AMPIVIEW™ HPV High-Risk RNA probes Set

REF ENZ-GEN148 2.0 mL

INTENDED USE:

For Research Use Only. Not for use in diagnostic procedures.

SUMMARY AND EXPLANATION

AMPIVIEW™ RNA probes are uniquely designed with the precision of targeted, sequence-specific RNA probes, powered by Enzo's LoopRNA ISH™ technology to deliver superior sensitivity and compatible with existing nanopolymer detection systems used in immunohistochemistry (IHC) procedures.

AMPIVIEW™ HPV High-Risk RNA probes is a cocktail of RNA probes that specifically detect HPV genotypes 16, 18, 31, 33 and 51. These high-risk HPV types are associated with either condyloma or cervical intraepithelial neoplasia (CIN) and carcinoma *in situ* (CIS). The probe mixture hybridizes to tissue sections fixed and pre-treated on microscope slides.

ASSAY PRINCIPLE

The digoxigenin-labeled probe mixture will denature and hybridize to the fixed and pre-treated tissue section on the microscope slide. The labeled probes can be detected with an unconjugated anti-digoxigenin antibody, followed by a polymer-based detection such as Enzo's POLYVIEW® PLUS reagents combined with HIGHDEF® chromogens. Results can be visualized under a light microscope. For more detection product information visit enzolifesciences.com/IHC).

KNOWN APPLICATION

in situ Hybridization (ISH) on formalin-fixed paraffin-embedded (FFPE) tissue specimens or cells.

PRODUCTS SUPPLIED

AMPIVIEW™ HPV High-Risk RNA probes (ENZ-GEN144)
AMPIVIEW™ Hybridization Buffer (ENZ-ACC152)

MATERIALS NEEDED (Not Provided)

Reagents and materials, such as detection kits, ancillary reagents and instruments are not provided. For information about reagents and additional materials needed refer to Enzo's Life Sciences website, www.enzolifesciences.com/AMPIVIEW.

STORAGE AND SHELF-LIFE

- Upon receipt, store probes solution at -20°C. For long-term storage, you can store at -80°C. These products are stable under these conditions up to the expiration date indicated in the vial label.

PERFORMANCE CONSIDERATIONS

1. Do not use reagents past their expiration date.
2. Do not allow the slides to dry completely during the hybridization and detection procedures, or erroneous results may occur. Avoid drying by ensuring that the entire specimen is covered with sufficient amounts of buffers and reagents as recommended in the procedures. While incubating, the slides may be covered with a cover slip to help prevent drying.
3. Cross-contamination of samples could cause false results. Use care preparing slides for more than one specimen.
4. Allow all components to reach room temperature (20-30°C) before beginning the test procedure.
5. Incubation times and temperatures other than those specified may give erroneous results.
6. Improper specimen preparation may cause false results.

CONTROLS

To assure the staining procedures are performed correctly, a control slide should be run with the first set of specimen slides. It serves as a hybridization/detection control and as an aid in interpretation of the specimen slides. Each laboratory can prepare tissue control slides from known HPV positive tissue blocks. If the control slides do not appear as expected, the test run should be invalid.

LIMITATIONS

- This procedure is for research use only. It is not intended for diagnostic or therapeutic use.
- Negative results do not rule out the possibility of HPV infection.
- It has been reported that there is a marked variability in the number of cells containing HPV DNA in different specimens.
- It is possible for the specimens to be infected with more than a single type of HPV.
- For specimens containing very few HPV-infected cells, it may not be possible to determine the HPV type.

PRECAUTIONS

1. Refer to reagent Safety Data Sheet (SDS) from precautions.
2. Specimens, before and after fixation, and all materials exposed to them should be handled and disposed of with proper precautions.
3. Never pipette reagents by mouth and avoid contact with skin and mucous membranes with reagents and specimens. If reagents and/or specimens come into contact with sensitive areas, rinse

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thoroughly with water and follow your institution's safety protocols.

TECHNICAL NOTES

1. AMPIVIEW™ RNA probes have been optimized with DIGX® anti-digoxigenin (mouse or rabbit) and POLYVIEW® PLUS Detection Systems. Use of other polymer-based reagents will require prior optimization.
2. Autostainers such as LEICA Bond III or Bond Max, Ventana Discovery Ultra or others can be used, but will require prior optimization.
3. Changes in the amount of probe or temperature incubation times from what's recommended may lead to inconsistent results.

