Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0981025	09/14/2018
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation in the laboratory and interview with the technical consultant, the laboratory did not have an eyewash in each of the rooms where the chemistry testing was being performed. Findings: 1. The laboratory is required to implement safety policies and procedures to ensure safety in the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. 2. The laboratory performs testing in two separate rooms. Observation of each room showed that there was no eyewash available in either room. 3. During the survey on 09/14/2018 at 12:00 PM the technical consultant confirmed that there were no eyewashes in either room.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the technical consultant, the laboratory's procedure manual did not include all the required instructions to perform the labeling of the proficiency testing (PT) samples. Findings: 1. During the survey the technical consultant stated that when entering and testing the PT samples into the chemistry analyzer, the sample identification (ID) number that is entered into the analyzer is the ID number listed on the PT bottle. 2. Review of the PT procedure showed that those instructions were not part of the procedure manual used by the testing personnel. 3. During the survey on 09/14/2018 at 12:00 PM the technical consultant confirmed that the PT procedure did not include all the instructions required to perform and document PT.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: 5407- Based on record review and interview with the technical consultant, the laboratory did not ensure that the procedures used by the laboratory staff were signed and dated by the current laboratory director. Findings: 1. The laboratory's standard operating procedure manual was reviewed. The Quality Assurance, Specimen Collection, and Proficiency Testing handling policies were not approved (signed and dated) by the current laboratory director. 2. During the survey on 09/14/2018 at 12:00 PM the technical consultant confirmed that not all policies and procedures were signed and dated by the current laboratory director.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the "Quality Assessment Plan for Moderately Complex Point-of-Care Testing" procedure and interview with the technical consultant, the laboratory

	director does not ensure that communications the laboratory staff are documented on a routine basis. Findings: 1. The "Quality Assessment Plan for Moderately Complex Point-of-Care Testing" states that the site medical director is to "Ensure functional communication with Unit Trainer/Liaison and the Point-of-Care Testing office and Directors." 2. Review of the laboratory records show that the only documented communication between the laboratory director and the technical consultant is documented review of the proficiency testing results. There is no documentation showing the status of the laboratory on a routine basis. 3. During the survey on 09/14 /2018 at 12:00 PM the technical consultant confirmed that there is no documentation showing the status of the laboratory on a routine basis communicated to laboratory director.