Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1032213	11/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Michigan Healthcare Professionals Pc	27900 Grand River Suite 220, 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, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to retain the Beckman Coulter DxH520 hematology analyzer quality control printouts for 20 (February 2022 to November 2023) of 22 months reviewed. Findings include: 1. A record review revealed for 20 (April 2022 to November 2023) of 22 months revealed a lack of documentation for the Beckman Coulter quality control records as follows: a. April 2022 - lack of documentation for April 20 and 28. b. September 2022 - lack of documentation for the low control for September 1, 2, 15, 19, 28, 30. c. February 2023 - lack of documentation for the normal and high control for February 1 and 8. d. February 2023 - lack of documentation for the normal control for February 9. e. February 2023 - lack of documentation for February 23. 2. Review of the "Quality Control" procedure states under "Section H Quality Control Requirement" step 1 "Recordkeeping" the following: "a. It is important that records be maintained listing the quality control date and patient tests performed; these records must be kept for a minimum of two years." 3. When queried on 11/29/2023 at 11:42 am, the TC was unable to provide further documentation to show that the above documents were retained. 4. An interview on 11 /29/2023 at 11:42 am, the TC confirmed the above dates listed for the Beckman Coulter DxH520 quality control records were not available on the day of the survey.
D5024	HEMATOLOGY CFR(s): 493.1215

	If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Hematology as specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to follow established written policies and procedures for its quality control testing for the Beckman Coulter DxH520 instrument. Refer to D5401. 2. The laboratory failed to follow the manufacturer's instructions for the Beckman Coulter DxH520 hematology instrument flags. Refer to D5411. 3. The laboratory failed to perform quality control testing at least each date of patient testing for its hematology complete blood cell count (CBC). Refer to D5445. 4. The laboratory failed to document at least two levels of acceptable hematology quality controls for the Beckman Coulter DxH520 analyzer at least each date of patient testing. Refer to D5447.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to follow established written policies and procedures for its quality control testing for the Beckman Coulter DxH520 instrument for 20 (April 2022 to November 2023) of 22 months of testing. Findings include: 1. A record review of the "Policies and Procedure Manual " revealed the laboratory did not follow the "Quality Control" policy as follows: a. " 2 out of 3 controls must be in range to proceed with run." b. "If a control is repeated, keep original printout and label "in range" one as "REPEAT."" 2. An interview on 11/29/2022 at 2:00 pm the TC confirmed the "Policies and Procedure Manual" was not followed or lacking current methods and technologies.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. 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 follow the manufacturer's instructions for the Beckman Coulter DxH520 hematology instrument flags for 20 (April 2022 to November 2023) of 22 months reviewed. Findings include. 1. A review of the daily

	Beckman Coulter DxH520 quality control results revealed instrument generated flags occurred that did not have any recourse action taken prior to accepting patient testing as follows: a. 9/09/2022 - Optical LED value error. b. 9/12/2022 - Optical LED value error. c. 9/15/2022 - Optical LED value error. d. 9/21/2022 - Optical LED value error. e. 9/22/2022 - Optical LED value error. f. 9/30/2022 - Optical LED value error. g. 2/27/2023 - +++++ flag on the hemoglobin. h. 2/27/2023 - ..... flag on the mean corpuscular hemoglobin (MCH) and mean corpuscular hemoglobin concentration (MCHC). 2. The Operator's Manual for the Beckman Coulter DxH520 instrument in chapter 6 states "Beckman Coulter recommends that you review all codes according to your laboratory's protocol." 3. A review of the "Policy And Procedure Manual" lacks a policy to trouble shoot the flags listed above and all other instrument generated flags. 4. An interview on 11/29/2022 at 2:00 pm, the TC confirmed there is not policy to troubleshoot instrument generated flags for operation of the Beckman Coulter analyzer.
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 quality control testing at least each day of patient testing for its hematology complete blood cell count (CBC) for 3 dates (4/20/2022, 4/28/2022, and 2/23/2023) of 23 months of records reviewed. Findings include: 1. A review of the patient testing logs, and the quality control logs revealed a lack of quality control performance at least once each day patient specimens were assayed and reported out results for the following dates: a. 4/20/2022 b. 4/28/2022 c. 2/23/2023 2. A review of the "Quality Control" procedure in section H "Quality Control Requirement" states in handwritten form "2 out of 3 controls must be in range to proceed with run." 3. When queried on 11/29/2023 at 11:42 am, the TC was unable to provide the surveyor the documents requested for the daily quality control testing. 4. An interview on 11/29/2022 at 11:42 am, the TC confirmed the laboratory had not performed quality control testing on the dates listed above and no other form of documentation was available on the day of the survey.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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--At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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), the laboratory failed to document at least two levels of acceptable hematology quality controls for the Beckman Coulter DxH520 analyzer at least each day of patient testing for 9 (April 2022 to November 2023) of 23 months of patient testing. Findings include: 1. A record review of the quality control documents revealed that 2 out of the 3 controls were not acceptable on the date of testing for 9 (April 2022 to November 2023) of 23 months as follows: 2 out of 3 controls a. no high control documentation - 4/8/2022 b. no low control documentation - 4/12/2022, 9/01/22, 9/02/2022, 9/15/2022, 9/19/2022, 9/28/2022, 9/30/2022, 12/28/20224/06/2023, and 6/22/2023. c. no normal or high control documentation - 2/01/2023 d. voided out white blood cell (WBC) on the high control, eosinophils (EOS) percent (%), and absolutes (ABS #) with flags on the normal control - 9/07/2022, 9/12/2022, 9/09/2022, 9/15/2022, 9/16/2022, 9/21/2022, 9/22/2022, 9/30/2022. e. EOS % and ABS # out on the normal and high control - 9/13/2022, 9/19/2022, 12/15/2022, 12/16/2022. 12/19-23/22, 12/27/2022, 12/28/2022, 2/10/2023, 2/27/2023, 4/06/2023, 6/22/2023, 8/07/2023. 2. When queried on 11/29/2023 at 11:19 am, the TC was unable to provide further documentation to show the control material which flagged had been repeated. 3. An interview on 11/29/2022 at 11:19 am, the TC confirmed quality control for the complete blood cell count testing dates listed above showed that the laboratory did not run at least 2 acceptable levels of 3 controls each date of testing.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the Technical Consultant failed to oversee that patient results were not reported out prior to corrective action being taken for the Beckman Coulter DxH520 hematology instrument that failed quality control testing for 20 (April to November 2023) of 22 months reviewed. Findings include: 1. A review of the laboratory's quality control records revealed that 2 of 3 controls levels were not within manufacturer's ranges without instrument flags prior to patient testing. 2. An interview on 11/29/2023 at 11:19 am with the TC confirmed the above.