Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0989675	09/02/2020
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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to retain proficiency testing corrective action documentation for 4 (event 2 of 2020, events 2 and 3 of 2019, and event 3 of 2018) of 4 proficiency testing events with scores less than 100%. Findings include: 1. A review of the laboratory's proficiency testing records revealed the following events with scores less than 100%: a. Chemistry event 2 of 2020, creatinine 60% b. Hematology event 3 of 2019, neutrophils 80% c. Hematology event 2 of 2019, hematocrit 40% d. Chemistry event 3 of 2018, creatinine 60% 2. A review of the laboratory's "Lab Policies" revealed a section stating, "If P.T. results are unsatisfactory, corrective action must be taken and documented within 5 working days of receipt of results. P.T. results are to be kept for two years." 3. The surveyor requested documentation of corrective actions performed for the testing events listed above and they were not made available. 4. An interview on 9/2/20 at 10:14 am with the Technical Consultant confirmed the laboratory did not retain proficiency testing corrective action documentation.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a

	minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to perform calibration verification activities for the chemistry analyte creatinine for 2 (1/21/19 and 7/10/19) of 3 calibration verification events reviewed. Findings include: 1. A review of the laboratory's calibration verification documentation revealed a lack of documentation for the following calibration verification events for the analyte creatinine: a. The 1/21/19 event did not have results for levels 1 and 4 out of a total of 4 levels. b. The 7/10/19 event did not have results for levels 1, 2, and 4 out of a total of 4 levels. 2. A review of the laboratory's established "Lab Policies" revealed a section stating, "Calibration verification must be done every 6 months or as needed after service or change of reagents." 3. An interview on 9/2/20 at 12:22 pm with the Technical Consultant confirmed the laboratory did not perform calibration verification activities for the analyte creatinine. ***This is a repeat deficiency from the 5/21/14 survey***