 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 3 of 10

PURPOSE:

The Tomcat Instrument is an integrated sample handling instrument that fully automates the steps necessary to perform sample aliquoting from Input Container to Output Tube.

The Tomcat Instrument consists of the instrumentation and computer together in a single unit. The instrument is operated via the touch-screen monitor that is connected to the Tomcat Instrument.

The purpose of this SOP is to instruct the user to on the proper way to operate the TomCat instrumentation

SCOPE:

Processing Department

RESPONSIBILITY:

The Medical or Section Director is responsible for ensuring that the procedure is in compliance with CAP and CLIA regulations. The Director must review and approve this procedure at appropriate intervals. The Medical Director may delegate some of the responsibilities to other CLIA/CAP qualified personnel.

The Processing Supervisor/Manager will have the overall responsibility for implementing this procedure. The supervisor/manager is responsible for ensuring that the procedure is followed accurately and that competency documentation is appropriate.

All processors performing this procedure are required to have appropriate training and competency approved. They are responsible for reading, understanding and competently performing this procedure without deviation.

EQUIPMENT: TomCat Instrument

SUPPLIES:


- Tips
- Reagent

PROCEDURE:

Tomcat Instrument Startup

To start the Tomcat Instrument:

1. Make sure that all input racks, output racks and the reagent vials are removed from the instrument
2. Turn the Tomcat Instrument on using the power switch on the lower left side of the instrument.
3. The Desktop Shield Utility starts and displays the Desktop Shield Screen

 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 4 of 10

4. From the Desktop Shield screen, select Tomcat **or** wait 25 seconds for the Tomcat Software to automatically initiate
5. Make sure that all doors and drawers are closed (you can close the waste bin and tip drawers when the red lights appear just above the drawers).


Instrument Inspection

1. Check the instrument for proper amount of tips, if not load tips before starting

- a. Each tip tray icon will be outlined in one of the following three (3) colors indicating the status of the tray
 - i. Red—Tip tray is empty
 - ii. Yellow—Tip tray is partially full
 - iii. Green—Tip tray is available
- b. How to Load Tip Trays
 - i. Touch either the *Tasks* screen or the Tip icon on the bottom left corner of the screen and unlock the tip drawer
 - ii. Remove empty or partially full tip trays
 - iii. Load new tip trays. Always load new tip trays carefully, making sure to avoid contact with tip surfaces
 1. Ensure that all tip rack icon on the screen have the appropriate colored borders and bottle color, indicating successful replacement, before proceeding
 - iv. Touch the tray icon(s) of the tray(s) that were replaced in the Resource Management window until the border turns to green
 - v. Close the Resource Drawer, the drawer will lock. The instrument updates the tip count and reagent count

2. Check the instrument for proper amount of waste

- a. The operator must manage the waste inventory
 - i. The waste can be emptied at any time the instrument is **not** in the Initialization, Shutdown or Error state
 - ii. If the instrument is processing a sample, the instrument will not unlock the Waste Drawer until the current sample being processed has been completed

 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 5 of 10

- iii. The instrument tracks the remaining capacity of the waste bin and displays the waste space available in number of tests remaining. This information is available in the Waste status bar at the bottom of the screen and on the *Waste Management* screen
- iv. The Tomcat Instrument has a waste bin capacity of up to 192 tests. All tip waste is deposited in the Waste Bin Container

b. To empty waste:


- i. Perform one of the following tasks to initiate the empty waste process:
 - Select the Waste Count status bar at the bottom of the screen
 - Select the **Empty Waste** button on the *Tasks* screen
 - Select **Unlock Waste Drawer** button
- ii. Slide the Waste Drawer completely open, remove the Waste Bin from the drawer
- iii. Dispose the Waste Bin according to laboratory policies
- iv. Fit a new Waste Bin into the Waste Container slot taking care to perform the following task: Snap a new waste bin lid into a new empty waste bin, and press the bin down into the Waste Container firmly
- v. Click the waste bin icon of the replaced full waste bin in the *Waste Management* screen until the border turns to green and the waste bin icon appears empty
- vi. Close the Waste Drawer.

