

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657274	(X3) Date Survey Completed 02/21/2018
Name of Provider or Supplier Gmg Grays Woods	Street Address, City, State 132 Abigail Lane, Port Matilda, PA	
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 the review of College of American Pathologist (CAP) Proficiency Testing (PT) scores and interview with General Supervisors (GS) #1 and #2, the laboratory director failed to identify problems that required a corrective action for CAP 2017 Event #1 Mononucleosis PT results. Findings Include: 1. On the date of survey, 02/21/2018, the laboratory could not provided corrective action documentation of CAP's 2017 Event #1 Mononucleosis score of 80%. 2. GS #1 and #2 confirmed the findings above on 02/21/2018 around 10:00 AM.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to</p>

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on, the review of testing personnel competency assessment records, the review of the laboratory's procedure manual and interview with the General Supervisor (GS) #1 and #2, the Laboratory Director failed to ensure that policies and procedure were established to assess the technical consultants and supervisors regulatory responsibilities from 2016 to the date of survey. Findings: 1. On the date of survey 02/15/2018, the laboratory failed to provide competency assessment documentation for: - 3 of 3 Technical Consultants - 1 of 1 Technical Supervisor 2. GS #1 and #2 confirmed the findings above on 02/21/2018 around 09:45 AM.