Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2078993	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Michigan Healthcare Professionals, P C	32255 Northwestern Hwy Suite 150, Farmington Hills, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to retain the daily hematology Beckman Coulter AcT 5diff CP instrument background count records for 2 (June 2017 to June 2019) of 2 years reviewed. Findings include: 1. Record review revealed the daily background counts were not maintained for 2 years as follows: a. Patient testing on 6/14/17 b. Patient testing on 9/22/17 c. Patient testing on 12/28/17 d. Patient testing on 2/22/18 e. Patient testing on 4/13/18 2. During the interview on 6/12/19 at approximately 11:00 am, TC acknowledged the background counts were not saved and the Beckman Coulter AcT 5diff CP instrument would not retrieve background counts back 2 years.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC) and Testing Personnel #1 (TP1), the laboratory failed to perform quality control as required for the chemistry testing for 2 (medical record number 1043667 and 1042070) of 10 patient charts audited. Findings include: 1. Review of the chemistry quality control records for 2 of 10 patient charts reviewed revealed 2 levels of acceptable control material was not performed and documented prior to patient testing as follows: a. Patient 1043667 performed on 4/13/18 1. chloride testing - controls #4 and #5 failed out of two controls (#4 and #5) 2. Approximately 42 patients were run on 4/13/18 b. Patient 1042070 performed on 1/11/19 1. Total bilirubin testing - controls #7 and #8 failed out of three controls (#7, #8, and #9) 2. Approximately 47 patients were run on 1/11/19 2. During the interview on 6/12/19, 2019 at 12:00 pm, TC and TP1 acknowledged 2 different levels of external controls were not acceptable on the day of testing prior to testing and reporting patient specimens.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review, procedure review, and interview with the Technical Consultant (TC) and Testing Personnel #1 (TP1), the laboratory failed to provide accurate and reliable patient test reports for 1 ("Patient ID" 1039600) of 10 patient charts audited. Findings include: 1. Record review of patient final test reports revealed the laboratory reported multiple (3) results for a complete blood cell count (CBC) on patient 1039600 collected on 6/02/19. 2. On 6/12/19 at approximately 1:31 pm when queried, TP1 stated that "all laboratory testing is generated across the interface and reported into the patient's electronic medical record (EMR)." 3. During the interview on 6/12/19 at approximately 1:31 pm, TP1 acknowledged that all patient testing is generated across the interface into the EMR system and no policy has been established or implemented to prevent multiple results from crossing into the EMR system.