

Instructions for use

LuciPac[®] Pen

From Kikkoman

For analysis of contamination of surfaces via ATP/AMP measuring by Lumitester PD20

1. Introduction

Using the LuciPac[®] Pen sampling pen, surfaces can be tested quickly and easily for organic contamination. The organic contamination of surfaces, e.g. by bacteria, is indicated by the presence of ATP or AMP in the samples. An enzyme/substrate complex in the LuciPac[®] Pen sampling tube reacts with ATP and AMP to produce bioluminescence whose intensity correlates directly with the amount of ATP/AMP present. The Lumitester PD20 then determines the bioluminescence as a direct measure of original contamination. The unit is easy to operate, even by non-professionals. Just probe the surface with the swab stick. Then put the swab back into the tube and push it down into the reaction chamber. Shake the tube until the reagents are released and measure the bioluminescence in the Lumitester PD20.

2. Shipment and storage

20 LuciPac[®] Pens each are packed in a resealable aluminium bag. 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 stored below 25 °C (77 °F) for up to 14 days or below 30 °C (86 °F) for up to 5 days before opening an aluminum bag without any adverse effect on the long term stability. Do not freeze the device.

We recommend that you use all 20 sampling devices in a single bag at one time after opening an aluminum bag. If you have leftover sampling 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 after opening.

Expiry date: printed on the label of the aluminum bag. Store protected from light.

3. Comments on application, detection limits

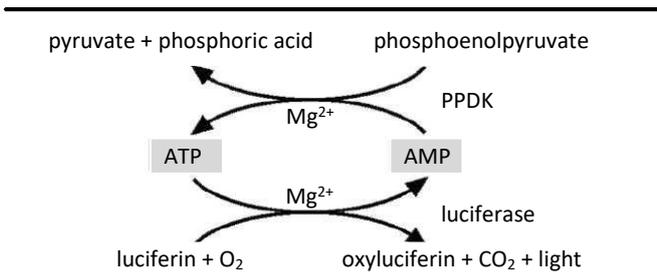
Do not use this device for any purpose other than what it was designed for as a tester of cleanliness levels of surfaces. Please be aware that this kit cannot be used to test or identify specific types of pathogenic bacteria.

Surfaces may carry ATP and/or AMP which are caused by improper cleaning of facilities or originate from microorganisms propagating in such environment. Since this device measures ATP+AMP levels immediately, indications of improper cleaning processes can be promptly detected.

This device shall not provide any guaranty that a given test sample is free of bacterial contamination. Also suitable for use with Lumitester PD30.

4. Mechanism

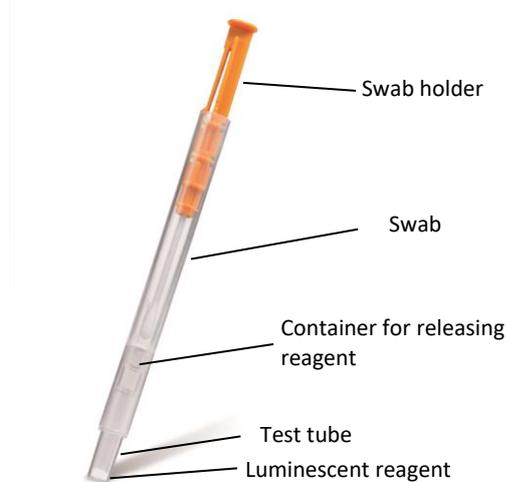
This kit uses an enzyme cycling method based on a swabination of luminescent reactions from firefly luciferase and pyruvate, orthophosphate dikinase (PPDK). This method produces a given amount of luminescence that is proportional to the amounts of adenosine triphosphate (ATP) and adenosine monophosphate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



Firefly luciferase emits light in the presence of ATP and luciferin. The AMP produced from this reaction is converted back into ATP using PPDK to enable a high but stable amount of luminescence to be obtained. ATP is a source of energy necessary for various forms of life that is present in organic residues, such as microorganisms, food residues, and biological substances that originate from other living organisms. This method allows you to measure and detect organic residues and micro-organisms at high speed and high sensitivity by detecting ATP using luciferase, to monitor cleaning processes and microbiological control of coolant or other industrially processed water.

In addition, this kit can be used to measure not only of ATP but also of AMP amounts, the latter produced from the breakdown of ATP, to increase the range of application to an even wider range of organic residues.

5. Composition of product



Reagent cocktail:

Luciferin, luciferase, phosphoenolpyruvate (PEP), magnesium acetate, pyrophosphopyruvate pyruvate/phosphate dikinase

Releasing reagent:

Alkyl dimethylbenzylammoniumchloride

<u>Structural parts</u>	<u>Raw material</u>
Stick holder (orange)	Polypropylene
Test tube (body)	Polypropylene
Container for releasing reagent	Polypropylene, aluminium
Measurement tube	aluminium

6. Please note

Please make sure to follow the instructions outlined below in order to obtain optimal performance from this device.

1. Do not use products with a shelf life that has already expired. Expired products may not yield accurate results (the expiry date is printed on the label of the aluminum bag holding the sampling devices).
2. Be sure to use only designated products, i.e. type of Lumitester when performing luminescent measurements. This device cannot be used with unqualified products.
3. Residual disinfectants may interfere with measurements. In case there is residual disinfectant on the surface to be probed, clean this surface using water prior to swabbing.

