PATHTEZT® INFINITY WITH AUTOLOADER

User's Manual

Version 2.0 (Original)

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Section 1: System Overview

Overview and function

The PathTezt® Infinity system is divided into two components:

1. PathTezt® Infinity processor
2. Autoloader

The PathTezt® Infinity processor is used to process liquid-based cytologic specimens to produce a thin, uniform preparation of cells that is transferred and fixed onto a microscope slide. The slide is delivered directly into a staining rack in an alcohol fixative bath. After processing, the slide is ready for staining, cover slipping and screening. The processor supports the preparation of gynecologic specimens and non-gynecologic specimens.

The Autoloader is a carousel conveyor system that consists of moving shelving unit and conveyor belt that transport loaded specimen vial to the processor.

The Autoloader accommodates up to 120 samples per loading and it allows continuous loading during the processing. Each batch may contain only gynecologic or non-gynecologic specimen.

Intended Use

The PathTezt® Infinity processor is intended as a replacement for the conventional method of Pap smear preparation for use in screening for the presence of atypical cells, cervical cancer, or its precursor lesions, as well as other cytologic categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses.

Principle

The filtration technology is adopted and during the slide preparation process, the specimen vial is rotated, creating currents in the fluid that are strong enough to separate the debris and disperse mucus with no adverse effect on cell appearance (step 1). Next, a gentle vacuum is created within the PathTezt® filter, which collects cells onto the exterior surface of the membrane. Cell collection is controlled by the PathTezt® Infinity processor's software (step 2). After the cells are collected onto the membrane, the PathTezt® filter is inverted and gently pressed against the PathTezt® Cyto-slide. Natural attraction and slight positive air pressure will promote the cells to adhere to the PathTezt® Cyto-slide creating an even distribution of cells in a defined 20mm circular area (step 3). The prepared slide is automatically delivered to a staining rack immersed in an alcohol fixative bath.

Limitations

- Gynecologic specimens collected for preparations using the PathTezt® Infinity processor should be collected using a broom-type cervical collection device or endocervical brush/plastic spatula combination collection device.
- Preparation of microscopic slides using the PathTezt® Infinity processor should be performed only by personnel who have been trained by Biocytech or by organizations or individuals designated by Biocytech.
- Evaluation of microscopic slides using the PathTezt® Infinity processor should be performed only by cytotechnologists and pathologists who have been trained to evaluate PathTezt®-prepared slide by Biocytech or by organizations or individuals designated by Biocytech.
- Supplies used in the PathTezt® Infinity system are those designed and supplied by Biocytech specifically for the PathTezt® Infinity processor with Autoloader. These include Preserved Cell Solution, Gyn Filters, Non-Gyn Filters, Urine Cell 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.

Warnings

- For In Vitro diagnostic use.
- Preserve Cell Solution contains Methanol. Refer to Material Safety Data Sheet (MSDS) for safety and handling instructions.
- Wear protective laboratory gear.
- Flammable liquid and vapor. Keep away from heat, sparks, open flames, and hot surfaces. Evaporating alcohol could create a fire hazard.
- Other solutions cannot be substituted for Preserve Cell Solution.
- Solution should be stored and disposed of in accordance with local, state, and federal regulations.

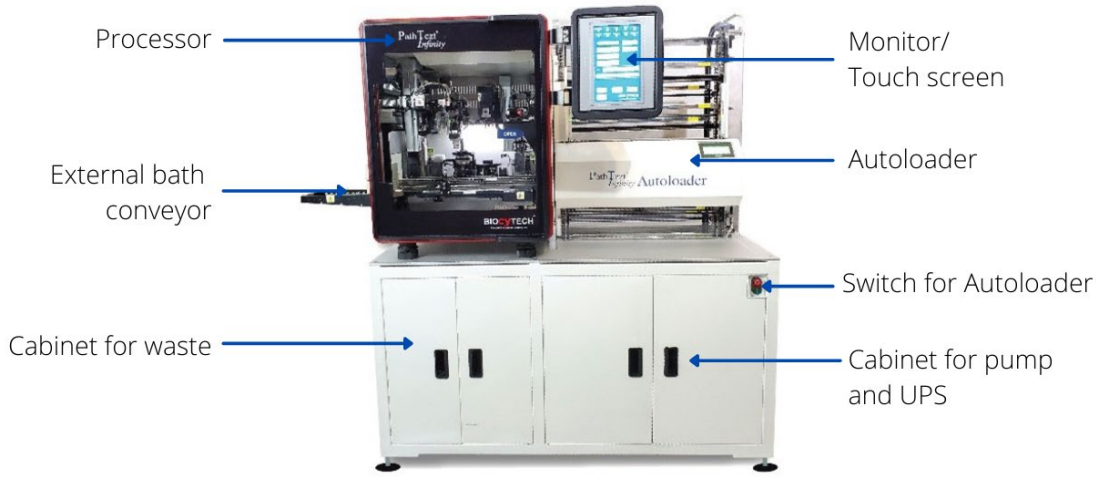
System Components Overview

System components

The components of the instrument system are discussed as follows:

