**From:** joannelannon@sslabconsultants.com

**To:** DPH-Testimony, Reg (DPH)

**Subject:** Clinical Laboratories

**Date:** Friday, February 19, 2016 3:25:54 PM

To Whom It May Concern:

South Shore Laboratory Consultants, Inc. has provided regulatory services to clinical laboratories in Massachusetts for the past 28 years. Our experience has not only been working with numerous physician office laboratories, but approximately 20 start-ups of molecular genetics and LDT laboratories in the state, assisting them in obtaining both MA licenses and CLIA certifications. We have also guided these molecular genetic and LDT testing laboratories through obtaining CAP Accreditations and licenses in RI, PA, MD, FL, CA and NY.

I would like to speak to the proposed regulations for the molecular genetics laboratories .

Our experience obtaining CAP Accreditation for genetics laboratories is that it takes approximately 1 year from applying to CAP for completion of inspection. I strongly feel that the 6 month window is too short for this process. I recommend at least 1 year from the provisional MA license to completion of CAP be acceptable to the department.

It must be acknowledged that by requiring Accreditation, a laboratory would be working through a third party system, not the usual DPH path that is managing the CLIA inspections. I am concerned the accrediting agencies will become backlogged and unable to complete the large volume of required inspections in such a short timeframe.

In addition, I see no provision for existing genetics laboratories that are currently MA state licensed and CLIA certified. There should be a grandfathering process for these laboratories which would allow them a reasonable window to switch to CLIA registration and CAP Accreditation.

Regards,

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