Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0663728	06/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bhadresh Nayak Md Plc	43243 Schoenherr Road, Sterling Heights, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Technical Supervisor #1 (TC1), the laboratory testing personnel failed to wear gloves while performing patient testing for 2 of 2 surveyor observations. Findings include: 1. An observation by the surveyor on 6/27/19 at 11:45 am exposed one testing personnel performing a CBC (Complete Blood Count) in the laboratory without wearing gloves. 2. An observation by the surveyor on 6/27/19 at 11:47 am exposed a second testing personnel performing a CBC in the the laboratory without wearing gloves. 3. A review of the "Laboratory Safety Policies" revealed a section titled, "Universal Precautions." It states, "gloves should be worn when touching laboratory specimens and tissues." 4. An interview on 6/27/19 at 12:13 pm with TC1 confirmed testing personnel had not been wearing gloves while performing CBC testing in the laboratory.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the

	laboratory failed to retain calibration verification data for 1 (5/14/19) of 4 calibration verification testing events. Findings include: 1. A record review of chemistry calibration verification data revealed a lack of documentation for the 5/14/19 testing event. The laboratory did not provide this information when requested by the surveyor on 6/27/19 at 9:48 am. The following chemistry assays lacked documentation: a. Alkaline Phosphatase b. Alanine Transaminase c. Aspartate Transaminase d. Total Cholesterol e. Creatinine f. High Density Lipoprotein g. Glucose h. Triglycerides i. Low Density Lipoprotein j. Blood Urea Nitrogen k. Hemoglobin A1C 2. An interview on 6/27/19 at 9:55 am with TC1 confirmed calibration verification data for the 5/14 /19 testing event was not retained by the laboratory.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #3 (TP3), the laboratory failed to retain copies of original CBC (Complete Blood Count) reports for 5 (patients #0913932, #0620845, #0313302, #0717266, and #0506672) of 5 patient charts audited. Findings include: 1. An audit of patient charts revealed the following patients had "CBC w/ diff, platelet count, in house" ordered: a. #0913932 b. #0620845 c. #0313302 d. #0717266 e. #0506672 2. An observation on 6/27/19 at 11:45 am was made by the surveyor of testing personnel performing a CBC and obtaining a printed copy from the analyzer. 3. When requested on 6/27/19 at 11:59 am, the laboratory did not produce the original analyzer printed reports for the patients #0913932, #0620845, #0313302, #0717266, and #0506672. 4. An interview on 6/27/19 at 11:59 am with TP3 revealed the original CBC report printouts from the analyzer were not available.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Technical Consultant #1 (TC1), the laboratory failed to label patient specimens with date of collection for 34 of 34 specimens observed. Findings include: 1. An observation by the surveyor on 6/27 /19 at 12:13 pm exposed a rack of 34 specimens near the centrifuge without a date of collection on the 34 specimens present. 2. A review of the laboratory's "Specimen Rejection Criteria" policy revealed a section stating, "specimen must be properly labeled with patient name and date." 3. An interview on 6/27/19 at 12:13 pm with TC1 confirmed 34 specimens in the rack near the centrifuge had not been labeled with the date.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation, and interview with Technical Consultant #1 (TC1), the laboratory failed to label chemistry reagents (glucose and cholesterol buffers) with preparation and expiration dates for the current lots in use. Findings include: 1. On 6 /27/19 at 9:02 am, during a tour of the laboratory, the surveyor observed the glucose and cholesterol buffers in use. There was a lack of documentation on the secondary reagent bottles with the preparation and expiration dates when the reagents were put into use. 3. An interview on 6/27/19 at 9:02 am with TC1 confirmed preparation and expiration dates were missing from secondary reagent bottles for glucose and cholesterol buffers.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform and document annual centrifuge function checks for 2 (June 2017- June 2018 and June 2018- June 2019) of 2 years. Findings include: 1. A review of the "Equipment Maintenance" procedure revealed "the centrifuge rpm's will be checked once per year with a digital tachometer." 2. A record review revealed a lack of documentation of annual RPM (rotations per minute)checks for the Horizon model 643E Centrifuge and the Horizon miniE centrifuge. Documentation was not made available when requested on 6/27/19 at 11:26 am. 3. An interview on 6/27/19 at 11:26 am with the TC confirmed the laboratory had not performed and documented annual centrifuge function checks for 2 of 2 years.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to document the corrective action taken for hemoglobin quality control errors for 9 (5/1/18, 5/2/18, 5/4/18, 5/7/18, 5/8/18, 5/9/18, 5/10/18, 5/15/18, and 5/16/18) of 9 days when quality control was out of range. Findings include: 1. A review of hemoglobin quality control from May 2018 revealed level 1 quality control was outside 2 standard deviations for 2 consecutive days for the following days: a. 5/1 /18 b. 5/2/18 c. 5/4/18 d. 5/7/18 e. 5/8/18 f. 5/9/18 g. 5/10/18 h. 5/15/18 i. 5/16/18 2. A record review of the laboratory's "Quality Control Review" of this period dated 6/20 /18 revealed a lack of documentation of corrective actions taken regarding hemoglobin quality control. 3. An interview on 6/27/19 at 10:31 am with TC1 confirmed no corrective action had been documented by the laboratory for hemoglobin quality control errors.