EasyNAT® Instrument-Free DNA Extraction Device - Instructions For Use

REF Y003-01 (20 Tests)

[Trade Name and Intended Use]

The ***EasyNAT*® Instrument-Free DNA Extraction Device** is intended for rapid extraction of nucleic acids from clinical specimens, such as sputum, blood (serum, plasma, and whole blood), urine, mouthwash, swab of oral, pharyngeal, genitourinary, or anal mucosa. It is also applicable to cultured bacteria and cells. The extracted nucleic acid may be used for downstream applications, including nucleic acid amplification.

[Chemical and Biological Principles of the Procedure]

This product utilizes a syringe to replace the driving force typically provided by a high-speed centrifuge. The syringe, coupled with an affinity membrane, removes insoluble particles from the specimen and purifies nucleic acids in a bind-wash-elute manner.

[Package Specification]

20 sets per box, 50 sets per box, and 100 sets per box

[Kit Components]

Components	20 Sets/Kit	50 Sets/Kit	100 Sets/Kit
Instrument-Free DNA Extraction Device & 1 ml Syringe	20 pieces	50 pieces	100 pieces
5 ml Vial	20 vials	50 vials	100 vials
2 ml Tube	20 tubes	50 tubes	100 tubes
0.6 ml Tube	20 tubes	50 tubes	100 tubes
Lysis Buffer	15 ml	40 ml	80 ml
Wash Buffer	20 ml	48 ml	96 ml
Elution Buffer	3 ml	7 ml	12 ml
Instructions For Use	1 copy	1 copy	1 copy

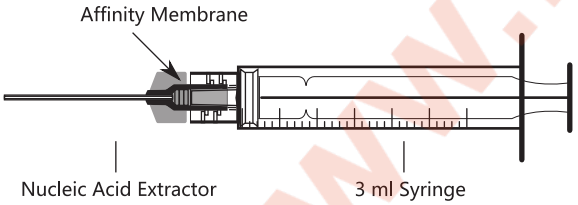

Figure 1. Illustration of the Instrument-Free DNA Extraction Device

[Storage]

1. Transport at ambient temperature and store at 15 to 30 ºC
2. Shelf life: 12 months

[To be prepared prior to use]

1. Materials not supplied: ≥95% ethanol, liquefying buffer (4% NaOH), saline (0.9% NaCl) for swab samples and bacterial colonies, pipettes and pipette tips.
2. Prior to the first use of this device, add ≥95% ethanol to the Wash Buffer as instructed on the bottle.
3. Prior to each use, it is recommended that the Lysis Buffer be checked for crystal precipitation. If crystals have formed, incubate the Lysis Buffer at 37 ºC for 5 to 10 min with occasional shaking to dissolve the crystals.

[Assay Procedures]

Please read the instructions carefully prior to use!

1. **Label:** Label all processing vials, tubes and syringes with sample ID.
2. **Pre-processing:**

- **Sputum:** Carefully open the sputum collection container (<5 ml of sputum), add 1 to 2 times volume of liquefying buffer into the container and close the lid. Shake vigorously or vortex the mixture for 30 seconds and place the sputum at room temperature until fully digested (roughly 20 to 30 min); Extra liquefying buffer can be added if necessary.
- **Serum, plasma, and whole blood:** Pipette 0.1 ml blood sample and 0.9ml liquefying buffer into a 1.5 ml tube. Mix well.
- **Swab:** Dip the swab into 1 ml saline, agitate several times to dissolve the sample, and discard the swab. Pipette 0.7 ml sample and 0.3 ml liquefying buffer into a 1.5 ml tube. Mix well.
- **Urine, mouthwash, and liquid culture:** Pipette 0.7 ml sample and 0.3 ml liquefying buffer into a 1.5 ml tube. Mix well.
- **Solid culture:** Pipette 0.7 ml saline and 0.3 ml liquefying buffer into a 1.5 ml tube. Dissolve bacterial colonies in the tube.

3. **Lyse sample:** Transfer 1 ml pre-processed sample and 0.6 ml Lysis Buffer into a 5 ml vial. Place the vial at 95 to 100 ºC for 10 min, and cool to room temperature.
4. **Bind DNA:** Add 1.4 ml ≥95% ethanol into the vial. Pipette 3 to 5 times to mix. Slowly Draw the lysed sample into the 3 ml DNA extraction device, and then push the plunger forward to expel the liquid back into the vial. Discard the vial properly.
   NOTE: DO NOT remove the Nucleic Acid Extractor from the 3 ml syringe before use.
5. **Wash DNA:** Add 2 ml Wash Buffer into a fresh 2 ml tube. Slowly draw the 2 ml Wash Buffer into the syringe, and push the plunger forward to discard the liquid. Discard the 2 ml tube. Slowly force the plunger back and forth 5 times to remove any remaining liquid.
   NOTE: Add ≥95% ethanol into the Wash Buffer before first use.
6. **Change syringe:** Loosen the Nucleic Acid Extractor and remove it from the 3 ml syringe. Discard the 3 ml syringe. Fit the Nucleic Acid Extractor onto a fresh 1 ml syringe, and make sure it is firmly in place.

