

LuciPac A3 Surface (Pre-Moistened) Instruction Manual

Product code:60367



CAUTION !

1. Do not attempt to drink the kit reagent, touch it with bare hands or allow it to splash into eyes.
2. Please make sure to read the precautions and instructions in this Instruction Manual before attempting to use the kit and exercise extreme caution when using it.

The ATP+ADP+AMP hygiene monitoring test kit LuciPac A3 Surface (Pre-Moistened) is a kit for testing cleanliness levels using bioluminescence techniques with firefly luciferase developed with Kikkoman's unique biotechnology.

[Applications]

This kit can be used to test cleanliness levels using a swab test.

Do not use this device for any purpose other than what it was designed for as a tester of cleanliness levels. Please be aware that this kit cannot be used to test or measure for viable bacteria counts levels or more specific types of pathogenic bacteria.

This kit is used to indicate cleanliness levels in food production centers and medical treatment facilities. This kit shall not provide any guarantee that a given test environment is free of bacterial contamination. This kit cannot be used to test food or food products directly.

[Measurement Principles]

This kit uses an enzyme cycling method based on a combination of luminescent reactions from firefly luciferase, pyruvate, orthophosphate dikinase (PPDK) and pyruvate kinase (PK). This method produces a given amount of luminescent that is proportional to the amounts of adenosine triphosphate (ATP), adenosine diphosphate (ADP) and adenosine monophosphate (AMP) present.

ATP is a source of energy necessary for various forms of life that are present in organic residues, such as microorganisms, food residue, and biological substances that originate from other living organisms. This ATP monitoring system allows you to measure and detect organic residues at high speed and high sensitivity by detecting ATP using luciferase, which is why it is widely used in determining cleanliness levels in food manufacturing site and medical treatment facilities. However, conventional ATP

monitoring system is insufficient because ADP and AMP generated from ATP degradation are completely overlooked. Kikkoman succeeded in developing a new ATP + ADP + AMP monitoring system as shown in Fig. 1. This method definitely enables high sensitive analyses of a wider range of organic residues.

This kit is a simple integrated testing instrument that contains both the test reagent and the swab device required for testing cleanliness levels.

[Contents]

The LuciPac A3 Surface (Pre-Moistened) kit contains five aluminum bags each containing 20 swab devices (for a total of 100 swab devices).

Table 1: Main components of each reagent

Reagent name	Main component
Enzyme solution	Luciferase Magnesium acetate Phosphoenolpyruvic acid Pyruvate, orthophosphate dikinase Pyruvate kinase
Substrate solution	Luciferin Pyrophosphoric acid
Moistening solution	Surfactant

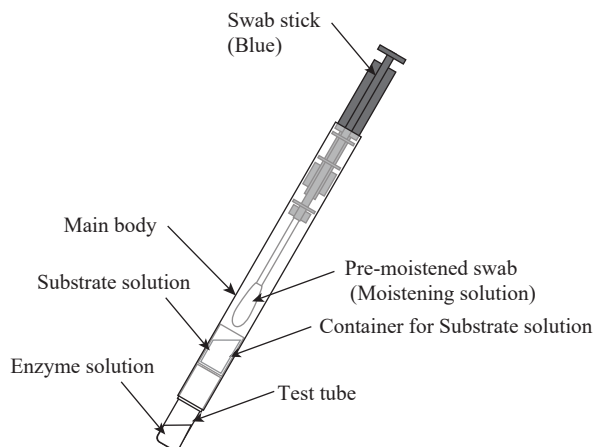


Fig. 2 : The name of each part of the LuciPac A3 Surface (Pre-Moistened)

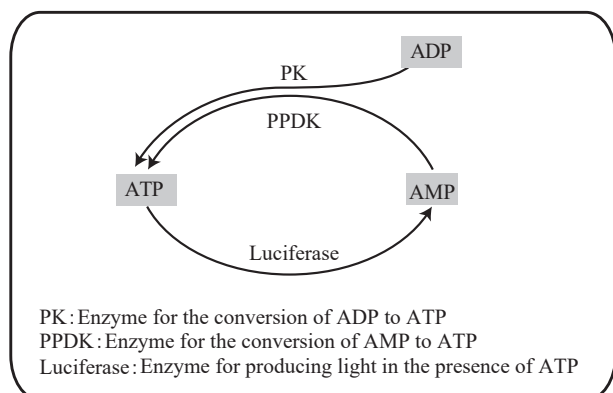


Fig. 1: Principle of luminescence method using the enzyme cycling

[Precautions for Use]

Please make sure to follow the precautions listed below in order to obtain optimal performance from this kit.

