



Department of Health

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Executive Deputy Commissioner

June 16, 2021

Sin H Lee, M.D.
Milford Molecular Diagnostics LLC
2044 Bridgeport Avenue
Milford, CT 06460

PFI: 8900
Project ID: 49777

Dear Dr. Lee:

Thank you for submitting portions of your standard operating procedure manual and validation data needed to evaluate your nested PCR and direct automated DNA sequencing-based method for qualitative detection/identification of *Borrelia burgdorferi* (Lyme disease) and *Borrelia miyamotoi* in whole blood specimens. After carefully evaluating all the information provided, the Clinical Laboratory Reference System's reviewers have found your validation data for this testing acceptable. You may offer this testing under your enclosed initial permit in the category of Bacteriology.

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

Enclosure