostic Menu
 - Remove all the disposables from instrument and press “PROCEED”.
 - Wait for the system to vent the waste bottle, and press “ENTER” when finished”. Message.
2. **Cap removal –** Open the waste bottle cap by rotating the waste cap while holding the bottle in place to avoid tangling the waste tubing.

See the Figure

Do not remove the length of tubing connected to the inside of cap.

Figure Opening / Closing the Waste Solution



3. **Bleaching the waste bottle (OPTIONAL)** – The contents of the waste bottle (Solution) are categorized as hazardous waste; however, bleach may be used to decontaminate the waste if desired.

WARNING: Solution contains a concentration of ethanol and a pH which are anti-microbial and anti-viral in this formulation. Solution has been shown to cause greater than 99.999 percent inactivation within 15 minutes for the following microbes and viruses: *Candida albicans*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Mycobacteria tuberculosis*, rabbitpox, Human immunodeficiency virus.

WARNING: Extreme care must be taken if bleaching the waste bottle because equipment failures may result if incorrectly performed. The waste bottle should never contain bleach when it is connected to the **PathTezt™** Processor. Prior to waste disposal, and after disconnecting the waste bottle cap from the waste bottle, add the desired amount of bleach to the bottle. After disposal, rinse the bottle with water to remove any remnants of bleach and then attach the bleach-free bottle to the cap assembly.

4. **Transport cover** – An extra plain cap without tubing fittings is included with the **PathTezt™** Processor for transporting the waste bottle. Place this cover on the waste bottle when transporting to the disposal area.
5. **Waste disposal** – Disposal of waste according to guidelines for hazardous waste. Solution contains ethanol.
6. **O-ring seal** – Inspect the O-ring seal located on the inside of the waste cap assembly for any debris. If required, clean the seal with water using a lint-free wipe and apply a thin layer of lubricant grease to the O-ring from the tube included with the **PathTezt™** Processor.

7. **Cap replacement** – Replace the waste cap onto the bottle being careful not to pinch the tubing located on the inside of the waste cap assembly.
8. **Inspection** – Make sure the waste cap is firmly tightened. The waste cap must be tight for proper waste bottle operation.

Check that the waste tubing between the waste bottle assembly and the **PathTezt™** Processor is not pinched or twisted.

Check that the quick disconnect fittings located at the rear of the **PathTezt™** Processor are secure. See Chapter 2, *Installation and Specifications*, for details.

9. **Completion** – Press the ENTER key when this operation is complete. The system will be available for sample processing when the display returns to the Test Menu.

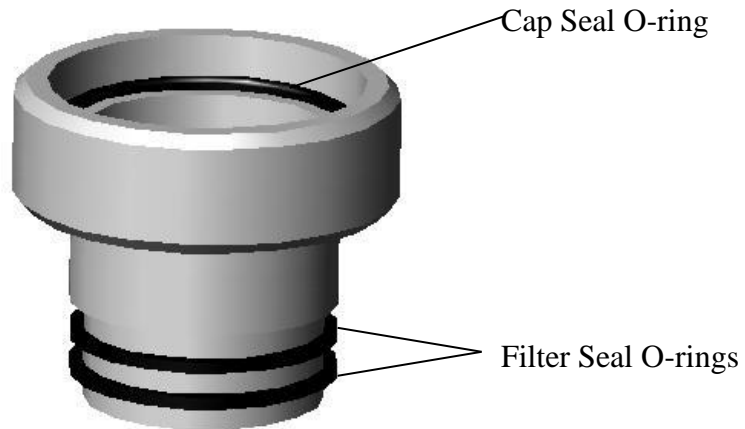
SECTION 3

FILTER CAP CLEANING

Clean the filter cap daily. It is important that the top surface of the filter cap and the cap seal O-ring are free of debris for proper operation of the system.

Wipe the entire filter cap with a lint-free wipe dampened with de-ionized or distilled water to remove deposits. Dry the filter cap after cleaning.

