Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0663728	07/19/2021
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure the Laboratory Director and analysts signed proficiency testing attestation statements for 2 (2020 Events 1 and 2) of 3 proficiency testing event documents reviewed. Findings include: 1. A review of the laboratory's "Proficiency Testing" policy revealed a section stating, "Copies of the original PT program report forms, printouts and signed attestation forms will be kept for two years." 2. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of signatures from the Laboratory Director and the analysts performing testing on the attestation statement for the following events: a. 2020 Hematology/Coagulation Event 1 b. 2020 Hematology/Coagulation Event 2 3. An interview on 7/19/21 at 4:22 pm with TP1 confirmed the attestations for the proficiency testing events listed above were not signed by the laboratory director or analysts performing testing.
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 Testing Personnel #1 (TP1), the laboratory failed to retain proficiency testing records for 2 (2020 Event 3 and 2019 Event 2) of 6 events reviewed. Findings include: 1. A review of the laboratory's "Proficiency Testing" policy revealed a section stating, "All Proficiency Testing results and attestation forms will be kept for a minimum of two years." 2. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of documentation for the following testing events: a. 2020 Hematology /Coagulation Event 3 b. 2019 Hematology/Coagulation Event 2 3. An interview on 7 /19/21 at 4:22 pm with TP1 confirmed the records for the proficiency testing events listed above were not available.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to ensure a procedure for the performance of Complete Blood Count (CBC) testing was available to testing personnel. Refer to D5401. 2. The laboratory failed to perform background counts prior to testing patient samples. Refer to D5431. 3. The laboratory failed to ensure quality control for Complete Blood Count (CBC) testing met established laboratory requirements. Refer to D5469.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure a procedure for the performance of Complete Blood Count (CBC) testing was available to testing personnel for the current test system in use. Findings include: 1. The surveyor performed a tour of the laboratory on 7/19/21 at 1: 13 pm and observed a Sysmex XN-330 hematology analyzer used in CBC testing. 2. The surveyor requested the procedure for the performance of CBC testing using the

	Sysmex XN-330 hematology analyzer on 7/19/21 at 2:45 pm and it was not made available. 3. An interview on 7/19/21 at 4:16 pm with TP1 confirmed the procedure for the performance of CBC testing using the Sysmex XN-330 hematology analyzer was not available.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to perform background counts prior to testing patient samples for 3 (6 /19/20, 2/3/20, and 1/10/20) of 10 patient testing dates reviewed. Findings include: 1. A review of the laboratory's maintenance documentation revealed a lack of documentation of background counts as part of daily function checks for the following dates: a. 06/19/20, 5 patients had testing completed this day. b. 02/03/20, 32 patients had testing completed this day. c. 01/10/20, 38 patients had testing completed this day. 2. A review of the laboratory's "Equipment Maintenance" policy revealed a section stating, "Maintenance for the Sysmex Analyzer will follow the maintenance print-out that comes with the instrument. All daily, weekly, monthly and as needed maintenance will be performed and documented." 3. An interview on 7/19/21 at 4:10 pm with TP1 confirmed the laboratory did not have documentation of background counts for the dates listed above available.
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 Testing Personnel #1 (TP1), the laboratory failed to ensure quality control for Complete Blood Count (CBC) testing met established laboratory requirements for 2 (6/19/20 and 3/30/20) of 11 testing dates reviewed. Findings include: 1. A review of the laboratory's "CBC Quality Control" policy revealed a section stating, "The controls will be run daily before patient's are run. When running CBC's it is acceptable to run patient's when two out of three controls are within there given ranges. If that parameter is out two days in a row, then troubleshooting procedures must be performed, and patients not run until the problem is fixed. Step-by-step instructions can be found in the Sysmex Operations Manual. The above data will be reviewed by the testing personnel each day of testing

