

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0888296	(X3) Date Survey Completed 07/16/2021
Name of Provider or Supplier J Richard Lilly Md Abfp Chartered	Street Address, City, State 5806 Baltimore Avenue, Hyattsville, MD	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on calibration record review and interview with the technical consultant (TC), the laboratory did not retain calibration records for the hematology analyzer for at least 2 years. Findings: 1. Calibration verification record review showed documentation that the Medonic M-Series hematology analyzer had been calibrated on 3/30/2020 and 1/21/2021. Calibration verification must be performed every 6 months. 2. In an email from 6/11/21 the TC stated, ""Medonic calibration: I did very regularly CBC calibration for Medonic. I think I misplaced couple calibration paper." 3. During an interview on 7/16/2021 at 1:00 PM, the TC confirmed that the laboratory did not retain calibration records for at least 2 years.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 8/29/2018 for not ensuring that the date and time that specimens are received into the laboratory is documented. The plan of correction stated that this would be corrected. Based on review of patient final reports and interview with the technical consultant (TC), the laboratory did not document the date and time that it</p>

receives patient specimens into the laboratory for testing. Findings: 1. A review of final patient reports showed that 5 of 5 reports did not include the date and time that the specimen was received into the laboratory for testing. 2. During the exit phone interview on 7/16/2021 at 1:00 PM, the TC stated that they enter the received date and time into the laboratory computer system (LABDAQ), but it does not always save it. They stated that LABDAQ also was not interfaced correctly with the office's computer system to ensure that this information is transferred over with the patient results, and that they had already contacted LABDAQ to correct the problem.