Figure Filter cap



SECTION 4

FILTER CAP O-RING LUBRICATION

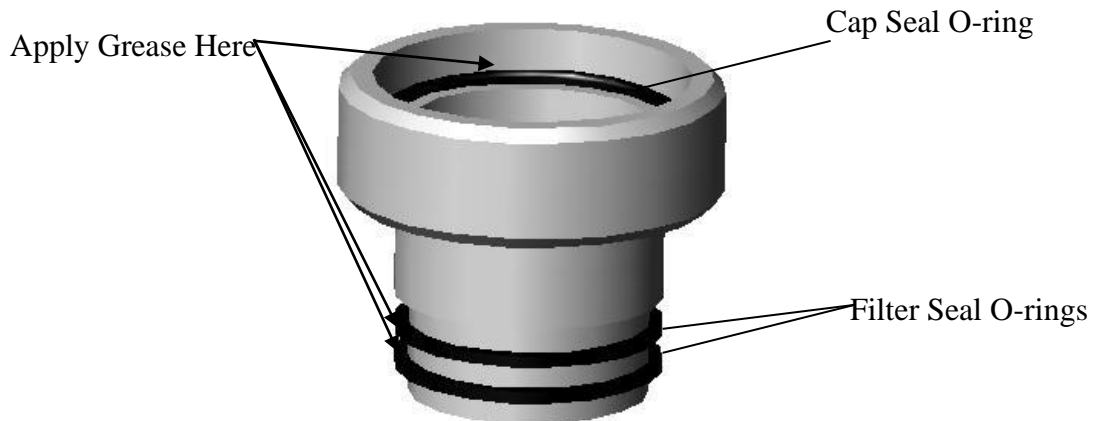
Inspect the filter seal O-rings located at the base of the filter cap for dryness. An indication of dryness us difficulty inserting a Filter onto the filter cap.

Inspect the cap seal O-ring located at the top of the filter cap for dryness. If the cap seal O-ring is damaged, replace the entire filter cap.

Perform the following procedure weekly on the cap seal O-ring and whenever any of the filter seal O-rings are dry.

1. Using the tube of high vacuum silicone grease included with the **PathTezt™** Processor, apply a small amount of grease to each of the three O-rings as shown in Figure.
2. Using a gloved finger, spread the grease until a thin layer of grease covers each of the O-rings. Remove any excess grease from the three O-rings with a lint-free wipe.

Figure *Filter cap O-ring lubrication*



SECTION 5

FILTER SEAL O-RING REPLACEMENT

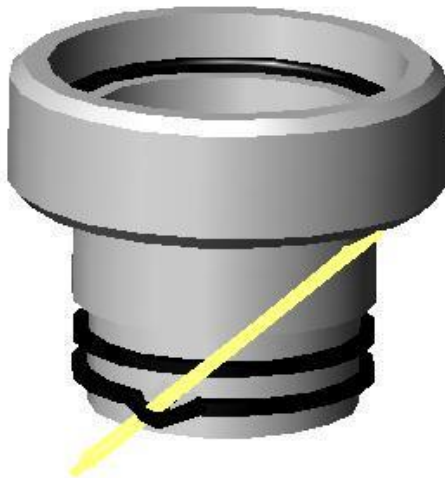
Inspect the filter seal O-rings located at the base of the filter cap for cracking or tearing. Perform the following procedure if the O-rings are cracked or torn.

If the cap seal O-ring is cracked or torn, replace the entire filter cap.

Do not attempt to remove the cap seal O-ring.

1. Using a plastic or wooden utensil (toothpick is ideal), lift filter seal O-ring out of groove then roll the O-ring off the edge of the filter cap base as in Figure.

Figure Filter seal O-ring replacement



2. Roll the new O-ring over the edge of the filter cap base until it is seated in the appropriate groove.

3. Make sure that the new filter seal O-ring is seated properly and not twisted. Lubricate the new filter seal O-ring as described in Section 4.

Note: Do not use the filter cap with only one filter seal O-ring installed. This may cause splashing during the dispersion phase and produce an insufficient seal for proper operation.

SECTION 6

CAP SEAL CLEANING

The cap seal is a stainless-steel part that covers the top of the filter cap during sample processing. The cap seal has two tubing connections on its top side. Debris can accumulate and dry on the underside of the cap seal; therefore, periodic cleaning is required.

To clean the underside of the cap seal, follow the instructions outlined below:

- From the Test Menu, press the “DIAGNOSTIC” button
- Press the “WASTE SYSTEM” button
- Remove all the disposables from the instrument and press “PROCEED”
- Wait for the system to complete its movements, and press “ENTER” when finish

This procedure inverts the rotating plate allowing a clear view of the underside of the cap seal.

Use a lint-free wipe dampened with de-ionized water to clean any dust, dried salts, etc. from the underside of the cap seal. Upon completion of the cleaning, press the ENTER key to return to the Diagnostic Menu.

This procedure should be performed daily.

SECTION 7

GENERAL CLEANING

Use a lint-free wipe, dampened with de-ionized water, to clean any dust from the filter cap bobbins, slide holder, and cabinet exterior. Turn off the power to the instrument before cleaning any areas except for the cap seal and below the sample holder.

Occasionally drops may fall off a filter as it rotates for evacuation. These drops accumulate and dry in an area below the sample holder. This area also requires periodic cleaning. To gain access to this area, execute the Waste System sequence as described in Section 7: CAP SEAL CLEANING.

