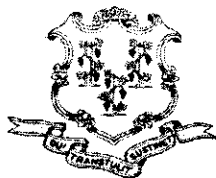


STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Facility Licensing and Investigations Section

Sin Hang Lee, M.D., Laboratory Director
Milford Molecular Diagnostics, LLC
2044 Bridgeport Avenue
Milford, CT 06460
CLIA# 07D2067401 State # CL-0699

August 17, 2017

RE: Application to begin offering BRCA mutation assays

Dear Dr. Lee,

Based on the FDA recommendations regarding your application to offer the Ashkenazi Jewish 3 Founder Mutation Analysis; or as *BRCA1* 185delAG, *BRCA1* 5382insC and *BRCA2* 6174delT mutations assay, your submission of additional documentation was received and reviewed.

It has been determined through consultation with CMS Regional and Central Offices that you be allowed to proceed with patient testing based on the CLIA requirements being met.

We will be contacting you this fall to schedule your biennial relicensure/recertification onsite survey for some time after the New Year.

Thank you for your patience throughout the review process.

Sincerely,

Lori A. Griffin, R.N., C.R.R.N.
Public Health Services Manager
Division of Health Systems Regulation



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