Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0667822	07/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Missouri State Public Health Lab	101 North Chestnut Street, Jefferson City, MO	

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	A routine recertification was performed from July 21, 2026, to July 22, 2026. The following Standard-level deficiencies were cited.
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 a review of the laboratory's policies and procedures, the lack of clinical consultant (CC) competency assessment documentation, and an interview with the laboratory director (LD), the laboratory failed to have a policy or procedure in place to assess CC competency for 2 of 2 years. Findings: 1. Review of laboratory policies and procedures on July 21, 2026, revealed that the laboratory's competency assessment procedures did not include the assessment for the CC. 2. The laboratory failed to provide competency assessment documentation for the CC for 2 of 2 years (2025 and 2026). 3. By interview on July 21, 2026, at 9:00 am, the LD confirmed that the competency assessment procedures did not include procedures for the assessment of competency for the CC, and the CC was not assessed for their responsibilities.
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: I. Based on observation of the laboratory, review of the manufacturer's humidity requirements, and interview with laboratory staff, the laboratory failed to follow manufacturer humidity requirements for 2 of 2 Hologic Panther analyzers currently in use. Findings: 1. Observation of the immunology laboratory (room 4301) on July 21, 2026, at 1:50 pm revealed that two Hologic Panther instruments were in use (Serial Numbers 03936 and 00676). 2. The Panther System Operators manual, page 20, Table 6. Environmental Requirements (Continued) stated: "Operating: 20-85% non-condensing." 3. Review of the laboratory temp logs revealed the laboratory's humidity acceptable ranges were 10 to 85%. 4. In an interview on July 21, 2026, at 2:00 pm, immunology staff confirmed the established humidity ranges were not in accordance with manufacturers' humidity requirements. II. Based on observation of the laboratory, review of the manufacturer's humidity requirements, lack of documentation of the immunology dark room humidity records, and interview with laboratory staff, the laboratory failed to follow the manufacturer's humidity requirements for 1 of 1 Motic BA310E Biological Microscope currently in use. Findings: 1. Observation of the immunology dark room (room 4303) on July 21, 2026, at 3:25 pm revealed that 1 Motic BA310E Microscope was in use. 2. The Motic BA310E Biological Microscope manual, page 29, 2.1 operating environment stated, "Maximum relative humidity: 75% for temperature up to 31C, decreasing linearly to 50% relative humidity at 40C". 3. Laboratory staff were unable to provide documented humidity in room 4303, where the Motic BA310E Biological Microscope was kept from July 2024 to July 2026. 4. In an interview on July 21, 2026, at 3:35 pm, immunology staff confirmed humidity was not monitored in room 4303. III. Based on observation of the mail room and storage room, lack of temperature records, and an interview with the laboratory staff, the laboratory failed to monitor and document temperatures for collection tubes and collection devices stored in the mail room and storage room for 2 of 2 years (July 2024 to July 2026). Findings: 1. Observation of the mailroom (room 3309) on July 22, 2026, at 2:30 pm revealed the following sampling of collection tubes and collection devices stored at room temperature with the following manufacturer storage requirements a. 4 to 25 degrees Celsius: - 306 tubes of BD Vacutainer SST (yellow top), Lot#5300862. - 87 tubes of BD Vacutainer K2 EDTA, Lot#5293061. b. 2 to 30 degrees Celsius: - 50 tubes of Remel Micro test, Lot#167359. c. 15 to 30 degrees Celsius: - 18 boxes of Aptima Urine Collection Devices, Lot#936011. - 06 boxes of Aptima Unisex Swab Specimen Collection, Lot#93196. - 17 boxes of Aptima Multitest Swab Specimen Collection, Lot#930710. 2. Observation of the storage area (room 3400) on July 22, 2026, at 3:00 pm revealed the following sampling of collection tubes and collection devices stored at room temperature with the following manufacturer storage requirements a. 4 to 25 degrees Celsius: - 24 cases of BD Vacutainer SST (yellow top), Lot#6007520. - 02 cases of BD Vacutainer SST (yellow top), Lot#5300862. b. 15 to 30 degrees Celsius: - 25 cases of Aptima Multitest Swab Specimen Collection, Lot#930710. - 15 cases of Aptima Unisex Swab Specimen Collection, Lot#93196. 3. Laboratory staff were unable to provide documentation of monitored temperatures for room 3309 and 3400 where specimen collection tubes and collection devices were stored for 2 years (July 2024 to July 2026). 4. In an interview on July 22, 2026, at 3:30 pm, the laboratory director confirmed the above findings.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations of the laboratory and interviews with laboratory staff, the laboratory failed to ensure that reagents and chemicals were labeled with expiration dates for 2 of 2 years (July 2024 to July 2026). Findings: 1. Observation of the NBS laboratory on July 21, 2026, at 9:15 am, revealed the following sampling of chemicals stored in safet cabinets: A. Corrosive cabinet: a. 12 - 500 mg bottles of Fisher Chemical Trichloroacetic Acid ACS Grade, Lot#245896A. B. Flammable cabinet #4: a. 12 - four-liter glass bottles of Fisher Chemical Methanol LC/MS, Lot number 255080. b. 14 - four-liter glass bottles of Fisher Chemical Methanol HPLC Grade, Lot number 262862. C. Flammable cabinet #5: a. 12 - four-liter glass bottles of Fisher Chemical Acetonitrile LC/MS Grade, lot number 353140. b. 06 - four-liter glass bottles of Thermo Scientific Acetonitrile LC/MS Grade, lot number Y41L708. 2. Observation of the microbiology laboratory on July 22, 2026, at 9:10 am, revealed 1 bottle of Pertussis / Tularensis buffer solution, lot number PTB61517, 1 bottle of Cargille Oil Immersion Type B, lot number 012191, and an aliquot of immersion oil without an expiration date. 3. Observation of the media preparation laboratory on July 22, 2026, at 9:30 am revealed the following sampling of chemicals not labeled with expiration dates: a. 01 bottle of DIFCO Labs D- Mannitol, lot number 017017, received 03-24-1988, opened 09-20-2022. b. 03 bottles of DIFCO Labs Dextrose, lot number 0115-17-4, received 05-07-1986, opened 04-29-2020. c. 03 bottles of Sigma Chemical Company Raffinose, Lot number 127F-0826, received 12-31-1989. d. 01 bottle of Sigma Chemical Company myo-Inositol, lot number SLCD9497, received 12-15-1989. 4. Observation of the Molecular clean room on July 22, 2026, at 10:35 am, revealed an aliquot of Milli-Q water not labeled with an expiration date. 5. By interview with the laboratory director and laboratory staff on July 22, 2026, at 3:35 pm, it was confirmed that the above sampling of chemicals and regents did not include expiration dates.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, review of laboratory procedures, and interview with the laboratory staff, the laboratory failed to perform maintenance per manufacturer's instructions for two of two Hologic Panther instruments in use from July 2024 to July 2026. Findings: 1. Observation of the immunology laboratory (room 4301) on July 21, 2026, at 1:50 pm revealed two Hologic Panther instruments were in use. 2. The Panther System Operators manual, Page 181, Mag Wash Clean, as part of system maintenance, states, "It is required that

	this task be performed daily after each testing day. For example, if processing test orders Monday-Friday, schedule the Mag Wash Clean task to run after working hours on Those Days. 3. By interview with the immunology laboratory lead confirmed on July 21, 2026, at 1:55 pm, Panther 1 (serial number 00676) mag wash is performed weekly, and Panther 2 (serial number 03936) mag wash is performed each day before testing begins. Maintenance was not performed per the manufacturer's instructions.