



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/viruses 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	150-200 nm



Test Procedure

Bacterial and viral challenges were performed by placing the appropriate challenge suspension on either side of the **Ameda HygieniKit®** silicone diaphragm. The collection system was then attached to a medical-grade, piston-driven, electric vacuum pump with maximum vacuum applied for one hour. The sides of the diaphragm opposite of the challenge suspensions were flushed with nutrient broth with 0.01% Tween® 80 to extract any organisms which may have penetrated the diaphragm.

Bacterial Penetration From Inside of Diaphragm

Representing bacterial contamination from a vacuum line or pump, 0.1 millilitre of the bacterial challenge suspension was introduced into the inside of the diaphragm. The nipple tunnel of the **Ameda HygieniKit®** collection system (designed to fit on the breast) was plugged with a rubber stopper. The pump was attached and a vacuum applied for one hour. At twenty (20) minute intervals, the pump was turned off and the collection bottle was inverted once so that the challenge suspension came in contact with the seal of the diaphragm. After the test period, the outside of the diaphragm was rinsed with nutrient broth. This broth was then cultured for any bacteria that may have penetrated.

This procedure was performed with a total of sixteen (16) new collection systems.

Bacterial Penetration From Outside the Diaphragm

Representing bacterial contamination from mothers milk inside the collection system bottle, the experiment was repeated using sixteen (16) new **Ameda HygieniKit®** breast milk collection systems, with 0.1 millilitre of the identical bacterial challenge suspension introduced into the outside of the diaphragm. To produce the most challenging environment, the collection system was inverted during the entire one hour testing period to ensure intimate contact between the diaphragm and challenge suspension.

After the test period, the inside of the diaphragm was rinsed with nutrient broth. This broth was then cultured to look for any bacteria that may have penetrated.

Viral Penetration From Inside and Outside of Diaphragm

Following the same format as the bacterial challenge, testing for viral penetration was done with new collection systems. One set of sixteen (16) collection systems was used to examine the potential for penetration from the inside of the diaphragm and a second set of sixteen (16) for penetration from the outside of the diaphragm.

Controls

Positive and negative controls were used to validate the test procedure. The positive control was a collection system with a deliberate pinhole made in the diaphragm. The negative control was saline.

Test Results

In two (2) sets of sixteen (16) replicates, bacteria and viral penetration was not detected through the outside of the diaphragm.

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Conclusion

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Discussion

The clinical application of this testing suggests that use of the **Ameda HygieniKit®** breast milk collection system with its silicone diaphragm will result in less contamination of breast milk during pumping. There is no pathway to allow microorganisms to:

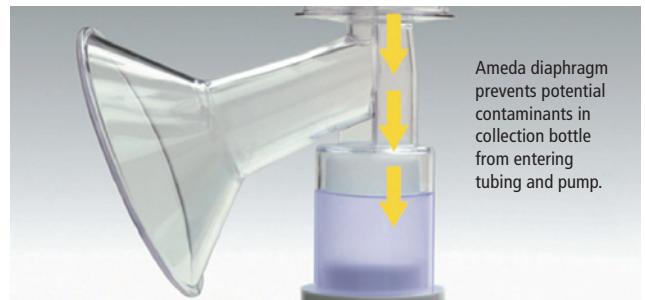
- enter the collection system and contaminate the breast milk.
- contaminate the kit tubing or vacuum source.

Often breast milk collection systems are used incorrectly leading to milk back up in a system or tubing. Should the vacuum source or tubing connected to the **Ameda HygieniKit®** breast milk collection system become contaminated, there is no mechanism for entry of a microorganism into the collection system and therefore the collected mothers milk. This provides a measure of assurance to the mother protecting her from nosocomial infections.

Independent study proves patented silicone diaphragm acts as a two-way barrier. (Purple colouration represents bacterial and viral contamination.)



Ameda diaphragm prevents potential contaminants in pump and tubing from entering collection bottle.



Ameda diaphragm prevents potential contaminants in collection bottle from entering tubing and pump.

Likewise, if the **Ameda HygieniKit®** breast milk collection system is used by someone who is infected, there is no mechanism for entry of a microorganism from the mother and collection system into the vacuum source or tubing. With the use of the **Ameda HygieniKit®** breast milk collection system, this would not be possible due to the silicone diaphragm. This eliminates an additional source of nosocomial infection.

Institutional wide use of the **Ameda HygieniKit®** breast milk collection system tested in this experiment will result in reduced risk of contamination of breast milk from mothers of infants in the NICU and nursery setting.

FDA Clears Product Claim:

Ameda HygieniKit® with Patented Diaphragm Protects Breast Milk from Bacteria and Viruses*

The Food and Drug Administration (FDA) has reviewed and cleared the claim that the patented silicone diaphragm used in the **Ameda HygieniKit®** milk collection system creates a barrier that protects both:

- Collected breast milk from potential contaminants such as viruses and bacteria that may be present in the pump and or kit tubing
- Pump and kit tubing from potential contaminants such as virus and bacteria that may be present in collected milk.

The **Ameda HygieniKit®** is the only breast milk collection system with FDA clearance to make strong protective claim.

The significance of the claim may be especially relevant to mothers using medical grade breast pumps and those pumping for premature or ill newborns who are at greater risk of succumbing to infection.

The new claim states

*"The Ameda HygieniKit® has a patented silicone diaphragm that creates a barrier protecting the pump and tubing from penetration of bacteria^{1,2} and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV)^{1,2} from contaminating liquids inside the collection bottle system.

The diaphragm in this product creates a barrier protecting liquids collected in the collection bottle system from penetration of bacteria^{1,2} and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV)^{1,2} from the pump and tubing in the event of contamination of these components during a prior use or by a prior user.

Note that the **Ameda HygieniKit®** neither removes bacteria and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV)^{1,2} from the breast milk being collected into the collection bottle nor does the Ameda HygieniKit® make it safe for infected mothers to feed their infants with milk collected using this device."

- Testing performed in situ using actual HygieniKits and SMB Piston Breast Pump with suspension of Phi-X174 bacteriophage and Escherichia coli, Staphylococcus pneumoniae and Pseudomonas aeruginosa. Procedure was adopted from ASTM 1671-97b 'Standard Test method Resistance of material Used in Protective Clothing to Penetration by Blood-borne Pathogens Using Phi-X174 Bacteriophage as a test System.
- The use of this product neither guarantees or warrants against the transmission of Hepatitis B and C and Human Immunodeficiency Virus HIV.

Note: Testing relating to this claim applies to stock numbers 17121,17126, 17131, 17101, 17111, 17128, 17070, 17072.



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