HOLOGIC®

Genfind® DNA Extraction Kit

REF 95-449

Intended Use: Kit for DNA Extraction

IVD

Rx only

Σ 384

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INTENDED USE

The Genfind® DNA Extraction Kit is intended for use in the extraction of DNA from cervical specimens collected in ThinPrep® Pap Test PreservCyt® Solution for testing by the Cervista® HPV HR and Cervista® HPV 16/18 tests.

REAGENTS PROVIDED AND STORAGE REQUIREMENTS

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologicsds.com.

Table 1: Genfind DNA Extraction Kit (REF 95-449) Contents and Storage Requirements

Reagent	Label Abbreviation	Component Description	Storage Requirement
Genfind Proteinase K	**PK**	Lyophilized Enzyme (1 mL vials) Ultrapure	-30° to -15°C Store Frozen
Genfind Lysis Buffer	**LB**	Cell Lysis Solution 0.45 µm filtered	15° to 30°C Store at room temperature
Genfind Binding Buffer	**BB**	Magnetic Bead Solution 0.45 µm filtered	2° to 8°C Refrigerate – Do Not Freeze
Genfind Wash Buffer	**WB**	DNA Wash Buffer (Label marked with blue stripes) 0.45 µm filtered	15° to 30°C Store at room temperature

WARNINGS AND PRECAUTIONS

1. Universal safety precautions should be used when handling any human tissues or fluids. Specimens should be disposed of according to local requirements.
2. Product components (product residuals, packaging) can be considered as laboratory waste. Dispose of unused reagents and waste in accordance with applicable federal, state, and local regulations.
3. Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock-sensitive compounds.

LIMITATIONS

1. Genfind® DNA Extraction Kit is not intended for use with any sample type other than cervical samples collected in ThinPrep Pap Test PreservCyt Solution.
2. Genfind DNA Extraction Kit is not intended for use with any assay other than the Cervista HPV HR and Cervista HPV 16/18 tests.

MATERIALS REQUIRED, BUT NOT PROVIDED

Consumable Supplies

- Pipette tips, filter barrier
- 96-well plates
- Foil plate sealers
- ABgene® 96-well 2.2 mL plates
- Appropriately-sized nuclease-free disposable tubes and screw caps

Reagents

- 2M Tris, pH 7.5
- Nuclease-free water
- 70% Ethanol (Molecular Biology grade)

Equipment

- Cervista® HTA System for automation users
- Pipettes
- Vortex
- Plate centrifuge and rotors
- SPRI® Plate 96R Super Magnet Plate
- Thermomixer R (Eppendorf)
- MTP Block (Eppendorf) and 96-well adapter plate

PREPARATION OF REAGENTS

Equilibrate all reagents to room temperature prior to use. Prepared reaction mixtures should not be stored for later use.

1. Prepare a 10 mM Tris solution from a 2M, pH 7.5 Tris stock solution. For processing a 96-well plate of samples, a recommended preparation is shown in Table 2.

Table 2: Preparation of 10 mM Tris.

Component	Volume
2M Tris, pH 7.5	100 µL
Nuclease-free water	19.9 mL
Total Solution Volume	**20 mL**

2. Combine the Lysis Buffer and Proteinase K (96 µg/µL) in an appropriate-sized conical tube according to Table 3. Mix by pipetting up and down.

Table 3: Preparation of Lysis Buffer.

Component	Volume/ Sample	Number of Samples (x)	Total Volume
Lysis Buffer	400 µL	x	(400 µL)(x)(1.2)
Proteinase K	9 µL	x	(9 µL)(x)(1.2)
LB/PK solution	409 µL	x	(409 µL)(x)(1.2)

INSTRUCTIONS FOR USE FOR CERVISTA HTA SYSTEM

Refer to the Cervista HTA Operator's Manual (P/N MAN-01522-001) for the instructions for use for the Cervista HTA System.

INSTRUCTIONS FOR USE FOR CERVISTA MANUAL SYSTEM

1. Mix the PreservCyt cervical specimen well by vortexing or shaking vigorously. Transfer 2.0 mL of each specimen to a well of a 96-well 2.2 mL plate.
2. Centrifuge the 96-well 2.2 mL plate at 1107 RCF for 10-15 minutes.
3. Place the 2.2 mL plate on the SPRI Plate 96R Super Magnet Plate. Remove the supernatant using a multi-channel pipette or a 96-well aspirator and pump (pressure of aspirator should be approximately 100 mm Hg vac). Remove approximately 1.9 mL of the supernatant leaving

50-100 µL of residual volume. Take care to only remove supernatant and not cellular material. **NOTE:** IF USING AN ASPIRATOR RINSE WITH FRESH DISTILLED WATER FOLLOWING STEPS 3, 8, 11, 12, and 14).