- ① Do not use products that are past the expiry date. Expired products may not yield accurate results (the expiry date is printed on the bottom of the aluminum bag holding the swab devices).

- ② Be sure to use only designated products when taking measurements for amounts of luminescence. This kit cannot be used with nondesignated products.
- ③ The swab devices should be allowed to reach room temperature (see Table 2) prior to testing, if they are from refrigerated stock. The temperature should be maintained 20 - 30°C (68 - 86°F) due to obtain consistent results. Measurement values may read lower than actual if the swab devices are used while still cold. Use the swab devices as soon as possible once they have returned to room temperature. Do not let the kit sit out in temperatures exceeding 35°C (95°F).High temperatures may cause product performance to drop.

Table 2: Appropriate measurement temperature

Model	Temperature compensation setting	Temperature range	Note
Lumitester PD-30/ Lumitester Smart	OFF	20 - 30°C (68 - 86°F)	Although Lumitester Smart/PD-30 is usable at 10-40°C, measurement value may be lower than the actual value if the swab devices are used outside of this temperature range.
	ON*1)	20 - 30°C (68 - 86°F)	Although Lumitester Smart/PD-30 is usable at 10-40°C, measurement values may be higher than the actual value if the swab devices are used outside of this temperature range.

*1) Temperature compensation is performed in accordance with the measured value of a thermometer incorporated in the main body of Lumitester Smart/PD-30. Consequently, the compensation cannot be performed precisely if the temperature of the main body of Smart/PD-30 is different from LuciPac. Please be sure that temperatures of the main body of Smart/PD-30 and LuciPac become equal before use.

- ④ Wherever possible, be sure to use up all swab devices from a single bag that has been opened at one time. If it's necessary to store leftover swab devices once finished with a test session, firmly close the aluminum bag and store it in a refrigerated environment (2°C to 8°C (35.6°F to 46.4°F)). High temperatures may cause product performance to drop.
- ⑤ Do not subject the kit or any part of it to direct sunlight for long periods of time. Strong light may cause product performance to drop.
- ⑥ Do not touch any of the parts inside the sampling devices, particularly not any part of the cotton swab itself, with a finger or other object before use. Touching the parts may affect cleanliness levels, making them hard to determine.
- ⑦ Do not drop the kit or any of its parts or allow any parts to be struck or jolted. The inner aluminum sheets and other parts in the kit may become damaged, causing product performance to drop.
- ⑧ Do not use the kit if any parts become damaged such as the inner aluminum sheet. Such damage may affect product performance, causing cleanliness levels to fail to be measured correctly. You can tell if the aluminum sheet is damaged or not by checking to see if the substrate solution is leaking.
- ⑨ Set the benchmark value at which the required cleanliness levels can be obtained. If the benchmark value is not set correctly, cleanliness levels may not be evaluated correctly.
- ⑩ Secure the test tube of the LuciPac to ensure that it does not become shifted or displaced. It may be difficult to accurately determine cleanliness levels if the test reagent begins leaking because the tube has been shifted. It may become difficult to remove the LuciPac from the measurement device once the measurements have been taken. Moreover, it may cause malfunction of the measurement device.

[Designated Product for Measurement]

Lumitester Smart/PD-30

(Manufactured for Kikkoman Biochemifa Company)

Be sure to use only designated products when taking measurements.

[Measurement Methods]

1. Measurement procedures

Complete the procedures listed below within the appropriate temperature range as shown in Table 2. Make sure to always run measurement tests at the same temperature to maintain repeatability from comparison. Get the LuciPac out of the refrigerator, and wait until they have reached room temperature (see Table 2). Use the swab devices as soon as possible once they have returned to room temperature.

- ① Remove the swab stick from the main body (casing).
- ② Use it to swab the test subject with constant pressure as much as possible. Under suitable pressure, the swab shaft will slightly bend as illustrated in panel 3 of page 8. If the test subject is a plane surface, swab 10 times horizontally and 10 times vertically while rotating the swab.
*Pre-moistened swab is gradually dried during storage. But the test result will not be affected by degree of moistness of the swab within the expiry period.
- ③ Return the swab stick to the the main body (casing) and push it all the way into the the main body (casing).
- ④ Hold the LuciPac casing firmly and shake it for at least 10 seconds to ensure the substrate solution and the enzyme solution are completely mixed.
- ⑤ Insert the LuciPac into the Lumitester to measure the results.