In general, be sure to clean up spills when they occur. Use a lint-free wipe to absorb any spills and then wipe the area of the spill with a lint-free wipe dampened with de-ionized water.

SECTION 8

WASTE TUBING REPLACEMENT

The tubing located inside the waste control box must be replaced every six months. The waste control box is accessible through the access panel located on the left side of the **PathTezt™** Processor.

1. Disable the waste system –
 - From the Test Menu, press the “DIAGNOSTIC” button
 - Press the “WASTE SYSTEM” button
 - Remove all the disposables from the instrument and press “PROCEED”
 - Wait for the system to complete its movements, and press “START” when finish
2. Using the #1 tip (small) Phillips head screwdriver provided, loosen the 4 Phillips head screws that secure the access panel.
3. Remove the access panel and set it aside.

SECTION 9

MOVING THE PathTezt™ Processor

If it becomes necessary to change the location of your **PathTezt™** Processor, be sure to follow one of the two procedures described below.

Unit moved within building:

1. Turn off power.
2. Disconnect power cord from the electrical outlet and instrument.
3. Empty the waste bottle.
4. Disconnect waste bottle from the instrument at connector fittings.
5. With the help of another person, hold the instrument level and carefully place the **PathTezt™** Processor onto the flat surface of a cart. Roll the unit to its new location.
6. With the help of another person, lift the unit from the cart and place it onto its new surface.
7. Reconnect the power cord and waste bottle.
8. Run a blank (Solution vial with no cells). Refer to the instructions in Chapter 2, section 7.

Unit shipped to new location:

1. Turn off power.
 2. Disconnect power cord from the electrical outlet and instrument.
 3. Empty the waste bottle.
 4. Disconnect waste bottle from the instrument at connector fittings.
 5. Reattach internal securements.
-
1. With the help of another person, hold the instrument level and carefully place the **PathTezt™** Processor into its box. Place the instrument's accessories in the box. Seal the box and ship the unit.
 2. When the unit arrives at its destination, follow the instructions in Chapter 2, *Installation and Specifications*, for unpacking the instrument.
 3. Run a blank (Solution vial with no cells).

SECTION 10

MAINTENANCE SCHEDULE

Table 5-1 Maintenance Schedule

PROCEDURE	FREQUENCY
Waste Bottle Emptying	As needed
Filter Cap Cleaning	Daily
Pneumatic System Test (See Chapter 3)	Biocytech Technical use
Cap Seal O-ring lubrication	Weekly (or as needed)
Filter Seal O-ring lubrication	As needed
Filter Seal O-ring Replacement	As needed
Door Cleaning	As needed
Waste System Cleaning	Weekly use 95% ethanol or 2% Clorox solution.
Waste Tubing Replacement (In pinch valve)	Yearly
Silencer Filter Replacement	Yearly
Cap Seal Cleaning	Daily

Please Contact Biocytech Technical Services Team at:

Biocytech Corporation Sdn. Bhd. (854649-T)

820, Simpang Empat, Jalan Lahat,
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Email: biocytech@gmail.com ; info@biocytech.com
www.biocytech.com
www.pathtest.com

Fixation and Staining

SECTION 1

INTRODUCTION

There is wide variation among laboratories in fixation, staining and cover slipping methods employed for logic specimens. The thin-layer characteristics of **PathTezt™** Processor prepared slides allow precise assessment of the effects of these differences in protocols and allows the laboratory personnel to optimize their methods by following the general guidelines provided in this section. These guidelines are recommendations and should not be considered absolute requirements.

Following is a description of these **recommended guidelines** for fixation procedures, staining protocols and cover slipping methods.

SECTION 2

FIXATION

The **PathTezt™** Processor deposits completed slides into a fixative bath vial that contains standard laboratory fixative alcohol. Use the following procedure to fix slide preparations.

1. Remove each slide after it is deposited into the fixative bath vial in the **PathTezt™** Processor.
2. Place the slide into a separate multi-slide holder containing standard laboratory 95% fixative alcohol. To minimize exposure of slides to air:
When transferring slides from the fixative bath vial to the multi-slide fixative container, care should be taken to perform this operation quickly.
If slides are being transferred to a staining rack, care should be taken that slides are continuously immersed in fixative.
3. Sides should be fixed for at least 10 minutes prior to staining.
4. If the slide will be stored dry and unstained, spray the slide with a spray fixative upon removal from the fixative bath vial. Follow spray fixative manufacturer's recommended procedure for spray fixation.

SECTION 3

STAINING

General guidelines to consider when staining **PathTezt™** slides are:

Staining times may be different and may require adjustment for **PathTezt™** slides compared to conventional preparations.

The use of graded concentrations of alcohol in the staining process will minimize cell distortion and possible cell shedding.

