

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2114032	(X3) Date Survey Completed 10/07/2024
Name of Provider or Supplier Johns Hopkins Imaging At Columbia	Street Address, City, State 10840 Little Patuxent Parkway Suite 300, Columbia, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey on 09/06/2023 for not ensuring that the personnel who routinely perform the testing in the laboratory also test the proficiency testing (PT) samples. The evidence of correction that was received stated that the PT samples would be rotated among all the testing personnel (TP). Based on review of the PT attestation worksheets and interview with the technical consultant (TC), the laboratory failed to ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has 18 TP listed on the "Laboratory Personnel Report" (CMS-209) who perform chemistry testing. 2. A review of chemistry PT attestation worksheets from 2023-C through 2024 A & B showed that PT was performed by three different TP in 3 of 3 events. 3. Unknown PT specimens are used to assess the ability of the TP to ensure accurate and reliable test results. 4. During the survey on 10/07/024 at 11:15 AM, the TC confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
Based on review of the policy and procedure manuals and interview with the technical consultant (TC), the laboratory failed to have all the policies and procedures approved by the current laboratory director (LD). Findings: 1. Review of the policy and procedure manuals showed that they were not signed by the LD listed on the Laboratory Personnel Report (CLIA) form. When interviewed the TC stated that the new LD had started at the beginning of September 2024. 2. During the survey on 10/20/2024 at 11:15 AM, the TC confirmed that the policy and procedure manuals were not signed by the current laboratory director.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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;

This STANDARD is not met as evidenced by:
The laboratory director failed to ensure that the testing personnel who routinely perform the creatinine testing in the laboratory also test the proficiency testing samples. Cross refer to Tag D2007 for details.