Refer to "Direction for LuciPac on page 8 for further details.

2. Handling of data

The benchmark values (RLU) are important guidelines for the evaluation of cleanliness. Benchmark values 1 and 2 are set by the end user to determine whether regular cleanliness has been achieved in their facility. Cleanliness is designated as Pass if the measured RLU falls below benchmark value 1 and as Fail if the RLU is higher than benchmark value 2. When cleanliness fails, it is recommended to reclean the test site, revise the cleaning procedures or replace the failed equipment part. The area should be retested after remediation. When the RLU falls between benchmark value 1 and value 2, cleanliness is designated as Caution. Cleaning procedures can be continued but the cleanliness of the test site should be monitored more frequently. If Caution is continuously repeated at the same site, it is recommended to revise the cleaning procedures, replace the equipment part or reset appropriate benchmark values.

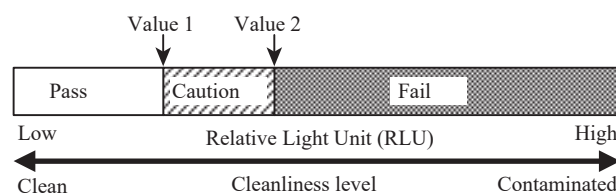


Fig. 3: Setting Benchmark Value for Cleanliness Level Control

[Disposal Methods]

This kit contains no hazardous materials. This kit can be disposed of as regular garbage, but when disposing of it, it would be better to separate the parts and dispose of each one properly in accordance with the local regulations outlined by the local governments for proper disposal of waste materials.

The main materials and parts used in this kit are listed below. No PVC materials are used in the making of the plastics in this kit.

Table 3: Main raw materials of the structural parts of this product

Structural parts	Raw materials
Swab stick (green part)	Polypropylene
Main body (casing)	Polypropylene
Swab shaft	Polypropylene
Container for substrate solution	Polypropylene, Aluminum
Measurement tube	Polypropylene, Aluminum
Aluminum bag	Aluminum, Polyethylene, Polyethylene terephthalate
Outer bag	Polyethylene

[Precautions for Handling]







- ① Be careful not to let the reagents or other substances in the kit get into your mouth or eyes, or onto bare hands before or after use. Rinse your mouth out thoroughly with water if any of the substances get into your mouth, rinse off your skin with copious amounts of water if any get onto your skin, and rinse out affected eyes thoroughly with copious amounts of water should it get into your eye. Immediately contact a physician for advice and follow the instructions given.
- ② Exercise enough caution when storing and disposing of the kit and its reagents to ensure that none of the substances become mixed in with food and other products.
- ③ Be careful not to get fingers caught when inserting the swab stick into the main body (casing).
- ④ Please make sure to store this kit and its parts out of the reach of young children.

[Storage]

- 1) Kit storage: Kits are to be stored at a low temperature (2°C to 8°C (35.6°F to 46.4°F)) for long term storage. The kit can be shipped below 25°C (77°F) for up to 5 days or below 30°C (86°F)for up to 3days before opening an aluminum bag without any adverse effect on the long term stability. Do not freeze the kit.
- 2) We recommend that you use all 20 swab devices in a single bag at one time after opening an aluminum bag. If you have leftover swab devices that you must store after opening a bag, be sure to store them at the recommended low temperature (2°C to 8°C (35.6°F to 46.4°F)) and use them within two weeks from when the bag is opened.
- 3) Expiry date: Printed on the aluminum bag.
- 4) Pre-moistened swab is gradually dried during storage. But the test result will not be affected by degree of moistness of the swab within the expiry period.

[Warranty]

Kikkoman Biochemifa Company warrants the products in this kit to have a certain level of quality. This warranty guarantees that Kikkoman Biochemifa Company shall replace defective products should any be found. This warranty does not provide any other guarantees. Kikkoman Biochemifa Company shall not be liable for any damages, including special or consequential damages, or expenses arising directly or indirectly from the use of this product.

