

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0293333	(X3) Date Survey Completed 05/08/2019
Name of Provider or Supplier Gessler Clinic Pa	Street Address, City, State 635 1st St N, Winter Haven, FL	
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	An announced CLIA recertification survey was conducted at Gessler Clinic PA on 05/07/2019-05/08/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of CAP (College of American Pathologists) proficiency testing and interview with the Technical Supervisor #B, the laboratory did not get at least 80% in 1 (2nd testing event in 2018) out of 6 (1st, 2nd, 3rd in 2017 and 2018) testing events reviewed. Findings Included: Review of CAP proficiency testing found that the laboratory got a 75% for the 2nd testing event in 2018 in Bacteriology. Interview on 05/07/2019 at 02:00 PM with the Technical Supervisor #B confirmed the failure.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of CAP (College of American Pathologists) proficiency testing and interview with the Technical Supervisor #B, the laboratory did not get at least 80% in 1 (1st testing event in 2018) out of 6 (1st, 2nd, 3rd in 2017 and 2018) testing events</p>

	<p>reviewed. Findings Included: Review of CAP proficiency testing found that the laboratory got a 40% for the 1st testing event in 2018 for Cortisol in the subspecialty of Endocrinology. Interview on 05/08/2019 at 10:50 AM with the Technical Supervisor #B confirmed the failure.</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of CAP (College of American Pathologists) proficiency testing and interview with the Technical Supervisor #B, the laboratory did not get at least 80% in 1 (1st testing event in 2018) out of 6 (1st, 2nd, 3rd in 2017 and 2018) testing events reviewed. Findings Included: Review of CAP proficiency testing found that the laboratory got a 0% on the 1st testing event in 2018 for Hematocrit and Hemoglobin in the specialty of Hematology. Interview on 05/07/2019 at 01:55 PM with the Technical Supervisor #B confirmed the failure.</p>
<p>D5209</p>	<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: Based on record review and interview with Technical Supervisor (#C) the laboratory failed to perform competency evaluation on one (#B) of two Clinical Consultants for 2 out of 2 years (2017-2018) reviewed. Findings Included: Review of the CMS 209 revealed 2 Clinical Consultants (#A-which was the Laboratory Director and #B). Review of competency evaluations revealed no competency evaluations were performed on Clinical Consultant #B in 2017 and 2018. Interview on 05/07/2019 at 11:00 AM with Technical Supervisor #C confirmed that no competency evaluations were performed on Clinical Consultant #B.</p>