Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0981025	02/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Johns Hopkins Imaging At White Marsh	4924 Campbell Blvd Ste 105, Baltimore, 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
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 review of calibration verification records and interview with the technical consultant (TC), the laboratory failed to perform calibration verification at least once every 6 months in 2023. Findings: 1. Calibration verification for creatinine was performed on 09/30/2022 and 09/28/2023. 2. In an email received on 02/29/2024 at 3: 02 PM, the TC confirmed that records for calibration verification performed around March 2023 could not be found.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure, review of quality control (QC) records, and interview with the technical consultant (TC), the laboratory failed validate one of four QC lot numbers prior to clinical use. Findings: 1. The laboratory used a Nova StatSensor handheld analyzer to test patient specimens for creatinine. 2. The procedure titled "Nova StatSensor Creatinine Control Validation" stated that "Each new lot number of Nova StatSensor control is to be validated by the POCT [point-of-care testing] office prior to its release for clinical use" and that "The Point-of-Care Testing office validation ensures the published range and precision can be reproduced on the reference meter with the current lot of test strips in use." 3. The QC validation was documented on the "Nova StatSensor Creatinine Quality Control Lot Check-In Logsheet" (logsheet). 4. The logsheets showed four QC lot numbers validated from 01/26/2023 through 11/07/2023. 5. The logsheet signed by the technologist on 01/26/2023 showed that QC level 3 lot number 5021089243 expired on 03/30/2023. 6. The next lot number for QC level 3 wasn't documented on the logsheet as validated until 06/16/2023 and was for lot number 5022103243. 7. On 02/29/2024 at 10:43 AM, the TC confirmed that lot number 5022103243 was put into clinical use on 03/31/2023 (the day after lot 5021089243 expired) prior to being validated and released by the POCT office.