3M

Clean-Trace™

Product Instructions
ATP10

EN Surface Positive Control (ATP10)

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Product Description and Intended Use

The 3M™ Clean-Trace™ Surface Positive Control (ATP10) is intended for use with the following instruments: The 3M™ Microbial Luminescence System (MLS), the 3M™ Microbial Luminescence System (MLS) – USB and the 3M™ Microbial Luminescence System (MLS) II. A reagent check should be performed at least once each day, just prior to using the 3M™ Microbial Luminescence System (MLS) Ultra High Temperature (UHT) Dairy Screen Kit or the 3M™ Microbial Luminescence System (MLS) Ultra High Temperature (UHT) Beverage Screen Kit. Use of these kits will verify the function of the instrument as well as the 3M MLS UHT Dairy Screen Kit and 3M MLS UHT Beverage Screen Kit reagents.

The 3M Clean-Trace Surface Positive Control (ATP10) utilizes a standard concentration of adenosine triphosphate (ATP) to ensure that the reagents in the 3M MLS UHT Screen Kits are performing satisfactorily. A vial of the 3M Clean-Trace Surface Positive Control (ATP10) is reconstituted with ATP-Free Water and this standardized solution of ATP is used to test the activity of both the 3M™ Microbial Luminescence System (MLS) ATPase and 3M™ Microbial Luminescence System (MLS) Luciferin/Luciferase (LL1) reagents. The intensity of light produced in the bioluminescent reaction of ATP with the LL1 reagent is proportional to the amount of ATP that is present in the test well. When 3M MLS ATPase is present in a test well, it degrades the ATP and low-level light readings are obtained. When no ATPase is present in a test well, the ATP and the 3M MLS LL1 react to produce light and high light readings are obtained.

Safety

The user should read, understand, and follow all safety information in the Product Instructions for the 3M Clean-Trace Surface Positive Control (ATP10). Retain the safety instructions for future reference.

NOTICE: Indicates a hazardous situation, which, if not avoided, could result in property damage.

NOTICE

3M Clean-Trace Surface Positive Control (ATP10) (before rehydration):

- May cause eye, skin, and respiratory tract irritation.
- Avoid eye and skin contact. Avoid breathing dust. Use only with adequate ventilation.
- Wash thoroughly after handling.
- For laboratory use only; follow established laboratory procedures.

Precautions

CAUTION! May cause eye, skin, and respiratory tract irritation. Avoid eye and skin contact. Avoid breathing dust. Consult Safety Data Sheet for additional information.

User Responsibility

Users are responsible for familiarizing themselves with product instructions and information.

Visit our website at **www.3M.com/foodsafety** or contact your local 3M representative or distributor for more information.

When selecting a test method, it is important to recognize that external factors such as sampling methods, testing protocols, sample preparation, handling, and laboratory technique may influence results.

It is the user's responsibility in selecting any test method or product to evaluate a sufficient number of samples with the appropriate matrices and microbial challenges to satisfy the user that the chosen test method meets the user's criteria. This product has not been tested with all possible UHT products, testing protocols, or with all possible strains of microorganisms.

It is also the user's responsibility to determine that any test methods and results meet its customers' and suppliers' requirements.

As with any test method, results obtained from use of any 3M Food Safety product do not constitute a guarantee of the quality of the matrices or processes tested.

Limitation of Warranties/Limited Remedy

EXCEPT AS EXPRESSLY STATED IN A LIMITED WARRANTY SECTION OF INDIVIDUAL PRODUCT PACKAGING, 3M DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE. If any 3M Food Safety Product is defective, 3M or its authorized distributor will, at its option, replace or refund the purchase price of the product.

These are your exclusive remedies. You must promptly notify 3M within sixty days of discovery of any suspected defects in a product and return it to 3M. Please call Customer Service (1-800- 328-1671 in the U.S.) or your official 3M Food Safety representative for a Returned Goods Authorization.

Limitation of 3M Liability

3M WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGES, WHETHER DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS. In no event shall 3M's liability under any legal theory exceed the purchase price of the product alleged to be defective. For detailed WARNINGS, CAUTIONS, STORAGE AND DISPOSAL information, and complete INSTRUCTIONS FOR USE see product instructions.

