Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0651409	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Minnesota Department Of Health	601 Robert Street N, Saint Paul, MN	

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 recertification survey was conducted from 12/03/2024 through 12/05/2024 and standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing (PT) records and in interview with general supervisor-7 (GS-7), the laboratory failed to ensure personnel signed attestation forms for 3 of 3 proficiency testing (PT) events (creatinine and specific gravity tests). Findings included: 1. Review of CAP PT documentation did not include the testing person and the laboratory director's (or designee) signatures on CM-B 2023 (specific gravity) and U-B 2024 (creatinine) attestation forms (signature required). For event CM-B 2024 (specific gravity), there was no testing person signature. 2. During an interview on 12/03/2024 at 2:05 pm, GS-7 reviewed and confirmed CAP PT attestation forms had not been signed.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by:

	Based on direct observation and media documents, the laboratory failed to retain American Type Culture Collection (ATCC) microorganism's manufacturer instructions to ensure instructions and expiration dates were followed for 9 of 9 microorganisms (random sampling). Findings included: 1. The laboratory was unable to provide ATCC microorganism's manufacturer instructions to ensure instructions and expiration dates were followed, the following was a sampling observed: a. During a tour of the mycology department on 12/05/2024 at 2:37 pm, the following expired quality control (QC) water stocks in glass vials with microorganisms and inoculated microorganism in media were observed stored in a cabinet (random sampling): T. mentagrophytes ATCC 9533, Lot 442-75-3, expiration date 06/2018 and the sterilized water it was in had a label with a made date of "Oct 06, 2016" and an expiration date of "April 06, 2017." (T. - Trichophyton) T. rubrum ATCC 28188, lot 444-86-4, expiration date 10/31/23 and the sterilized water it was in had a label with a made date of "Jan 24, 2022" and an expiration date of "July 24, 2022." T. interdigitale ATCC 9533 (no lot number or expiration date) in deionized water with a label that stated, made date of "3/11/24" and an expiration date of "9/11/24." T. tonsurans ATCC 28942 (no lot number), 10/31/23 (was not labeled with the meaning of this date) in deionized water with a label that stated, made date of "6/1/23" and an expiration date of "12/1/23." "Asp Glaucus 14/Aug/14" in distilled water with a label that stated, made date "July 23, 2014" and expiration date of "Jan 22, 2015." (Asp - aspergillus) Four slants that included inoculated microorganisms Trichophytum equinum ATCC 12545 on 11/1/24 (three slants) and T. interdigitale ATCC 9533 on 11/7/24 (one slant). b. During a tour of the mycology department on 12/05/2024 at 2:37 pm, yeast microorganisms were observed in a 30C (degrees Celsius) incubator: C. Albicans ATCC 60193 inoculated on Sabdex slant 12/2/24, C. Glabrata ATCC 66032 inoculated on Sabdex slant 12/2/24, and S. Aureus ATCC 25923 inoculated on a blood agar plate 12/2/24. (C. - Candida, S. - Staphylococcus) c. During a tour of the microbiology department on 12/05/2024 at 3:00 pm, the following microorganisms in vials with glycerol were observed stored in a -76C freezer (random sampling): "C. Albicans 90028 3-5-21" "S. Aureus 25923 2/3/23" "C. Glabrata ATCC 66032" The laboratory failed to ensure microorganisms were not used past the manufacturer's expiration date and water stock expiration dates (refer to D5417); and failed to ensure microorganisms stored in vials and inoculated in media were labeled with expiration dates to ensure they were used within those dates (refer to D5415).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation and review of laboratory procedures, the laboratory failed to define temperature acceptable criteria for three of three syphilis test methods (random sampling of tests). Findings included: 1. During an observation of central accessioning on 12/05/2024 at 10:00 am, twelve red top Vacuette Serum Separator Tubes (SST) patient specimens for Rapid Plasmin Reagin (RPR) testing were observed in a rack on a counter. They were received at 9:17 am with the "condition"

