

Ameda Hygienikit® Milk Collection Set

REDUCING RISK FOR CONTAMINATION IN THE EXPRESSION OF MOTHER'S MILK

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ABSTRACT In an institutional setting, breast pumps can provide a mechanism for the spread of bacteria and virus. Investigations have linked pathogens to infections in high-risk infants who have received expressed breast milk from contaminated breast pumps. For this reason, barrier properties of the silicone diaphragm in a commercially available breast milk collection system, Ameda HygieniKit® were challenged with representative bacterial (*E. coli*, *S. aureus*, *S. pneumoniae* and *P. aeruginosa*) and viral suspensions (Phi-X174 bacteriophage) in simulated-use conditions.

Penetration was not observed past the diaphragm providing reduction of the risk from bacterial and viral contamination. The unique design of the Ameda HygieniKit® breast milk collection system with its silicone diaphragm appears to reduce the risk of contamination of:

- expressed mother's milk from bacteria and virus in vacuum pumps and tubing
- vacuum pumps and tubing from contaminated mother's milk

BACKGROUND Several studies have been conducted that demonstrate that bacteria can be isolated from pumped breast milk. Table 1 illustrates some of the bacteria and viruses that have been isolated in breast milk. Some of these microorganisms are known to transmit disease or infection.

TABLE 1

Bacteria and Viruses isolated from human milk	
Bacteria	Virus
• <i>Staphylococcus epidermidis</i>	• Cytomegalovirus
• <i>S. aureus</i>	• Human Immunodeficiency Virus
• <i>Klebsiella pneumoniae</i>	• Hepatitis B
• <i>Pseudomonas</i> species	• Hepatitis C
• <i>Acinetobacter</i> species	• Rubella
• <i>Enterococcus</i>	• HTLV-1
• <i>Bacillus</i> species	
• <i>E. coli</i>	
• Gentamicin-resistant GNR	

There are several modes of contamination of breast milk, Table 2. In case reports, infants developed neonatal sepsis from the same bacteria isolated from their mother's breast milk. Outbreak investigations in NICU settings have linked pumped breast milk to a contaminated breast pump. While NICU patients are not the only persons at risk, they are the most fragile and represent the greatest institutional risk and potential liability. Since it has been reported that milk can back up into tubing, it is possible that the collected milk could become infected or colonized from contaminated tubing. The fertile media of the milk back up and subsequent condensation could easily promote bacterial growth.

TABLE 2

Modes of breast milk contamination
• Spread of bacteria/virus from mother to milk
• Contamination during pumping
• Contamination during storage
• Contamination during preparation for infant

In light of the potential for breast milk contamination, an in vitro study was undertaken to determine whether the silicone diaphragm in the Ameda HygieniKit® breast milk collection system was an effective barrier to viral and bacterial penetration, thus reducing the risk for contamination.

TEST METHOD

A standard test procedure developed by the American Society for Testing Material (ASTM) 167197b "Standard Test Method Resistance of Materials Used in Protective Clothing to Penetration by Blood-borne Pathogens Using Phi-X174 Bacteriophage as a Test System" was chosen as a starting point. Developed to assess the effectiveness of protective clothing materials in contact with blood-borne pathogens, this method used a static test fixture to test individual materials. In breast milk collection systems, components are not static but rather in continuous motion and dynamic. Revisions were made to better examine the effect of actual use of the Ameda HygieniKit® breast milk collection system being investigated.

The test procedure was set up to mimic use conditions. Since the breast pump collection systems can be used under a wide variety of conditions, severe simulated use conditions were selected to test the diaphragm for its ability to act as a barrier.

Ameda HygieniKit® Milk Collection System



Ameda diaphragm (in left hand) prevents bacteria and viruses from backing up into tubing and from contacting collected milk.*

Test Conditions

Pump	SMB: Ameda Medical Grade Breast Pump
Pressure	≥ 230 mm Hg
Pumping Time	One hour
Pumping Cycle	Continuous pumping @ 48 cpm
Flow Rate	20 litres/min

Two groupings of representative microbes were selected: bacteria and virus. Representative microorganisms were selected to function as surrogate microbes for this testing.

Bacterial Selection

Input from lactation consultants was solicited to select representative bacteria. In addition, an independent microbiological testing laboratory was contacted for input concerning the viability of mixing the various suggested bacteria strains. The following bacteria were selected to be mixed together as a challenge suspension:

- *E. coli*
- *S. aureus*
- *S. pneumoniae*
- *P. aeruginosa*

The challenge suspension of these bacteria was prepared by inoculating sterile soybean casein digest broth with a stock solution of the microorganisms. Aliquots of the stock suspension were transferred to nutrient broth with 0.01% Tween® 80 to achieve an approximate titer of 1.0 x 10⁷ colony forming units (CFU) per millilitre.

Viral Selection

Viral pathogens of major concern are hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). Phi-X174 bacteriophage, one of the smallest known viruses, a non-enveloped, icosahedral virus (as is HCV), was selected as a representative pathogenic virus to form a challenge suspension.

The challenge suspension of Phi-X174 bacteriophage was maintained at a concentration of at least 1.0 x 10⁸ plaque forming units (PFU) per millilitre.

Virus	Size
Phi-X174	25-27 nm
HCV	27-30 nm
HBV	42-47 nm
HIV	80-110 nm
CMV	150-200nm