The use of mild bluing solutions and dilute acid baths will optimize nuclear staining and minimize possible cell shedding.

STAINING PROTOCOL:

A recommended staining protocol for **PathTezt™** slides is attached. This protocol incorporates the general staining guidelines stated above and the following specific recommendations:

1. If slides have been sprayed fixed, remove the spray fixative by soaking in a standard laboratory fixative for at least 10 minutes.
2. Stain the slides with standard modified Papanicolaou stains according to the manufacturer's routine procedures adjusting to the general guidelines for slide staining stated above.
3. Standard staining times for slides may be different from conventional slides, and it may be necessary to increase or decrease these times. It is recommended that staining times be optimized following laboratory standard operating procedures. These differences may necessitate staining **PathTezt™** slides and conventional slides separately.
4. BIOCYTECH recommends minimizing exposure of slides to strong acidic or strong basic solutions since this may result in possible cell shedding. Below are recommended maximum concentrations of some solutions:
 - Hydrochloric acid (HCL) 0.025%
 - Lithium Carbonate 10mg per liter
 - Acetic acid 0.1%
 - Ammonium Hydroxide 0.1%
5. During the hydration dehydration process, use graded concentration e.g., 50%, 70% of alcohol. This lowers the potential of osmotic shock and possible cell shedding during staining.

6. Bath solution heights should be sufficient to completely cover the slides.
7. Slides should be agitated for at least 10 dips in each bath.

BIOCYTECH Corporation Staining Protocol

	Solution	Time
1.	70% Reagent Alcohol	1 minute with agitation
2.	50% Reagent Alcohol	1 minute with agitation
3.	Distilled H ₂ O (dH ₂ O)	1 minute with agitation
4.	Richard-Allan Hematoxylin I	30 seconds with agitation *
5.	Distilled H ₂ O (dH ₂ O)	15 seconds with agitation
6.	Distilled H ₂ O (dH ₂ O)	15 seconds with agitation
7.	Clarifier (0.025% glacial acetic acid)	30 seconds with agitation
8.	Distilled H ₂ O (dH ₂ O)	30 seconds with agitation
9.	Bluing Reagent (10mg LiCarb / 1L)	30 seconds with agitation
10.	50% Reagent Alcohol	30 seconds with agitation
11.	95% Reagent Alcohol	30 seconds with agitation
12.	Richard-Allan Cytology Stain	1 minute with agitation
13.	95% Reagent Alcohol	30 seconds with agitation
14.	95% Reagent Alcohol	30 seconds with agitation
15.	100% Reagent Alcohol	30 seconds with agitation
16.	100% Reagent Alcohol	30 seconds with agitation
17.	100% Reagent Alcohol	30 seconds with agitation
18.	Xylene	1 minute with agitation
19.	Xylene	1 minute with agitation
20.	Xylene	3 minutes with agitation
21.	Mount in Permout	

Stains may be ordered from Richard-Allan Medical Industries, inc. · 8850, M89, Box 351, Richard, MI · 49083-0351 · 1-800-253-7900. Hematoxylin I (7221), Richard-Allan Cytology Stain (7511). Permout is a trademark of Fisher Scientific Corp.

* Time may vary with stain lot or age. *

SECTION 4

COVERSLIPPING

The use of Permount mounting media has been evaluated and is recommended for use with slides by BIOCYTECH. Since some mounting media cause ‘floating’ of cells to occur on **PathTezt™** or conventional slides, each laboratory should evaluate their choice of mounting media to insure compatibility with **PathTezt™** slides. BIOCYTECH recommends the use of 24mm X 30mm coverslips.

Other approved mounting media

- Baxter ACCU-MOUNT 60
- Shandon Clearium

Safety Data Sheet

Biocytech Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

1) **Substance Identification**

Material/Trade Name : PathTezt™ Preserve Cell Solution
Material type : Buffer preservative solution
Specific use : A methanol based, buffer preservative solution used to support cells during transport and slide preparation

Company : Biocytech Corporation Sdn Bhd
Address : 820, Simpang Empat,
Jalan Lahat,
31450 Menglembu Ipoh, Perak, Malaysia.