Storage

Store 3M Clean-Trace Surface Positive Control (ATP10) at 2-8°C. DO NOT FREEZE. Store any unused, reconstituted ATP at 2-8°C for no longer than 24 hours. Expiration date and lot number are noted on each vial of ATP positive control. 3M Clean-Trace Surface Positive Control (ATP10) reagents should not be used past their expiration date.

Instructions for Use

Follow all product instructions carefully. Failure to do so may lead to inaccurate results. Wear appropriate protective apparel and follow standard good laboratory safety practices (GLP)[1].

Reagent Preparation

1. Allow all solutions and reagents to reach ambient temperature prior to use. Cold reagents may produce low relative light unit (RLU) readings, and samples may be incorrectly interpreted as sterile (false negative result). Do not heat reagents to warm them, as this may inactivate the reagents.
2. Carefully open a vial of lyophilized ATP; be careful not to touch the rubber stopper. Pipette 0.5 mL of ATP-Free Water into the vial. Replace the stopper and invert the vial 5-10 times. Allow at least 5 minutes for the ATP to rehydrate. The rehydrated ATP is ready to use and contains sufficient volume for 2 reagent control assays. Once rehydrated, the ATP control solution is active for 24 hours when stored at 2-8°C.
3. Prepare fresh ATPase and LL1 OR verify previously rehydrated reagents were recently prepared. When stored at 2-8°C, rehydrated ATPase is active for 2 days and LL1 is active for 5 days if using the 3M MLS UHT Dairy Screen Kit. If using the 3M MLS UHT Beverage Screen Kit, rehydrated ATPase and LL1 are both active for 5 days when stored at 2-8°C.

Instrument Preparation

(See 3M™ Microbial Luminescence System (MLS) User Manual for detailed instructions).

1. Rinse the instrument lines A, B and C with Injector cleaning fluid using the **"Wash Assay"**.
2. Rinse the instrument lines A, B and C with ATP-Free water using the **"Wash Assay"**.
3. Load the assay reagents (ATPase on injector A, Extractant on injector B, and LL1 on injector C) onto the 3M MLS Instrument.
4. Place a 3M™ Microbial Luminescence System (MLS) Microwell Plate onto the plate carrier ensuring well 'A1' is positioned at the left corner of the plate carrier, closest to the user.
5. Prime injectors A, B, and C using the **"Prime Assay"**.

Instructions for Reagent Control Check

1. Using a strip of six 3M™ Microbial Luminescence System (MLS) Microwell Strip (3008), pipette 50 µL of rehydrated ATP into each of the last four microwells (C1-F1). Do not deposit 3M MLS ATP onto the sides of the wells.

2. Place the 3M MLS Microwell Strip into a 3M™ Microbial Luminescence System (MLS) Microwell Strip Holder (3009) and place the holder onto the instrument plate carrier, so Well A1 is in the left upper corner of the plate carrier (closest to the instrument).
3. Select the **"Reagent Control Assay"** from the list assays and click start to run the reagent control check.
4. Complete file and user information, then click **OK**.
5. Following favorable reagent check results, the instrument and reagents are ready for use.
6. Perform **UHT Assay(s)** according to the 3M MLS UHT Dairy/Beverage Screen Kit Instructions for Use.

Interpretation of results

The specifications for a reagent check will vary depending on the kit that is being utilized. Refer to appropriate standards for the 3M MLS UHT Dairy Screen Kit or 3M MLS UHT Beverage Screen Kit. To adjust the standards in the 3M™ Microbial Luminescence System II Software, contact your 3M Food Safety Representative.

The default specifications for a reagent check are as follows:

a. For the use of the 3M MLS UHT Dairy Screen Kit
Wells A1, B1: Readings of **<35 RLU** in both wells indicate that there is no contamination in the instrument or reagents.

Wells C1, D1: Readings of **<100 RLU** in both wells indicate that the ATPase enzyme is active.

Wells E1, F1: Readings of **>1500 RLU** in both wells indicate that the LL1 enzyme and ATP control are active.

b. For the use of the 3M MLS UHT Beverage Screen Kit
Wells A1, B1: Readings of **<35 RLU** in both wells indicate that there is no contamination in the instrument or reagents.