- Outside view of instrument
- Inside processor view
- Ancillary items

Instrument Outside View

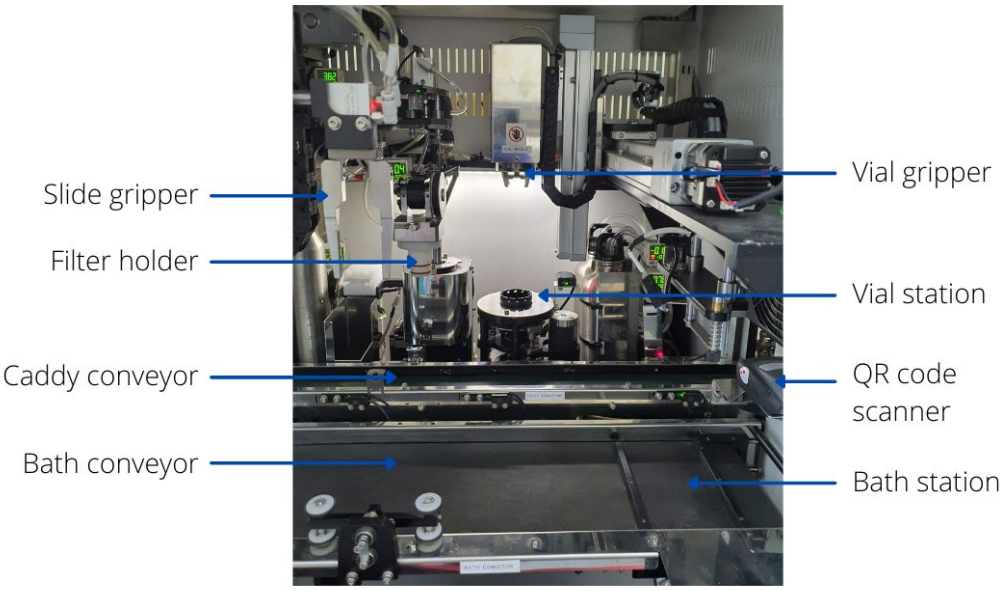


Item	Description
Monitor screen/touch screen	Color, touch screen monitor for selecting the programs and performing maintenance. The monitor can be adjusted by grasping right side of the monitor and push or pull to desired position in 180° rotation.
Processor	The slide preparation takes place inside the processor. The robotic arms and pumps are located inside here.
External bath conveyor	Alcohol baths filled with slides are pushed towards the end of the bath conveyor which is located outside of the processer. These slides are ready for staining.
Autoloader	Located on the right side of the instrument. This is a carousel system transports the caddy filled with specimen vial, microscope slide and filter to the processor.
Switch for Autoloader	Power switch for the Autoloader. Located on the right-side corner of the cabinet. When is turned on, homing and startup take about 2 minutes to complete. Press “OK” to go to the main screen which is in green color.

Item	Description	
Main power switch for processor		Located on the top left towards the rear of the instrument. When the instrument is turned on, initialization and startup take about 2 minutes to complete.

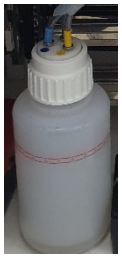
Cabinet for waste		Used filter and processed specimen are discarded into the waste bins located inside the cabinet.
Cabinet for pump and UPS/battery backup		One pump and one UPS/ battery backup are located inside the cabinet.
USB port		One USB port is located behind the monitor. This allows the user to perform data download functions with a memory stick.

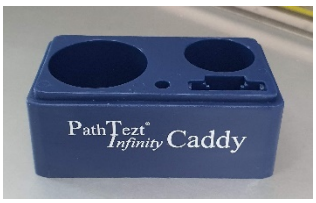
Inside PathTezt® Infinity Processor View



Item	Description
Slide gripper	Dedicated to pick up the microscopic slide and gently press onto the filter
Filter holder	Pick up a filter and transfer it into the specimen vial. The used filter will be ejected into the waste bin after completion of specimen processing.
Vial gripper	The arm located at the center is used to pick up the specimen vial and position it at the vial station. It does the de-capping and capping automatically.
Caddy conveyor	Transport filled caddy from autoloader to the processor.
Bath conveyor	Transport alcohol bath from the alcohol bath station to the end of the conveyor located outside of the processor.
Bath station	Alcohol bath container is placed at this location. Processed slide is immersed into the bath filled with alcohol prior to staining.
Vial station	Dedicated area for the placement of the specimen vial. It spins the vial to homogenize the specimen prior to de-capping by the vial gripper.
QR code scanner	Scans QR code on the specimen vial and microscopic slide to establish chain of custody.

Ancillary Items

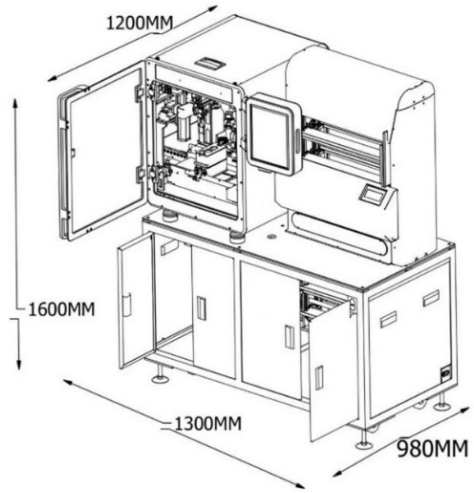
Item	Description	
Liquid waste bottle	 	Contains liquid waste. Connects to the instrument via tubing that connects to the liquid waste trough the back of the instrument. The tubing connected to top of the bottle.
UPS/ battery backup		Provides backup power when regular power source fails
Staining rack		The rack holds 30 microscopic slides. Total of 120 slides per batch.
Alcohol bath		Fill the container with alcohol prior to start of run. Remove the bath at the end of the bath conveyor once the cycle is complete. Total of 4 baths are provided.

Caddy		Holder for microsopic slide, filter and specimen vial. The filled caddy is loaded into the autoloader waiting to be transferred to the processor via the caddy conveyor.

Materials Provided
• PathTezt® Infinity Processor • Autoloader • PathTezt® Infinity user's manual • Empty baths • Waste bottle assembly – includes bottle, bottle cap, tubing set, fittings, waste filter • Power cord • UPS/ battery backup • Cabinet with wheels • Caddy • Staining racks

Materials required but not provided
• Slide staining system and reagents • Standard laboratory fixative • Coverslips and mounting media • PathTezt® Cyto-slide • 20 mL PathTezt® Preserve Cell Solution • PathTezt® filter • Cervical collection device

Technical Specification



	PathTezt® Infinity Processor with Autoloader	**Waste Bottle**
Dimensions	W = 1300 mm H = 1600 mm D = 650 mm	W = 6” / 15 cm H = 17” / 43 cm
Weight	220kg (approx.)	
Clearance	W = 1300 mm H = 1600 mm D = 1200 mm	
Operating temperature	16 - 32°C 60 - 90°F	
Operating humidity	20% - 80% RH Non-condensing	
Electrical voltage	100/130 VAC at 2amps	200/240 VAC at 1A
Frequency	47 – 63 Hz	
Power	Max 240 watts	

Technical Specification (continue)

Autoloader System: Vertical carousel with horizontal deck.

Carousel deck loading capacity: 6 samples per deck, total 20 deck.

Total samples per batch: 120 samples, continuous loading.

Processing time per sample: 2 to 2.5 minutes per sample.

Processing time per batch: 4 - 5 hours per batch of 120 samples.

Processing Method: Thin Layer Pap Preparation by Filtration Technology

Cells Detection & Smearing: Pneumatic Pressure Control Sensor Technology

Advance Mode Technology: Sample Processing with Cervical Brush Head in Vial

Gyn Filter: 20mm diameter for cells collection

Cyto-Slide: Special Nano-coated with Hydrophilic Positive Charged Formulation.