Telephone : (006) 012 519 9098

Fax : (006) 05 282 8891

Emergency Telephone : (006) 012 507 0899

2) **Hazards Identification**

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity – Oral (Category 3)

Acute toxicity – Dermal (Category 3)

Acute toxicity – Inhalation Vapors (Category 3)

Specific target organ toxicity – Single exposure (Category 1)

Physical hazards – Flammable liquids (Category 3)

Emergency Overview

Label Elements



Signal word – Danger

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

Hazard Statements

H301 – Toxic if swallowed

H311 – Toxic in contact with skin

H331 – Toxic if inhaled

H370 – Causes damage to organs

H226 – Flammable liquid and vapor

Precautionary Statements – Prevention

P210 – Keep away from heat/sparks/open flames/hot surfaces – No smoking

P280 – Wear protective gloves/protective clothing/eye protection/face protection

P260 – Do not breathe dust/fume/gas/mist/vapors/spray

P270 – Do not eat, drink or smoke when using this product

P264 – Wash face, hands and any exposed skin thoroughly after handling

P233 – Keep container tightly closed

Precautionary Statements – Response

P307 + P311 – IF exposed: Call a POISON CENTER or doctor/physician

P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P303 + P361 + P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

P363 – Wash contaminated clothing before reuse

P304 + P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P311 – Call a POISON CENTER or doctor/physician

P301 + P310 – IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

P330 – Rinse mouth

Fire

In case of fire: Use CO2, dry chemical or foam for extinction

Precautionary Statements – Storage

P405 – Store locked up

P403 + P233 – Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements – Disposal

P501 – Dispose of contents/container in accordance with local/regional/national/international regulation.

Hazards not otherwise classified (HNOC)

Other Information

50% of the mixture consists of ingredient(s) of unknown toxicity

3) **Composition**

Substance	%Wt.	CAS No.
Methanol	30-60	67-56-1
Water	40-70	7732-18-5

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

4) First-aid Measures

General advice – Immediate medical attention is required. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Inhalation	:	Remove to fresh air and rest If recovery is not rapid call for prompt medical attention Show this safety data sheet to medical personnel
Eyes	:	Irrigate with water for at least 15 minutes Take care not to wash chemical from one eye to another Get prompt medical attention
Skin	:	Remove contaminated clothing Wash with soap/cleanser and rinse with plenty of water If irritation persists, obtain medical attention
Ingestion	:	Do not induce vomiting Give plenty of water to drink Beware of aspiration if vomiting occurs Seek medical attention immediately
Self-protection of the first aider	:	Remove all sources of ignition.
Symptoms	:	Treat symptomatically.

Indication of any immediate medical attention and special treatment needed

Note to physicians : Treat symptomatically.

5) Fire-fighting Measures

Flammability	:	Flammable liquid and vapor.
Suitable Extinguishing Media	:	Dry chemical, Foam, Carbon dioxide (CO ₂)
Unsuitable Extinguishing Media	:	Do not use a solid water stream as it may scatter and spread fire.
Special hazards arising from	:	Most vapors are heavier than air. They will spread along ground and collect in low the chemical or confined areas (sewers, basements, tanks). Vapors may form explosive mixtures with air. Flammable.
Protective equipment and	:	As in any fire, wear self-contained breathing apparatus pressure-demand, Precautions for firefighters MSHA/NIOSH (approved or equivalent) and full protective gear.

Safety Data Sheet

Biocytech Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

6) Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal precautions : Remove all sources of ignition. Evacuate personnel to safe areas. Ensure adequate ventilation, especially in confined areas. Use personal protective equipment as required.
- Environmental precautions : Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system.

Methods and material for containment and cleaning up

- Methods for containment : Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
- Methods for cleaning up : Dam up. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Pick up and transfer to properly labeled containers. Soak up with inert absorbent material.

7) Handling and Storage

- Precautions for safe handling : Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep container tightly closed. Ensure adequate ventilation, especially in confined areas.
- Advice on safe handling : Ensure adequate ventilation, especially in confined areas. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Take precautionary measures against static discharges. Use spark-proof tools and explosion-proof equipment. All equipment used when handling the product must be grounded.

Conditions for safe storage, including any incompatibilities

- Storage : Store in accordance with local regulations. Use appropriate containment to avoid environmental contamination.
- Storage Conditions : Keep tightly closed in a dry and cool place. Keep in properly labeled containers. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity).
- Incompatible materials : Strong oxidizing agents. Acids. Metals.

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

8) Exposure Controls / Personal Protection

Occupational Exposure Limit : 266mg/m³ 8hrTWA 333mg/m³ 15minSTEL OES
Methanol (Sk) 1920mg/m³ 8hrTWA OES ethanol

Appropriate engineering controls

Engineering Controls : Provide adequate ventilation. Showers. Eyewash stations.

Individual protection measures, such as personal protective equipment

Wear polythene, nitrile or rubber gloves
Wear suitable overalls or apron and change if contaminated
Wear suitable eye protection such as BS EN 166 Grade 3
Use in well ventilated areas
Use mechanical ventilation if possible
If excessive inhalation in a poorly ventilated area is likely then use a respirator with filter type A
After contact with skin wash off immediately

General Hygiene Considerations : Regular cleaning of equipment, work area and clothing is recommended. When using do not eat, drink or smoke.

