Contamination Prevention

Background:

The Visby device is a single-use (disposable), fully integrated, rapid, automated in vitro diagnostic test that utilizes PCR technology to amplify and detect nucleic acid targets.

A Polymerase Chain Reaction (PCR) is the process of making millions of copies of a specific DNA segment of interest. If the starting genetic material is RNA, the RNA is first converted to DNA in a process called reverse transcription. PCR utilizes reagents and temperature cycling to duplicate each copy of DNA per cycle. At the end of 35 to 40 cycles the reaction has made almost half a billion copies. The amplified DNA segment of interest is called amplicon.

PCR is an invaluable diagnostic tool because it amplifies genetic targets from organisms making them easier to find at very low levels. When paired with detection methods, PCR helps determine the presence or absence of the organism of interest in a patient sample. Since PCR is a highly sensitive diagnostic tool, the reaction is susceptible to contamination.

Contamination occurs when a pathogen or amplicon is introduced by the user to a sample or test accidentally. The introduction of contaminants can result in a false positive. Unlike pathogen contamination, amplicon are harmless, very small, and very difficult to clean. It is best practice to avoid all potential causes of contamination by following good lab practices and the following guidelines:

Tips for Avoiding Contamination:

1. Follow your Institution's safety procedures for working with chemicals and handling biological samples.
2. Visby Respiratory Health Buffer may contain irritants. Do not ingest the contents of the tube. If the contents of the tube are splashed in your eyes, flush your eyes with water. If the contents splash onto your skin, wash with soap and water. If irritation persists, notify a health care provider (HCP).
3. Wear gloves while handling samples. If the gloves come in contact with specimen or appear to be wet, change gloves to avoid contaminating other specimens. Change gloves between the processing of each specimen and before leaving the work area and upon entry into work areas.
4. Keep the work area clean to prevent contamination.
5. Do not try to disassemble the Visby Respiratory Health device.
6. Treat all biological specimens, including used Visby Medical Respiratory Health devices, as if capable of transmitting infectious agents. All biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical Laboratory Standards Institute.

If a Spill or Drip Occurs:

1. If a spill occurs with Visby Medical Respiratory Health Test and/or Visby Respiratory Health Buffer Tube, soak up the spill with an absorbent material. Spray the contaminated area and materials with 10% bleach. Wipe down the surface so that it is saturated with bleach and let rest for at least 10 minutes. Once 10 minutes have passed, wipe the area down with an absorbent material, such as paper towels, followed by rinsing the area with water. Discard the Visby Medical Respiratory Health device according to your institution's standard practices.
2. If a spill occurs on the Visby power adapter, unplug, and wipe it down vigorously with 70% ethyl or isopropyl alcohol. Allow the power adapter to completely dry before using it again.
3. Safety Data Sheets (SDS) are available at Visby Medical Customer Support 1-833-GoVisby (1-833-468-4729).

For help, contact Visby Medical Customer Support at **1-833-GoVisby** (1-833-468-4729) or email **support@visby.com**.