

TECHNICAL BULLETIN

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TO: County Health Department Personnel

Overview of 2017 ACHDLS CLIA inspection & forthcoming quality process improvements.

The ACHDLS had its' biannual CLIA/CMS inspection on 10/31/17 - 11/02/17. The laboratory system received one citation but was found in substantial compliance with CLIA regulations. The citation received was for a lack of corrective action regarding RPR proficiency testing for the first quadrimester of 2016. Technical consultants are currently working on documentation to comply with the corrective action plan approved by the surveyors for the citation received. More information about this will be coming before the end of 2017. During the inspection, the CLIA surveyor indicated several areas where the ACHDLS could improve its' quality processes. As a result of these recommendations, the ACHDLS will be making some quality improvements.

- Diplomas of all ACHDLS testing staff performing non-waived testing will now be kept at the QM offices and at the base CHD of the individual testers. Detailed emails regarding this requirement were sent on 11/30/17 and diplomas are due back to QM by 12/22/17.
- Any patient specimen collected for testing within the CHD or at a referral laboratory must be labeled with two unique patient identifiers. This policy also includes secondary containers, swab tubes, and microscope slides. Detailed information will be forthcoming.
- Starting in 2018, competency testing will include off-site examinations as have been conducted in the past as well as on-site observational competencies for every tester. Technical Consultants are working on a viable plan for this CLIA requirement and more information will follow before county visits begin in 2018.
- A teaching module in the form of a PowerPoint presentation will be available to CHD staff to encourage better understanding of the CHD internal auditing process (county visits) to include how to prepare a Corrective Action Report in response to a County Visit Report. Technical Consultants are working on the module which will be available before county visits begin in 2018.
 - When CHD staff have meetings that include discussion items related to laboratory testing and/or county visit findings, meeting minutes along with a list of meeting attendees should be submitted to QM to document the discussion. This includes one-on-one meetings, as well.
- As completed in 2016, Technical Consultants will hold group phone consultations during the first two weeks of January 2018. Topics covered will include updated maintenance forms, changes to the ACHDLS manual, county visits, on-site competency observations, competency exam dates, training classes, etc. Multiple time slots will be available and each CHD will be expected to have a representative listen in and pass on information to the rest of the staff in their CHD. An email will be sent with an agenda and available time slots.

The items in this list that are policy changes will be added to the 2018 version of the ACHDLS Policies and Procedures Manual.

Please contact Ashley Megelin at 334-260-3427 if you have questions regarding this bulletin.

Alabama Department of Public Health Bureau of Clinical Laboratories Quality Management Division