

Bleach Enhancer for Cleaning

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General Information

Intended Use

The Bleach Enhancer for Cleaning is to be used in conjunction with sodium hypochlorite solutions for routine cleaning of laboratory surfaces and Hologic equipment including instrumentation intended for performing Hologic assays (DTS System, Tigris DTS System, and the Panther System) as well as Hologic general purpose instruments not intended for performing Hologic assays (Tomcat Instrument). Use of the Cleaning Solution along with strict adherence to the cleaning procedures outlined in this document provides an alternate method for routine cleaning from that described in Hologic assay package inserts or the operator's manuals for each respective instrument. See the applicable assay package insert or operator's manual 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.

Hologic 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 Hologic equipment. 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 indicated, results are equivalent to those obtained using a 1:1 dilution of 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution.

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 Hologic assay package inserts and operator's manuals.

Laboratory Recommendations

Prior to implementation, laboratory directors should review this alternate cleaning method using the Cleaning Solution to determine if it should be adopted in their laboratories for routine cleaning of laboratory surfaces and equipment. In considering adoption, laboratory directors should evaluate and implement procedures for validating and monitoring the effectiveness of this alternate cleaning method in their laboratories.

Materials Provided

Hologic Bleach Enhancer for Cleaning (Cat. No. 302101)
Store at room temperature (15° to 30°C)

2 x 3,800 mL bottles

Materials Required But Not Provided

- Appropriately sized container(s) for preparing the Cleaning Solution
- Graduated cylinder(s) for measuring 750 mL, 150 mL, and 100 mL
- Bleach: 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution
- Deionized (DI) water
- Squirt bottle
- Disposable gloves
- Paper towels

Note: *The paper towels used for cleaning should not react significantly with bleach. For example, they should not discolor and/or produce an unpleasant odor when exposed to bleach. Towels should be white, as pigmented and unbleached paper products are more likely to react with bleach.*

Warnings and Precautions

- A. Use gloves at all times when handling the Cleaning Solution. It is critical to change gloves at the proper times. Change gloves immediately whenever they may have become contaminated.
- B. Use one gloved hand for cleaning/wiping surfaces and the other gloved hand for handling the squirt bottle.
- C. For laboratories using DTS Systems, to help prevent lab areas from becoming contaminated with amplicon, the laboratory area should be arranged with a unidirectional workflow from reagent preparation through detection. Specimens, equipment, and reagents should not be returned to the area where a previous step was performed. Also, personnel should not move back into previous work areas without proper contamination safeguards.
- 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 Waste Bottles should be treated as potential sources 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).

Cleaning Solution Preparation

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.*

1. Add 750 mL DI water to an appropriately sized container.
2. 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.*

3. Add 100 mL 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution.
4. Gently swirl to thoroughly mix contents for 15-20 seconds. Store at room temperature (15° to 30°C) for up to two weeks.
5. Before starting cleaning procedures, fill a squirt bottle with the Cleaning Solution. Refill as needed.

Cleaning Method

- A. Instrument Surfaces and Workspaces
 1. 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.
 2. Thoroughly clean/wipe the surface with the wet paper towels. Discard the paper towels after use.
 3. Immediately wipe the wet surface dry with dry paper towels. Do NOT allow the Cleaning Solution to dry by itself on the surface.
 4. After drying the surface completely, repeat steps A1- A3 above to apply the Cleaning Solution for a second time. Do not rinse the surface with water.

B. Bench Surfaces

1. 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.
2. Thoroughly and completely spread the Cleaning Solution over the surface using paper towels. Discard wet towels after use.
3. Immediately dry the wet surface with dry paper towels. Do NOT allow the Cleaning Solution to dry by itself on the surface.
4. After drying the surface completely, repeat steps B1 - B3 to apply the Cleaning Solution for a second time. Do not rinse the surface with water.

Note: *DTS instrument components and other surfaces that require different procedures for using Cleaning Solution are indicated in their sections below.*

DTS Systems Procedure

A. 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 10 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

B. 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 Hologic 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

C. Decontamination of Vacuum Trap Liquid Waste

Warning: 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.

D. 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 10 minutes. Rinse thoroughly under running water. Do not soak in a bath of rinse water. Allow to air dry completely.

Tigris DTS System Procedure

Cleaning Solution may be used to replace bleach solutions in certain cleaning procedures outlined in the *Tigris DTS System Operator's Manual*, as indicated below. **Not all cleaning procedures that call for bleach may be substituted with Cleaning Solution.** Only use Cleaning Solution for the components and surfaces indicated.

A. Routine Cleaning of Surfaces

1. Preparing a Work Surface for Reconstituting ARs
 - a. Use the Cleaning Method to clean all work surfaces.
 - b. Cover the work surface(s) with clean, plastic-backed, absorbent laboratory bench cover(s).
2. External Surfaces of the Analyzer
 - a. Use the Cleaning Method to wipe down all external panels and operator-accessible doors and handles with Cleaning Solution.

B. Routine Cleaning of Instrument Components

Use the Cleaning Method to wipe down the following instrument components.

Note: For details on the procedures for cleaning the components listed below, refer to the *Tigris DTS System Operator's Manual* or other appropriate instructions.

1. System Fluid bottle exterior

Warning: Do not use the Bleach Enhancer for Cleaning Solution to clean or decontaminate the interior of the System Fluid Bottle or the Pipettor Fluid Lines.

2. Assay Reagent (AR) Bay
3. The Sample Bay
4. The Fluids Drawer
5. The Waste Drawer

C. Routine Cleaning of Sample Racks

1. After use, completely submerge the sample racks in an appropriately sized container of Cleaning Solution and allow to soak for 10 minutes.
2. Rinse thoroughly with running water. Do not soak in rinse water.
3. Dry completely with paper towels or allow to air dry.

D. Cleaning Up Spills

Immediately clean up any accidental sample or solution spills *outside* the system by using the cleaning method.

Note: *Dispose of all liquid and solid wastes generated by spills according to laboratory guidelines.*

Panther System Procedure

Cleaning Solution may be used as indicated in the *Panther System Operator's Manual*. Refer to the *Panther System Operator's Manual* for components and procedures that may use Bleach Enhancer for Cleaning.

Tomcat Instrument Procedure

Cleaning Solution may be used as indicated in the *Tomcat Instrument Operator's Manual*. Refer to the *Tomcat Instrument Operator's Manual* for components and procedures that may use Bleach Enhancer for Cleaning.

Limitations

- A. 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 Hologic assay package inserts.

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