4. Prior to testing the sampling devices should be allowed about 20 min to reach room temperature (20 °C to 35 °C (68 °F to 95 °F)), if they are from a refrigerated stock. Measurement values may deviate from the real value, if the swabs are used without equilibration. Use the sampling devices as soon as possible once they are available at room temperature. Do not keep the device at temperatures exceeding 35 °C (95 °F). High temperatures may cause product performance to drop.
5. Wherever possible, be sure to use up all sampling devices from a single bag that has been opened at one time. However, If you must store leftover sampling 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.
6. Do not subject the device or any part of it to direct sunlight for long periods of time. Strong light may cause product performance to drop.
7. Do not touch any of the parts inside the device, particularly not any part of the sampling stick (swab) itself with a finger or other object before use. Touching the parts may affect cleanliness levels, making them hard to discriminate.
8. Do not drop the device or any of its parts or allow any parts to be struck or jolted. The interior aluminum sheets and other parts in the kit may become damaged, causing product performance to drop.
9. Do not use the device if any parts become damaged, e.g. the inner aluminum sheets separating the reagent chamber from the swab as well as the luminescent reagent. Such damage will affect product performance. The aluminum sheet is not damaged if the releasing reagent stays in the chamber upon agitation.
10. Ensure that the LuciPac® Pen is not shifted or displaced, discard the item, because accuracy cannot be guaranteed, swabs are not removable from the Lumitester PD-20, or the instrument may cause an error (malfunction)
11. If the test reagent is leaking please don't use the swab.

7. Measurement

Complete the procedures listed below within a temperature range of 20 °C to 35 °C (68 °F to 95 °F). Make sure to always run measurement tests at the same temperature to maintain repeatability for comparison. Remove the LuciPac® Pen from refrigerator and wait until they have reached room temperature (about 20 min, 20 °C to 35 °C (68 °F to 95 °F)). Use the sampling devices then as soon as possible.

Residual disinfectants may interfere with measurements. In case there is residual disinfectant on the surface to be probed, clean this surface using water prior to swabbing.

1. Remove the swab from the main body (casing).
2. Moisten the tip of the swab with tap water.
3. Swab the respective surface repeatedly with the swab tip.
4. Return the sampling stick to the main body (casing) and push it all the way into the main body.
5. In order to open the reaction chamber, push firmly onto LuciPac® Pen casing.
6. Shake the whole LuciPac® Pen repeatedly so that all remaining liquid in the capsule falls into the reaction tube.
7. Allow the leftover luminescent reagent to thoroughly dissolve. Slightly shake the test tube in order to promote this process.
8. Insert the LuciPac® Pen into the Lumitester to measure the results.

8. Safety recommendations

Please observe the following items to ensure safe use of this product.

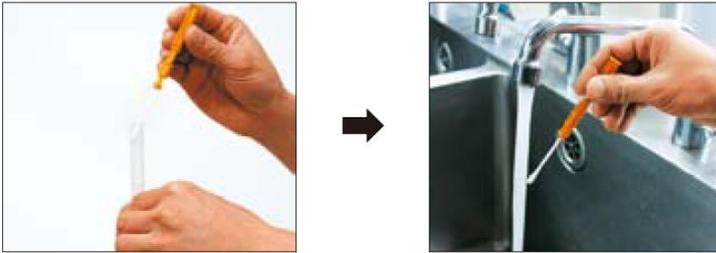
- Please note safety recommendations given in the Safety Data Sheet!
- Do not attempt to drink the kit reagent or touch it with bare hands or allow it to splash into eyes. Please make sure to read the precautions and instructions in this Instruction Manual before attempting to use the kit and exercise extreme caution when using it.
- Be careful not to get fingers caught when inserting the sampling stick into the main body (casing).
- Handle with care when storing and disposing of the device and its reagents to ensure that none of the substances become mixed with food and other products.

- Please make sure to store this kit and its parts out of the reach of young children.
- Take precaution when disposing of this kit after use to ensure that such substances do not become mixed with food products at food production centers and similar facilities.

9. Short instruction

Prior to use, make sure the LuciPac® Pen sticks have come to room temperature. But then use immediately.

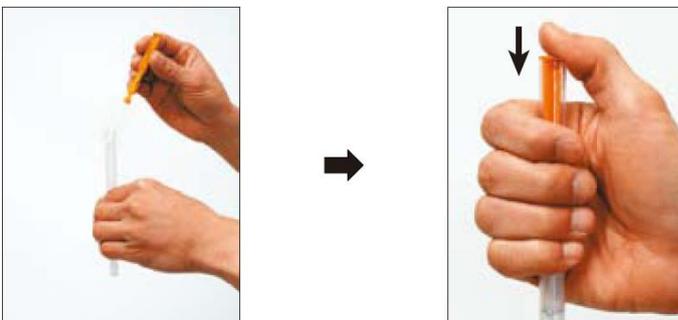
- ① Remove the cotton swab stick (orange holder) from the main tube. Then, moisten the tip of the cotton swab with tap water.



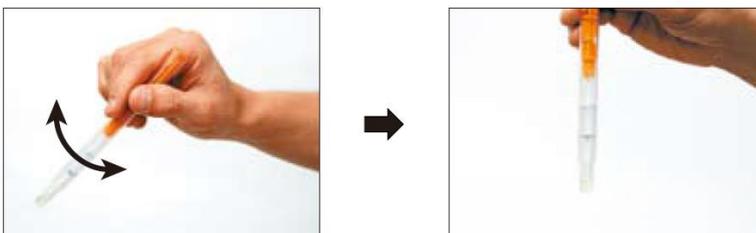
- ② Performing the Swab Test.



- ③ Put the swab stick back into the main tube. And then push the swab stick downwards to break the capsule in the tube.



- ④ Shake the whole LuciPac Pen tube repeatedly so that all remaining liquid in the capsule falls into the reaction tube and dissolves the reagent in the tube.



LuciPac® Pen

20 pieces

NC59.1

100 pieces

NC59.2

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