Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0241866	12/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with testing personal (TP) 12/4/19, the laboratory failed to ensure 1 of 2 TP who perform testing in the speciality of hematology participated in PT. Findings: Review of 2018 and 2019 AAB PT records revealed TP # 2 failed to participate in 6 of 6 "Hematology with Differential analytes" AAB PT events for the speciality of hematology. Interview with TP #2 at approximately 10:25 a.m. confirmed she had not participated in the 6 AAB PT events for the "Hematology with Differential analytes", she stated she only performs testing if she is needed and did not realize she should be participating in PT.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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;

	This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 AAB PT records and interview with TP 12/4/19, the laboratory director (LD) failed to document corrective actions for incorrect and ungraded PT results. Findings: Review of 2018 and 2019 AAB PT records revealed the LD had signed his review of the PT results. The LD review failed to document corrective action for incorrect and ungraded PT results for the following: 1. AAB Q1 Nonchemistry 2018 PT result summary; Erythrocytes - Module A, Sample #2, result is not graded and Hematocrit - Module A, Sample #4, result is incorrect. 2. AAB Q1 Chemistry 2018 PT result summary; KOH Skin Prep result is incorrect. 3. AAB Q1 Nonchemistry 2019 PT result summary; Erythrocytes - Module A, Samples #3 and #4, results are not graded and Hematocrit - Module A, Sample #1, result is not graded and Samples #2 and #4 are incorrect. 4. AAB Q2 Chemistry 2019 PT result summary, Nasal Eosinophils result is not graded. 5. AAB Q3 Chemistry 2019 Pt result summary, KOH Skin Prep result is "0", incorrect. Interview with TP#3 at approximately 10:25 confirmed the LD had not documented corrective actions for the incorrect and ungraded PT results she stated she was unaware it was required.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and interview with TP 12/4/19, the LD failed to ensure the establishment of a corrective action plan for unacceptable PT results. Findings: Review of laboratory procedure manual revealed no documentation of a corrective action plan for unacceptable PT results. Exit interview with TP #2 and TP #3 at approximately 2:30 p.m. confirmed the laboratory did not have a corrective action plan for unacceptable PT results.
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 review of laboratory procedures, review of laboratory records and interview with TP 12/04/19, the laboratory director (LD) failed to establish and maintain quality assessment programs to assure the quality of laboratory services provided. Findings: Review of laboratory procedure manual revealed quality assessment practices either written as separate policies or incorporated into separate laboratory procedures. There

	was no documentation that a specific quality assessment program had been established for the preanalytical, analytical and post-analytical assessment of the laboratory services provided or that the policies or the policies incorporated into procedures were maintained. For example: 1. Review of laboratory policy "Quality Assurance Review with Staff" revealed "The laboratory director will discuss with the staff on at least a monthly basis the results of quality assurance reviews and ways the laboratory can improve on the quality of work." The policy fails to describe what the quality assurance reviews include. And review of laboratory records revealed no documentation of quality assurance reviews or documentation of monthly meetings in which the quality assurance reviews were discussed. 2. Review of laboratory policy "Quality Control Assessment" revealed "The laboratory director will review all monthly quality control charts and logs on at least a monthly basis..." Review of laboratory quality control records for 2018 and 2019 revealed no documentation of LD review. 3. Review of laboratory procedure "Quality Control Policies & Procedures for Drew Scientific Drew 3" revealed "QC reports and Levy-Jennings graphs should be printed every 3 months when control lot # changes...Reports and graphs should be signed off by Lab Director and Lab Tech and dated." Review of laboratory records revealed the laboratory had printed the Levy-Jennings graphs every 3 months. Review of 2018 and 2019 Levy-Jennings graphs revealed no documentation the "Lab Director and Lab Tech" had signed off their review of the graphs. Exit interview with TP #2 and TP #3 at approximately 2:30 p.m. confirmed there was no documentation of monthly quality assurance reviews with staff and no documentation of monthly or quarterly reviews of quality control charts or Levy-Jennings graph print outs.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review laboratory procedure manual, review of 2018 and 2019 testing personnel (TP) competency records, and interview with TP 12/4/19, the technical consultant (laboratory director) failed to perform annual competency evaluations in 2018 for 2 of 2 TP. Findings: Review of laboratory procedure manual revealed 2 policies. One policy, "Lab Policy Statement". dated "11 June 09" states " 4.) 1 Time each year Do Lab personal performance review." Another policy "Personnel Assessment" states "The laboratory director will use proficiency testing results and results of quality control charts and personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance." Review of 2018 and 2019 TP competency records revealed no documentation the LD had performed competency evaluations for TP #2 and TP #3 in 2018. Interview with TP #2 at approximately 11:30 a.m. confirmed the competency evaluations for TP #2 and TP #3 had not been performed by the LD for 2018.