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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Method of Detecting Circulating Cell-Free HPV 6 and 11 DNA in Patients Afflicted With Diseases Caused by Chronic HPV 6 or 11 Infection and Use Thereof

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) and Frederick National Laboratory for Cancer Research (FNLCR) seek research co-development partners and/or licensees for commercial development of a novel liquid biopsy diagnostic for non-invasive detection of cell-free HPV 6 and 11 DNA for recurrent respiratory papillomatosis (RRP).

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *suna.gulay@nih.gov* or Phone: 240-276-7424.

SUPPLEMENTARY INFORMATION: RRP, caused by chronic infection with human papillomavirus (HPV) types 6 and 11, is a rare but potentially fatal disease characterized by the growth of papillomas throughout the respiratory tract. While HPV 6/11 infections are common, affecting approximately 40% of U.S. adults, a subset of patients can develop a range of conditions from benign papillomas to dysplasia and invasive cancers. Current treatment for RRP typically involves repetitive surgical intervention or laser ablation to alleviate symptoms, which carries significant procedural risks. A recent breakthrough with a therapeutic HPV vaccine demonstrated that 51% of patients avoided surgery for at least a year, with some experiencing durable

remission. However, there remains no reliable diagnostic tool to confirm viral clearance or guide systemic therapy decisions.

Researchers at the NCI and FNLCR have developed a novel hybridization-based next-generation sequencing (NGS) liquid biopsy method to detect circulating cell-free HPV 6 and 11 DNA in the plasma of patients with RRP. This innovative approach uses the established relevance of circulating viral DNA as a valuable biomarker for disease monitoring and therapeutic decision-making in other virally-associated conditions. The method is designed to target multiple regions across the entire HPV 6 and 11 genomes. It employs a pull-down DNA technology to enhance coverage – overcoming limitations of fixed-primer PCR for small cell-free DNA fragments. While low-risk HPV-associated diseases like RRP exhibit less tumor cell turnover compared to advanced cancers, the inherent high vascularity of papillomas may facilitate the release of viral DNA into peripheral blood. This method offers a non-invasive, sensitive and potentially prognostic tool to aid in (1) diagnosis, (2) monitoring progression and (3) guiding systemic therapies such as HPV vaccination or predicting severity – including pulmonary risk.

Investigators at the NCI and FNLCR continue to evaluate circulating HPV 6 and 11 DNA in patients previously treated in clinical trials to further assess its prognostic and predictive capabilities. This technology presents a compelling opportunity for commercial development and seamless integration into existing diagnostic platforms. NCI and FNLCR offer licensing and collaborative development opportunities to advance this critical diagnostic and prognostic tool for RRP.

"This Notice is in accordance with 37 C.F.R. § 404.4 Authority to grant licenses."

NIH Reference Number: E-019-2025.

Related Technologies: N/A.

Product Type: Diagnostic.

Therapeutic Area(s): Pulmonology | Infectious Disease | Oncology.

Development Stage: Pre-clinical (*in vivo* validation).

Publications:

- Norberg SM, et al. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. (PMID 39855244).

Patents: PCT/US2026/027273, filed May 8, 2026.

Potential Commercial Applications:

- Liquid biopsy diagnostic for RRP confirmation.
- Monitoring RRP disease progression.
- Prognostic test for RRP severity, especially pulmonary disease.
- Companion diagnostic to guide systemic RRP therapies.
- HPV 6/11 detection assay for anogenital condyloma.

Competitive Advantages:

- Non-invasive, sensitive and potentially prognostic and diagnostic tool.
- Reduces the need for, and risk from, repeat surgical procedures.
- Detects disease even with a Derkay score of 0 (minimal laryngeal involvement).

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for commercial development of a novel liquid biopsy diagnostic for non-invasive detection of cell-free HPV 6 and 11 DNA for RRP.

Dated: July 6, 2026.

Richard U. Rodriguez,

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National Cancer Institute.

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