Symbols Used in the Packaging and Labeling of this product	
	Symbol for "temperature limitation." The upper and lower temperature limits will be indicated on either side of the symbol. Please store this product at the indicated temperature range.
	Symbol for "Caution" or "Attention" for use.
	Symbol for "Lot Number." This symbol shall be adjacent to the manufacturer's lot number (e.g. 20240410M) or description of its printed location.
	Symbol for "Use By." This symbol shall be adjacent to the expiration date, expressed as YYYYMMDD (e.g. 20240709), or description of its printed location.
	Symbol for "Consult Instructions Manual."
	Symbol for "Manufacturer." This symbol shall be adjacent to the name and address of the manufacturer.

"LuciPac" and "Lumitester" are registered trademarks of Kikkoman Corporation in Japan and other countries.

Manufacturer:

Kikkoman Biochemifa Company

2-1-1 Nishi-shinbashi, Minato-ku, Tokyo 105-0003, Japan

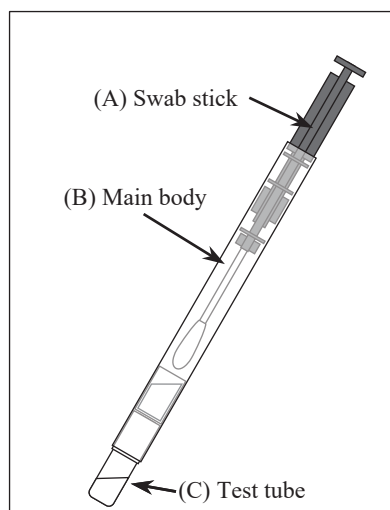
Phone: +81-3-5521-5481 / Fax: +81-3-5521-5498

E-mail: biochemifa@mail.kikkoman.co.jp

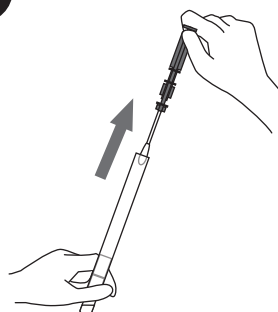
URL: <https://biochemifa.kikkoman.com/e/>

[Directions for LuciPac A3 Surface]

<Leave “LuciPac” at room temperature (see Table 2) until they have reached room temperature.>

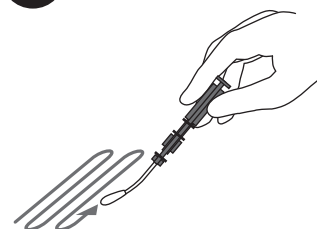


1



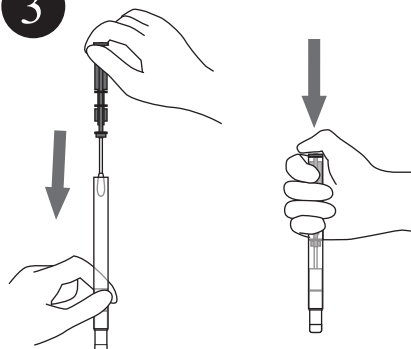
Pull the cotton swab stick (A) out of the main body (B).

2



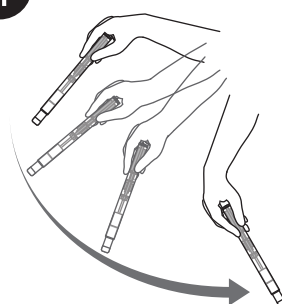
Swab the test object with the swab stick (A).

3



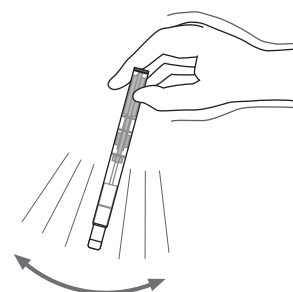
Put the swab stick (A) back into the main body (B) and push it through all the way by putting the tip of the test tube (C) on the palm of a hand or on a table. (Be careful not to get fingers caught when pushing it.)

4



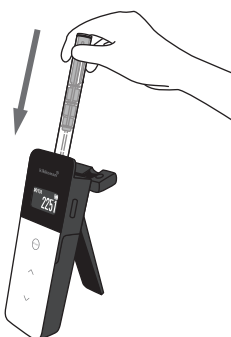
Shake the whole body of the LuciPac a few times so that the liquid in the capsule falls into the test tube (C).

5



Gently shake the whole body of the LuciPac so that the substrate solution and the enzyme solution are entirely mixed.

6



Insert the whole body of the LuciPac into the measurement chamber of the Lumitester. Then, close the chamber cover.

7



Press the "START" key. Results are obtained in 10 seconds.