



380237-C

REF 970000

English

Loopamp™ PURE DNA Extraction Kit

INTENDED USE

The Loopamp™ PURE DNA Extraction Kit provides a fast and simple method for extraction and purification of DNA from clinical samples including raw or NALC-NaOH treated sputum. The extraction and purification step of the kit is not automated. The kit is intended to be used in professional laboratories and hospitals by adequately trained personnel. The DNA solution obtained using the Loopamp™ PURE DNA Extraction Kit is suitable for LAMP-based amplification.

CONTENTS OF THE KIT

Reagents are stable until the date on the label assuming the container remains unopened at a storage temperature of 2 – 30°C.

- 1) Heating Tube 1 x 90 tubes

The following reagents in each heating tube.

Sodium hydroxide

Sodium chloride

- 2) Adsorbent Tube 1 x 90 tubes

- 3) Injection Cap 1 x 90 caps

PRINCIPLE OF THE METHOD

The Loopamp™ PURE DNA Extraction Kit is based on the PURE (Procedure for Ultra Rapid Extraction) method. The Loopamp™ PURE DNA Extraction Kit comprises three components:

- 1) Heating Tube

The sample is added to the Heating Tube, which contains Sodium Hydroxide solution (extraction solution). By incubating at an appropriate temperature, microorganisms in the sample are lysed and DNA is released into the solution.

- 2) Adsorbent Tube

The Adsorbent Tube contains a porous adsorbent powder. When the Heating Tube is attached to the Adsorbent Tube, the extraction solution in the Heating Tube is mixed with the porous adsorbent powder in the Adsorbent Tube which removes proteins and other contaminants from extraction solution that might inhibit LAMP-based amplification.

- 3) Injection Cap

The Injection Cap is attached to the Adsorbent Tube before eluting the DNA. The Injection Cap has a built in membrane which filters nucleic acids through it while blocking the porous adsorbent powder and the contaminants.

WARNING AND PRECAUTIONS

- (1) For *in vitro* diagnostic use only.
- (2) Samples should be handled as infectious using established laboratory procedures and/or institutional guidelines. Always wear disposable gloves, masks, goggles, and other appropriate protective equipment. Whenever possible, handle any sample in a safety cabinet.
- (3) The Loopamp™ PURE DNA Extraction Kit can be used for raw or NALC-NaOH sputum sediments, and other samples. If using raw sputum, use the most purulent sputum whenever possible.
- (4) A sample containing a large amount of blood may affect LAMP-based amplification, if using samples other than blood.

- (5) To use a blood sample, 30 µL of the 334 mM NaCl solution should be added to the Heating Tube.
- (6) Do not freeze and thaw any sample repeatedly before use.
- (7) Clean the entire work area (counter tops, incubator surfaces and pipettes) with over 0.5% sodium hypochlorite before and after performing the test and rinse with water. Allow to dry completely before proceeding with additional testing.
- (8) In handling this product, pay due attention to sample-sample or sample-reagent contamination. In particular, the pipette tip should be changed every time.
- (9) Do not pipette by mouth.
- (10) Aerosol discharged during sample collection may allow template DNA to disperse in the testing area, leading to contamination. The Loopamp™ PURE DNA Extraction Kit should not be used in the same room where sample is collected.
- (11) The transfer of sample to the Heating Tube and the DNA amplification should be carried out in separate rooms or areas in order to avoid cross-contamination.
- (12) If gloves come in contact with sample or DNA solution, immediately change gloves to avoid contaminating other samples.
- (13) In the event of contamination of the work area or equipment with processed sample or DNA solution, thoroughly clean the contaminated area with over 0.5% sodium hypochlorite and rinse thoroughly with water. Allow surfaces to dry completely before performing the operation again.
- (14) After the heating step, the Heating Tube and any solution treated with this product should be used immediately.
- (15) After dispensing the DNA solution, carefully dispose of all tubes as described in the measurement procedure in a plastic bag with zipper, in order to avoid DNA contamination of the work area.
- (16) Reagent pouches containing unused tube must be carefully resealed after opening.
- (17) Do not use the Loopamp™ PURE DNA Extraction Kit after its expiration date.
- (18) The Heating Tube contains 0.74% Sodium Hydroxide (CAS No. 1310-73-2) which is classified by applicable European Community Regulation as Skin and Eye Irritant. The pH of Sodium Hydroxide solution in the Heating Tube is about 13. Avoid any contact with eyes, mouth, or skin. In case of accidental contact of any reagent with eyes, mouth, or skin, immediately rinse the affected site with running water and seek medical advice.



