

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0356272	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Methodist Hospitals, Inc, The	Street Address, City, State 200 E 89th Ave, Suite 2a, Merrillville, IN	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to follow its written policies and procedures for review and evaluation of proficiency scores less than 100% for 2 of 6 events reviewed (Event 1 2018 and Event 1 2017), for 2 of 6 analytes (Leukocyte Count and White Blood Cell Differential) in hematology. 1. Review of the policy "Laboratory Quality Assurance Action Plan" signed by the Laboratory Director on January 21, 2018, required the laboratory to perform proficiency testing through the American Proficiency Institute (API), but did not address investigation of unsatisfactory proficiency test scores, or results less than 100% and greater than 80%. 2. Review of the policy "Laboratory Quality Assurance Meetings" signed by the Laboratory Director on January 15, 2018, indicated "Proficiency testing performance" would be reviewed. 3. Review of the policy "Proficiency Testing" last signed by the Laboratory Director on April 2, 2015, indicated "any result below 100% would be investigated". 4. Review of the "American Proficiency Institute Performance Summary 2018 Hematology/Coagulation" report for 2018, Event 1, indicated the score for "Leukocyte Count" was 80%. 5. The "Quarterly Lab Quality Assurance Minutes" dated 06/21/18 and signed by the Laboratory Director and SP #6 (Practice Manager), documented a comment for the proficiency testing (Event 1 2018) as "Reviewed". There was no indication the score of less than 100% was investigated as required in the "Proficiency Testing" policy. 6. In interview on 03/14/19 at 12:20 PM, SP #6 and SP #5 confirmed there was no other documentation of an investigation for the 80% score for "Leukocyte Count". 7. Review of the "American Proficiency</p>

Institute Performance Summary 2017 Hematology/Coagulation" report for 2017, Event 1, indicated the score for "White Blood Cell Differential" was 93%. 8. The "Quarterly Lab Quality Assurance Minutes" dated 07/13/17 and signed by the Laboratory Director and SP #6 (Practice Manager), documented a comment for the proficiency testing (Event 1 2017) as "Reviewed". There was no indication the score of less than 100% was investigated as required in the "Proficiency Testing" policy. 9. In interview on 03/14/19 at 12:33 PM, SP #6 confirmed there was no other documentation of an investigation for the 93% score for "White Blood Cell Differential".