Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	21D2114032	09/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Johns Hopkins Imaging At Columbia	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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has 20 TP listed on the "Laboratory Personnel Report" (CMS-209) who perform chemistry testing. 2. A review of chemistry PT attestation worksheets from 2021 through 2023 showed that PT was performed by TP #1 in 5 of 6 events. TP #1 performed the PT alone in 3 of those 5 events. 3. During an interview on 09/06/2023 at 11:45 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on procedure manual and record review and interview with the technical

	consultant (TC), the laboratory did not have a written procedure for documenting corrective action for out of range refrigerator temperatures. Findings: 1. The procedure, "Quality Assessment Plan for Point of Care Testing at Johns Hopkins Medicine Radiology Imaging Sites" states that "consumables" which need "refrigeration before and/or after opening" should be stored in a "lab grade refrigerator capable of maintaining temperature at 2-8 C" and that "refrigerators are monitored either by a remote monitoring system contracted by the JHH or with a Min/Max thermometer." 2. During an interview at 11:30 AM the TC stated that when refrigerator temperatures are out of range, the testing personnel (TP) can document corrective action in the online temperature monitoring software themselves or they can notify the TC of the problem. If that occurs, the TC advises the TP on what corrective action to take and documents the corrective action in the online record. 3. Procedure manual review showed that the laboratory did not have an approved procedure for what actions to take if the laboratory refrigerator temperature is out of the acceptable range. 4. This was confirmed by the TC during an interview on 09/06 /2023 at 11:30 AM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration verification record review and interview with the technical consultant (TC), the laboratory failed to ensure that the calibration of the chemistry instruments are verified at least once every 6 months. Findings: 1. The laboratory performed point of care creatinine testing in 2022 using two Nova Biomedical StatSensor chemistry analyzers, labeled "RAD2" and "RAD3". 2. A review of calibration verification records from 2022 showed that on 09/30/2022 a calibration verification was performed on 1 of 2 chemistry analyzers (RAD2). There was no documentation that a calibration verification had been performed on RAD3 on 09/30 /2023 at the time of the survey. As a result, RAD2's calibration verification was

	performed once in 2022. 3. During an interview on 09/06/2023 at 11:45 AM, the TC confirmed that RAD2's calibration verification was not performed and documented every 6 months.