Section 2: Reagents and Supplies

The Reagents and Supplies information is presented in the following tables:

- Gynae Sample Collection
- Gynae Consumables
- Non-Gynae Consumables

Gynae Sample Collection

Item	Description	
PathTezt® Preserve Cell Solution (20ml) Storage and Handling Requirements • 15°C to 30°C Packaging Part no: PCS200920 Quantity: 2000/box		• 20ml in a vial • Methanol based preservative fluid • Pink cap • Designed to preserve cells during transport • Store up to 2 years from date manufacture at 15° to 30°C.
Cervical Broom Storage and Handling Requirements • 15°C to 30°C. Packaging Part no: CB10100 Quantity: 500/box		• Blue plastic shaft • Brush head • Transparent remover tube enables detachment of the brush-head from the handle

Gynae Consumables

Item	Description	
PathTezt® Cyto-slide Storage and Handling Requirements • 15°C to 30°C. Packaging Part no: FST36100 Quantity: NA		• Precoated slide • 20mm circle area
PathTezt® filter Storage and Handling Requirements • Ambient environment and out of direct sunlight. • Store the filters in their trays with the cover on until ready for use. Packaging Part no: GF0825100 Quantity: NA		• Pink in color • Single use only and cannot be reused
PathTezt® Preserve Cell Solution Storage and Handling Requirements • 15°C to 30°C. Packaging Part no: PCS926 Quantity: 6 bottles/box		• 926ml in a bottle • Methanol-based, buffered transport solution • Used in specimen preparation prior to processing • Solutions are flammable and toxic

PathTezt® Cytolysis Solution Storage and Handling Requirements • 15°C to 30°C Packaging Part no: CTLS9260604 Quantity: 6 bottles/box		• 946ml in a bottle • Methanol-based buffered transport solution • Designed to lyse red blood cells, prevent protein precipitation, dissolve mucus, and preserve morphology of general samples

Non-Gynae Consumables

Item	Description	
UrineCell Preserve Cell Solution Storage and Handling Requirements • 15°C to 30°C Packaging Part no: UCPCS200920 Quantity: 2000/box		• 20ml in a vial • Methanol-based solution • Used with urine sample
Non-Gynae Preserve Cell Solution Storage and Handling Requirements • 15°C to 30°C Packaging Part no: NGPCS200920 Quantity: 2000/box		• 20ml in a vial • Methanol-based solution • Used with thyroid FNA, sputum and body fluid samples
PathTezt® Pre-Filter Storage and Handling Requirements • Ambient environment and out of direct sunlight. • Store the filters in their trays with the		• Transparent in color • For removal mucus and non-diagnostic materials • Single use only and cannot be reused

cover on until ready for use. Packaging Part no: PS250 Quantity: 250/box		
PathTezt® Urine Filter Storage and Handling Requirements • Ambient environment and out of direct sunlight. • Store the filters in their trays with the cover on until ready for use. Packaging Part no: UCF-0812100 Quantity: 250/box		• Yellow in color • Prepare 10mm circle area • Used with urine sample or slide-based molecular testing • Single use only and cannot be reused
PathTezt® Non-Gynae Filter Storage and Handling Requirements • Ambient environment and out of direct sunlight. • Store the filters in their trays with the cover on until ready for use. Packaging Part no: NGF-0525100 Quantity: 250/box		• Blue in color • Prepare 20mm circle area • Used with thyroid FNA, sputum and body fluid • Single use only and cannot be reused
PathTezt® UrineCell Slide Storage and Handling Requirements • 15°C to 30°C. Packaging Part no: US36100 Quantity: NA		• Pre-coated slide • 10mm circle area

Section 3: Specimen Management

Gynae Specimen Management

Preparation and Collection for Gynae Specimen

Patient Preparation

- Schedule the examination 2 weeks after the first day of the last menstrual period. (It is preferable to avoid examination during menses because blood may obscure significant findings).
- Do not use vaginal medication, vaginal contraceptives, or douches for 48 hours before the appointment.
- Intercourse is not recommended the night before the appointment.

Specimen Collection Preparation

- Specimens should be obtained after a nonlubricated speculum (moistened only with warm water if needed) is inserted.
- Excess mucus or other discharge should be removed gently with ring forceps holding a folded gauze pad.
- Remove inflammatory exudate from the cervical canal before taking the sample. Remove by placing a dry piece of gauze over the cervix and peeling it away after it absorbs the exudate or by using a dry proctoswab or scopette
- The cervix should not be cleaned by washing with saline or it may result in a relatively acellular specimen.
- The sample should be obtained before other testing eg: application of acetic acid or Lugol iodine., cultures and tissue sampling.

Specimen Collection Procedure Using the Endocervical Brush with Remover Tube

- Prepare the broom-type device and PathTezt® vial.
- Insert the central bristles of the brush into the endocervical canal until the shorter bristles are in contact with the ectocervix. Maintaining a gentle pressure, rotate the brush 5 x times in a clockwise direction.
- Insert the brush head into the PathTezt® vial with preservative fluid and detach the brush head using the transparent remover tube. Discard the blue handle.
- Tighten the cap on the vial.
- Record the patient's name and ID number on the vial. Record the patient information and medical history on the cytology request form.
- Place the vial and requisition in a specimen bag for transport to the laboratory.

Instructions For Use with Remover Tube

Precautions

After sample transfer to the PathTezt® preserve cell solution vial, the sample should stand for at least 15 minutes before processing.
Interfering Substances
The Clinical and Laboratory Standard Institute Guidelines (formerly NCCLS) recommend that no lubricant be used during Pap testing. ACOG recommends that care be taken not to contaminate the specimen with lubricant because this may lead to unsatisfactory results. This applies to both conventional Pap testing and liquid-based cytology. If you are using a plastic speculum, or in instances where a lubricant must be used, take care not to contaminate the cervix or collection devices with the lubricant. A tiny amount of lubricant may be used, just enough to sparingly coat the speculum with a gloved finger, avoiding the tip of the speculum. The Clinical and Laboratory Standard Institute Guidelines and ACOG recommend that you not take a Pap during menses. For samples to be processed on the PathTezt® Infinity processor, lubricants can adhere to the filter membrane and may cause poor cell transfer to the slide. If its use is unavoidable, the lubricant should be used in minimum amounts.

Storage and transport

Storage and Transport for Gynae Specimen

	Storage: • Ensure that the brush head is in the vial. • Store up to 4 weeks at room temperature. • Store up to 6 months if refrigerated. Transport: • Make sure the vial is tightly sealed. • The shipping category is “diagnostic sample”.

Non-Gynae Specimen Management

Methods for preparation, fixation and staining vary from laboratory to laboratory, but the basic principles are the same. The goal is to reduce cellular artefacts and obtain optimal diagnostic specimen.

Liquid-based cytology (LBC) for non-gynaecological application provides excellent cell preservation, reduce background debris and cellular material which has been stored in the preservative solution can be used for the application of immunocytochemical, molecular and cell block techniques.

