

## BACKGROUND

Formalin fixing and transporting tissue specimens is a process over 100 years old that potentially exposes healthcare workers to toxic, carcinogenic formaldehyde. Formalin spilled in operating room (OR) or laboratory is a health hazard to be contained as a hazardous material. We seek to redesign this work process so formalin is removed from 4 hospitals in the process of transportation of human specimens to an Anatomic Pathology Core Laboratory.

## DESIGN

TissueSAFE high vacuum biospecimen transfer system (Milestone Medical, Kalamazoo, MI) was evaluated for vacuum sealed, formalin-free transfer and storage in 3 validations: 1) Preservation of surgical specimens vacuum sealed and stored at 4° C and 7° C for 24, 48 and 72 hours compared to paired formalin fixed tissue; 2) Transport and storage of specimens sealed in OR of a community hospital 25 miles away at 4° C for 24 and 48 hours; 3) Preservation of surgical specimens sealed in FS Room adjacent to 30 ORs then transported at 4° C to the Core Lab within the same hospital, range of storage times 1-10 hours before tissue examination, fixation, processing and histologic assessment. All slides were H+E stained and evaluated by pathologists using a 3 part scale of Acceptable for Diagnosis, Inferior Quality for Diagnosis or Unacceptable for Diagnosis.

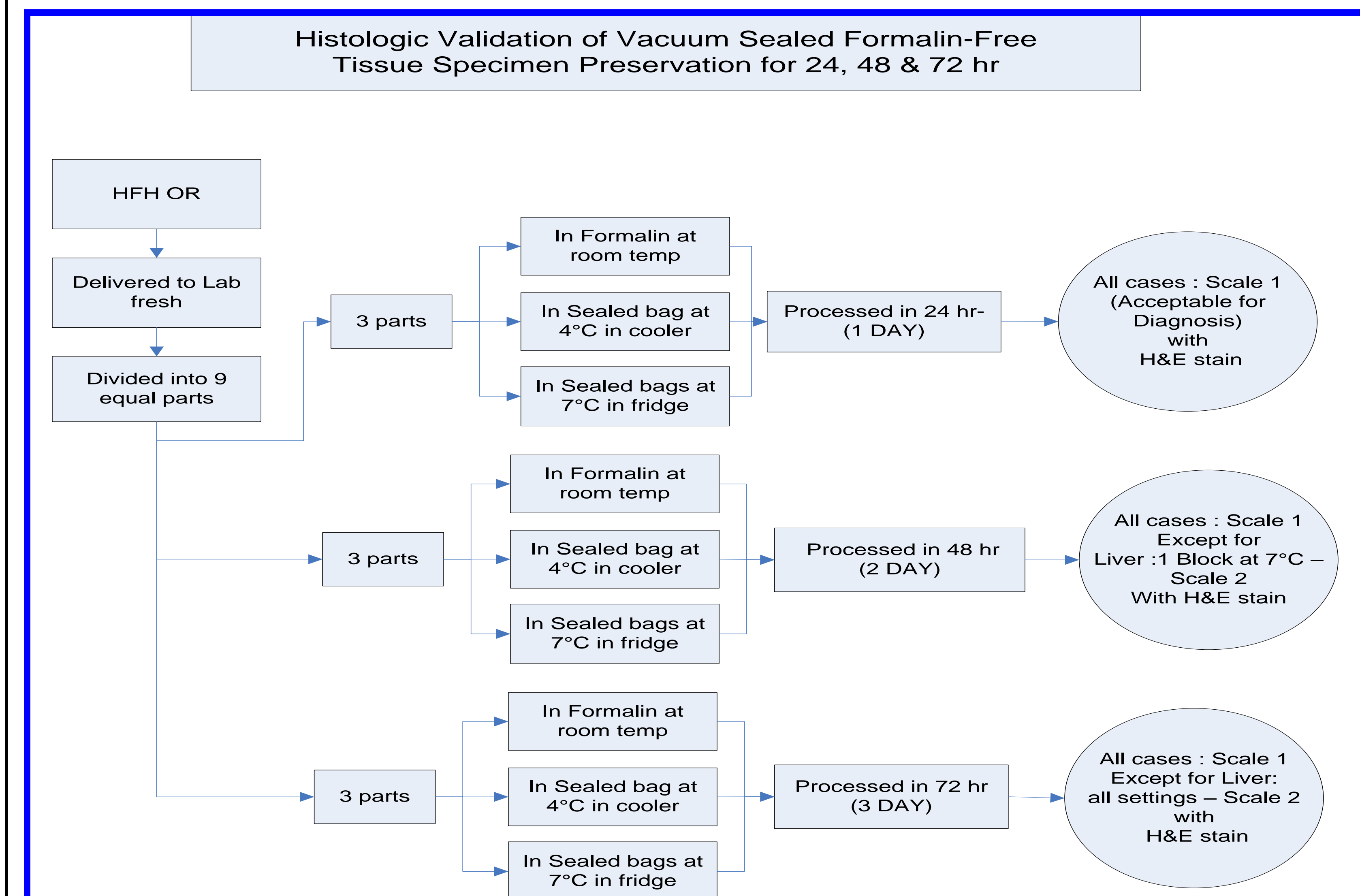
## RESULTS

**SCHEME #1:** 9 cases, 7 tissue types (50 blocks): liver, uterus, ovary, lymph node, leg, lung, fatty pannus. All were Acceptable for Diagnosis except for 4 blocks of liver that were under processed and coded as Inferior Quality for Diagnosis. **SCHEME #2:** 9 cases, 8 tissue types (56 blocks): stomach, gallbladder, placenta, fallopian tube, uterus, thyroid, bowel, fistula. All were Acceptable for Diagnosis by histologic evaluation at 1 and 2 days storage under vacuum in the cold. **SCHEME #3:** 30 cases, 16 tissue types, (164 blocks): lung, kidney, stomach, uterus, colon, small intestine, gallbladder, thyroid, brain, tonsil, skin, TURBT, TURP, hemorrhoid, appendix, arterial plaque. All but 2 cases were Acceptable for Diagnosis with 1 TURBT (5 hour storage) and kidney (2.5 hour storage) deemed Inferior Quality for Diagnosis due to “air-drying” and lack of crisp cytologic tumor detail, respectively.

