Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2161552	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pathgroup Labs Llc Tupelo	499 Gloster St Village Bldg A1 - Lab Room 1, Tupelo, MS	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of TOSOH AIA 360 PSA (prostate specific antigen) calibration records through the day of survey, 8/21/19, and confirmation with laboratory manager/ testing personnel #1 at 3:30 pm on 8/21/19, the laboratory failed to perform calibration verification on the TOSOH AIA 360 analyzer every 6 months for PSA. Findings include: 1. Review of TOSOH AIA 360 calibration verification records

	revealed that a calibration verification had not been performed on the PSA assay since 6/12/18. The laboratory failed to perform PSA calibration verifications that were due in December 2018 and June 2019. 2. This chemistry test has only 2 calibration points and is therefore required to have a calibration verification performed at least every 6 months. 2. Interview with the laboratory manager/testing personnel #1 at 3:30 pm on 8 /21/19 confirmed that no calibration verification had been performed since 6/12/18.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on lack of qualifying documentation for a technical consultant available on the day of survey and confirmation by clinic ownership staff at 10:30 am on the day of survey, 8/2/19, the laboratory did not have a designated technical consultant who qualified in accordance with 493.1411 of this subpart that would provide technical oversight, in accordance with paragraph 493.1413 of this subpart from the initial application with CLIA, 2/5/19 through 8/21/19.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of personnel records on the initial survey, the CMS 209 personnel form, and lack of qualifying documentation available for review for the technical consultant designated on the day of survey, the laboratory did not have an individual designated as technical consultant who meets the qualification requirements of 493. 1411 of this subpart from the initial application with CLIA, 2/5/19 through 8/21/19. The technical consultant must-- Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; AND Be certified in anatomic or clinical pathology, or both, by the America Board of Pathology or the America Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; OR Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service of which the technical consultant is responsible; OR Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; AND Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or

	subspecialty areas of service for which the technical consultant is responsible; OR Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; AND Have at least two years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory records (including quality control, calibrations, temperatures, proficiency testing results, and preventive maintenance records) and interview with laboratory manager/testing personnel #1 and ownership staff at 10:30 am on the day of survey, 8/21/19, the following records had not been documented as reviewed by a qualified Technical Consultant. Findings include: The records below had been documented as reviewed by a staff member not qualified to act as the Technical Consultant. 1. Temperature logs (room, reagent refrigerator, Advanco refrigerator, freezer and humidity) from 1/3/19 through 8/21/19. 2. TOSOH AIA 360 chemistry analyzer maintenance, QC (Quality Control), and calibration records from 1 /3/19 through 8/2/19. 3. Clinitek Advantus urinalysis analyzer QC and maintenance from 2/1/19 through 8/21/19. 4. Siemens PFA 100 Platelet Function analyzer QC and maintenance from 1/17/19 through 8/2/19. 5. Proficiency testing results for the 1st and 2nd events of 2019.