

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1055942	(X3) Date Survey Completed 01/29/2018
Name of Provider or Supplier Mark A Alagna Md Pa	Street Address, City, State 13906 Lakeshore Blvd Ste 320, Hudson, 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
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 WSLH (Wisconsin State Laboratory of Hygiene proficiency testing results and interview with the Laboratory Director, the laboratory failed to get at least 80% for 1 (3rd testing event in 2016) out of 6 testing events reviewed (1st, 2nd, and 3rd testing events in 2016 and 2017) in the specialty of Bacteriology. Findings Included: Review of WSLH proficiency testing results revealed in the 3rd testing event in 2016 a 0% for Ciprofloxacin, Gentamicin, and Nitrofurantoin giving an overall score of 73% for Bacteriology. During an interview on 01/29/18 at 12:30 PM the Laboratory Director confirmed the proficiency testing failure.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of WSLH (Wisconsin State Laboratory of Hygiene proficiency testing results and interview with the Laboratory Director, the laboratory failed to verify the accuracy of analytes that did not receive a grade for 6 out of 6 testing events (1st, 2nd, 3rd testing events in 2016 and 2017) reviewed. Findings Included: Review of WSLH bacteriology proficiency testing results revealed for the 1st testing event</p>

2016 an ungraded analyte of Cephalothin and Ampicillin, 2nd testing event 2016 Cephalothin, Gentamicin, and Trimethoprim/Sulfameth oxazole ungraded, 3rd testing event 2016 Ampicillin, Cephalothin, and Trimethoprim/Sulfameth oxazole were ungraded. The 1st testing event 2017 Cephalothin and Ampicillin were not graded, 2nd testing event 2017 Ampicillin, Cephalothin, and one urine culture sample were ungraded, and 3rd testing event in 2017 had Cephalothin that was ungraded. During an interview on 01/29/18 at 12:30 PM the Laboratory Director confirmed that corrective action was not documented for the ungraded analytes.