



STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

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Dear Health Officer:

This letter is to inform you of fundamental organizational and oversight changes in the Michigan Regional Laboratory System (MRLS) that will be discussed at the March 14, MALPH meeting in Ann Arbor and initiated during October 2011. Even if your agency does not currently participate in the MRLS, these changes may impact your decisions about engaging the MRLS in the future.

For almost two decades the MRLS has provided a structure of quality assurance for local public health agencies performing testing on human specimens in a non-traditional laboratory or point-of-care setting. The MRLS has enabled local public health agencies to meet the federal regulatory requirements of CLIA '88. However, in the years between the inception of MRLS and now, there have been profound changes in diagnostic technology and state and local public health resources (detail provided at conclusion of letter).

To address these profound changes, the MDCH initiated a process last year to examine how well the current MRLS structure meets all participant needs, identify participant values, and explore how the MRLS could be restructured to meet needs of today's public health system. The process included "Lean-trained" MDCH facilitators who worked with Dr. Jeff Massey and me to solicit MRLS stakeholder feedback. Together we engaged a representative group of stakeholders (health officers from participating and non-participating agencies, public health programs that support tests performed in the MRLS, technical consultants and MDCH personnel) in a 3-day planning workshop.

Workshop participants, in consensus, proposed a cost-effective reorganization more responsive to local needs. The plan will be presented at the March MALPH Board meeting, so I want to introduce you to the major changes to facilitate our upcoming discussion. Key elements follow:

- 1) Each local public health agency will obtain and manage its own CLIA certificate, (Waived, PPM or moderately complex depending on the range of tests offered). This change will empower agencies to determine the level of quality assurance practices that best suits their setting. Each agency will need to designate a laboratory director (e.g., Medical Officer) and an on-site coordinator to serve as the General Supervisor and depending on the tests offered, enroll in an external proficiency testing service (if needed).
- 2) Before October 1, 2011, MDCH Lab will provide training to prepare on-site coordinators for their future roles. The on-site coordinator will be responsible for training and monitoring quality (similar to the food service program on-site trainer).

3) The current Technical Consultants will continue to provide assistance with basic membership in the MRLS for a minimal fee. These services will be defined in an agreement between the technical consultant's employing agency and the participating agency and will include:

- Consultation
- Training at state-wide conferences and meetings
- Annual or biannual meetings

4) Enhanced services (e.g., on-site training, assessments and competency checks) will be available from the Technical Consultants for additional charges.

5) The Michigan Local Public Health Accreditation tool will be amended to reflect the changes to the MRLS.

The background and rationale for these changes includes the following information. Local public health agencies have been grouped geographically into regions under CLIA Umbrella Public Health Certificates held jointly by MRLS participating agencies, which allows them to conduct simple-to-perform, or waived, tests (e.g., pregnancy or hemoglobin by Hemacue) and moderately complex tests (e.g., wet mounts). Local public health agencies monitor their own day-to-day quality of testing. Quality oversight is provided by high complexity public health laboratories acting as technical consultants and MDCH doctoral-level scientists acting as laboratory directors.

In addition to regulatory compliance the MRLS has succeeded in providing the following:

- Technical and quality assurance consultation from laboratory professionals
- Standardized quality and technical procedures, forms and tools available on an unrestricted web site supported and maintained by MDCH lab personnel
- Internal proficiency testing
- On-site quality assessment visits
- Assistance/support for Accreditation and CLIA surveys
- Services provided at low cost compared to similar services from private consultants

Many of the tests that originally required the non-waived Umbrella Public Health certificate, have now been re-designed and re-introduced as waived tests. Public health resources at the MDCH laboratory, which provides over half the funding for the MRLS have shrunk with fewer doctoral level scientists available to serve as laboratory directors. And finally, local public health agency personnel have become more familiar with testing quality assurance and CLIA requirements. For these reasons, the local and state workshop participants and stakeholders mentioned previously proposed a viable alternative.

Attached is a tool that will assist your agency in estimating the cost of the proposed structure. I look forward to discussing this exciting development with you in March. Please contact me or Dr. Massey at (517)335-8063 if you have questions or need more information prior to the MALPH meeting.

Sincerely,

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Laboratory Director

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Quality Assurance Section Manager

Cc: Medical Officers, Site Coordinators, Regional Laboratory Technical Consultants, Mark Miller, Elizabeth Pash, Jean Chabut