## CONCLUSIONS

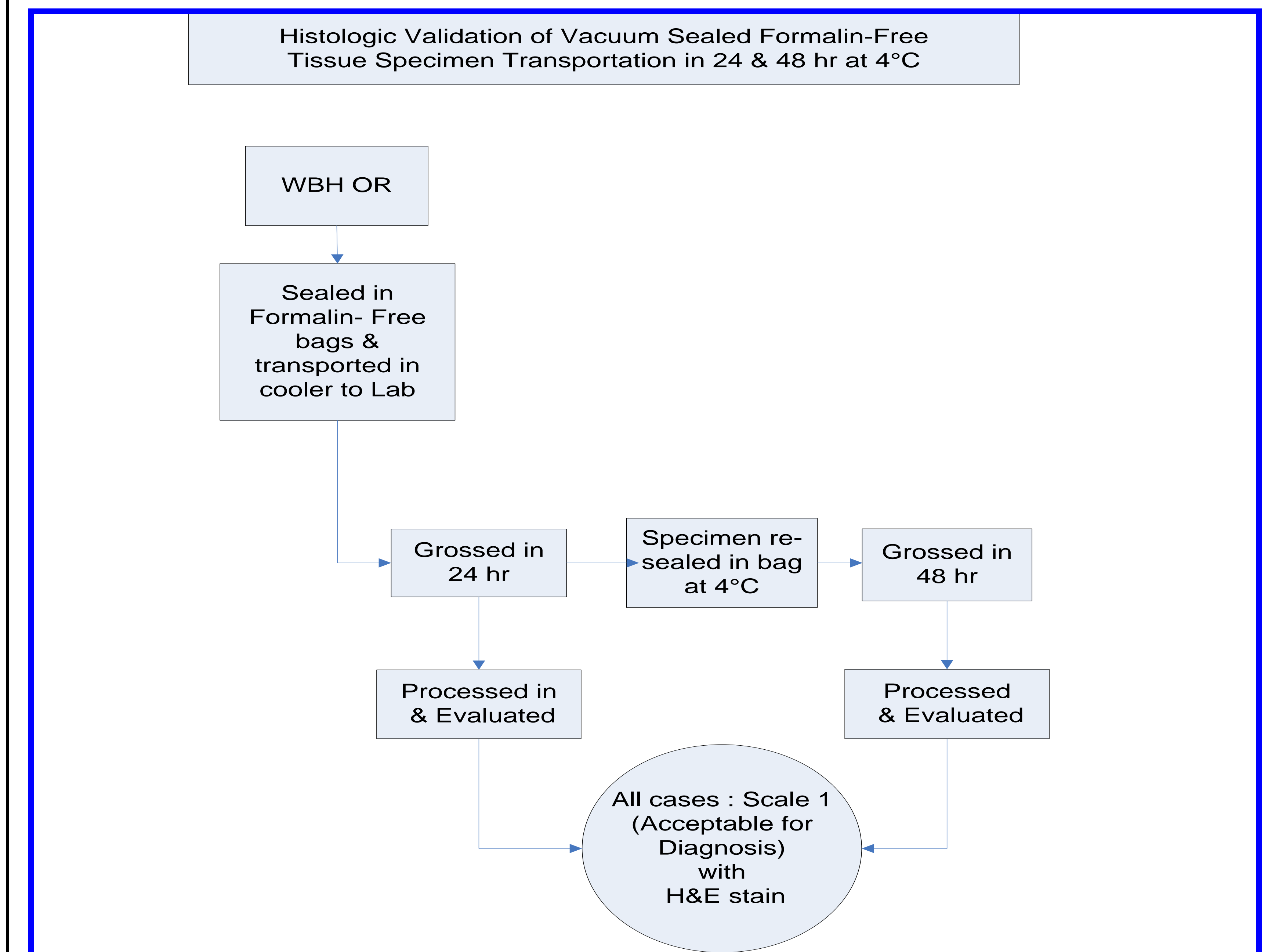
Vacuum sealed tissue held at 4° C are preserved for histologic assessment when held in that state up to 48 hours. The nature of the 2 histologically inferior exceptions with low storage times require further study. TissueSAFE vacuum transport shows promise to provide a platform for designing formalin-free ORs and transport of tissue specimens to processing laboratories.

## Process Design: Timed Tissue Preservation Under Vacuum at Various Cold Temperatures and Times



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 Design: Tissue Transportation from Community Hospital to Core Lab Under Vacuum at 4° C



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 Small Bowel A1-2 = 1 4hr A2 = 1 A2 = 1 A2 = 1 A2 = 1 A5-7 = 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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## TECHNOLOGY



## CONCLUSIONS

**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.

**Reference:**  
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