	and reviewed by the Technical Consultant monthly." 2. A review of the laboratory's quality control data revealed the following dates when quality control was not within limits: a. 3/30/20 two of three quality control levels were tested, and both levels failed for the analyte Mean Corpuscular Volume (MCV). The patient testing log showed two patients had testing performed that day. b. 6/19/20 no records of quality control performance were available. The patient testing log showed five patients had testing performed that day. 3. An interview on 7/19/21 at 3:38 pm with TP1 confirmed quality control was not in range for MCV on 3/30/20. 4. An interview on 7/19/21 at 4: 03 pm with TP1 confirmed the laboratory did not have documentation of quality control performed on 6/19/20 available.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to verify criteria for acceptability of control materials prior to use for 17 (March 2020 to July 2021) of 24 months reviewed. Findings include: 1. A review of the laboratory's records revealed the most recent verification of criteria for acceptability of control materials was performed on 2/28/20. 2. The surveyor requested the verification for acceptability of control materials for the lot numbers since 2/28/20 on 7/19/21 at 3:30 pm and they were not made available. 3. An interview on 7/19/21 at 3:40 pm with TP1 confirmed the laboratory did not have documentation of verifying the criteria of acceptability of control materials available.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The Laboratory Director failed to ensure quality assessment programs were maintained. Refer to D6021. 2. The Laboratory Director failed to ensure all testing personnel received the appropriate training for the performance of

	Complete Blood Count (CBC) testing prior to performing patient testing. Refer to D6029. 3. The Laboratory Director failed to identify the need for remedial training when laboratory personnel did not meet competency requirements. Refer to D6030 A. 4. The Laboratory Director failed to ensure competency assessment procedures were followed and performed at the intervals specified by the laboratory. Refer to D6030 B.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the Laboratory Director failed to ensure quality assessment programs were maintained for 15 (March 2020 to June 2021) of 24 months reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance Program" policy revealed a section stating, "Our laboratory has an ongoing quality assurance program to evaluate the quality of service we provide. The Laboratory Director oversees the implementation of our plan and helps identify and correct problems as they occur. We periodically review our quality assurance plan to minimize the possibility of recurrence of identified problems." 2. A review of the laboratory's quality assessment documentation revealed the last documented assessment was performed on 3/6/20. 3. An interview on 7/19/21 at 4:18 pm with TP1 confirmed the laboratory did not have documented quality assessments for dates after 3/6/20 available.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to ensure all testing personnel received the appropriate training for the performance of Complete Blood Count (CBC) testing prior to performing patient testing for 3 (Testing Personnel #2-#4) of 4 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's "Personnel Competency Policy/Procedure" revealed a section stating, "Initial training indicating that the testing personnel have demonstrated testing, read the procedure manual, performs quality control, recognize test failures, and follow reporting procedures must be documented. The director is

	responsible for ensuring that the testing personnel have received the appropriate training for the type of testing being performed." 2. An interview on 7/19/21 at 2:55 pm with the Office Manager revealed the following testing personnel had been hired in the last two years: a. Testing Personnel #2 hire date of 10/12/20 b. Testing Personnel #3 hire date of 6/6/20 c. Testing Personnel #4 hire date of 5/6/21 3. A review of the laboratory's personnel records revealed a lack of training documentation for Testing Personnel #2-#4. 4. An interview on 7/19/21 at 2:55 pm with Testing Personnel #1 confirmed documented training for Testing Personnel #2-#4 was not available.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: . A. Based on record review and interview with Testing Personnel #1 (TP1), the Laboratory Director failed to identify the need for remedial training when laboratory personnel did not meet competency requirements for 4 (Testing Personnel #1-#4) 4 of testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's competency assessment documentation revealed Testing Personnel #1-#4 had the "No" boxes checked, showing personnel did not meet competency requirements, during the assessments performed on 7/19/21 for the performance of instrument maintenance and function checks, assessment of test performance through external proficiency testing, and the assessment of problem-solving skills. 2. A review of the competency assessment for Testing Personnel #2 performed on 9/23/19 had the "No" boxes checked showing a failure to demonstrate competency for the performance of instrument maintenance and function checks, assessment of test performance through external proficiency testing, and the assessment of problem-solving skills. 3. A review of the laboratory's competency assessment documentation showed additional "No" boxes checked for Testing Personnel #1-#4 competency assessments performed on 7/19/21, and the competency assessment for Testing Personnel #2 performed on 9/23/19 in the following categories: a. A category titled "Reagents" containing, "Storage", "Stability", "Preparation", and "Disposal". b. A category titled "Quality Control" containing, "Materials", "Frequency", "Documentation", and "Corrective Action". c. A category titled, "Trouble Shooting" containing, "Instrument Calibration", "Instrument Maintenance", and "Problem Identification". d. A category titled "Package Insert/Written Procedure" containing, "Reviewed" and "Interpretation of Results" e. A category titled "Proficiency Testing" containing, "Scheduling", "Handling", "Testing", "Reporting" and "Evaluation". 4. A review of the laboratory's "Personnel Competency Policy/Procedure" revealed a section stating, "All testing personnel must be reviewed for their ability to perform patient testing correctly and accuracy." and a section stating, "The director is

