Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0661910	09/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Wisconsin Laboratory, Inc	2323 N Lake Dr, Milwaukee, WI	

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
D0000	Complaint Survey 9/18-19/2024 The laboratory was found NOT in compliance with the following 42 CFR Part 493: 493.1230 Condition: General laboratory systems
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 lack of procedures, email, interview, and lack of cleaning records, the laboratory failed to establish cleaning procedures, and document those activities to ensure protection from biohazardous materials, during one of one exposure incident August 2024 as evidenced by: 1. In review of an email from the microbiology supervisor on August 19,2024 at 1359 to the quality team, the microbiology supervisor stated that they had a biohazardous fungus environmental laboratory exposure. 2. The laboratory did not provide any procedures on what to clean or what laboratory personnel were required to do after environmental exposure in the lab. The laboratory could not provide any post-incident cleaning records or corrective action measures taken within the negative pressure room. 3. In interview with the microbiology supervisor on 9-19-2024 at 0916 stated that they knew what to do but didn't have a formal procedure and did not document all of the cleaning that they did post exposure.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves

	a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory's records, emails, laboratory's procedure, and interviews, the laboratory failed to meet the requirement of general laboratory systems as evidenced by: 1. The laboratory failed to have a system in place to ensure all complaints reported to the laboratory were investigated and documented according to their complaint procedures for one of one event. (see D5205).
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory procedures, emails, and interviews, the laboratory failed to have a system in place to ensure all complaints were investigated and documented according to their complaint procedures for one of one event as evidenced by: 1. In review of the laboratory's event reporting policy under the heading response to event stated, "Any associate who witnesses, discovers, or involved in patient event should first ensure medical treatment is provided and appropriate steps are taken to minimize the immediate potential for future event. Entry into the Event reporting system (ERS) should occur as timely as possible and before the end of an individuals shift." 2. In review of the laboratory's event reporting policy states, "specific events will be reviewed by the safety event team (SERT) or SERT sub team to determine the need of investigation or root cause analysis (RCA)." 3. The laboratory was notified by email on August 12 at 1200 from their reference laboratory that there was an issue with patient sample 1012532144 mycobacterium results. It stated, "we received M. tuberculosis, genotype results on a isolate submitted to us by your laboratory in February/March that indicated laboratory contamination with an ATCC strain." 4. The microbiology supervisor respond to the email on August 12 at 1531 stated "...I am deeply troubled, we are looking into this matter." 5. An email from the microbiology supervisor to laboratory's management team on August 13 at 1627 stated, "Unfortunately, we made a grievous error earlier this year when labeling a migit tube by AFB testing... I don't know what happened as we are still reviewing the details." 6. An email from the quality manager to the microbiology supervisor on August 20, 2024 at 1007 stated, "Anything further on this investigation?" There was no response from the microbiology supervisor. 7. In review of the laboratory's ERS records the laboratory did not report the occurrence into into ERS before the end of the shift on August 12, 2024. The laboratory did not launch an investigation and input the error into ERS system until September 18, 2024 during the onsite CLIA surveyor investigation. 8. In interview with the microbiology manager 9-19-2024 at 0918 he stated that previous to the surveyors arrival the notification of the event had not gone through ERS system with the event and only suspected what actually happened. 9.

	During the survey in the conference room on 9-19-2024 at 0934 at 1001 it was the first time that the two individuals involved (setting up the profiency testing and the patient, day later), were asked what happened, as part of an the event investigation.
D5511	MYCOBACTERIOLOGY CFR(s): 493.1262(a)(c) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control worksheets, and interview with microbiology supervisor, the laboratory failed to follow and document weekly MGIT Quality control (QC) required for Mycobacterium media for the 3 of 9 weeks reviewed in 2024 as evidenced by: 1. In review of the laboratory's QC worksheet, stated that for MGIT media is to be quality controlled weekly. 2. In review of the laboratory's QC worksheets for February 2024, May 2024, and June 2024, the laboratory did not perform QC for the following weeks: Week of 4-10 February 2024 Week of 12-18 May 2024 Week of 23-29 June 2024 3. In interview at 1332 on 09-18-2024, the microbiology supervisor confirmed that QC weeks were missing within the MGIT media.