

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0684048	(X3) Date Survey Completed 06/03/2019
Name of Provider or Supplier Marion County Public Health Stat Laboratories	Street Address, City, State 640 Eskenazi Avenue, Fifth Third Bank, Indianapolis, IN	
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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and staff interview, the laboratory director failed to ensure policies were followed for quality assessment (QA) quarterly reviews, sharing reviews at monthly meetings, and sharing at all labs semiannual meetings for two of two subspecialties (microbiology and general immunology) for five of five quarters reviewed (2018 - Q1, Q2, Q3, Q4 and 2019 - Q1). Finding(s) included: 1. The policy "Management Review and Audit Program for Public Health Laboratories", "policy Stat ID: 4805661", revised 5/2018, read: "2 ...A summary of the quarterly reports is shared at the next monthly Management Meeting4. Corrective Action Summaries and effectiveness evaluations are shared at the All Labs semi-annual meeting." 2. Review of monthly management meeting and all labs semiannual meeting for 2018 and 2019 indicated no review and documentation of QA quarterly reports occurred. 3. Upon request for documentation of quarterly QA reports, review at monthly meetings and sharing at all labs semiannual meeting on 06/03/19 at 1:55 p.m., staff person (SP) #1 (Quality Manager) confirmed none was available for review.</p>