The management of the non-gynae specimen is presented in the following tables.

Collection and Preparation for Non-Gynae Specimen

Information on different sample types and general collection instructions are given below.

Sputum

- Spontaneous, deep cough specimens directly into a sterile universal container
- The sputum should be sent to the laboratory immediately following production.

Brush Specimens

- Includes Bronchial, Biliary tract, Esophageal and Gastric brush specimens.
- The brush is detached and placed immediately into 20ml Non-Gynae Preserve Cell Solution to prevent air-drying artefact.

Bronchial Lavage

- The washing/lavage specimen is placed directly into 20ml Non Gynae Preserve Cell Solution.

EBUS Specimens

- The needle cores are carefully ejected into 20ml Non Gynae Preserve Cell Solution and the needle is rinsed with the solution.

Fine Needle Aspiration (FNA)

- Prepare appropriate number of slides and spread quickly to produce monolayers if air-dry smear is required.
- When all slides have been prepared, flush the needle into a 20ml Non Gynae Preserve Cell Solution and send with the slides to the cytology department.

Urine

- Collect random freshly voided urine sample into a sterile universal bottle.
- Only mid-stream clean catch and do not use the first urine sample of the day.
- Specimens obtained via cystoscope, catheter or bladder washings must be clearly labelled on the bottle.

Body Cavity Fluids (Pleural/Peritoneal/Ascitic Fluid, Washings etc.)

- Collect the specimens in universal containers.

Cerebrospinal fluid (CSF)

- Collect a minimum of 1mls into a sterile container or flush the needle directly into the Non Gynae Preservative Cell Solution.

Storage and Transport for Non-Gynae Specimen

Storage:

- Store up to 3 weeks at 4°C to 37°C

Transport:

- Fresh specimens should be sent to the laboratory as soon as possible to minimize deterioration of the cell content if immediate fixation is not possible.
- Ensure the vial is tightly sealed.

	Storage: • Store up to 3 weeks at 4°C to 37°C

General Non-Gynae Procedure

For fresh or unfixed specimen

Step 1: Concentrate:

- Asses the sample and remove clots, particles and mucus using PathTezt® Pre-Filter.
- Transfer the sample to a centrifuge tube.
- Centrifuge at 600g for 10 minutes.
- Decant supernatant and vortex to resuspend cell pellet.

Step 2: Wash

- Assess the cell pellet appearance to determine the next approach.

Cell Pellet Appearance	Approach
White, pale pink, tan, or not visible	Add specimen to Non Gynae Preserve Cell Solution or UrineCell Preserve Cell Solution (for urine sample only)
Red or brown indicating presence of blood.	Perform Cytolysis Solution wash
Mucoid	Refer to procedure for DTT with mucoid specimen

Step 3: Fix

- Assess the cell pellet size to determine the next approach.

Cell Pellet Size	Approach
No visible or small pellet.	Add entire specimen to Non Gynae Preserve Cell Solution vial
Clearly visible and the pellet size is less than 1ml.	Transfer 2 drops of the pellet to Non Gynae Preserve Cell Solution vial
Pellet volume is greater than 1ml	Dilute the cell pellet with 1ml of Non Gynae Preserve Cell Solution. Transfer 1 drop of the specimen to Non-Gynae Preserve Cell Solution vial.

After sample transfer to the Non Gynae Preserve Cell Solution vial, the sample should stand for at least 15 minutes before processing.

Step 4: Process

- Load on PathTezt® Infinity Processor with Autoloader using the Non-Gynae mode.

Procedure for Urine Specimen

1. Concentrate by centrifugation. (Refer to Step 1)
2. Assess cell pellet appearance. (Refer to Step 2)
3. Assess cell pellet size. (Refer to Step 3)
4. Allow to stand in **UrineCell Preserve Cell Solution** vial for 15 minutes.
5. Process on PathTezt® Infinity Processor using the Urine mode. Use the yellow urine filter and UrineCell slide.

Procedure for DiThioThreitol (DTT) with Mucoid Specimen

Mucus is considered a visible particle and needs to be removed from the sample prior to processing.

DTT stock solution

- Add 2.5g DTT to 30ml of Cytolysis Solution.
- This solution is suitable for use for 1 week when stored at room temperature (15°C–30°C).

Method

1. Add 30ml Cytolysis Solution to the fresh mucoid specimen.
2. Add 1ml of DTT stock solution to the fixed mucoid specimen.
3. Vortex the sample and leave it to stand for 5 to 10 minutes.
4. Centrifuge at 600g for 10 minutes.
5. Decant the supernatant and vortex to resuspend cell pellet.
6. Assess cell pellet appearance. Repeat the above steps if needed.
7. Assess cell pellet size. Transfer the specimen to Non Gynae Preserve Cell Solution vial.
8. Allow the sample to stand 15 minutes prior to loading onto the PathTezt® Infinity Autoloader.

Note: if air-dried-slide is required, prepare direct smear first and place residual pellet directly into Non Gynae Preserve Cell Solution vial.

Procedure for Cytolysis Solution Wash

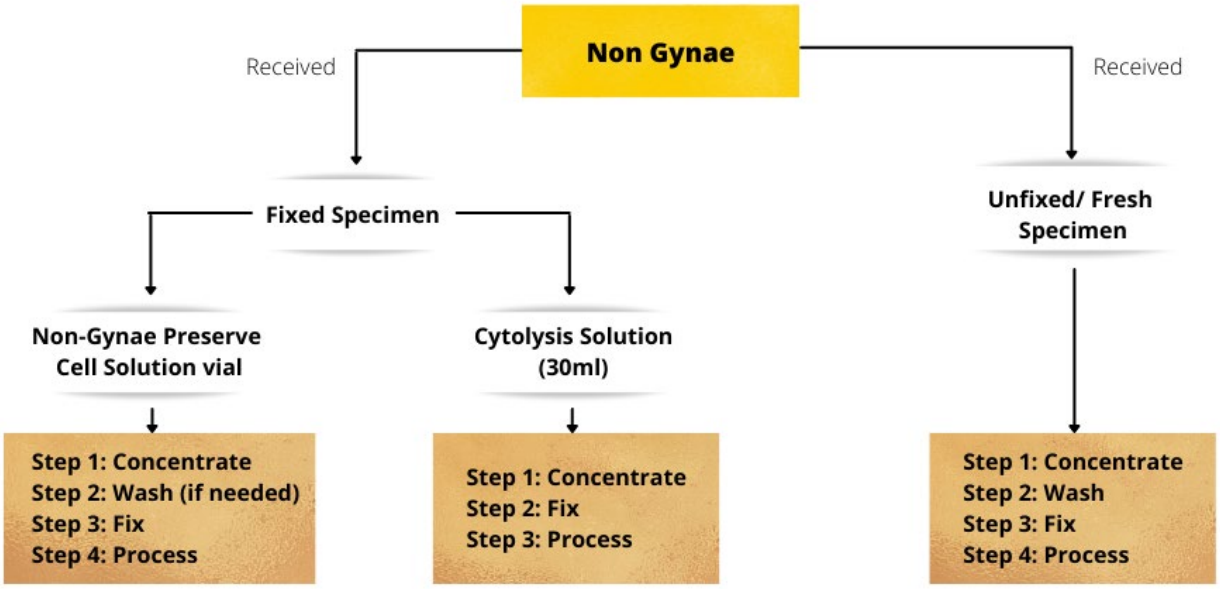
Addition of Cytolysis Solution to cell pellets is required to wash the sample. A Cytolysis Solution Wash performs the following functions while preserving cellular morphology:

