



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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Board of Clinical Laboratory Personnel
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**Comments to State of Florida Board of Clinical Laboratory Personnel regarding
Licensure Requirements for Molecular Pathology Technologists (64B3-10.005)**

The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 1,500 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Since the beginning of our organization we have dedicated ourselves to the development and implementation of molecular diagnostic testing, which includes genetic testing in all its definitions, in a manner consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. Our members populate the majority of clinical molecular diagnostic laboratories in the United States. They are frequently involved in the origination of novel molecular tests, whether these are laboratory developed or commercially developed.

We recommend revision to section 14 to read as follows:

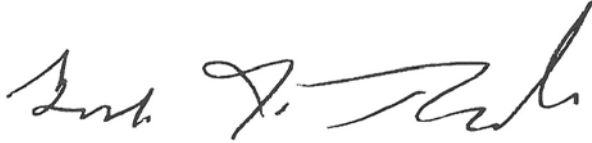
(14) The purpose of the specialty of molecular pathology is the use of molecular techniques for the diagnosis, treatment, and prognosis of genetic disorders, cancer, infectious diseases, identity, pharmacogenetics and histocompatibility. It includes the study of how the changes found lead to the disease process, monitoring of the effectiveness of therapy, and detection of residual disease. Techniques included are but not limited to, hybridization, mutational analysis, polymerase chain reaction, nucleic acid sequencing, and microarrays.

We also respectfully recommend revision to the current licensure requirements in the Florida State Scope of Practice Relative to Specialty of Licensure regarding moderate and high complexity testing as it relates to laboratory technologists using molecular detection techniques (section 18 of 64B3-10.005). Though the Federal Standard for Testing Personnel Qualifications (CFR42. Sec 493.1423 and Sec 493.1489) allows for state licensure of individuals who perform testing using molecular detection techniques, no such state exam exists in Florida. We believe that CLIA requirements are adequate and that the licensure requirement places undue burden upon medical technologists and the laboratories that hire them particularly if documentation of appropriate training can be provided that fulfills the criteria in the Federal Standard for Testing Personnel Qualifications.

We recommend revision to section 18 to read as follows:

(18) Individuals using flow cytometry or molecular detection techniques must be able to meet CLIA standard §493.1489 and demonstrate training or experience in the procedure.

Thank you for the opportunity to comment on this very important document. Please do not hesitate to contact me at gregory.j.tsongalis@hitchcock.org if we can be of further assistance.

A handwritten signature in black ink, appearing to read "Greg. J. Tsongalis". The signature is fluid and cursive, with the first name "Greg." written in a smaller, more legible script than the last name "Tsongalis".

Gregory J. Tsongalis, PhD
AMP President