

MEL-MONT MEDICAL RECEIVES CPT® PROPRIETARY LABORATORY ASSAY CODE FROM THE AMERICAN MEDICAL ASSOCIATION

Proofer 7 mRNA Test for effective clinical triage from HPV screening

ATLANTA, GEORGIA, UNITED STATES, May 3, 2024 /EINPresswire.com/ -- Mel-Mont Medical, Inc., an innovative leader in precision HPV mRNA extended genotyping and sample collection devices,

Enabling payer billing and reimbursement is key to commercialization success and serves to facilitate wider adoption of best-in-class HPV biomarker triage testing for patients." *Frank Melendez, CEO & co-Founder, Mel-Mont Medical* announced today that the Proprietary Laboratory Analyses (PLA) Common Procedural Terminology (CPT[®]) Code 0463U has been issued from the American Medical Association (AMA) for the Proofer 7 mRNA E6 and E7 Biomarker Test.

This dedicated PLA code was published online April 1, 2024, and is included in the AMA's most current CPT publication. Medicare rate setting is currently in process and is expected to be finalized following the CMS Annual Lab Meeting June 25, 2024.

"Receipt of our own PLA code is another big step toward

broadening access to the Proofer 7 mRNA test for improved clinical decision-making," Frank Melendez, Mel-Mont Medical's Co-Founder and CEO commented. "Enabling payer billing and reimbursement is key to commercialization success and serves to facilitate wider adoption of best-in-class HPV biomarker triage testing for patients."

The Proofer 7 HPV mRNA E6 and E7 Biomarker Test utilizes gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), via real-time nucleic acid sequence-based amplification (NASBA) to analyze epithelial cells collected from and around a patient's cervix. Positive or negative status of each separate HPV type is resulted on each clinical report.

The company began providing the Proofer 7 mRNA test to physicians and patients in Norway, Spain, Mexico, Greece, Poland, Italy, and the United Kingdom, in response to the need for more accurate and efficient triage from HPV DNA positive or abnormal Pap smear test results. While clinical studies for IVD kit FDA submission are underway, Mel-Mont Medical's Global 7 Diagnostics CAP/CLIA laboratory will be accepting and processing clinical patient samples. Email info@mel-montmedical.com for Proofer 7 HPV mRNA Laboratory Developed Test (LDT) ordering details.

About Mel-Mont Medical, Inc.

Mel-Mont Medical, Inc. is an innovative leader in precision HPV mRNA extended genotyping and sample collection devices that address global health concerns. The company designs, develops, and markets state-of-the-art technologies and medical services that preserve life through the prevention, early diagnosis, and informed management of virus-related pathologies. Since 2020, Mel-Mont Medical has been facilitating HPV testing for women in Europe and North America, where it operates multiple high-complexity laboratories. The company is continually growing and expanding to meet worldwide demand.

Mel-Mont Medical Inc.'s wholly owned subsidiaries:

- PreTect, AS: an ISO 13485:2016 manufacturing facility in Klokkarstua, Norway
- MC2 Molecular Biology, SL: a clinical testing facility in Palma de Mallorca, Spain
- MHS Farma 72, SL: a licensed EU logistics center in Palma de Mallorca, Spain

• Global 7 Diagnostics Labs, LLC: a CAP (#8168228)/CLIA (#11D2130154) clinical testing lab in Atlanta, GA

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