- Lysis red blood cells
- Dissolve mucus
- Reduce protein precipitation

Method:

1. Add 30ml Cytolysis Solution to a cell pellet.
2. Vortex centrifuge tube approximately 5 seconds.
3. Centrifuge tube at 600g for 10 minutes.
4. After centrifugation, decant the supernatant, leaving only the button at the base of the centrifuge tube.
5. Assess for cell pellet size. Transfer the sample accordingly to a fresh Non Gynae Preserve Cell Solution vial.
6. Vortex the mixture for 4 to 6 seconds until thoroughly mixed.
7. Allow the sample to stand 15 minutes prior to loading onto the PathTezt® Infinity Autoloader.

Non-Gynae Process Flow Chart



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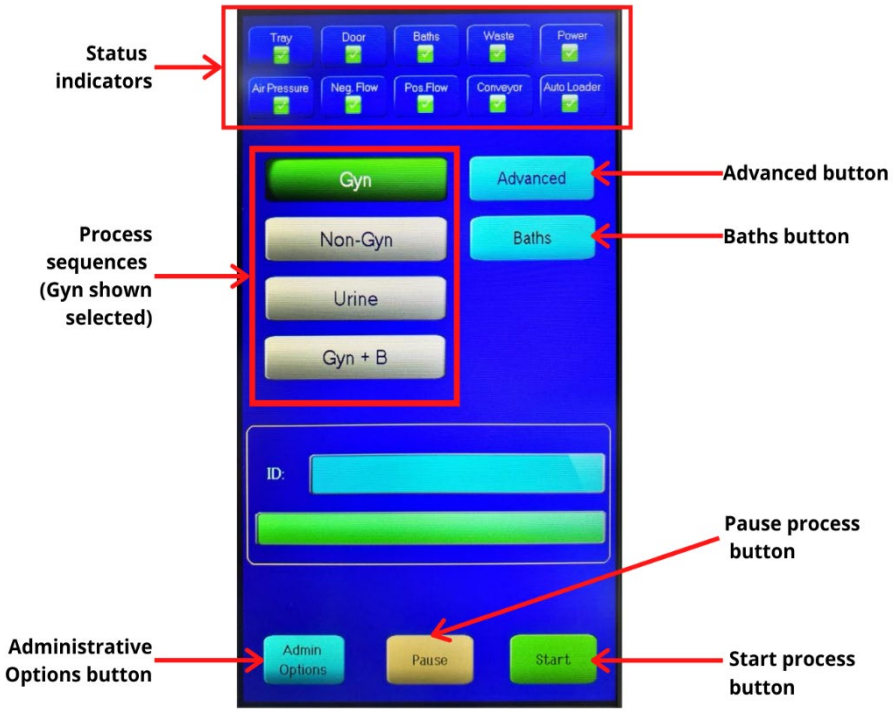
Section 4: Instrument Operation

Gynae Processing Steps Overview

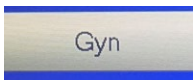
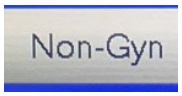
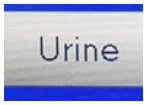
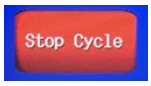
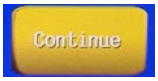
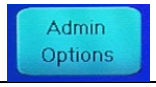
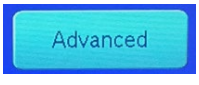
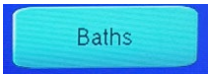
Main Status Screen

The Main Status Screen is the default screen that is displayed immediately after the processor initialization. This screen contains buttons that allow you to access other menus. To access a menu, tap the associated button on the screen.



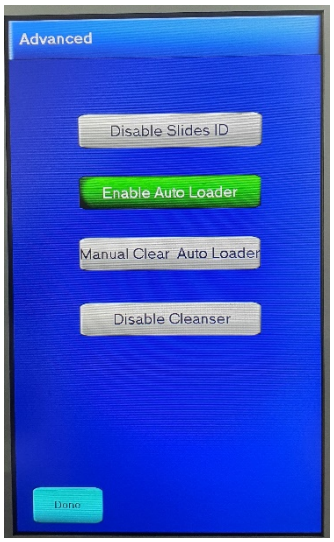
Status indicators

The status indicators are located at the top of the main screen display. The checklist must be checked before the start of a cycle. The buttons turned green after the completion of initialization step except baths button will remain in red color.

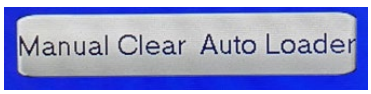
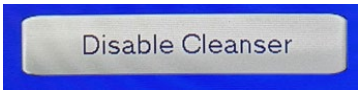
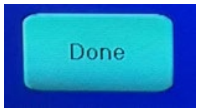
Main Status Buttons	
Button	**Description**
	Program for Gynae specimen without brush head inside the vial.
	Program for Non-Gynae specimen.
	Program for urine specimen.
	Program for Gynae specimen with brush head inside the vial.
	Tap to start a batch of run after selecting the preferred program.
	Tap to end the run.
	Tap to resume the process.
	Tap to temporary stop the process.
	Tap to open the processor's door.
	Tap to go to the admin options screen.
	Tap to go to the advanced screen.
	Tap to go to the baths screen.