INSTRUCTIONS FOR USE

AMPIVIEW™ HPV High-Risk RNA probes are developed for manual and automated systems in combination with a nanopolymer IHC detection system such as Enzo's POLYVIEW® PLUS detection reagents and HIGHDEF® chromogens.

Deparaffinization and Antigen Retrieval

Perform specimen pre-treatment (e.g. dewaxing, proteolysis) according to instructions for use of AMPIVIEW™ POLYVIEW® PLUS detection kit (ENZ-ACC159 or ENZ-ACC160).

Hybridization

1. Add 50 to 100 µL AMPIVIEW™ HPV High-Risk RNA probes onto dried slide and cover the specimen with a cover slip.
2. Denature samples at 80°C for 2 minutes.
3. Place the slides in the hybridization oven at 55°C for 2 hours.

Post-hybridization and Detection

Perform post-hybridization processing and detection according to detection kit.

For specific protocols, visit enzolifesciences.com/AMPIVIEW

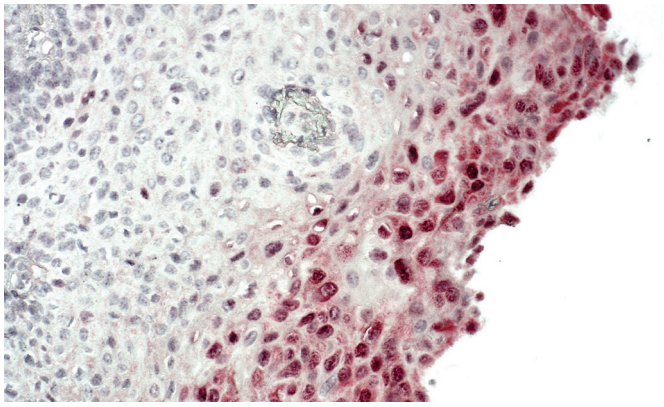
INTERPRETATION OF RESULTS

Using POLYVIEW® PLUS detection systems and HIGHDEF® chromogens, hybridized AMPIVIEW™ HPV High-Risk RNA probes appear as [chromogen color] pattern when detected with POLYVIEW® PLUS AP or HRP.

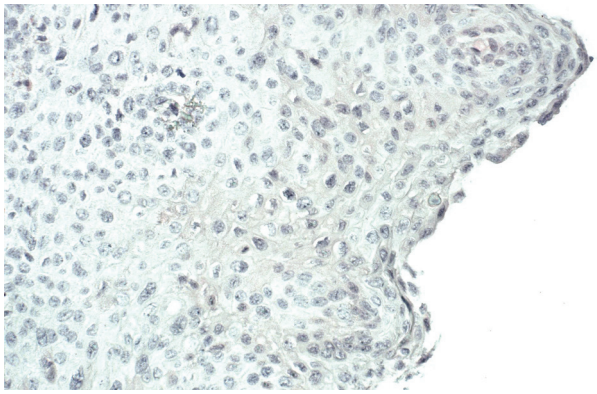
A cytoplasmic staining is observed with RNA sequences of HPV are detected.

Please note:

- Do not evaluate areas of necrosis, overlapping nuclei, over-digested nuclei, nuclei with weak signal intensity.
- A negative or unspecific result can be caused by multiple factors.
- In order to correctly interpret the results, the used must validate this product prior to use.



HPV high-risk detected (red) in HPV-positive cervical tissue specimen with AMPIVIEW™ HPV High-Risk RNA probes, POLYVIEW® PLUS AP and HIGHDEF® red AP chromogen/substrate.



AMPIVIEW™ NSP-Bio (negative control) shows no signal with POLYVIEW® PLUS AP and HIGHDEF® red AP chromogen/substrate.

REFERENCES

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2. Burd, EM. Human papillomavirus and cervical cancer. Clinical Microbiology Reviews, 2003, p1-17. DOI: 10.1128/CMR.16.1.1-17.2003
3. Nuovo, GJ. Et al. Recent improvements in immunohistochemistry and *in situ* hybridization. *In situ* molecular pathology and co-expression analyses. 2nd Ed. Chapter 7.DOI: https://doi.org/10.1016/B978-0-12-820653-9.00007-9.

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