

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0396895	<b>(X3) Date Survey Completed</b> 10/18/2018
<b>Name of Provider or Supplier</b> Aspirus Stanley Hospital Laboratory	<b>Street Address, City, State</b> 1120 Pine St, Stanley, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the laboratory has not evaluated proficiency testing event 2017-3 for antibody detection, ABO/RH, D(RHO), and compatibility testing that received 0% scores by the PT provider. Findings include: 1. Review of immunohematology PT records for event 2017-3 shows that the laboratory received 0% scores for antibody detection, ABO/RH, D(RHO), and compatibility testing due to a computer issue when submitting the PT results to the PT provider. There is no evidence that the laboratory evaluated the results from the PT provider's participant summary results to verify the accuracy of their responses. 2. Interview with the general supervisor on October 17, 2018 at 10:45 AM confirmed the accuracy of the results were not verified by the laboratory for the zero scores from the PT provider. This is a repeat deficiency previously cited on July 2, 2008.</p>
<b>D5477</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or</p>

produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of Blood Agar Plate (BAP), Chocolate agar (CHOC), and MacConkey agar (MAC) media records and interview with the technical consultant, the laboratory does not check each batch of BAP, CHOC, and MAC media for its ability to support growth, inhibit specified organisms or document the physical characteristics of each lot of media. Findings include: 1. Review of BAP and MAC media records show no evidence the laboratory documents the media's growth characteristics or condition for each lot of media. Review of CHOC media records show no evidence the laboratory documents the condition for each lot of media. 2. Interview with the technical consultant on October 18, 2018 at 9 AM confirmed the laboratory does not document the media's growth characteristics or condition for each lot of BAP and MAC media and the media condition for each lot of CHOC media.