Wells C1, D1: Readings of **<100 RLU** in both wells indicate that the ATPase enzyme is active.

Wells E1, F1: Readings of **>4000 RLU** in both wells indicate that the LL1 enzyme and ATP control are active.

NOTE: Pass/Fail criteria for reagent checks and UHT testing may vary depending on customer or product requirements.

Troubleshooting tips

1. If the reagent check produces an unsatisfactory reading, repeat the procedure with a fresh vial of 3M Clean-Trace Surface Positive Control (ATP10) and/or 3M MLS ATPase and 3M MLS LL1. If the reagent check fails again, it may indicate a problem with one or more reagents, or with the 3M MLS Instrument itself. Refer to Table 1 for specific result scenarios during reagent control check.
2. Check the expiration date on all reagent bottles and ensure that the reagents have been properly stored. The shelf-life of rehydrated reagents are as follows:

Dairy ATPase = 2 days at 2-8°C

Dairy LL1 = 5 days at 2-8°C

BEV ATPase = 5 days at 2-8°C

BEV LL1 = 5 days at 2-8°C

ATP10 control = 24 hours at 2-8°C

Table 1. Reagent control check, troubleshooting overview for the 3M MLS UHT Dairy Screen Kit.

CONTROL WELLS	WELL CONTENTS	TESTS FOR:	PASS CRITERIA (RLU)	A	B	C	D	E	F	G
A1	Ext, ATPase, LL1 (no ATP)	Reagent contamination	<35	6	**36**	5	7	9	**154**	4
B1			<35	5	**37**	7	8	7	**189**	8
C1	Ext, ATPase, LL1, ATP	ATPase activity	<100	8	45	6	**158**	**2346**	**204**	11
D1			<100	9	55	9	**106**	**2560**	**132**	12
E1*	Ext, LL1, ATP (no ATPase)	ATP control, LL1 activity	>1,500	2653	2527	**6**	2765	2450	**8518**	**1380**
F1*			>1,500	2240	2597	**9**	2930	2950	**9573**	**1310**
				Results OK	**Potential Problem**	**Potential Problem**	**Potential Problem**	**Potential Problem**	**Potential Problem**	**Potential Problem**
					Wells A1 & B1 are marginal failures, may indicate a problem with contamination or biofilm in reagent lines.	- LL1 not properly dispensed. - No ATP. control in wells E1, F1. - Well strip placed horizontally in holder.	- ATP control left on the wall of wells C1, D1. - Improper pipetting technique. - Underactive ATPase.	- ATPase not properly dispensed. - ATPase inactive.	Contamination or biofilm in reagent lines.	- Decreased LL1 activity. - Decreased ATP signal. - Injector C not dispensing properly.
					Potential Solution	**Potential Solution**	**Potential Solution**	**Potential Solution**	**Potential Solution**	**Potential Solution**
					- Remove reagents without recovering. - Replace amber bottles and solutions; rinse reagent lines with fresh ATP-Free Water and Cleaning Solution. - Weekly Cleaning Procedure. - Repeat Reagent control assay.	- Verify proper dispensing. - Repeat Reagent control assay.	- Repeat Reagent Check, take care to pipette ATP control into **bottom** of microwells. - Replace with fresh ATPase. - Repeat Reagent control assay.	- Verify proper dispensing. - Replace ATPase and repeat Reagent control check.	- Remove reagents without recovering. - Replace amber bottles and solutions; rinse reagent lines with fresh ATP-free water and cleaning solution. - Weekly Cleaning Procedure. - Repeat Reagent control assay.	- Check temperature of lab and 3M MLS; should be <25°C. - Prepare fresh LL1 enzyme. - Prepare fresh ATP vial. - Repeat Reagent control check using new ATP. - Weekly Cleaning Procedure.

(*) When using the 3M MLS UHT Beverage Screen Kit the Pass criteria for E1 and F1 wells should be > 4000 RLU.

References

1. U.S. Food and Drug Administration. Code of Federal Regulations, Title 21, Part 58. Good Laboratory Practice for Nonclinical Laboratory Studies.

Explanation of Symbols

www.3M.com/foodsafety/symbols

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