Warning

H315	Causes skin irritation
H319	Causes serious eye irritation
P264	Wash hands thoroughly after handling
P280	Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352	IF ON SKIN: Wash with plenty of soap and water
P332 + P313	If skin irritation occurs: Get medical advice/ attention
P362	Take off contaminated clothing and wash before reuse
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313	If eye irritation persists: Get medical advice/ attention

WASTE DISPOSAL

- (1) Leftover samples and kit components that have come in contact with the samples pose a potential risk for infection. When handling such materials, abide by your institution's standard for handling biohazard substances.
- (2) In discarding any remaining portion of the reagent in this product and waste fluid after use, abide by your institution's standard for handling biohazard substances.
- (3) The main materials for the packages and containers of the reagent are PP and PE, and that for the kit case is paper.
- (4) Dispose of any used kit component, packaging or labware in accordance with local regulations.

MATERIALS REQUIRED BUT NOT PROVIDED

- 1) HumaLoop T, M, HumaHeat or other heating block
When a heating block is used, use one with a temperature setting of an appropriate temperature and compatibility with the Heating Tube. For usage, refer to the instruction for use of the heating block.
- 2) Pipette-60 Set

STORAGE AND HANDLING

- (1) The Loopamp™ PURE DNA Extraction Kit should be stored at 2 – 30°C. The reagents are stable until the expiration date on the label.
- (2) After opening, aluminum pouches containing unused tubes must be carefully re-sealed to avoid contamination and moisture absorption. If stored as described above, this product is stable until the expiration date on the label.

OPERATION PROCEDURE

- (1) Turn on the HumaLoop T, M, the HumaHeat or the other heating block.
- (2) Wipe down work surfaces and pipettes with over 0.5% sodium hypochlorite prior to starting. Sodium hypochlorite must be in contact with the surface for at least 5 minutes. Work surfaces may be wiped with water to remove the sodium hypochlorite.
- (3) Label a sufficient number of Heating Tubes to test the samples and 1 negative control.
- (4) Dispense 60 µL of sample into the Heating Tube using the Pipette-60 Set or any pipette-like tool. To use a blood sample, dispense 30 µL of it and 30 µL of the 334 mM NaCl solution into the Heating Tube using any pipette-like tool.

- (5) Invert the Heating Tube three to five times to mix the content, and then flick the tube down to collect the solution to the bottom.
- (6) Change gloves.
- (7) Place the Heating Tube in the heating block pre-heated up to proper temperature and incubate the tube for 5 minutes.

Note: Refer to the manual of the heater. Do not touch the block to avoid burns.

- (8) Remove the Heating Tubes immediately and allow the tubes to cool down at room temperature for 2 minutes. Invert each tube three to five times to mix the content.

Note: Be careful in removing the Heating Tube from the heating block to avoid burns.

- (9) Remove the cap of the Adsorbent Tube, and connect the Heating Tube to the Adsorbent Tube by twisting the Heating Tube. **DO NOT DISCARD THE CAP.** See Step 11
- (10) Shake the obtained tube assembly vigorously: Ten times in horizontal directions and ten times in vertical directions or until all the powder has become slurry. After that, lay it down on the rack.

Note: Make sure that the extraction solution and the adsorbent powder are properly mixed and all the adsorbent powder has become slurry. If any portion of the powder or a blue color remains, repeat this step. Note that the color indicator serves only as a reference, and might be affected by the color of the sample (e.g. bloody samples). In such a case, check for any remaining portion of white powder only.

- (11) Attach the cap removed in Step 9 to the nozzle of the Injection Cap.
- (12) Hold the Adsorbent Tube upside-down (Heating Tube facing down) and connect the Injection Cap to the Adsorbent Tube. The tabs on the Adsorbent Tube (located on the outer side) should be aligned with those on the Injection Cap, then push the tube into the cap and twist the tube until both tabs are aligned again.
- (13) Flick the tube to collect the solution to the bottom of the tube.
- (14) Carefully remove the cap from the Injection Cap. Do not discard the cap. Avoid touching the nozzle. Squeeze the Adsorbent Tube and dispense 30 µL of DNA solution in the reaction tube.

Note: Do not squeeze the Adsorbent Tube forcefully. Wait about five seconds for the solution coming out.

- (15) After dispensing the DNA solution, carefully recap the Injection Cap and dispose of it in a plastic bag with zipper immediately in order to avoid DNA contamination of the work area.










NOTICE

In case of occurrence of any serious incident that has occurred in relation to the device shall be reported to the authorised representative, the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

ORDERING INFORMATION

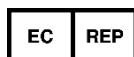
Product Code	Product Name	Contents
970000	Loopamp™ PURE DNA Extraction Kit	90 tests
971000	Pipette-60 Set	1 pipette; 4 x 96 tips
961000	HumaLoop T	1 Main unit; 1 Fluorescence Detection Unit
962000	HumaLoop M	1 Main unit; 1 Fluorescence Detection Unit
964000	HumaHeat Incubator	Heat Block

TABLE OF SYMBOLS

 Catalog number	 Consult instructions for use	 Expiration date
 <i>In vitro</i> diagnostic medical device	 Manufacturer	 Temperature limitation
 Batch code	 Contains sufficient for <n> tests	 Authorized Representative in the European Community



Importer



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und Diagnostica mbH**

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