



Bleach Enhancer for Cleaning

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Intended Use

The Bleach Enhancer for Cleaning is to be used in conjunction with sodium hypochlorite solutions for routine cleaning of laboratory surfaces and equipment when performing Gen-Probe assays. Use of the Cleaning Solution along with strict adherence to the cleaning procedures outlined in this document provides an optional alternate cleaning method for routine cleaning to that described in Gen-Probe assay package inserts. See the applicable assay package insert for information on the appropriateness of using Bleach Enhancer for Cleaning.

Summary

Because of their extraordinary sensitivity, nucleic acid amplified tests (NAATs) are able to detect as little as one nucleic acid target molecule. Therefore, laboratories running NAATs need to take special precautions to prevent contamination of laboratory surfaces and equipment with specimens, positive controls, and amplification reaction mixtures that may be accidentally transferred to test reactions, causing false results.

Gen-Probe recommends the use of a 1:1 dilution of 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution in water for routine cleaning of surfaces and equipment when running Gen-Probe assays. At this concentration, bleach very effectively destroys nucleic acid targets.

As an alternative, a Cleaning Solution can be prepared with the Bleach Enhancer for Cleaning and a resulting lower concentration of sodium hypochlorite solution to eliminate strong bleach odor and reduce corrosion of equipment associated with a stronger sodium hypochlorite solution.

When the Cleaning Solution is used in conjunction with strict adherence to the routine cleaning procedures outlined in this document, results are equivalent to those obtained using a 1:1 dilution of 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution.

- D. Decontaminate surfaces by thoroughly wetting them, followed by wiping them while wet, in order to dissolve dried residues, dirt, and greasy films.
- E. Do not allow the Cleaning Solution to dry by itself on a surface. Do not decontaminate too large of a surface area or too many surfaces at one time to prevent air drying. This is especially critical for bench surfaces. Overlap the cleaning areas of a large surface if it won't be cleaned all at one time.
- F. Carefully discard all towels and gloves in a closed, leak-proof receptacle, making sure that no dripping occurs during transfer.
- G. After decontaminating a surface with the Cleaning Solution, do not rinse the surface with water.
- H. Before applying the Cleaning Solution for a second time to a surface, make sure that the surface has been thoroughly dried.
- I. Use Universal Precautions when handling and disposing of liquid and solid waste. Dispose of liquid and solid waste according to local, state, and federal regulations. The contents of the Waste Bottle should be treated as a potential source of assay contamination. Take precautions to avoid contaminating yourself or the laboratory environment.

Storage and Handling Requirements

- A. Store unused Bleach Enhancer for Cleaning at room temperature (15° to 30°C) until the expiration date on the label.
- B. If the Bleach Enhancer for Cleaning is cloudy or a precipitate is present, heat the bottle at 42°C for 5 minutes and swirl gently to clear. Repeat if necessary. Allow any heated Bleach Enhancer for Cleaning to reach room temperature before preparing Cleaning Solution.
- C. Cleaning Solution is stable for 2 weeks when stored at room temperature (15° to 30°C).

Procedure

- A. Cleaning Solution Preparation
 - 1. Prepare 1 liter of the Cleaning Solution. If a larger volume is needed, scale up proportionally.
Note: *Cleaning Solution used for cleaning racks and other components may be prepared in the container to be used for soaking the equipment.*
 - a. Add 750 mL DI water to an appropriately sized container.
 - b. Add 150 mL Bleach Enhancer for Cleaning to the container.
Note: *If the Bleach Enhancer for Cleaning is cloudy or a precipitate is present, heat the bottle at 42°C for 5 minutes and swirl gently to clear. Repeat if necessary. Allow any heated Bleach Enhancer for Cleaning to reach room temperature before preparing Cleaning Solution.*
 - c. Add 100 mL 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution.

- d. Gently swirl to thoroughly mix contents for 15-20 seconds. Store at room temperature (15° to 30°C) for up to two weeks.
- e. Before starting cleaning procedures, fill a squirt bottle with the Cleaning Solution. Refill as needed.

B. Cleaning Method

1. Instrument Surfaces and Workspace

- a. Use a squirt bottle to wet paper towels with the Cleaning Solution until they are saturated but not dripping. Do not squirt the Cleaning Solution directly onto the instrument surface or workspace.
- b. Thoroughly clean/wipe the surface with the wet paper towels. Discard the paper towels after use.
- c. Immediately wipe the wet surface dry with dry paper towels. Do NOT allow the Cleaning Solution to dry by itself on the surface.
- d. After drying the surface completely, repeat steps 1a - 1c above to apply the Cleaning Solution for a second time. Do not rinse the surface with water.