	as "refrigerated", and on the requisitions a temperature of 14.4C was documented. They were transported via courier from Ramsey County. A continued observation of central accessioning on 12/05/2024 at 10:35 am, five aliquoted serum specimens for RPR testing were observed being received and temperatures taken that included 13.3 C, 12.4C, 13.3C, 14.4C. The biohazard bag they were in had a "Refrigerated" label and were transported via courier from Alina Health. There was no documentation that defined an acceptable temperature range for RPR/syphilis testing specimens. 2. Review of "Specimen Receipt in the Infectious Disease Laboratory" standard operating procedure (SOP) 1002 on page 4 stated, "7.5 Perform specimen temperature readings" with step-by-step instructions of taking temperatures of specimens but no defined acceptability criteria or range of temperatures. 3. Review of the RPR procedure SOP 1001 stated, "7.3 Shipping, handling, and storage: 7.3.1 Specimens are usually transported at ambient temperatures. Specimens should not be exposed to extreme temperatures or long transport delays." Review of the syphilis antibody detection in cerebralspinal fluid (CSF) by venereal disease reserach laboratory (VDRL) SOP 1002 and syphilis antibody detection in serum by treponema pallidum particle agglutination (TPPA) SOP 1003 stated, "7.4 Specimens are usually transported at ambient temperatures. However, care must be taken to not expose them to extreme temperatures or long transport delays." Review of the laboratory's online instructions for submitting syphilis specimens stated, "Transport/Stability Store and ship at refrigeration temperature within 5 days of collection. Alternatively, ship frozen." The laboratory's SOPs of "transported at ambient temperatures" were not consistent with online instructions of "ship at refrigeration temperature." The laboratory did not define "ambient", "refrigeration", "extreme temperatures" and an acceptable temperature range when taking temperatures at receipt.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: A. Based on observation, review of the laboratory online test catalogue, review of laboratory policy, and interview with staff, the laboratory failed to define storage and transport temperature requirements for specimens. I. (a) The following samples were observed received from United Parcel Service (UPS) in the accessioning area, room 151, at approximately 10am on 12/05/2024 with a temperature recorded as 16.2C. 1. #240059677 - stool specimen in Cary Blair transport medium for Enteropathogenic E. coli (EPEC) testing, submission form marked "Refrigerated" by the laboratory. 2. #240059679 - stool specimen in Cary Blair transport medium for Salmonella species testing, submission form marked "Refrigerated" by the laboratory. 3. #240059681 - stool specimen in Cary Blair transport medium for Enteropathogenic E.coli (EPEC) testing, submission form marked "Refrigerated" by the laboratory. 4. #240059431 - isolate on blood agar slant for Streptococcus agalactiae testing, submission form marked "Ambient" by the laboratory. I. (b) The following sample was observed received from United Parcel Service (UPS) in the accessioning area, room 151, at approximately 10am on 12/05/2024 with a temperature recorded as 16.4C. 1. #240059743 - stool specimen (rectal swab) in Cary Blair transport medium for Shigatoxin producing gene testing, submission form marked "Ambient" by the laboratory. I. (c) The following isolates were observed in the TS Series "Whale

Shark" refrigerator in room 151 at approximately 10:30am on 12/05/2024. Laboratory receipt and accessioning date/time unknown. 1. #240059594 - isolate for CRPA Carbapenem-resistant Pseudomonas aeruginosa Project 2175 (CRPA). Recorded temperature "11.4" and submission form marked "Room Temp" by the laboratory. 2. #240059596 - isolate for Neisseria gonorrhoeae testing. Recorded temperature "11.3" and submission form marked "Room Temp" by the laboratory. 3. #240059640 - isolate for Carbapenem-resistant Acinetobacter (CRA) testing. Recorded temperature "15.4" and submission form marked "Room Temp" by the laboratory. 4. #240059602 - isolate for Methicillin-resistant Staphylococcus aureus (MRSA) testing. Recorded temperature "18.6" and submission form marked "Room Temp" by the laboratory. 