	responsible for ensuring that the testing personnel have received the appropriate training for the type of testing being performed. All testing personnel must have an annual review stating that they have reviewed all three phases of testing (preanalytical, analytical and post analytical) and that the required components for monitoring testing competency are included as follows: a. Direct observation of routine patient performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of results. c. Review of intermediate test results or worksheets, if applicable, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observation of instrument maintenance and function checks, if applicable. e. Assessment of test performance through testing of previously analyzed specimens, internal blind test samples or external proficiency testing samples. f. Assessment of problem solving skills." 5. An interview on 7/19/21 at 2:55 pm with TP1 confirmed the competency assessments for Testing Personnel #1-#4 did not meet the laboratory's policy and no additional competency assessments for Testing Personnel #1-#4 were available. B. Based on record review and interviews, the Laboratory Director failed to ensure competency assessment procedures were followed and performed at the intervals specified by the laboratory for 2 (July 2019 to July 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Personnel Competency Policy/Procedure" revealed a section stating, "Laboratory compliance requires training /competency to be completed initially, 6 months after the original start date and annually there after." 2. An interview on 7/19/21 at 2:55 pm with the Office Manager revealed the following testing personnel had been hired since the previous recertification survey: a. Testing Personnel #2 hire date 10/12/20 b. Testing Personnel #3 hire date of 6/6/20 c. Testing Personnel #4 hire date of 5/6/21 3. A review of the laboratory's testing personnel competency assessment documentation revealed a lack of competency assessments for the following personnel: a. Testing Personnel #1 was missing annual competency assessments from 2019 and 2020. b. Testing Personnel #2 was missing a semiannual competency assessment due in 2020. c. Testing Personnel #3 was missing two competency assessments within the first year of employment. d. Testing Personnel #4 was missing the initial competency assessment. 4. The surveyor requested the missing competency assessments listed above at 7/19/21 at 2:55 pm and they were not made available. 5. An interview on 7/19/21 at 2:55 pm with Testing Personnel confirmed the competency assessment for the personnel listed above were not available.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel #1, the laboratory failed to ensure the Testing Personnel #4, performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure Testing Personnel #4 acting as the Technical Consultant was qualified. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411

	(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on a record review, a lack of documentation, and interviews, the laboratory failed to ensure Testing Personnel #4, acting as the Technical Consultant, was qualified for 2 (May 2021 to July 2021) of 2 months. Findings include: 1. A review of the laboratory's personnel competency assessments revealed Testing Personnel #4 had assessed the competency of Testing Personnel #1-#3 on 7/19/21, performing the duty of a Technical Consultant. 2. A record review of personnel records revealed a lack of documentation of qualification documentation for Testing Personnel #4. 3. The surveyor requested qualification documentation for Testing Personnel #4 showing they were qualified as a Technical Consultant on 7/19/21 at 2:15 pm and it was not made available. 4. An interview on 7/19/21 at 2:55 pm with the Office Manager revealed Testing Personnel #4 was hired on 5/6/21. 5. An interview on 7/19/21 at 2:55 pm with TP1 confirmed Testing Personnel #4 assessed the competency of Testing Personnel #1-#3. 6. The laboratory was provided 7 days to supply documentation and it was not made available.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

	The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel were qualified. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on a lack of documentation and record review, the laboratory failed to ensure testing personnel were qualified for 3 (Testing Personnel #2-#4) of 4 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed a lack of qualification documentation for Testing Personnel #2-#4 listed on the CMS-209 form performing moderate complexity testing. 2. A review of the laboratory's "Employee Evaluation" policy revealed a section stating, "At there initial evaluation, a copy of their education must be present to show they have the level of education required to perform the laboratory testing." 3. The surveyor requested qualification documentation for Testing Personnel #2-#4 showing they were qualified to perform moderate complexity testing on 7/19/21 at 2: 15 pm and it was not made available. 4. The laboratory was provided 7 days to supply documentation and it was not made available.