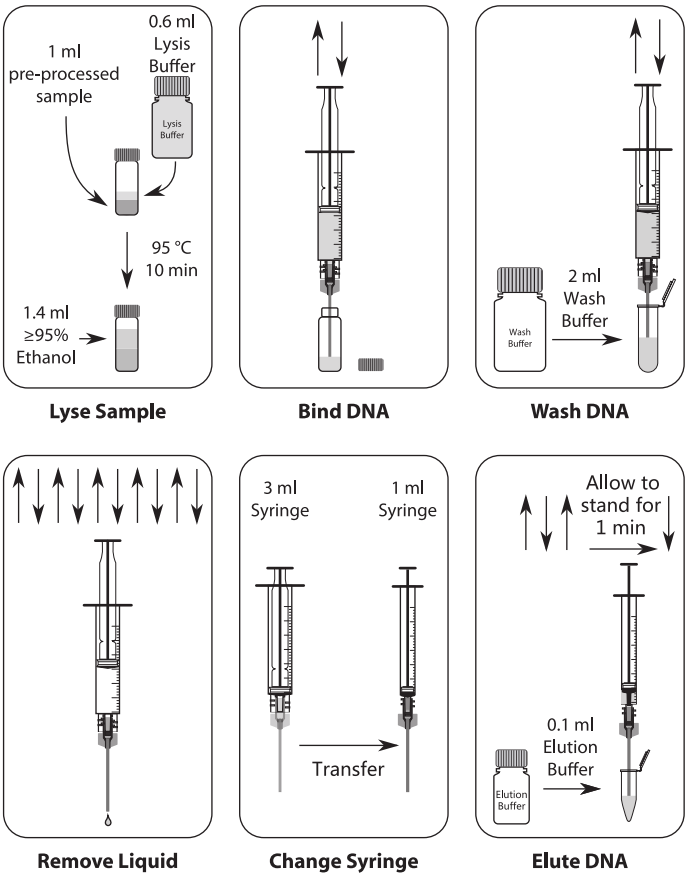

Figure 2. Schematic illustration of operating procedures

7. **Elute DNA:** Add 0.1 ml Elution Buffer into a fresh 0.6 ml tube. Slowly draw the Elution Buffer back and forth 3 times across the membrane. Draw the Elution Buffer into the Nucleic Acid Extractor, and ensuring that the buffer is in contact with the membrane. Incubate at room temperature for 1 min. Force the buffer out into the 0.6 ml tube. Save the eluted buffer as the amplification template and discard used device as bio-hazardous waste.

[Safety Information]

1. The preparation area should be cleaned prior to use by wiping down the area, preferably with a 1% bleach solution.
2. It is important that the lysis temperature is above 95 ˚C for complete lysis. Routine temperature checks are suggested.
3. Make sure ≥95% ethanol is added to the Wash Buffer prior to first use.
4. Slowly draw up and expel out liquids when using the device.
5. Each time a liquid is expelled, ensure that the liquid is fully expelled. This will limit the negative effects of buffer carry-over.
6. If drawing up or expelling out a liquid becomes difficult, due to blockage of the affinity memberane, use less force to slowly move the liquid through the memberane. This will ensure that the memberane remains intact and fully extracts the nucleic acids. **DO NOT** use excessive force to pass the fluid through the memberane as this may damage the memberane and may cause contaminating aerosols.
7. The Lysis Buffer contains guanidinium thiocyanate. Gloves should be worn during sample processing and procedures to prevent contact with skin, mouth and eyes should be followed. If the buffer comes in contact with your eyes, wash immediately and seek medical attention. If swallowed seek medical attention.
8. Guanidinium thiocyanate reacts with acids to release a toxic gas. Do not mix the Lysis Buffer with an acidic solution.
9. Dispose of used devices as bio-hazardous waste. Do not recyle used ones.

[Description of Symbols Used]

The following are graphical symbols used in or found on Ustar nucleic acid diagnostic products and packaging. These symbols are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the British and European Standard BS EN ISO 15223-1:2012.

IVD	In vitro diagnostic medical device		Temperature limitation
	Caution, consult accompanying documents		Consult instructions for use
EC REP	Authorised representative in the European Community		Do not re-use
Σ	Sufficient for <n> tests		Keep away from sunlight
	Manufacturer	REF	Catalogue number

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