



Department of Health

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Executive Deputy Commissioner

April 28, 2021

Robert A. Bever, Ph.D.
Bode Cellmark Forensics d/b/a Bode Technology
10430 Furnace Rd Suite 107
Lorton, VA 22079

PFI: 7965
Project ID: 71479

Dear Dr. Bever:

This letter amends your August 5, 2020 approval to perform Forensic Genealogy analyses to include release of the SNP data prior to upload to publicly available databases when your previously-described quality control measures have been verified (sample/case identifier, analysis method, gender check and call rate, etc.) and a report accompanies the release.

You may offer this testing under an amended analyte approval to include data analysis, ancestry, kinship and genetic genealogy of single source samples.

The laboratory may only perform testing using data derived from a laboratory that has a CLEP permit and approval to perform a large SNP panel.

The patient report must include information on any limitations of the assay as evidenced by the validation studies and any disclaimer required by the federal government, including the Food and Drug Administration (FDA) for the use of analyte specific reagents (ASR). Since this method is not currently cleared or approved by the FDA, please retain this letter to verify that the procedure for this test has been submitted to and approved by this department. Please note that any modifications of your present test methods must be immediately forwarded to this office for evaluation by the program's professional staff. You will be informed if additional validation studies are required to support the modifications of your procedure. Although the approval is granted for an indefinite period, it is subject to demonstration of ongoing compliance with Department regulations and standards. We reserve the right to request more information and to withdraw the approval should evidence of non-compliance be identified.

Also, please provide the CLEP Validation Unit with updates to the laboratory's test approval records (viewable list on the eCLEP page of the Health Commerce System (HCS) website) should this or other assays replace tests previously submitted for approval. When requested, we share test-specific approvals with clients seeking services and thereby need to keep records relevant.

Questions can be sent by e-mail to clepval@health.ny.gov or you may call 518-485-5378.

Sincerely,

Michael Neal, BSMT (ASCP)
Clinical Laboratory Evaluation Program