SUBPART A: GENERAL

Section

450.5 Scope and Applicability

450.10 Definitions

450.20 License Application

450.30 Laboratories Covered

450.35 Testing Limitations for Exempt, Permit, and Licensed Laboratories (Repealed)

450.40 Penalties and Fines

450.50 Incorporated and Referenced Materials

450.60 Administrative Hearings

SUBPART B: DIRECTORS OF CLINICAL LABORATORIES

Section

450.210 Qualifications of the Director of a Clinical Laboratory

450.220 Operational Participation of the Director

450.230 Number of Laboratories Permitted to Operate

SUBPART C: LOCATION, CONSTRUCTION AND SANITATION

Section

450.310 Location

450.320 Conformance to Local Ordinances

450.330 Safety and Sanitation Manual

SUBPART D: QUALIFICATIONS OF PERSONNEL

Section

450.410 General Supervisor

450.420 Testing Personnel

450.430 Cytotechnologist (Repealed)

450.440 Technician (Repealed)

450.450 Laboratory Assistant (Repealed)

450.460 Technical Supervisor

450.470 Clinical Consultant

SUBPART E: EQUIPMENT

Section

450.510 Facilities and Equipment

450.520 Preventive Maintenance of Equipment and Instruments

450.530 Glassware (Repealed)

450.540 Lancets, Needles and Syringes (Repealed)

450.550 Electrical Equipment (Repealed)

450.560 Photometric and Spectrophotometric Equipment (Repealed)

450.570 Analytic Balances and Weights (Repealed)

SUBPART F: OUT OF STATE LABORATORIES

Section

450.610 Criteria for Licensure

SUBPART G: PROFICIENCY SURVEY PROGRAM AND

INSPECTION OF FACILITIES

Section

450.710 Inspections

450.720 Proficiency Survey Program

450.730 Western Blot Assay Testing Procedures

SUBPART H: SPECIAL REQUIREMENTS PERTAINING TO BLOOD BANKS

Section

450.810 General

450.820 Applicability of Other Parts of the Regulations (Repealed)

450.830 Donors and Donor Blood/Criteria for Donor Selection (Repealed)

450.835 Directed Blood Donations (Repealed)

450.840 Donors and Donor Blood/Identification of Donor Blood (Repealed)

450.845 Donors and Donor Blood/Storage and Transportation (Repealed)

450.848 Preparation of Blood Components (Repealed)

450.850 Plasmapheresis (or Plateletpheresis) (Repealed)

450.860 Autologous Transfusion (Repealed)

450.870 Transfusion Service Records (Repealed)

SUBPART I: PROHIBITED PRACTICE

Section

450.920 Terms Not to be Used in Names of Laboratories

450.930 Prohibitions in Advertising and Announcements

450.940 Acceptance of Specimens and Reporting of Results

450.950 Referral of Specimens for Examination to Unlicensed Laboratories

SUBPART J: RECORDS AND REPORTS

Section

450.1010 Necessary Records

SUBPART K: QUALITY CONTROL

Section

450.1110 Responsibilities of Director

450.1120 Reference Materials

450.1130 Preventative Corrective Maintenance Program

450.1140 Procedure Manuals

450.1150 Quality Control System Methodologies

450.1155 Cytology

SUBPART L: HIV CONTAMINATED BLOOD AND HUMAN TISSUE

Section

450.1200 Handling and Disposal of HIV Contaminated Blood and Human Tissue

SUBPART M: HEALTH SCREENING

Section

450.1300 Health Screening and Approved Health Screening Tests

450.1310 Protocol for Conducting Health Screening

450.1320 Application for a Class III Permit to Conduct Health Screening (Repealed)

450.1330 Reporting and Notification

450.APPENDIX A Application for Registration, Class I Permit, Class II Permit, and Licensed Laboratory (Repealed)

450.APPENDIX B Application for Class III Permit Laboratory (Repealed)

450.APPENDIX C Exempt, Permit, and License Requirements – An Overview (Repealed)