

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0948951	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier LvH Hematology Oncology Hecktown	Street Address, City, State 3788 Hecktown Rd, Suite 210, Easton, 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
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based upon on quality assurance record review and interview with laboratory personnel #2 (TP#2) , the laboratory failed to retain all quality assurance activity records for 2 years as required. Findings include: 1. On the day of survey (03/15 /2018) records reviewed revealed quality assurance activities were missing from 2016 and 2017 records 9 of 12 months in 2017 1 of 12 months in 2016 2. TP#2 confirmed the findings above on 3/15/2018 around 10:15 am.</p>
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) 2017 proficiency scores and interview with laboratory personnel #2 (TP#2), the laboratory director failed to identify problems that required a corrective action for Hematology, Platelets</p>

analyte results. Findings Include: 1) CAP Hematology 2017 proficiency Event # 1 had a score of 80% for Platelets. No corrective action assessment was established. 2) The laboratory director acknowledged the score of 80% with their signature, but no assessment was made. 3) Testing Staff #2 confirmed the findings above at 10/13/2017 around 9:45 am.