Other Information

Environmental exposure controls : No information available

9) Physical & Chemical Properties

Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear, colorless, liquid
Odor : Alcohol
Odor threshold : No information available
pH : 5.8-6.3
Boiling point/range : 71°C / 159°F
Melting point/range : -48°C / -54°F
Flash point : 35°C / 95°F (Closed Cup)
Evaporation rate : No information available
Flammability (solid,gas) : No information available
Upper flammability limits : 36%
Lower flammability limits : 6.7%
Vapor pressure : No information available
Vapor density : No information available
Relative density : No information available
Water solubility : Miscible in water
Solubility(ies) : No information available
Partition coefficient : No information available
Autoignition temperature : 385
Decomposition temperature : No information available
Viscosity : No information available
Explosive properties : No information available

Safety Data Sheet

Biocytech Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

Oxidising properties	:	No information available
Percent Volatile	:	> 99%

10) Stability and Reactivity

Reactivity	None under normal use conditions.
Stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal use conditions.
Hazardous polymerization	None under normal use conditions.
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	Strong oxidizing agents. Acids. Metals.
Hazardous Decomposition Products	None under normal use conditions.
Material to avoid	Strong oxidizing agents. Acids. Metals.

11) Toxicological Information

Information on likely routes of exposure

Product information	Repeated or prolonged exposure may cause central nervous system damage. May be harmful by inhalation, ingestion, or skin absorption.
Inhalation	Harmful by inhalation.
Eye contact	May cause irritation.
Skin contact	Harmful in contact with skin.
Ingestion	Harmful if swallowed.

Information on toxicological effects

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT – single exposure	No information available.
STOT – repeated exposure	No information available.
Target Organ Effects	Central nervous system, Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.
Aspiration hazard	No information available.

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

Numerical measures of toxicity – Product Information

Unknown Acute Toxicity 50.133% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

12) Ecological Information

Ecotoxicity 20 – 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

Persistence and degradability No information available.

Bioaccumulation No information available.

Mobility No information available.

<u>Component Name</u>	<u>Partition Coefficient</u>
Methanol (67-56-1)	-0.77

Other adverse effects No information available.

13) Disposal Considerations

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Waste from Residues / Unused Disposal should be in accordance with applicable regional, national and local laws Products and regulations.

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number D001 U154

Component name	RCRA	RCRA-Basis for listing	RURA – D Series Wastes	RCRA – U Series Wastes
Methanol 67-56-1		Included in waste stream: F039		U154

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

14) Transport Information:

DOT (Department of Transportation)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III
Emergency Response Guide No. : 128

TDG (Transportation of Dangerous Goods)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III

IATA (International Air Transport Association)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
ERG Code : 3L
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III

IMDG (International Maritime Dangerous Goods)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
EmS-No : F-E , S-E
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : PCS 200920

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Preserve Cell Solution (Methanol Based)

15) Regulatory Information

International Inventories

Component Name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Methanol 67-56-1	Present	X	X	X
EDTA Disodium Salt 6381-92-6	-	-	X	X
Glacial Acetic Acid 758-12-3	-	X	-	-

Component Name	ENCS	IECSC	AICS	KECL
Methanol 67-56-1	Present	X	X	Present
EDTA Disodium Salt 6381-92-6	-	X	X	-

Legend

X – Present

-Not Listed

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS – European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDSL – Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

16) Other Information

Not Applicable

Safety Data Sheet

Biocytech Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

1) Substance Identification

Material/Trade Name : PathTezt™ CytoLysis Solution

Recommended use of the chemical and restrictions on use

Specific use(s) : A methanol based, buffer preservative solution used to support cells during transport

Recommended use : In vitro diagnostic

Details of the supplier of the safety data sheet

Manufacturer : Biocytech Corporation Sdn Bhd
Address : 820, Simpang Empat,
Jalan Lahat,
31450 Menglembu Ipoh, Perak, Malaysia.
Telephone : (006) 012 519 9098
Fax : (006) 05 282 8891
Emergency Telephone : (006) 012 507 0899

2) Hazards Identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity – Oral (Category 4)

Acute toxicity – Dermal (Category 4)

Acute toxicity – Inhalation – Dusts/Mists (Category 4)

Specific target organ toxicity – Single exposure (Category 1)

Flammable liquids (Category 3)

Emergency Overview

Label Elements



Signal word – Danger

Safety Data Sheet

Biocytech Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

Hazard Statements

H302 – Harmful if swallowed

H312 – Harmful in contact with skin

H332 – Harmful if inhaled

H370 – Causes damage to organs

H225 – Highly flammable liquid and vapor

Precautionary Statements – Prevention

P210 – Keep away from heat/sparks/open flames/hot surfaces – No smoking

P280 – Wear protective gloves/protective clothing/eye protection/face protection

P260 – Do not breathe dust/fume/gas/mist/vapors/spray

P270 – Do not eat, drink or smoke when using this product

P264 – Wash face, hands and any exposed skin thoroughly after handling

P243 – Take precautionary measures against static discharge

P403 + P233 – Store in a well-ventilated place. Keep container tightly closed.

