

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1032213	(X3) Date Survey Completed 01/30/2020
Name of Provider or Supplier Michigan Healthcare Professionals Pc	Street Address, City, State 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>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 retain quality control records for chemistry testing for 21 (February 2018 to October 2019) of 24 months reviewed. Findings include: 1. A review of the laboratory's quality control records revealed a lack of documentation of quality control testing between February 2018 and October 2019 for the following chemistry analytes: a. Total Bilirubin b. Sodium c. Potassium d. Chloride e. Calcium f. Magnesium g. Glucose h. Blood Urea Nitrogen i. Creatinine 2. An interview on 1/30/19 at 12:48 pm with the TC and TP1 confirmed quality control records were not available.</p>
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements</p>

for the specialty in Chemistry as specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to perform control procedures for chemistry testing . Refer to D5445.

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 document control procedures for chemistry testing for 21 (February 2018 to October 2019) of 24 months reviewed. Findings include: 1. A review of the laboratory's quality control records revealed a lack of documentation of quality control records between February 2018 and October 2019 for the following analytes: a. Total Bilirubin b. Sodium c. Potassium d. Chloride e. Calcium f. Magnesium g. Glucose h. Blood Urea Nitrogen i. Creatinine 2. An interview on 1/30/19 at 12:48 pm with the TC and TP1 confirmed quality control records were not available.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant (TC), the Technical Consultant failed to evaluate the competency of testing personnel performing chemistry and hematology testing for 2 (Testing Personnel #2 and #3) of 3 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of the laboratory's established "Personnel Policy" revealed a section stating, "The Technical Consultant: Evaluate and document the competency of all testing personnel on an ongoing basis by: Directly observing performance including patient preparation, specimen handling, processing and testing. Monitoring the recording and reporting of test results. Reviewing intermediate test result or worksheets. Quality control records, proficiency testing results and preventive maintenance records. Directly observing performance of instrument maintenance and function checks. Assessing test performance of instrument maintenance and function checks. Assessing test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Assessing personnel problem solving skills." 2. A record review of testing personnel competency assessments revealed testing personnel competencies were assessed by Testing Personnel #1 for the

following testing personnel: a. Testing Personnel #2 with competency assessment dates of 5/22/2018 and 5/22/2019. b. Testing Personnel #3 with competency assessment dates of 2/14/2018 and 2/2019. 3. An interview on 1/30/2020 at 9:18 am with the TC confirmed Testing Personnel #1 assessing testing personnel competencies was not qualified as a Technical Consultant and was not listed on the CMS-209 form as a Technical Consultant.