

# Histologic Validation of Vacuum Sealed Formalin-Free Tissue Preservation and Transport System

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## Background:

Human specimens for pathologic examination are routinely fixed in formalin, a process that is over 100 years old. This potentially exposes healthcare personnel to potentially toxic and critical exposure to the class 1 carcinogen, formaldehyde. A formalin spill in the operating room (OR) or laboratory must be contained as a hazardous material and may present a major health hazard. It is our goal to redesign a work process so that formalin is removed from hospital OR's for the purpose of fixation and transportation of human specimens to the Anatomic Pathology Core Laboratory of the Henry Ford Health System, Detroit, Michigan.

## Design:

TissueSAFE high vacuum biospecimen transfer system (Milestone Medical, Kalamazoo, MI) was evaluated as a potential technology to pursue the goal of a formalin-free operation. Two validation schemes were designed to involve 2 hospital operating rooms and laboratories of the Henry Ford Health System. In the 1st validation scheme we evaluated by routine histology, the tissue preservation of 9 human tissues that were vacuum sealed, formalin-free transfer and storage at 4 and 7°C for 24, 48 and 72 hours compared to paired formalin fixed tissue. In the 2nd scheme, we evaluated a mechanism to transport and store 9 human specimens stored under vacuum, formalin-free at 4°C for 24 and 48 hours before tissue examination, processing and histologic assessment.

## Results:

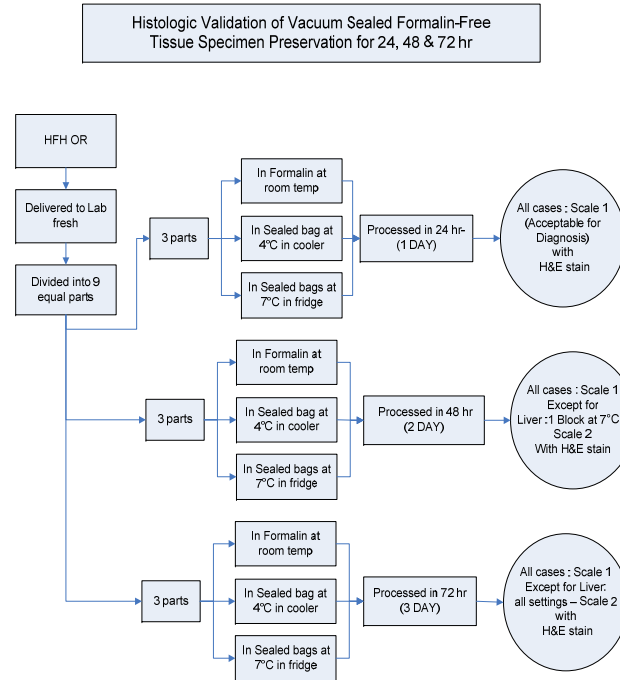
In the tissue preservation validation we evaluated 7 tissue types: liver, uterus, ovary, lymph node, leg, lung and fatty pannus comprising 50 blocks. All slides were hematoxylin and eosin stained and evaluated by surgical pathologists using a 3 part scale of Acceptable for Diagnosis, Inferior Quality for Diagnosis or Unacceptable for Diagnosis. All 9 cases with 46 blocks were Acceptable for Diagnosis except for 4 blocks of liver that were under processed and coded as Inferior Quality for Diagnosis.

For validation of transportation we evaluated 8 tissue types comprising 56 blocks: stomach, gallbladder, placenta, fallopian tube, uterus, thyroid, bowel, and fistula. All tissues were evaluated histologically at 1 day and 2 day of storage under vacuum in the cold using the same scale. All tissue types and blocks were Acceptable for Diagnosis by histologic evaluation up to 2 days.

## Discussion:

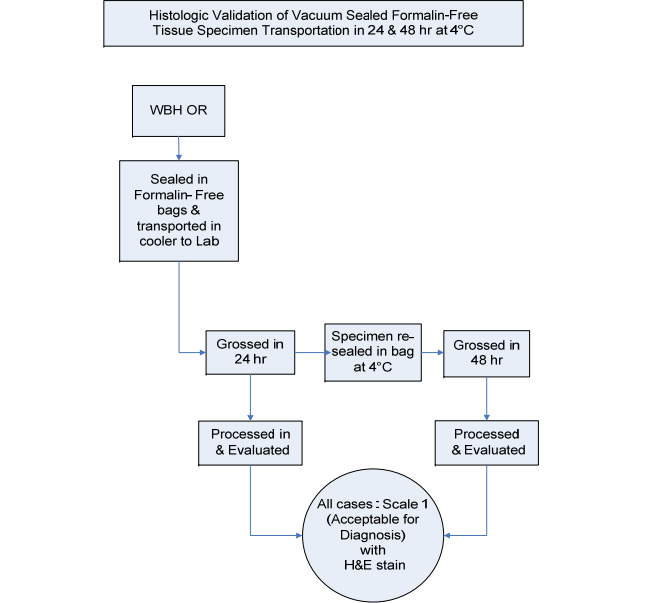
In this study we have shown that the vacuum sealed airless tissues held at 4°C are preserved for histologic assessment when held in that state from 24-48 hours. We have also designed an inexpensive means of using regular ice in a small transport cooler to facilitate the transfer of these specimens from remote hospitals to core anatomic pathology processing laboratories. This TissueSAFE vacuum transport system provides a platform for designing future conditions of formalin-free Operating Room Suites and formalin-free transport of human tissue specimens to processing laboratories.

## Process Flow Design: Tissue Preservation Under Vacuum



N= 9 Tissue Types: Liver x2 Uteri x2 Ovary Lymph Node Leg Lung Pannus	Evaluation: Liver A10-18 A10-14 = 1 A15-18 = 2 under processed Liver B11-19 = 1 Uterus A6-14 = 1 Uterus A11-19 = 1 Ovary A10-18 = 1 Lymph Node C10-18 = 1 Leg A8-15 = 1 Lung A11-19 = 1 Pannus A2-10 = 1	Pathologist's Evaluation Scale with H&E Stain:  Acceptable for Diagnosis = 1 Inferior Quality = 2 Unacceptable for Diagnosis = 3
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## Process Flow Design: Tissue Transportation Under Vacuum



N= 11 Tissue Types: Stomach X 3 Gallbladder Placenta Fallopian Tube Uterus Thyroid Small bowel X 2 Fistula	Evaluation: 24 hr Stomach A1 = 1 Stomach A1 = 1 Stomach A1 = 1 Gallbladder A1 = 1 Placenta A1-4 = 1 Fallopian Tube A1 B1 = 1 Uterus A1-10 = 1 Thyroid A4-13 = 1 Small Bowel A1 = 1 Fistula A1-2 = 1 4hr A2 = 1 A2 = 1 A2 = 1 A2 = 1 AS-7 = N/A A11-15 = 1 A14-18 = 1 A2 = 1 A3 = 1 A3-4 = 1	Pathologist's Evaluation Scale with H&E Stain:  Acceptable for Diagnosis = 1 Inferior Quality = 2 Unacceptable for Diagnosis = 3
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## Conclusion:

The TissueSAFE high vacuum specimen transfer system shows promise as a technology that will promote environments safe from the toxic, hazardous and carcinogenic formaldehyde solutions that form the current work systems of operating rooms and anatomic pathology laboratories.

## References:

Bussolati G, Chiusa L, Cimino A, D'Armento G: Tissue transfer to pathology labs: under vacuum is safe alternative to formalin. Virch Arch 2008;452:229-231