

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0984131	(X3) Date Survey Completed 11/14/2019
Name of Provider or Supplier Sudipta And Bindu Dey, Md, Inc	Street Address, City, State 127 Pines Bridge Rd, Beacon Falls, CT	
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
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide an acceptable plan of correction to prevent recurrence when receiving unacceptable proficiency testing (PT) scores for the American Proficiency Institute (API) survey's in the specialty of chemistry and hematology. Findings include: 1. Record review of the laboratory's API final testing results on 11/14/19 revealed the following: a. Event 3 in 2018 and 2019 a score of 40% for chloride (CL). b. Event 2 in 2019 a score of 40% for percent lymphocytes and monocytes (LYMP%) (Mono%). 2. Record review of the laboratory's plan of correction for the above PT survey's on 11/14/19 revealed: a. The electrode for CL was close to expiration date for Event 3 in 2018 and 2019 repeated samples and were in range. b. LYMP % and Mono% samples were repeated and still out. Service called and computer crashed unable to look back at data. c. No documentation or plan of correction available to prevent recurrence for the unsatisfactory PT scores above. 3. Staff interview with the technical consultant 11/4/19 at 12:00 PM confirmed the above findings. 4. The laboratory performs 1000 CL and 4000 automated differential tests annually.</p>
D6027	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(9)</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)(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to investigate or document corrective action for proficiency test (PT) scores less than 100%. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) glucose PT records on 11/14/19 revealed: a. The laboratory failed to investigate or take corrective action when PT scores of less than 100% were received for 2019 event 1. b. The CAP score sheets were signed as reviewed by the technical consultant. 2. Staff interview with the technical consultant and testing personnel #1 (TP1) on 11/14/19 at 12:30 PM confirmed the laboratory failed to investigate and take corrective action when a PT score of less than 100% is received by the laboratory. TP1 and TC stated they were not aware remedial action had to be taken. 3. The laboratory performs 1000 glucose tests annually in the specialty of chemistry.