Precautionary Statements – Response

P307 + P311 – IF exposed : Call a POISON CENTER or doctor/physician

P303 + P 361 + P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing.

Rinse skin with water/shower

P363 – Wash contaminated clothing before reuse

P304 + P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P301 + P312 – IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P330 – Rinse mouth

Fire

In case of fire: Use CO₂, dry chemical or foam for extinction

Precautionary Statements – Storage

P403 + P233 – Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements – Disposal

Dispose of contents/container to an approval waste disposal plant.

Hazards not otherwise classified (HNOC)

Not Applicable

Other Information

Not Applicable

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

3) Composition / information on ingredients

Substances

Not Applicable

Mixtures

Mixtures

OSHA Hazard Classification

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Component name	CAS No	%
Methanol	67-56-1	20-40

4) First-aid Measures

General advice

Immediate medical attention is required. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Inhalation	:	Remove to fresh air and rest If recovery is not rapid call for prompt medical attention Show this safety data sheet to medical personnel
Eyes	:	Irrigate with water for at least 15 minutes Take care not to wash chemical from one eye to another Get prompt medical attention
Skin	:	Remove contaminated clothing Wash with soap/cleanser and rinse with plenty of water If irritation persists, obtain medical attention
Ingestion	:	Do not induce vomiting Give plenty of water to drink Beware of aspiration if vomiting occurs Seek medical attention immediately
Self-protection of the first aider	:	Remove all sources of ignition.

Indication of any immediate medical attention and special treatment needed

Note to physicians	:	Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed. Keep victim warm and quiet. Treat for CNS depression and possible renal failure. Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Ethanol and fomepizole are effective antidotes for methanol poisoning, although fomepizole is preferred.
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Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

5) Fire-fighting Measures

- Flammability : Flammable liquid and vapor.
- Suitable Extinguishing Media : Dry chemical, CO₂, water spray or alcohol-resistant foam. Water spray, fog or alcohol-resistant foam. Move containers from fire area if you can do it without risk. Dike fire control water for later disposal; do not scatter the material. Use water spray or fog; do not use straight streams.
- Unsuitable Extinguishing Media : CAUTION: All these products have a very low flash point. Use of water spray when fighting fire may be inefficient.
- Special hazards arising from : Vapors may form explosive mixtures with air. Vapors may travel to source of ignition and flash back. Most vapors are heavier than air. They will spread along ground and collect in low the chemical or confined areas (sewers, basements, tanks). Vapor explosion hazard indoors, outdoors or in sewers. Those substances designated with a "P" may polymerize explosively when heated or involved in a fire. Runoff to sewer may create fire or explosion hazard. Flammable.
- Protective equipment and : As in any fire, wear self-contained breathing apparatus pressure-demand, Precautions for firefighters MSHA/NIOSH (approved or equivalent) and full protective gear.

6) Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal precautions : Remove all sources of ignition. Evacuate personnel to safe areas. Ensure adequate ventilation, especially in confined areas. Use personal protective equipment as required.
- Other Information : Water spray may reduce vapor; but may not prevent ignition in closed spaces.

- Environmental precautions : Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system.

Methods and material for containment and cleaning up

- Methods for containment : Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
- Methods for cleaning up : Dam up. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Pick up and transfer to properly labeled containers. Soak up with inert absorbent material.

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

7) Handling and Storage

Precautions for safe handling : Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep container tightly closed. Ensure adequate ventilation, especially in confined areas.

Advice on safe handling : Ensure adequate ventilation, especially in confined areas. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Take precautionary measures against static discharges. Use spark-proof tools and explosion-proof equipment. All equipment used when handling the product must be grounded.

Conditions for safe storage, including any incompatibilities

Storage : Store in accordance with local regulations. Use appropriate containment to avoid environmental contamination.

Storage Conditions : Keep tightly closed in a dry and cool place. Keep in properly labeled containers. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity).

Incompatible materials : Strong oxidizing agents. Acids. Aluminum.

8) Exposure Controls / Personal Protection

Occupational Exposure Limit : 266mg/m³ 8hrTWA 333mg/m³ 15minSTEL OES
Methanol (Sk) 1920mg/m³ 8hrTWA OES ethanol

Other Information : Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F. 2d 962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Controls : Provide adequate ventilation. Showers. Eyewash stations.