Advanced Screen

Click on the advanced button found on the Main Status screen. Four buttons appear. Click on one of the four available buttons as shown below:



Advanced Screen Buttons

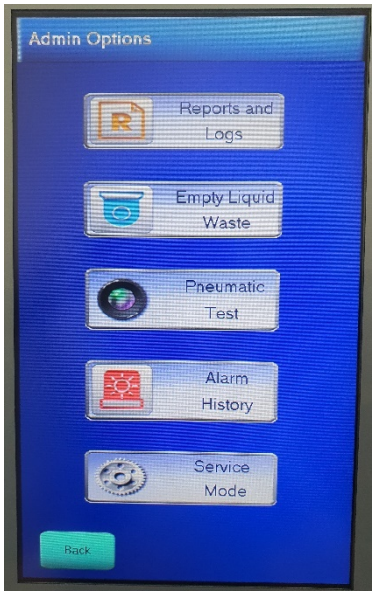
Button	Description
	Click to enabled/disabled slide QR code function.
	Indicates AutoLoader connected to the processor.
	Click to manually remove any vials remained inside the AutoLoader.
	Click to enabled/disabled cleanser used for maintenance.
	Click to return to Main Menu

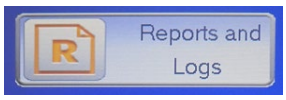
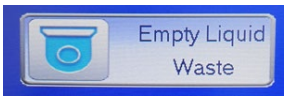
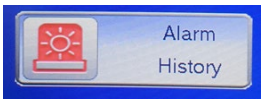
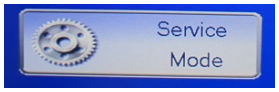
Baths Screen

Click on the baths button found on the Main Status screen. Bath details screen appear. Load the first bath container filled with alcohol and staining rack. The processor's door must be opened prior to loading the alcohol bath. Click on the load empty baths button to complete the alcohol baths loading. Click load done to return to the Main Menu.

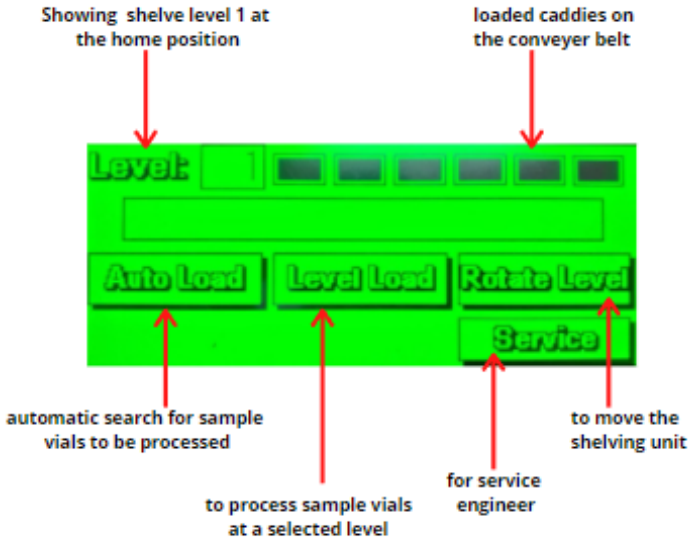
Admin Options Screen

Click on the admin options button found on the Main Status screen. Admin options screen appear. Click on one of the four available buttons. Click back to return to the Main Status screen.

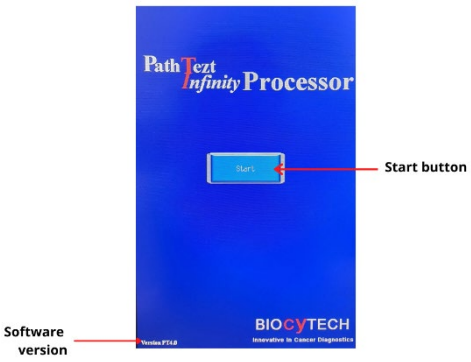


Admin Options Button	
Button	**Description**
	Allows user to see how many samples succefully processed by the processor according to the process sequence.
	Two ways are available on the processor to empty the liquid waste bottle. • Admin options • Starting a run (Section 4) Refer to section 8 (maintenance) or section 4 (starting a run) for more details on how to empty liquid waste bottle.
	A tool to test the pressure system in the processor. Can only be accesed by the engineer.
	Shows the error message occurred with date and time recorded respectivly.
	For preventive manitenance by the engineer.

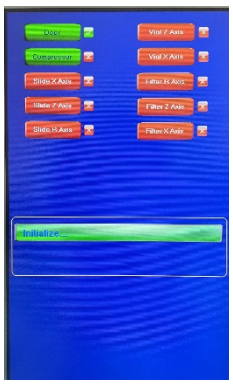
AutoLoader Screen



Starting A Run - PathTezt® Infinity Processor



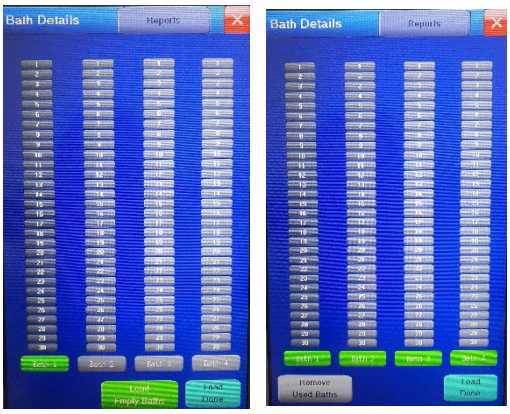
1. The start screen is the default screen that is displayed immediately after the boot up. Press the “Start” button to proceed with processor initialization.



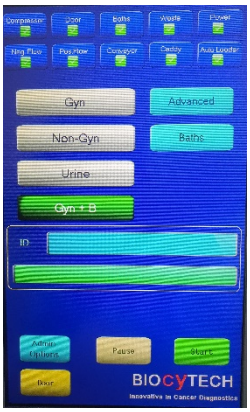
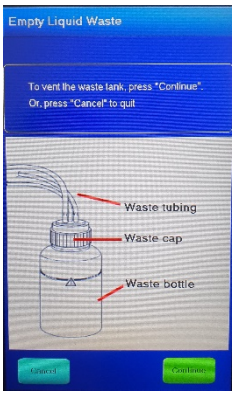
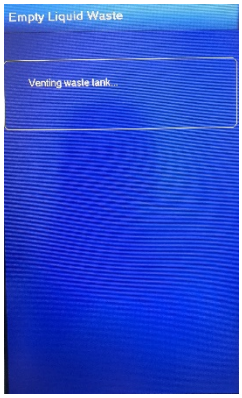
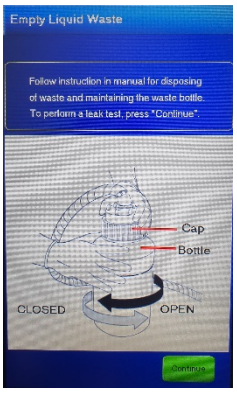
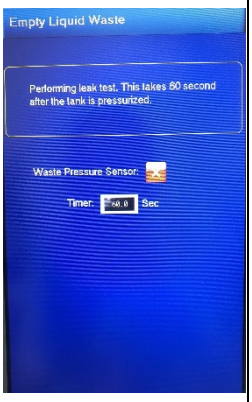
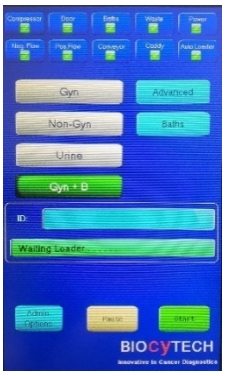
2. The instrument initializing checks for air pressure, door is closed, slide X axis, slide Z axis, slide R axis, vial Z axis, vial X axis, filter R axis, filter Z axis and filter S axis.

