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## r-biopharm Art. No. ZLA1002672

### LuciPac Pen-AQUA Instruction for Lumitester PD-20

#### ATP+AMP Hygiene Monitoring test kit - for water and liquid sample

LuciPac Pen-AQUA is a kit for testing cleanliness levels of water and other liquid samples using bioluminescence techniques using firefly luciferase developed with Kikkoman's unique biotechnology.

#### Applications

This kit can be used to test cleanliness levels of water and other liquid samples.

Do not use this device for any purpose other than what it was designed for as a tester of cleanliness levels of water, other liquid samples, or other application which is instructed to use by the manufacturer. Please be aware that this kit cannot be used to test or identify specific types of pathogenic bacteria.

Water and other liquid samples may contain ATP and/or AMP which are caused by improper cleaning of facilities or originate from microorganisms propagating in such samples. Since this device measures ATP+AMP levels immediately, indications of improper cleaning processes, e.g. inadequate microbiological control of coolant or other industrial process water can be promptly detected.

This device shall not provide any guaranty that a given test sample is free of bacterial contamination. Thus it is not suitable for microbial testing of originally ATP rich beverages, such as fruit juices.

#### **Measurement Principles**

This kit uses an enzyme cycling method based on a combination 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.

The sampling stick (comb) of this device can collect up to 0.15 ml of water and ATP and/or AMP can be measured from  $10^{-11}$  mol/1 to  $10^{-6}$  mol/1 using LuciPac Pen-AQUA combined with Lumitester PD-20. Therefore, the minimum measurable level of bacteria would correspond to about  $10^4$  cells/ml calculated from said ATP content of  $10^{-18}$  mol in a single bacterium. Please be aware that you cannot detect very low concentration of bacteria by this method.

#### Contents

LuciPac Pen-AQUA is provided with five aluminum bags each containing 20 sampling devices (for a total of 100 samples). This swab is a simple integrated testing instrument that contains both the test reagent and the sampling stick required for testing cleanliness levels of water and other liquid samples.



#### **Precautions for Use**

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. 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.
- 4. 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.
- 5. 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.
- 6. Do not touch any of the parts inside the device, particularly not any part of the sampling stick (comb) itself with a finger or other object before use. Touching the parts may affect cleanliness levels, making them hard to discriminate.

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- 7. 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.
- 8. Do not use the device if any parts become damaged, e.g. the inner aluminum sheets separating the reagent chamber from the comb 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.
- 9. Do not soak more than 3 cm from the tip of the sampling stick (comb) into water or other liquid samples. Water or other liquid samples which wet the shaft of the sampling stick (orange) may affect test results.
- 10. Ensure that the LuciPac Pen-AQUA is not shifted or displaced, discard the item, because:
  - accuracy cannot be guaranteed
  - swabs are not removable from the Lumitester PD-20
  - the instrument may cause an error (malfunction)
  - If the test reagent is leaking please don't use the swab.

#### Designated Product for Measurement

Lumitester PD-20 (Manufacturer: Kikkoman Biochemifa Company<u>) Be sure to use only designated products when</u> taking measurements.

#### **Measurement Methods**

- 1. Measurement procedures
- 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-AQUA 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.
- a) Remove the sampling stick from the main body (casing).
- b) Soak sampling stick about 3 cm from the tip of the sampling stick into water or other liquid samples, and shake gently. Make sure no bubbles remain within sampling stick's comb.
- c) Pull out the sampling stick slowly and straight up from the sample.
- d) Return the sampling stick to the main body (casing) and push it all the way into the main body.
- e) Push firmly onto LuciPac Pen-AQUA casing and agitate.
- f) Allow the leftover luminescent reagent to thoroughly dissolve.
- g) Insert the LuciPac Pen-AQUA into the Lumitester to measure the results.
- 2. Handling of data

Normal / out-of-spec criteria should be decided by the user based on the data for a certain period of time under normal operation in consideration of the data's fluctuation. Furthermore, depending on the results obtained inadequate artificial cleaning or contaminated conditions should be taken into account.

#### **Disposal Methods**

This device does not contain any hazardous materials, and thus can be disposed of as regular garbage. However, when to be disposed of, we recommend 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 material is used for production of the device.



Structural parts	Raw material
Stick holder (orange part)	Polypropylene
Main body (casing)	Polypropylene
Sampling stick (red part)	ABS Resin
Container for releasing reagent	Polypropylene, aluminum
Measurement tube	Polypropylene, aluminum
Desiccant	Silica gel, polypropylene,
	polyethylene
Aluminum bag	Aluminium, polyethylene
Outer bag	polypropylene terephthalate Polyethylene

#### Precautions for Handling

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

- Be careful neither to swallow reagents or other substances of the device, nor get in contact with your eyes or bare hands before or after use. If such cases occur however, rinse your mouth, your skin or affected eyes thoroughly with copious amounts of water. In addition, immediately contact a physician for advice and follow the given instructions.
- 2. 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.
- 3. Be careful not to get fingers caught when inserting the sampling stick into the main body (casing).
- 4. Please make sure to store this kit and its parts out of the reach of young children.
- 5. Note that the releasing reagent used in this kit contains cationic surfactants (benzalkonium chloride\*). 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.
- 6. 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.

\* benzalkonium chloride is a disinfectant and antiseptic commonly used in hand and finger sterilizer solutions.

#### Storage

- 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 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.
- 2. 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.
- 3. Expiry date: printed on the label of the aluminum bag.

#### 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 any defective products. 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.

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Luminescent reagent



### Instruction manual for LuciPac Pen -AQUA



Il the sampling stick (A) out of the main body (B). (Be careful not to touch the sampling stick.)



Soak sampling stick into water or other liquid samples and shake gently. Make sure no bubbles remain in sampling stick's comb.



Container for releasing reagent

Test tube (C)

Pull out the sampling stick slowly and straight up from the sample.



push it through all the way by putting the tip of the test tube (C) on a palm of hand or table. (Be careful not to get fingers caught when pushing it.)



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



Gently shake the whole body of the LuciPac Pen-AQUA to completely dissolve the luminescent reagent.



Insert the whole body of LuciPac Pen-AQUA into the measurement chamber of Lumitester and close the chamber's cover.



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