5. #240059604 - isolate for Methicillin-resistant Staphylococcus aureus (MRSA) testing. Recorded temperature "18.3" and submission form marked "Room Temp" by the laboratory. II. (a) Review of the laboratory's online test catalogue (https://labinventory.web.health.state.mn.us/#/) found the following: 1. "Test Name ...EPEC (Enteropathogenic Escherichia coli) PCR Panel ...Transport/Stability Store at ambient temperature. Ship at ambient or refrigeration temperature." 2. "Test Name ... Salmonella Culture - Stool ... Transport/Stability Store at ambient temperature. Ship at ambient or refrigeration temperature." 3. "Test Name ...Streptococcus (Group B) Identification - Isolate ... Transport/Stability Store and ship at ambient temperature." II. (b) Review of the laboratory's online test catalogue (https://labinventory.web.health.state.mn.us/#/) found the following: 1. "Test Name Shiga toxin-producing E. coli (STEC) Culture - Stool ... Transport/Stability Store at ambient temperature. Ship at ambient or refrigeration temperature." II. (c) Review of the laboratory's online test catalogue (https://labinventory.web.health.state.mn.us/#/) found the following: 1. "Test Name Carbapenemase Detection in Pseudomonas - Isolate ... Transport/Stability Store and ship at ambient or refrigeration temperature." 2." Test Name Carbapenemase Detection in Acinetobacter - Isolate ... Transport/Stability Store and ship at ambient or refrigeration temperature." 3. "Test Name Neisseria gonorrhoeae - Isolate ... Transport/Stability Store and ship at ambient temperature." 4. "Test Name MRSA Isolate Submission ...Transport/Stability Store and ship at ambient temperature." III. Review of the laboratory policy titled "Specimen Receipt in the Infectious Disease Laboratory" index number "IDL OPS ACC SOP 1002" version 2 found the following: "7.5 Perform specimen temperature readings. 7.5.1 Open shipping packages one at a time. 7.5.2 Remove specimens from shipping cylinder /canisters ... 7.5.3.6 Record temperature reading from IR thermometer on submission form ... 7.5.5 Document intended shipping and IR thermometer temperatures on the upper right of the submission form or manifest. 7.5.6 Document intended shipping in the "Receipt Temp" column on the Specimen Receipt Time/Temperature Log. 7.5.6.1 Circle: AMB, REF, or FRZ." The laboratory policy did not define the temperature range for "AMB" (ambient)," REF" (refrigerated) or "FRZ" (frozen). IV. During interview on 12/04/2024 at 11am, the Quality Specialist of the Infectious Disease Laboratory confirmed the online test catalogue did not define specimen storage and transport temperatures. 43232 B. Based on review of laboratory's client services manual, laboratory's procedures, and direct observation, the laboratory failed to define storage and transport conditions temperature ranges in their instructions for submitters for three of three test methods (random sampling). Findings included: 1. Review of the laboratory's online instructions (client services manual) for submitting syphilis specimens stated, "Transport/Stability Store and ship at refrigeration temperature within 5 days of collection. Alternatively, ship frozen." "Refrigeration" and "frozen" was not defined. 2. Review of the RPR procedure SOP 1001 stated, "7.3 Shipping, handling, and storage: 7.3.1 Specimens are usually transported at ambient temperatures. Specimens should not be exposed to extreme temperatures or long transport delays." Review of the syphilis antibody detection in CSF by VDRL SOP

	1002 and syphilis antibody detection in serum by TPPA SOP 1003 stated, "7.4 Specimens are usually transported at ambient temperatures. However, care must be taken to not expose them to extreme temperatures or long transport delays." The laboratory's SOPs of "transported at ambient temperatures" was not consistent with online instructions of "ship at refrigeration temperature." 3. During an observation of central accessioning on 12/05/2024 at 10:35 am, the staff was observed taking and documenting temperatures of specimens for RPR testing but the laboratory had not defined acceptability criteria for temperatures. Refer to D5311.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's PT procedure, CAP PT records, and interview with GS-7, the laboratory failed to follow their own written procedure for reviewing and documenting their review of CAP PT within 30 days for 2 of 8 events (creatinine and specific gravity tests). Findings included: 1. Review of the laboratory's proficiency testing standard operating procedure (SOP 1001) stated, "6.4 Transcribing and Submitting (Testing personnel or unit supervisor) ...6.6.4 Submit results per the instructions pf the proficiency provider (fax, mail, or electronic reporting). 