   If checks fail, then the button remain in red color. The user to address the issue and continue the process.

3. After initialization, all buttons at the status indicator are in green color except the bath button. Press the “Bath” button to proceed to load empty bath.



4. Press “Bath 1” button and press “Load Empty Bath” button to start the loading of alcohol fixative bath. The bath conveyor moves the bath station to allow user to load the alcohol bath accordingly. Continue this process until “Bath 4”. Press “Load Done” when the loading of alcohol baths is completed.

	5. Select the preferred sequence or program and tap start button to begin the run.
 	6. Press “Continue” to empty the liquid waste bottle. or press “Cancel” to skip this step and proceed with the sample processing. If “Continue” button is selected, the processor automatically releases the pressure from the waste bottle to allow the opening of the bottle’s cap.for waste disposal.
 	7. Attach the bottle’s cap back into position and press “Continue” to perform the leak test after emptying the waste bottle.
	8. The processor is ready to prepare slide and is waiting for vial specimen to be processed.

Starting A Run - AutoLoader

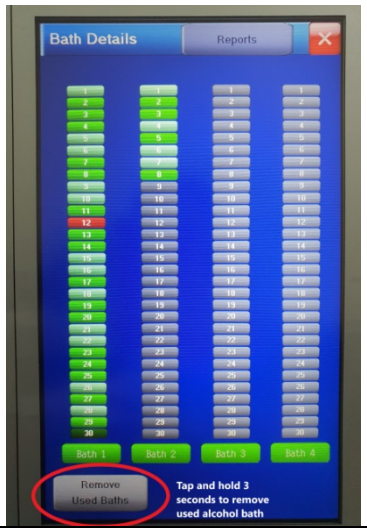
Method	Description
	1. The Biocytech screen is the default screen that is displayed immediately after the boot up. Tap on this screen to proceed with AutoLoader initialization.
	2. The carousel system moves to position the shelving unit level 1 back to the home.
	3. The initialization step complete. The number showing level 1 which is the home position.
	4. After specimen vials have been loaded in the shelving units and the PathTezt® Infinity processor has been prepared, the run can be started. Tap the AutoLoad button to begin the process.

Removing Alcohol Baths

Each staining rack fits maximum 30 slides. The staining rack must be inserted into the alcohol bath before loading into the processor.

The alcohol baths are removed in 2 ways:

- Once the process complete
- Tap the Baths button on the Main Status screen. Bath Details screen appear. Tap the Remove Used Baths button and hold for 3 seconds.



Section 5: Staining and Cover Slipping

Recommended Staining Steps as below:

STEP	REAGENTS	TIME(MN:SEC)	AGITATION
1	70% Ethanol	1:00	Yes
2	50% Ethanol	1:00	Yes
3	Distilled water	1:00	Yes
4	Richard-Allan Hematoxylin I	0:30	Yes
5	Distilled water	0:15	Yes
6	Distilled water	0:15	Yes
7	Clarifier (0.025% glacial acetic acid)	0:30	Yes
8	Distilled water	0:30	Yes
9	Bluing agent (10mg LiCarb/1L)	0:30	Yes
10	50% Ethanol	0:30	Yes
11	95% Ethanol	0:30	Yes
12	Richard-Allan cytology stain	1:00	Yes
13	95% Ethanol	0:30	Yes
14	95% Ethanol	0:30	Yes
15	100% Ethanol	0:30	Yes
16	100% Ethanol	0:30	Yes
17	100% Ethanol	0:30	Yes
18	Xylene	1:00	Yes
19	Xylene	1:00	Yes
20	Xylene	3:00	No
21	Mount with coverslip	NA	

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 CytologyStain (7511). Permount is a trademark of Fisher Scientific Corp.

The above protocol is adapted to Gyn samples. It could be adapted to non-gyn samples with some adjustment. Time may vary with stain lot or age.

Cover Slipping

The use of Permount mounting media has been evaluated and is recommended for use with PathTezt® Cyto-Slide. Since some mounting media cause 'floating' of cells to occur on PathTezt® Cyto-Slide or conventional slides, each laboratory should evaluate their choice of mounting media to ensure compatibility with PathTezt® Cyto-Slides.

Recommend using 24mm X 30mm coverslips.

Other approved mounting media:
- Baxter ACCU-MOUNT 60
- Shandon Clearium

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Section 6: System Messages, Alerts and Symbols

System Messages and Alerts (PathTezt® Infinity Processor)

PathTezt® Infinity's processor system alerts cause the Alert Tone (repeating low pitch beep) to sound.

A System Alert message pops up on the Main Status screen. The error code is displayed as "XXXX" (where XXXX is numeric codes) and appears in the center of the message box.

The errors must be acknowledged by tapping the "Reset" or "Bypass Continue" button to dismiss the message box.

Error codes indicate specific conditions detected by the processor and serve as alert to the operator that a condition exists.

See below for complete listing and condition of Error Codes.

Error codes	Condition
6300	Slide - X Axis Homing Error
6301	Slide - Z Axis Homing Error
6302	Slide - R Axis Homing Error
6100	Vial - X Axis Homing Error
6101	Vial - Z Axis Homing Error
6200	Filter - X Axis Homing Error
6201	Filter - Z Axis Homing Error
6202	Filter - R Axis Homing Error
6110	Vial - X Axis Error
6111	Vial - Z Axis Error
6210	Filter - X Axis Error
6211	Filter - Z Axis Error
6212	Filter - R Axis Error
6310	Slide - X Axis Error
6311	Slide - Z Axis Error
6312	Slide - R Axis Error
6112	Vial - Gripper Error
6500	Waste Pinch Valve Error
6600	Conveyor Caddy Error
6601	Conveyor Bath Error
6120	Vial - Gripper Error
6320	Slide - Gripper Error
6321	Slide - Press Error
6620	Caddy Clamper Error
6630	Compressor Error

Two basic types of alerts exist: **Self-clearing** and **Persistent.**

- **Self-clearing**
  - These alerts are removed from the screen after they have been acknowledged by tapping "Reset" or "Bypass Continue" button in the popup alert window.