Individual protection measures, such as personal protective equipment

Wear polythene, nitrile or rubber gloves
Wear suitable overalls or apron and change if contaminated
Wear suitable eye protection such as BS EN 166 Grade 3
Use in well ventilated areas
Use mechanical ventilation if possible
If excessive inhalation in a poorly ventilated area is likely then use a respirator with filter type A
After contact with skin wash off immediately

Safety Data Sheet

Biocytech Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

General Hygiene Considerations : Regular cleaning of equipment, work area and clothing is recommended. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse. Handle in accordance with good industrial hygiene and safety practice.

Other Information

Environmental exposure controls : No information available

9) Physical & Chemical Properties

Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear, colorless, liquid
Odor : Alcohol-like
Odor threshold : No information available

Property

Values

pH : 7
Boiling point/range : 71°C / 159°F
Melting point/range : -48°C / -54°F
Flash point : 35°C / 95°F (Closed Cup)
Evaporation rate : No information available
Flammability (solid,gas) : No information available
Upper flammability limits : 36%
Lower flammability limits : 6.7%
Vapor pressure : No information available
Vapor density : No information available
Relative density : No information available
Water solubility : Miscible in water
Solubility(ies) : No information available

Partition coefficient : No information available
Autoignition temperature : 385°C / 725°F
Decomposition temperature : No information available
Viscosity : No information available
Explosive properties : No information available
Oxidising properties : No information available
Percent Volatile : > 99%

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

10) Stability and Reactivity

Reactivity	None under normal use conditions.
Stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal use conditions.
Hazardous polymerization	None under normal use conditions.
Conditions to avoid	Heat, flames and sparks. Avoid temperatures exceeding the flash point. Incompatible materials.
Incompatible materials	Strong oxidizing agents. Acids. Aluminum.
Hazardous Decomposition Products	None under normal use conditions.
Material to avoid	None under normal use conditions.

11) Toxicological Information Information on likely routes of exposure

Product information	May be harmful by inhalation, ingestion, or skin absorption.
Inhalation	None under normal use conditions.
Eye contact	Risk of serious damage to eyes.
Skin contact	None under normal use conditions.
Ingestion	None under normal use conditions.

Information on toxicological effects

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Irritation	May cause skin and eye irritation.
Sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT – single exposure	No information available.
STOT – repeated exposure	No information available.
Target Organ Effects	Central nervous system, Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.
Aspiration hazard	No information available.

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

Numerical measures of toxicity – Product Information

The following values are calculated based on chapter 3.1 of the GHS document. mg/kg mg/l

12) Ecological Information

Ecotoxicity 20 – 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

Component name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Chloride 7647-14-5		12946: 96h Lepomis macrochirus mg/L LC50 static		1000: 48h Daphnia magna mg/L EC50 340.7 – 469.2: 48h Daphnia magna mg/L EC50 Static
Potassium Chloride 7447-40-7	2500: 72h Desmodesmus subspicatus mg/L EC50	1060: 96h Lepomis macrochirus mg/L LC50 static		825: 48h Daphnia magna mg/L EC50 83: 48h Daphnia magna mg/L EC50 Static

Persistence and degradability No information available.

Bioaccumulation No information available.

Mobility No information available.

Component name	Partition coefficient
Methanol 67-56-1	-0.77

Other adverse effects No information available.

13) Disposal Considerations

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Waste from Residues / Unused Products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number D001 U154

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

Component name	RCRA	RCRA-Basis for listing	RURA – D Series Wastes	RCRA – U Series Wastes
Methanol 67-56-1		Included in waste stream: F039		U154

14) Transport Information:

DOT (Department of Transportation)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III
Emergency Response Guide No. : 128

TDG (Transportation of Dangerous Goods)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III

IATA (International Air Transport Association)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
ERG Code : 3L
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III

IMDG (International Maritime Dangerous Goods)

UN/ID No. : UN1992
Proper Shipping Name : Flammable liquids, Toxic, n.o.s
Hazard Class : 3
Packing Group : III
EmS-No : F-E , S-E
Description : UN1992 Flammable liquids, Toxic, n.o.s (Methanol), 3, III

Safety Data Sheet

Biocytch Corporation Sdn Bhd

Part Number : CTLS-9004

Revision Date : 01.01.2022

Revision No. : 5

Material/Trade Name : PATHTEZT™ Cytolysis Solution (Methanol Based)

15) Regulatory Information

International Inventories

Component Name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Methanol 67-56-1	Present	X	X	X
EDTA Disodium Salt 6381-92-6	-	-	X	X
Glacial Acetic Acid 758-12-3	-	X	-	-

Component Name	ENCS	IECSC	AICS	KECL
Methanol 67-56-1	Present	X	X	Present
EDTA Disodium Salt 6381-92-6	-	X	X	-

Legend

X – Present

-Not Listed

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS – European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDSL – Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

16) Other Information

Not Applicable