

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0663728	(X3) Date Survey Completed 10/11/2021
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
D0000	<p>. An unannounced revisit survey was completed on October 7, 2021, as a follow-up to the recertification survey performed on July 19, 2021. During the survey, it was determined the laboratory was not in compliance for the following Condition-Level deficiencies: Analytic Systems, D5400 Moderate Complexity Laboratory Director, D6000</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1) and the Office Manager, the Laboratory Director failed to ensure corrective action was performed when proficiency testing results were unacceptable for 1 (2021 Event 2) of 1 testing event reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the following unacceptable scores received from Event 2 performed on 8/2/21: a. Erythrocyte Count, 80% b. Hematocrit, 80% c. Hemoglobin, 80% d. Leukocyte Count, 80% e. Mean Corpuscular Hemoglobin (MCH), 80% f. Mean Corpuscular Volume (MCV), 80% g. Platelet Count, 80% h. Red Cell Distribution Width (RDW), 80% 2. The surveyor requested corrective action performed to correct the unacceptable results from Event 2 on 10/7/21 at 10:27 am and it was not made available 3. An interview on</p>

10/7/21 at 10:27 am with TP1 and the Office Manager confirmed corrective action had not been performed for the unacceptable results found during the proficiency testing event.