- No further intervention is required by the operator.

- **Persistent**
  - These alerts remain in the Instrument Alert Screen (even after displaying the alert code) until the instrument determines that the error causing the alert has been corrected.
  - Correction can be accomplished with or without user intervention, depending on the alert.
  - If user intervention is needed, the alert code must be acknowledged by tapping the "Reset" button in the popup alert window.

If the error does not clear, please contact Biocytech, Technical Services (refer Section 9 for contact information) or your local Biocytech representative for service-related needs.

System Messages (AutoLoader)

Alert	Action
	This alert is removed from the screen after they have been acknowledged by tapping "Reset" button in the popup alert window.

Symbol use on Instrument

Symbol	Description
	Attention, refer to accompanying document
	Mind your head
	Do not touch

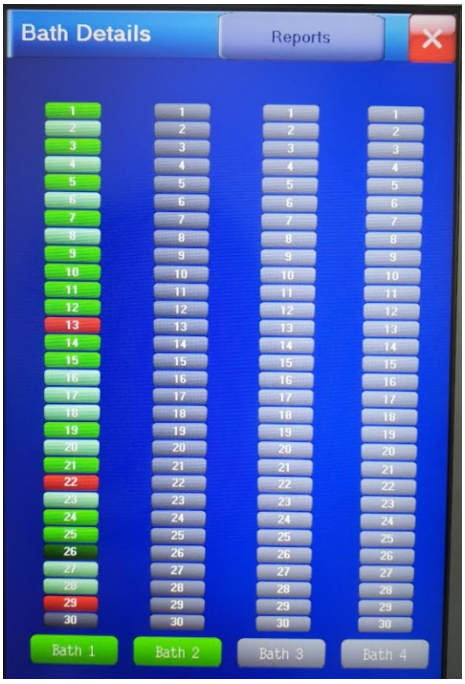
	Red button - Power switch off Green button - Power switch on

Color Symbolism

The below picture showing numerical order with different colors can be found in the Bath Details screen. The number order represents the position of processed slide in the staining rack immersed in the alcohol bath.

The table shows the meaning of each color representation.

Color	Description
Green	Successfully processed sample
Red	Rejected sample
Grey	No sample to be processed



The 3 different shades of green color represent the cellularity in the vial.

Shades of Green	Description
Light green	Completed sample but sample is dilute or low cellularity
Green	Completed sample. Sample cellularity is OK
Dark green	Completed sample but sample is dense or high cellularity

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Section 7: Data Downloads

General Information

- Reports can be saved for troubleshooting and record purpose.
- This report allow user to export information to an Excel file.
- This function is initiated by assessing the reports in the baths screen.
- The data download can be downloaded directly to a USB memory stick located behind the touch screen monitor.

Data Download Procedure

Save Data Procedure
1. Locate the USB port behind the touch screen monitor. 2. Insert a USB memrory stick into the port. 3. Tap the Save To USB button. 4. Data download is complete.

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Section 8: Maintenance

Maintenance activities are as follows:

Daily Maintenance

Change Fixative Reagent

- The fixative alcohol in the baths should be changed out every 100 slides, or daily, whichever comes first.
- Dispose of fix reagents according to your laboratory's protocols.
- Clean the fixative bath containers, covers and staining racks according to your laboratory's protocols.

Empty the used filter waste bin

- Remove the waste bin from the waste cabinet.
- Dispose of the used filter according to your laboratory's protocols.

Store the processed vials

- Remove the carton box from the waste cabinet.
- Store the processed samples accordingly.

Weekly Maintenance

Clean around the processing area

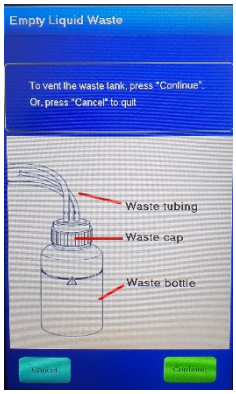
- On a weekly basis, clean around the processing area inside Pathtezt® Infinity Processor using deionized water and lint-free towels.
- If there is build-up of residue from PreservCyt Solution, use a cloth or swab soaked with 70% alcohol to dissolve any crust and clean away precipitate.

As Needed - Empty the waste bottle

Waste resulting from sample processing is routed to and stored in the waste bottle. Check the waste level manually prior to each run.

There are 2 ways to perform this task:

- Start a run. Empty liquid waste message appears.
- Go to admin options from the Main Status Screen. Select the empty liquid waste button.

Empty waste bottle instructions	
 	1. Vent the waste tank before removing the waste cap. 2. To remove the waste cap, rotate the waste cap with one hand while holding the waste bottle in place with the other hand. If the waste tubing becomes dislodged from the waste cap during this process, reconnect the tubing before continuing. 3. Dispose of the liquid waste from the waste bottle according to your laboratory guidelines. Dispose of all solvents as hazardous waste. Follow state, local, provincial, and federal or county guidelines. As with all laboratory procedures, universal precautions should be followed. 4. Return the waste bottle back to its original location and retighten the waste cap onto the bottle. Verify that the waste cap is firmly tightened and confirm that the waste tubing is not pinched or twisted.

PathTezt® Infinity Processor Maintenance Log

Department: _____

Month/Year: _____

Instrument serial #: _____

Please initial each space. If a problem, found take appropriate steps to resolve. For further assistance, call Biocytech Technical Support.

Daily	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Change fixative bath containers																															
Empty filter waste bin																															
Empty sample bin																															

Weekly	**Week 1 (/ /)**	**Week 2 (/ /)**	**Week 3 (/ /)**	**Week 4 (/ /)**	**Week 5 (/ /)**
Clean dispersion area					
Clean slide holder pneumatic suction cups					

As Needed	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Clean touch screen																															
Clean instrument cover																															
Empty waste bottle																															

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Section 9: Service and Order Information

Manufacturer contacts information:
Biocytech Corporation Sdn. Bhd.
No.820, Simpang Empat, Jalan Lahat
31450 Menglembu, Ipoh, Perak Malaysia
Tel: +6052826133
Fax: +6052828891
Hotline: +60125199098
Email: info@biocytech.com
Hours: 9am – 6pm

Version	Date	Changes
1.0 (Original)	November 2021	
2.0	September 2023	Page number re-format and relocated “this page intentionally left blank” from footer to the center of the page.