

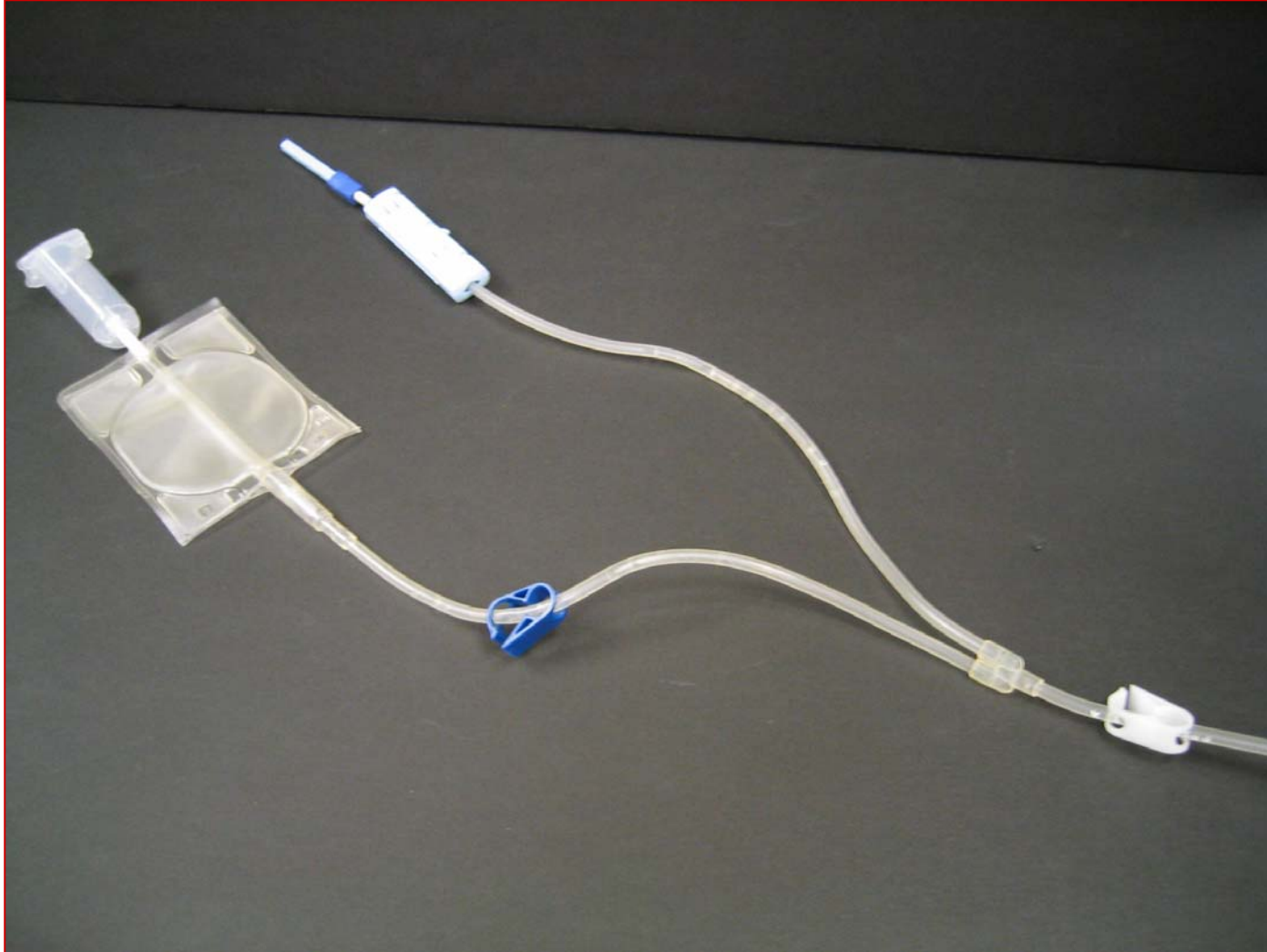
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# Diversion of Initial Blood Collection Sample First Sampling System Overview and Update

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# Sample First Sampling System

U.S. version introduced in Q3 2003



# Sample First Issue Summary

— 2004 —

## Jan 30

- A blood center reports diluted testing samples
- Report discussed with CBER
- All Sample First product put on corporate hold

## Wk of Feb 1

- Letter sent to Sample First customers (14) reinforcing instructions for use, requesting inspection of current & retained infectious disease testing samples
- Baxter representatives visit all Sample First accounts and provide additional training

## Wk of Feb 8

- Additional letter sent to customers regarding instructions for use, inspections of infectious disease testing samples and collected products
- Conference calls with ABC and BCA members providing situation overview and announcing decision to redesign product to incorporate more user-friendly design

# Additional Follow Up Activities

- Sample First customers converted to other Baxter Blood Pack Units
- Production of current U.S. Sample First Blood Pack Units halted pending redesign
- Met with representatives of the AABB Standards Committee regarding customer compliance with 5.1.5.1 standard during transition period
- Ongoing communication with customers and CBER

# Investigation Summary

- Sample dilution may occur if sample pouch cannula is inadvertently broken or if clamping is compromised during Blood Pack Unit handling
- No evidence of a manufacturing defect or product failure mode that would result in the presence of anticoagulant in the sample pouch in the absence of the breakage of the sample pouch cannula and/or compromised clamping

# Conclusion

Based on customer experience, a more user-friendly design is needed, which is the focus for the redesigned product

# Redesign Priorities

Rapid introduction of redesigned Blood Pack Unit system

Incorporate more user-friendly design to further limit potential for anticoagulant to inadvertently enter sample pouch

Renewed focus on customer training and educational activities associated with use of new sampling procedure

# Q&A