4. Add 400 µL of the Lysis Buffer/Proteinase K mixture to each well containing sample of the 96-well plate. **NOTE:** USE NEW TIPS FOR EACH SAMPLE WELL IN ALL LIQUID TRANSFER STEPS.
5. Incubate the plate on a thermomixer for 15 minutes at 37°C +/-2°C and 1000 rpm. **NOTE:** AFTER THIS STEP, TURN THE THERMOMIXER THERMOSTAT OFF. THE THERMOMIXER THERMOSTAT SHOULD REMAIN OFF FOR ALL SUBSEQUENT STEPS.
6. IMPORTANT: Mix the Binding Buffer thoroughly by inverting the bottle many times, making sure the beads are fully resuspended. After mixing, add 200 µL to each well containing sample of the 96-well plate.
7. Place the plate on a thermomixer and mix at 1000 rpm for 2-3 minutes.
8. Place the SPRI Plate 96R Super Magnet Plate on the spacer and place the 2.2 mL plate on the magnet for 4-6 minutes or until beads form a distinct ring and solution is clear. Aspirate the entire supernatant taking care not to disturb the beads. **NOTE:** USE OF A SPACER IS NECESSARY FOR ALL SUBSEQUENT ASPIRATION STEPS IF USING THE 96-WELL ASPIRATOR AND PUMP.
9. Remove the plate from the magnet and spacer and add 400 µL of Wash Buffer to the plate wells containing beads.
10. Place the plate on a thermomixer and mix at 1000 rpm for 4-6 minutes.
11. Place the SPRI Plate 96R Super Magnet Plate on the spacer and place the 2.2 mL plate on the magnet for 4-6 minutes or until beads form a distinct ring and solution is clear. Aspirate entire supernatant taking care to not disturb the beads. **NOTE:** THE PLATE SHOULD REMAIN ON THE MAGNET AND SPACER DURING STEPS 12-14.
12. Add 400 µL of 70% ethanol to the wells containing beads and incubate for 30-60 seconds. The beads should form a distinct ring. Aspirate entire supernatant.
13. Repeat the 70% ethanol wash by adding 400 µL 70% of ethanol to the wells containing beads and incubate for 30-60 seconds. The beads should form a distinct ring. Aspirate entire supernatant.
14. Allow the beads to air dry for 3-4 minutes. **NOTE:** IT IS IMPORTANT TO REMOVE ALL RESIDUAL ETHANOL BEFORE PROCEEDING TO THE NEXT STEP.
15. Remove the plate from the magnet and add 120 µL of 10 mM Tris to each well containing beads.
16. Place the plate on a thermomixer and alternate mixing at:
    i. 1000 rpm for 2-3 minutes
    ii. Let stand for 2-3 minutes.
    iii. 1000 rpm for 2-3 minutes.
17. Place the plate on a magnet for 10 minutes or until beads form a distinct ring and solution is clear.
18. While the plate is still on the magnet, transfer 110 µL of the DNA solution to a clean 96-well PCR plate using a multi-channel pipette.
19. If the beads are present visually in the DNA solution, place the 96-well PCR plate on the magnet and allow any particles to settle. While the plate is still on a magnet, transfer 100 µL of DNA to a clean 96-well PCR plate. Seal the plate with a foil plate sealer.
20. DNA can be stored at 4–8°C for up to four weeks. For storage longer than four weeks, store the sample DNA in a –20° or –80°C non-frost-free freezer.

PROCEDURAL NOTES AND PRECAUTIONS

For *in vitro* diagnostic use.

1. Multiple storage conditions exist; see Table 1.
2. Follow good laboratory practices. Wear protective disposable gloves, laboratory coats, and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and reagents.
3. Do not pool reagents from different lots or from different vials/bottles of the same lot.
4. Do not use reagents after their expiration date.
5. Prior to use, the Proteinase K lyophilized enzyme should be dissolved in nuclease-free water. A volume of 1 mL of water should be added to each vial as needed. When resuspended with water, the 1 mL vial of Proteinase K should be divided into aliquots and again frozen at -30° to -15°C in a non-frost-free freezer. Thaw only as much Proteinase K as needed for each extraction. Repeated freezing and thawing of the enzyme can cause a loss of function.
6. If a white precipitate has formed in the Wash Buffer, prior to use, gently shake or stir at room temperature until the solids dissolve. Do not heat to recombine.

CONTACT INFORMATION

Manufacturer:
Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA
Customer Support: +1 800 442 9892
customersupport@hologic.com

Technical Support: +1 888 484 4747
molecularsupport@hologic.com

For more contact information visit www.hologic.com.

NOTICE TO RECIPIENT ABOUT LIMITED LICENSE

The Genfind® DNA Extraction Kit utilizes SPRI® paramagnetic bead technology and additional components, covered under U.S. Patent Nos. 5,705,628; 5,898,071; 6,534,262 and any corresponding international equivalents.

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