Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0989675	12/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Michigan Healthcare Professionals Pc	3577 W 13 Mile Road, Suite 310, Royal Oak, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to establish personnel competency procedures to include a process for new test systems for 2 (Testing Personnel (TP) #1 and #2) of 3 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's hematology maintenance log sheets revealed the laboratory added a new test system for its hematology complete blood cell count (CBC) in October 2023. 2. A review of the laboratory's "Personnel Competency Policy/Procedure" revealed a lack of a process to follow when the laboratory changes or adds new test methods/systems. 3. A review for 2 of 3 TP competency assessment records revealed a lack of competency assessment performed at a 6-month and a 12-month interval from the initial training checklist (9/21/2022) as follows: a. TP #1 - missing a 6-month assessment which was due 3/2023. b. TP #2 - missing a 12-month assessment which was due 9/2023. 4. An interview on 12/12/2023 at 10:55 am, the TC confirmed competency using the new method was not assessed and documented.
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, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to perform control procedures each date of hematology complete blood cell counts patient testing for 1 (11/04/2022) of 8 testing dates reviewed. Findings include: 1. A review of the laboratory's daily control sheets generated from the Beckman Coulter DxH520 series hematology analyzer revealed a lack of documentation for 1 (11/04/2022) of 8 days chosen for review. 2. On 12/12 /2023 at 11:47 am the surveyor requested the documentation for the quality control material for 11/04/2022 and it was not made available. 3. An interview on 12/12/2023 at 11:47 am, the TC confirmed the laboratory had no documentation to show the controls (low, normal, and high) had been performed and documented prior to patient testing.