2. Bench Surface

- a. Use a squirt bottle to apply Cleaning Solution to the bench surface. Take care to avoid splashing the Cleaning Solution onto surrounding areas, equipment, or the floor.
- b. Thoroughly and completely spread the Cleaning Solution over the surface using paper towels. Discard wet towels after use.
- c. Immediately dry the wet surface with dry paper towels. Do NOT allow the Cleaning Solution to dry by itself on the surface.
- d. After drying the surface completely, repeat steps 2a - 2c to apply the Cleaning Solution for a second time. Do not rinse the surface with water.

C. Routine Cleaning of Pre-Amp Surfaces and Equipment

1. Prior to Starting an Assay

Note: *Change gloves immediately whenever they may have become contaminated during the procedure. Use one gloved hand for cleaning/wiping surfaces and the other gloved hand for handling the squirt bottle.*

Use the Cleaning Method to clean all surfaces as follows:

- a. Automated Pipetting Unit
Clean parts above the deck followed by the deck itself.
- b. Target Capture System
- c. Bench Surfaces
Do not decontaminate too large of a surface area or too many surfaces at one time, as the Cleaning Solution should not dry by itself on the surface. Overlap the cleaning areas of a large surface if it won't be cleaned all at one time.
- d. Pipettors

When finished cleaning the pre-amp area, carefully change both gloves. Change gloves sooner if there is any suspicion of possible contamination.

2. After Specimen Preparation

Put on clean gloves and use the Cleaning Method to clean all surfaces and components as follows:

- a. Automated Pipetting Unit
Clean parts above the deck followed by the deck itself.
- b. Components to Be Soaked
After use, completely submerge racks and components such as reagent reservoirs, deck plates, disposable tip racks, and waste chute in the Cleaning Solution. Allow to soak for 30-60 minutes. Rinse thoroughly under running water. Do not soak in a bath of rinse water. Dry completely with paper towels or air dry, if preferred.
- c. Bench Surfaces
- d. Pipettors

3. After Target Capture

Use the Cleaning Method to clean all surfaces or components as follows:

- a. Aspiration Manifold
 1. Place a new Ten Tip Cassette (TTC) into the target capture unit.
 2. Turn on the vacuum pump.
 3. Move the Wash Solution dispense manifold out of the way.
 4. Attach the tips in the TTC to the aspiration manifold and carefully aspirate all remaining Wash Solution from the trough of the Wash Solution dispense station.
 5. Add 100 mL of the Cleaning Solution to the trough, then carefully aspirate all of the Cleaning Solution through the aspiration manifold.
 6. Add 100 mL of DI water to the trough, then carefully aspirate all of the DI water through the aspiration manifold.
 7. Eject the tips into their original TTC.
 8. Leave the vacuum pump on for at least 1 minute after the last aspiration.
- b. Other surfaces of the Target Capture System
- c. Bench Surfaces
- d. Pipettors

4. After starting the Amplification Incubation

Use the Cleaning Method to clean all surfaces as follows:

- a. Bench Surfaces
- b. Equipment Surfaces
- c. Pipettors

D. Routine Cleaning of Post-Amp Surfaces and Equipment

After the last cleaning in the pre-amp area, enter the post-amp area and put on new gloves.

1. Prior to Continuing the Assay

Use the Cleaning Method to clean all surfaces as follows:

- a. Bench Surfaces
- b. Equipment Surfaces
- c. Pipettors

2. After Detection
 - a. Remove the used Ten-Tube units (TTUs) from the LEADER HC+ luminometer and place the TTUs into the container of Deactivation Fluid. Refer to the procedure in the appropriate Gen-Probe assay package insert.
 - b. Use the Cleaning Method to clean all surfaces and components as follows:
 1. Bench Surfaces
 2. Equipment Surfaces
 3. Exterior of LEADER HC+ Luminometer
 4. Pipettors
- E. Decontamination of Vacuum Trap Liquid Waste

Do not use the Bleach Enhancer for Cleaning Solution to decontaminate Vacuum Trap liquid waste. Refer to the assay package insert for details on how to complete this procedure.
- F. Cleaning of LEADER HC+ Luminometer Interior

Clean the interior of the LEADER HC+ Luminometer and cassettes every 1-2 weeks, or as needed:

 1. Clean the interior of the LEADER HC+ Luminometer with DI water, as described in the *LEADER HC+ Luminometer Operator's Manual*.
 2. Completely submerge the LEADER HC+ Luminometer cassettes in the Cleaning Solution. Allow to soak for 30-60 minutes. Rinse thoroughly under running water. Do not soak in a bath of rinse water. Allow to air dry completely.

Limitations

- A. This Cleaning Method has only been evaluated for those Gen-Probe assays whose package inserts contain information on the appropriateness of using Bleach Enhancer for Cleaning. This Cleaning Method has not been validated for use with other assays.
- B. This Cleaning Method is only for routine cleaning and decontamination. A 1:1 dilution of 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution should still be used to treat gross spills of specimens, positive controls, and amplified reaction mixtures, to deactivate vacuum trap liquid waste, and to deactivate completed NAAT assay tubes, as described in Gen-Probe assay package inserts.

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