

# **PATHTEZT™ PROCESSOR**

## **OPERATING INSTRUCTIONS.**

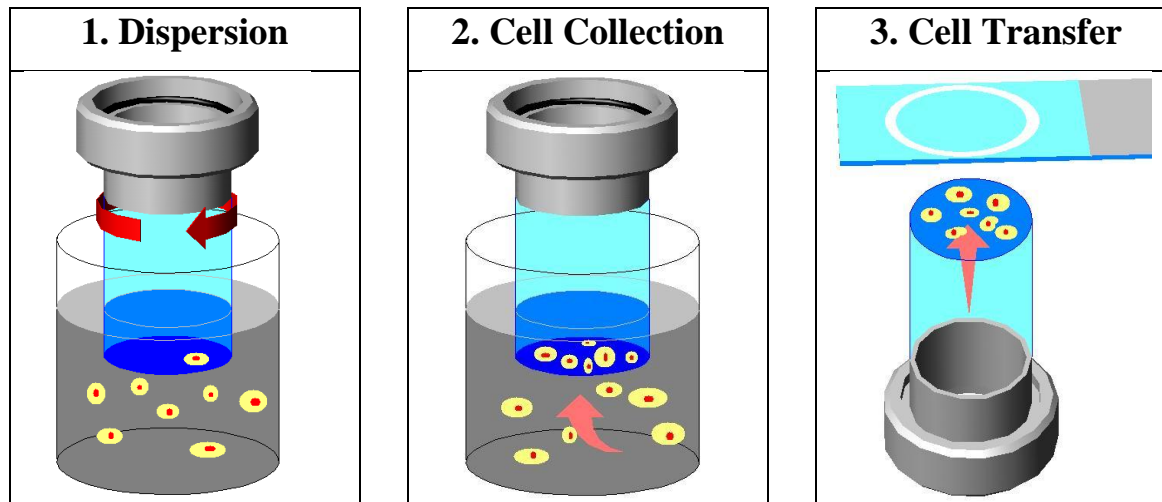


### **PRINCIPLE OF THE TEST.**

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 in order 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 20 mm-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.**