3. After the instrument inspection has been done the reagent (for surepaths only) can be now be loaded onto the instrument

- a. Check the Reagent Status to get volume remaining in the reagent bottle
- b. Always load new reagents carefully, making sure to avoid contact with tip surface

c. How to Reconstitute the Aptima Transfer Solution (ATS)

- i. Remove the lid and stopper from the amber colored bottle and pour enough liquid into the amber colored bottle to fill half way. Recap and shake the bottle to make sure and get all of the powder on the rubber stopper
- ii. Allow the amber bottle to sit for 15-20 min or until the powder goes entirely into solution

 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 6 of 10

iii. Pour the liquid from the amber bottle into the clear plastic bottle. Recap and invert 10 times to mix. Allow the bottle to sit 10 min before use

iv. **The ATS is good for 30 days off of the instrument and 24hours on the instrument**

d. How to Load a Reagent Bottle

i. If previously used ATS is going to be placed onto the instrument, allow for the reagent to reach room temperature by sitting out for 20-25 min before putting onto the instrument

ii. If a reagent bottle is already loaded, remove the reagent bottle from drawer

iii. Load new reagent bottle into drawer

iv. Ensure barcode on reagent bottle is aligned with barcode reader

v. If prompted, enter the Reagent Lot ID and/or Expiration

vi. If Reagent Lot ID or Expiration are entered, then select the enabled **Save New Bottle** button

4. Close the Resource Drawer, and the drawer will lock. The instrument will update the reagent count

a. Ensure that all reagent bottle icons on the screen have the appropriate colored borders and bottle color, indicating successful replacement, before proceeding

i. The reagent icon will be black indicating the status of the reagent bottle position being empty

ii. The reagent icon will be green indicating the status of the reagent bottle is loaded.


5. Load Input Bay

a. Load Output Tubes and Input Containers (Types 1 or 2) in the appropriate Input Racks

b. Up to 8 Input Container/Output Tube pairs can be loaded into a single Input Rack

c. Container Type 1 or Container Type 2 specimens can be loaded in any order and any position in the appropriate Input Rack


d. Obtain an Input Rack (one of the two (2) different types) and position the rack on a clean work surface.

 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 7 of 10

- i. Obtain an Input Container
 - ii. Create or obtain an Output Tube that has an identical barcode to the Input Container
 - iii. Load an input and output pair (either container Type 1 or container Type 2) with identical matching barcodes into the appropriate slots of the correct Input Rack type and have the tubes firmly seated in the rack
- e. Perform steps i-iii for all samples that need to be loaded into Input Racks
- f. Loading Input Racks into the Input Bay**
- i. Up to eight (8) Input Racks can be loaded onto the instrument at a time.
 - ii. Ensure that all drawers and doors other than the Input Bay Door are closed when loading Input Racks.
- g. To load Input Racks:
- i. Open the Input Bay Door. The *Input Bay* screen opens
 - ii. Load the rack into an open Input Bay Lane, by gently slide the Input Rack into an Input Lane until it reaches the back of the bay
 - iii. Load up to eight (8) Input Racks (64 samples) as necessary following steps 2-4
 - iv. Load additional Input Racks one at a time
 - v. Close the Input Bay Door after all racks have been loaded. If all of the criteria to initiate sample pipetting have been met, the instrument will automatically start processing the samples based upon the order that the racks were loaded

6. Unloading Input Racks

- a. Unload Input Racks from the instrument when processing has finished for the rack
 - i. All sample icons are blue on the Input Bay and Run Status screens and the Input Bay Lane LED is disabled once sample handling has been completed on an Input Rack
 - ii. The instrument will unlock the input rack once all samples have been processed or the instrument enters the Setup state
- b. To unload Input Racks:
 - i. Open the Input Bay Door. The *Input Bay* screen opens

 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 8 of 10


- ii. From the *Input Bay* screen, ensure that the icon(s) of the rack(s) to be removed are not yellow
- iii. Ensure that the Input Bay Lane LED(s) of the rack(s) to be removed are not red
- iv. Pull the rack by the handle and remove it from the Input Bay Lane
 - 1. The rack and tube icons on the screen turn gray
- v. Remove up to eight (8) Input Racks as necessary
- vi. Multiple racks can be removed at the same time if the criteria in steps i-iv are met.
- vii. If necessary, load new Input Racks into the empty Input Bay Lanes
- c. Close the Input Bay Door.

