Terms of Accreditation - Attachment B

AU ID:

CAP #:

Accreditation by the College of American Pathologists' (CAP) Accreditation Programs is contingent on compliance with the terms and obligations listed below.

A laboratory that is accredited by CAP or that has applied for accreditation must:

- Cooperate in any CAP investigation or inspection and promptly notify the CAP if the laboratory becomes:
  a. The subject of an investigation by a government entity (including federal, state, local, or foreign), or
  b. The subject of a validation inspection, or
  c. The subject of adverse media attention.

  To report any of the items related to a, b, or c send an e-mail to accred@cap.org.
- Promptly notify the CAP if the laboratory discovers actions by laboratory personnel that appear to violate federal, state, or local laws that regulate laboratories.
- Have a written procedure for employees to communicate concerns about quality and safety to management and for management to investigate employee complaints. Incorporate corrective or preventive actions into the laboratory Quality Management Plan.
- Provide a trained inspection team comparable in size and scope to that required for its own inspection if requested by the regional and/or state commissioner at least once during the two-year accreditation period.
- Participate annually in a CAP accepted proficiency testing program, if applicable and, if subject to US CLIA regulations, meet the proficiency testing requirements in subpart H of the US CLIA regulations.
- Promptly notify the CAP and, if subject to US CLIA regulations, the US Department of Health and Human Services (HHS), in writing 30 days prior to any changes in the following: directorship, location, ownership, name, insolvency or bankruptcy.
- Promptly notify the CAP when there is a change in the laboratory's test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.
- Authorize the CAP to release its inspection and proficiency testing data and other information required by law to the appropriate regulatory or oversight agencies such as CMS, Department of Veterans Affairs, Department of Defense, Joint Commission, HFAP(AOA), UNOS, or state/provincial agencies.
- If the laboratory is subject to US CLIA regulations:
  - Make available on a reasonable basis the laboratory's annual PT results upon request of any person;
  - Allow HHS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operation and permit HHS to monitor the correction of any deficiencies found through such an inspection;
  - Obtain a CLIA Certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory if it will use CAP accreditation to meet CLIA certification requirements.
- Submit a completed Self-Inspection Verification Form in the interim year.
- Accept and adhere to the *Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design*, if the laboratory is/or will use the CAP Certification Mark of accreditation. The Agreement may be downloaded and printed from the CAP web site.
- Submit only documentation and other materials to CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations unless the laboratory must submit PHI to CAP in order to respond to a deficiency or patient complaint.
- Refrain from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.

The CAP may, at its sole discretion, discontinue an accreditation program(s) with six (6) months written notice. In such event, the laboratory will be entitled to receive a prorated refund of any prepaid annual fee.

I hereby authorize the CAP to release data to the appropriate agencies, agree to the Terms of Accreditation, and attest that:

- All laboratory personnel are appropriately licensed, if required.
- I am not named as director of record for more laboratories than allowed by applicable federal or state laws.
- This laboratory is in compliance with all other applicable federal, state, and local laws and regulations.
- Except as noted above, there have been (1) no investigations of this laboratory by any state, federal, or other regulatory body, and (2) no instances of adverse media attention in the past two years.
- All information provided to CAP is truthful and complete.

Laboratory Director's Signature _____ Date ☐☐ / ☐☐ / ☐☐☐☐

Print or Type Director's Name