Appendix A

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Nathan Deal, Governor | Frank Berry, Commissioner

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-656-4507 | www.dch.georgia.gov

Date of Letter:

Laboratory Director: Name, Title
CLIA Number:
District Name:
District Address:

RE: CLIA Recertification Survey

This letter is to confirm your upcoming Clinical Laboratory Improvement Amendment of 1988 (CLIA) recertification survey by the Georgia Department of Community Health. **Your laboratory, CLIA # _____, is scheduled for survey on __Date_____. We will arrive at the _____Location____ laboratory at approximately __Time__**. Successful completion of this survey process is a requirement for continued participation in the CLIA Program. You can find CLIA survey specific information for your survey under Interpretive Guidelines for Laboratories on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html.

In order to facilitate the survey process I request:

- A list of all non-waived testing performed by your laboratory, test volumes, including all kits and instrumentation/analyzers currently in use to complete my preparation for the survey.
- You complete the attached forms:
  - CMS-116 (Clinical Laboratory Improvement Amendment Application for Certification)
  - CMS-209 (Laboratory Personnel Report (allow one line for each position selected for each name
    entered)
  - Disclosure of Ownership and Control Interest Statement
  - Include with documents below.
- Have the following information available the date of the survey for our review (for the past two years or since last survey date):
  - Approved laboratory policy/procedure manuals, including instrument operator's manuals, package inserts and reference lab manual(s)
  - Personnel records - training experience, (**high school diplomas, college degrees, or transcripts), competency evaluation records, continuing** education, personnel changes, duties and responsibilities
  - Quality Control – testing records, statistical limits, remedial action, instrument maintenance, calibration, calibration verification and temperature charts
  - Proficiency Testing (PT) – PT report, Test run with PT results, Direct print outs, remedial action, unsatisfactory results, copies of signed attestation records and non-waived test procedures not listed in subpart I for verification of test or procedure accuracy twice yearly
  - Quality assessment policy and monitoring activities
  - Safety information
  - Patient test records – requisition, work records, and patient test report
  - Records of test referred to other laboratories

Appendix A

As required under CLIA section §493.1773 (c) all records and pertinent data must be readily accessible and retrievable within a reasonable time frame during the course of the inspection.

If you have questions regarding this letter, please contact me at 404-558-5092.

Sincerely

Compliance Specialist
Diagnostic Services Unit
Healthcare Facility Regulation Division