

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0663728	(X3) Date Survey Completed 01/05/2023
Name of Provider or Supplier Bhadresh Nayak Md Plc	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review and interview with the Technical Consultant, the laboratory failed to follow its policy to assess testing personnel competency for 2 (Testing Personnel #2 and #3) of 3 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Employee Evaluations" policy revealed a section stating, "The Director, Clinical Consultant, Technical Supervisor, Technical Consultant, General Supervisor and Testing Personnel all need an initial evaluation based on Federal Regulatory Responsibilities. 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. The Competency Evaluation form, based on Federal Regulatory Responsibilities will be filled-out." 2. A review of the laboratory's "Competency Assessment" form included a section titled "Elements" stating, "1. Direct observation of performance: patient ID, collection, preparation, specimen acceptability, loading instruments. 2. Monitoring results: recording and reporting of results and critical values. 3. Review results: reviewing test results, QC, maintenance and PT records. 4. Maintenance: direct observation of maintenance and function checks. 5. Assessment: test performance of external PT/unknown specimens. 6. Problem Solving: troubleshooting instruments, rejection of samples, QC outliers" 2. A review of the laboratory's personnel competency record revealed the following testing personnel were missing elements of the competency assessment: a. Testing Personnel #2 i. Competency assessment dated 6/6/22 a. Lack of review for reviewing test results, quality control, maintenance, and proficiency testing records. b. Lack of direct observation of maintenance and function checks. c. Lack of test performance of</p>

external proficiency testing/unknown specimens. d. Lack of troubleshooting, rejection of samples, and quality control outliers. ii. Competency assessment dated 12/30/22 a. Lack of direct observation of maintenance and function checks. b. Lack of test performance of external proficiency testing/unknown specimens. b. Testing Personnel #3 i. Competency assessment dated 6/6/22 a. Lack of review for reviewing test results, quality control, maintenance, and proficiency testing records. b. Lack of direct observation of maintenance and function checks. c. Lack of test performance of external proficiency testing/unknown specimens. d. Lack of troubleshooting, rejection of samples, and quality control outliers. ii. Competency assessment dated 12/30/22 a. Lack of review for reviewing test results, quality control, maintenance, and proficiency testing records. b. Lack of test performance of external proficiency testing/unknown specimens. c. Lack of troubleshooting, rejection of samples, and quality control outliers. 3. An interview on 1/5/23 at 1:51 pm with the Technical Consultant confirmed Testing Personnel #2 and #3 had not competency assessments completed according to the laboratory's policy.

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.
 This is a repeat Condition from the 7/19/21 recertification survey

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 1 (Testing Personnel #3) of 3 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 #3 listed on the CMS-209 form performing moderate complexity hematology testing. 2. The surveyor requested qualification documentation for

Testing Personnel #3 showing they were qualified to perform moderate complexity testing on 1/5/23 at 1:51 pm and it was not made available. 3. The laboratory was provided 7 days to supply documentation and it was not made available. **This is a repeat deficiency from the 7/19/21 recertification survey**