Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2080840	01/04/2024
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
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 and interview with the Technical Consultant, the laboratory failed to retain calibration documentation for 1 (October 2023) of 4 calibration events reviewed for its Horiba hematology analyzer. Findings include: 1. A review of the laboratory's Horiba hematology analyzer's calibration documentation revealed the manufacturer's service representative performed service and calibration on 10/2/23. 2. The surveyor requested the laboratory's documentation of the calibration performed on 10/2/23 on 10:52 am and it was not made available. 3. An interview on 1/4/24 at 11:04 am with the Technical Consultant confirmed documentation of the calibration performed on 10/2/23 was not available.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and

	indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to include the date and time of specimen collection for its hematology and routine chemistry testing on the request for testing for 7 (Patient's 1-7) of 7 patient test requests reviewed. Findings include: 1. A review of 10 patient test requests revealed the following patients had a lack of date and time of specimen collection: a. Patient #1 had a Complete Blood Count (CBC) and a Complete Metabolic Panel (CMP) performed on 11/21/23 and 11/22/23 respectively. b. Patient #2 had a CBC and a Basic Metabolic Panel (BMP) performed on 9/13/23. c. Patient #3 had a CBC and a Lipid Panel performed on 7/17/23. d. Patient #4 had a CBC and a BMP performed on 3/31/23. e. Patient #5 had a CBC and a BMP performed on 1/3/23. f. Patient #6 had a CBC and a BMP performed on 11/1/22. g. Patient #7 had a CBC and a BMP performed on 10/20/22. 2. An interview on 1/4/24 at 11:32 am with the Technical Consultant confirmed the laboratory did not document the date and time of specimen collection on the test requests for the patients listed above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Consultant, the laboratory failed to ensure its sodium citrate blue-top BD Vacutainer blood specimen collection tubes had not exceeded their expiration date for 24 of 24 blue-top tubes available for use in the draw station. Findings include. 1. The surveyor observed 24 sodium citrate blue-top BD Vacutainer blood specimen collection tubes with the expiration date of 12 /31/23 in the phlebotomy draw station on 1/4/24 at 8:59 am. 2. An interview on 1/4/24 at 9:10 am with the Technical Consultant confirmed the sodium citrate blue-top BD Vacutainer blood specimen collection tubes had exceeded their expiration date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the Technical Consultant, the laboratory failed to verify the reportable range of its routine chemistry testing on the Alfa Wassermann Ace Axcel analyzer for 13 of 17 analytes. Findings include: 1. An interview on 1/4/24 at 8:51 am with the Technical Consultant revealed the laboratory started testing using the Alfa Wassermann Ace Axcel chemistry analyzer in February 2022. 2. A review of the laboratory's verification of performance specifications for the Alfa Wassermann Ace Axcel chemistry analyzer and the instrument reportable range settings revealed the laboratory failed to verify the breadth of the reportable range for the following analytes: a. Total Protein linearity study ranged 2.2 to 11.0 g/dL and the instrument settings were 0.4 to 14.0 g/dL. b. High-Density Lipoproteins (HDL) Cholesterol linearity study ranged 11.0 to 102.0 mg/dL and the instrument settings were "N/A." c. Total Cholesterol linearity study ranged 18.0 to 527 mg/dL and the instrument settings were "N/A." d. Glucose linearity study ranged 6.0 to 594 mg/dL and the instrument settings were 4 to 750 mg/dL. e. Triglycerides linearity study ranged 23 to 877 mg/dL and the instrument settings were 16 to 1000 mg/dL. f. Albumin linearity study ranged 1.6 to 6.4 g/dL and the instrument settings were 0.3 to 7/0 g/dL. g. Creatinine linearity study ranged 0.46 to 23.563 mg/dL and the instrument settings were "N/A." h. Blood Urea Nitrogen (BUN) linearity study ranged 1.0 to 95.333 mg/dL and the instrument settings were 0 to 100 mg/dL. i. Alkaline Phosphatase (ALP) linearity study ranged 4.667 to 1,228 IU/L and the instrument settings were 1 to 1,400 IU/L. j. Alanine Transaminase (ALT) linearity study ranged 13.0 to 408.333 IU/L and the instrument settings were 4 to 480 IU/L. k. Calcium linearity study ranged 1.8 to 13.367 mg/dL and the instrument settings were 0.4 to 15.0 mg/dL. l. Total Bilirubin linearity study ranged 0.567 to 38.967 mg/dL and the instrument settings were "N/A." m. Aspartate Transaminase (AST) linearity study ranged 13.333 to 388.0 IU/L and the instrument settings were 4 to 450 IU/L. 3. An interview on 1/4/24 at 10:43 am with the Technical Consultant confirmed the analytes above had reportable limits outside the reportable range study performed as part of the verification of performance specifications.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to notify the State Agency when adding a new testing specialty in accordance with 493.51 for 23 (February 2022 to January 20240 of 23 months since the laboratory added its routine chemistry testing. Findings include: 1. An interview on 1/4/24 at 8:51 am with the Technical Consultant revealed the laboratory started testing using the Alfa Wassermann Ace Axcel chemistry analyzer in February 2022 and had not notified the State Agency in accordance with 493.51 Notification Requirements for Laboratories Issued a Certificate of Compliance. 2. The surveyor reviewed the CMS database for

	the laboratory revealed a lack of documentation of the laboratory adding routine chemistry testing.