Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2080840	12/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Rochester Primary Care	1349 S Rochester Rd Ste 100, Rochester 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
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to 1) document corrective action for improper storage of the Minotrol Horiba Medical ABX Micros 60 hematology analyzer quality control material for 2 (December 2017 to December 2019) of 2 years reviewed and 2) document corrective action for improper humidity readings for the operation of the Horiba Medical ABX Micros 60 hematology analyzer for 2 (December 2017 to December 2019) of 2 years reviewed. Findings include: 1. Record review of the "Daily Temperature Check Log" revealed the refrigerator temperature for the proper storage of the Minotrol quality control material was below the range of 2-8 C and no corrective action was documented as follows: a. March 2018 - 3, 13, 20, and 28 b. April 2018 - 1-5, 9-11, 14, 16, 18, 20, and 24 c. September 2018 - 3-4, 6, 10, 12, 14, 17-23, 24-26, 29, and 31 d. October 2018 - 2-3, 6, 8-9, 11, 14-19, 23-26, and 29-31 e. January 2019 - 2-4, 7-10, 16-17, 24, and 28-31 f. March 2019 - 2-5, 7-8, 12-16, 19, 21-22, 25-27, and 29 2. Record review of the "Daily Temperature Check Log" revealed the humidity readings for the proper operation of the Horiba Medical ABX Micros 60 hematology analyzer was below the stated range of 15-80% and no corrective action was documented as follows: a. December 2017 - 1, 4-8, 11-15, 18-21, and 26-29 b. February 2018 - 1-3, 5-9, 12-16, 19-23, and 26-29 c. March 2018 - 1-3, 5-9, 12-17, 19-23, and 26-30 d. April 2018 - 1-6, 9-14, 16-20, 23-26, 28, and 30 e. November 2019 - 6, 11-12, 15-16, and 18 3. During the interview on 12/23/19 at approximately 12:00 pm, TC1 confirmed no corrective action was documented for the refrigerator and humidity temperatures that were outside the stated ranges.

D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to maintain the patient's final complete blood cell (CBC) test report as part of the patient's electronic medical record (EMR) for 2 (#3 and #5) of 12 patient charts audited. Findings include: 1. Record review revealed for 2 of 12 patient charts audited the following final patient test reports were not available in the EMR system for the surveyor on the day of the survey when requested as follows: a. Patient #3 - no final CBC report in the EMR system for 5/25/18 b. Patient #5 - no final CBC report in the EMR system for 9/28/18 2. During the interview on 12/23/19 at 11:57 am, TC1 confirmed final patient test results were not in the EMR system.