Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2024697	10/31/2025
Name of Provider or Supplier	**Street Address, City, State**	
Jhi Bethesda	6420 Rockledge Drive Suite 3100, Bethesda, 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 surveyor observation, procedure manual review, and interview with the technical consultant (TC #1), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. The laboratory performs whole blood creatinine testing using three handheld "StatSensor Creatinine Meters." The analyzers are stored for use in three different rooms in a large medical imaging office, and are used for patient testing in other nearby rooms. 2. During a tour of the facility at 9:55 AM, it was observed that the eye wash station was located at one end of the office, behind a door which required a badge to be swiped in order to unlock the door and to gain access. 3. The procedure, "Emergency Equipment: Eyewash, Drenching Hose, and Shower Equipment" was reviewed. The procedure stated that "no more than ten (10) seconds shall be required to reach the emergency equipment from the site of the hazard" and that "if the hazard is not corrosive, one intervening door can be present between the hazard and the emergency equipment so long as" "the door is equipped with a closing mechanism that cannot be locked to impede access to the emergency equipment." 4. During an interview on 10/29/2025 at 11:50 AM, TC #1 confirmed that the eye wash station was not located in an easily accessible area near where laboratory testing was performed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on competency assessment record review and interview with the technical consultant (TC #1), the laboratory failed to establish and follow written policies and procedures for assessing the competency of the TCs based on the position responsibilities listed in Subpart M- CFR 493.1413. Findings: 1. The procedure, "Competency Assessment Guidelines" states under section "E. Competency Assessment Documentation" that "Each laboratory must appropriately document each employee's competency assessment (for each test system/task)" and that "Each competency assessment must also state clearly if the assessment was satisfactory or unsatisfactory," however the procedure did not specify how the laboratory would evaluate the competency of the TCs or with what frequency it should be performed. 2. The "Laboratory Personnel Report" (CMS-209) form submitted at the time of the onsite survey listed five testing personnel (TP) who were also designated as TCs. 3. During an interview at approximately 11:30 AM, TC #1 stated that the four TCs (TC #2 - TC #5) who worked onsite were designated as TCs because they performed competency assessments on the other TP. 4. A review of competency records from 2024 and 2025 showed that there were no competency assessments available at the time of the onsite survey for five out of five TCs, showing that they had been evaluated for the duties they performed as TC. 5. In an email received on 10/31/2025, TC #1 submitted a copy of their own competency assessment (performed 09/12/2024) but did not provide competency assessment records for the other four TCs. 6. During an interview on 10/29/2025 at 11:50 AM, TC #1 confirmed that competency assessment records were not available for the onsite TP who were designated as TCs on the CMS-209 form.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the chemistry analyzer instrument manual and reagent test strip instructions for use (IFU), laboratory temperature records, and interview with the technical consultant (TC #1), the laboratory failed to define, monitor, and document laboratory room temperature to ensure proper reagent storage and reliable test system operation. Findings: 1. The laboratory performs whole blood creatinine testing using three handheld "StatSensor Creatinine Meters." The analyzers and the "StatSensor Test Strips" (reagent test strips) used for testing are stored for use in three different rooms in a large medical imaging office, and are used for patient testing in other nearby rooms. 2. Review of the instrument manual's IFU showed that the acceptable temperature range for analyzer operation is "59F - 104F (15C - 40C)"; however, the

	IFU for the reagent test strips stated to store them at "room temperature" but failed to define what the acceptable room temperature was. 3. Record review showed that there were no temperature logs available for review at the time of the survey, documenting the room temperature where the three analyzers and reagent test strips were stored. 4. During an interview on 10/29/2025 at 11:30 AM, TC #1 stated that the laboratory did not monitor room temperature in the laboratory where testing was conducted.