7. Loading Output Racks into the Output Bay

- a. Up to eight (8) Output Racks can be loaded onto the instrument at a time.
 - i. Ensure that all drawers and doors other than the Output Bay Door are closed when loading Sample Racks.
- b. To load Output Racks:
 - i. Open the Output Bay Door. The *Output Bay* screen opens.
 - ii. Load the rack into an open Output Bay Lane by gently slide the Output Rack into an Output Bay Lane until it reaches the back of the bay.
 - iii. Load up to eight (8) empty Output Racks (120 completed samples) as necessary. Load additional Output Racks one at a time
 - iv. Close the Output Bay Door after all racks have been loaded
- c. If all of the criteria to initiate sample pipetting have been met, the instrument will automatically start processing the samples from the Input Bay based upon the order that the racks were loaded

8. Initiating Sample Processing


- a. The instrument automatically initiates processing when the following requirements have been met:
 - i. The instrument is in the Setup state.
 - ii. The Workflow has been activated on the *Workflow Configuration* screen.

 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 9 of 10

- iii. Adequate consumables are available
- iv. The required Input Racks are loaded on the instrument
- v. The required Output Racks are loaded on the instrument
- vi. All drawers have been closed.
- b. Once these conditions have been met, the instrument transitions into the Processing state.
 - i. The samples will be processed based upon load order and processing efficiency.
- c. Continue to monitor and manage sample pipetting by referring to the *Run Status* screen.
- d. Continue to monitor and manage the status of the consumables by referring to the Resource inventories in the Status Panel.

9. Unloading Output Racks

- a. Unload Output Racks from the instrument when sample pipetting has finished for the rack.
 - i. All sample icons are blue on the *Output Bay* and *Run Status* screens and the Output Bay Lane LED is disabled once sample handling has been completed on an Output Rack.
 - ii. The instrument will unlock the Output Rack once the Output Rack is completely filled with samples or the Output Rack has at least one Output Tube in it when the instrument enters the Setup state.
- b. To unload Output Racks:
 - i. Open the Output Bay Door. The *Output Bay* screen appears on the touch screen.
 - ii. From the *Output Bay* screen, ensure that the icon(s) of the rack(s) to be removed are not yellow.
 - iii. Ensure that the Output Bay Lane LED(s) of the rack(s) to be removed are not red.
 - iv. Pull the rack by the handle and remove it from the Output Bay Lane.
 - v. Remove up to eight (8) Output Racks as necessary
 - vi. Multiple racks can be removed at the same time if the criteria in steps i-v are met
- c. If necessary, load new Output Racks into the empty Output Bay Lanes
- d. Close the Output Bay Door

 Processing SOP Manual	Title: TomCat Procedure	
	SOP: Processing Department	Version: 1.0
	Effective Date: 10/6/2017	Page 10 of 10

10. Instrument Shutdown

- a. To Shutdown the Tomcat Instrument:
 - i. The **shutdown** button is not available when the instrument is in the Processing state.
 - ii. Ensure that the instrument is not in the Processing state
 - iii. Unload all racks and reagent bottle from the instrument.
- b. From the Menu Bar, select **Shutdown**
 - i. Select **Yes** to confirm shutdown. The Tomcat Instrument Software properly shuts down to the *Desktop Shield* screen
 - ii. From the *Desktop Shield* screen, select the **shutdown** icon(on the bottom right hand corner of the screen). The Tomcat Instrument Computer properly shuts down.
- c. Use the power switch on the rear left of the instrument to turn the Tomcat Instrument off
- d. To restart the instrument, follow the Instrument Startup procedure

11. Dead Space Volume Requirements

- a. Dead space volume is defined as the volume of sample in a tube that must be present in order for the instrument to initiate pipetting
- b. For example, the dead space volume for a Surepath (34mm diameter) round-bottom tube is 3000 μ L. Each sample of this type must have at least the required specimen aspirating volume of 1000 μ L, plus the dead space volume of 3000 μ L of specimen. Refer to the table below for total specimen volume requirements.

Container Minimum Volume Requirement

Surepath (34mm): 4000 μ L

Thinprep (26mm): 6500 μ L or 7000 μ L