

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0118305	(X3) Date Survey Completed 08/15/2019
Name of Provider or Supplier Lourdes Medical Associates, Pa DbA	Street Address, City, State 101 Burrs Road Suite C Burrs Road Office Center, Westampton, NJ	
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when they received an unacceptable score in Hematology tests performed on the Abbott Cell Dyn Emerald series analyzer with the One World Accuracy AccuTest (OWAA) in the 2018 Cycle 1 and 2 events. The findings include: 1. The laboratory received "UNACC" unacceptable in 2018 cycle 1 on samples B - for Granulocytes %, B - for Lymphocytes %, D - for Red Blood Cell Count, D - for Hematocrit, and D for Platelets. 2. The laboratory received "UNACC" unacceptable in 2018 cycle 2 on sample D - for Lymphocyte concentration. 3. The laboratory received "*ACC" ungradable results in 2018 cycle 2 on samples A through D for Monocytes 4. The laboratory received "*ACC" ungradable results in 2018 cycle 2 on samples A through E for Granulocytes. 5. There was no documented evidence that the laboratory evaluated and verified the failures. 6. The TP confirmed on 8/15/19 at 10:42 am that the laboratory did not perform and document an evaluation of unacceptable PT results.</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</p>

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to 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 surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements from 8/31/17 to the date of the survey. The PT confirmed on 8/15/19 at 10:45 am that CA procedure was not established by LD.