Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2046929	08/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Fairview Pathology	17000 Executive Plaza Suite 202, Dearborn, MI	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to monitor and document humidity for 2 (August 2017 to August 2019) of 2 years. Findings include: 1. A review of the installation manual for the Leica ASP300S instrument stated the operating maximum relative humidity is "less than 80%." 2. A record review of the installation manual for the Hacker-Meisei coverslipper stated, "operational humidity range is 30% to 90%" 3. When requested, the LD was not able to provide documentation for humidity monitoring for August 2017 to August 2019. 4. During the interview on 8/26/19 at 10:37 am, the LD confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Director (LD), the laboratory was using phosphomolybdic-phosphotungstic acid solution that exceeded the manufacturer's expiration date for the current lot in use. Findings include: 1. During a tour of the laboratory on 8/26/19 at 9:11 am, the surveyor observed one open bottle of phosphomolybdic-phosphotungstic acid solution, used in Masson's Trichrome staining, with the expiration date of 7/25/19. 2. A review of the laboratory's "Quality Assurance" procedure under the "Special Stains" section stated, "all stains and reagents are monitored to ensure that only stable chemicals are used in patient testing." 3. A review of the laboratory's log "Fairview Pathology Daily Total Numbers" revealed two patients were tested on 8/6/19 using the Trichrome method and the expired phosphomolybdic-phosphotungstic acid solution. 4. During the interview on 8/26/19 at 9:11 am with the LD confirmed the laboratory retained and used expired reagents.