6.4.4.1 Compile the completed PT survey forms and all testing paperwork. Complete Section 1 of Proficiency Testing Summary Report as a coversheet and await receipt of the survey results from the provider. 6.4.4.2 Partially completed Proficiency Testing Summary Report and testing paperwork may be stored in an electronic or paper location of the unit's choice until the result summary is received and the packet is ready to be submitted for approvals through iPassport ....6.5 Reviewing Final Survey Results: ...NOTE: This review should be conducted within 30 days of receiving results. This is to ensure any failures are promptly investigated and appropriate follow-up resolution initiated." 2. Review of CAP PT documentation in iPassport for events U-B 2024 (results submitted 07/15/2024, creatinine) and CM-B 2024 (results submitted 09/10/2024, specific gravity) did not have documentation of their review within 30 days with a Proficiency Testing Summary Report. Both events included results recieved by the PT company. 3. During an interview on 12/03/2024 at 2:05 pm, GS-7 was asked for the timeline of Proficiency Testing Summary Reports, and she confirmed within 30 days.
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 laboratory personnel interviews and virology culture written policies and procedures record review on December 5, 2024 at 11:15 am, the laboratory failed to include in its written procedure manual any information regarding the use of frozen patient specimens for viral cultures. Findings included: a. In the Virology Section, according to laboratory personnel, it was the practice of the laboratory to culture refrigerated or frozen patient specimens for viruses.. b. Laboratory personnel confirmed on December 5, 2024 at 11:15 am that the laboratory maintained no written protocols for the use of frozen patient specimens for viral cultures. c. According laboratory records, from December 1, 2024 to December 5, 2024, the laboratory performed and reported approximately 16 patient viral cultures. Laboratory personnel could not determine whether any of these 16 patient specimens had been frozen.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 laboratory personnel interviews and LSD (Lysosomal Storage Disorders) patient testing records review on December 4, 2024 at 10:45 am, the laboratory failed to document the temperatures of the incubators used in the testing of patient LSD specimens. Findings included: a. In the Newborn Screening Section, it was the practice of the laboratory to test patient LSD specimens using the NeoLSD Kit test system. According to the laboratory's written protocol, foil sealed plates containing patient specimens mixed with the NeoLSD Incubation Cocktail are to incubated at 37 + 0.5 degrees C for 18 + 2 hours. b. Laboratory personnel confirmed on December 4, 2024 at 10:45 am that the laboratory maintained no documentation to indicate that the foil sealed plates containing patient specimens mixed with the NeoLSD Incubation Cocktail were incubated at 37 + 0.5 degrees C. c. According laboratory personnel, the laboratory performed and reported approximately 60,000 patient LSD test results annually. 27526 II. Based on observation, review of manufacturer's instructions, lack of temperature/humidity records, and interview with staff, the laboratory failed to ensure the temperature and humidly ranges were within manufacturer's specifications for the operation of the BD MGIT 960 analyzer. Findings included: 1. One BD MGIT

	960 analyzer was observed during a tour of room 357 at approximately 9am on 12/04 /2024. 2. The operator manual for the BD MGIT 950 system stated the following: "2.3 Instrument Specification ... Environmental Requirements ...MGIT 960 ...Operating Conditions ...Temperature 19C - 30C ....Humidity 30% - 80% RH, non-condensing". 3. The surveyor requested and did not receive records documenting temperature and humidity levels for room 357. 4. During interview on 12/04/2024 at approximately 9am, the Technical Supervisor of the Mycobacteriology section stated temperature and humidity levels were not documented in room 357. III. Based on direct observation, review of temperature logs, review of the instrument operator's manual and interview with staff, the laboratory failed to ensure room temperature was within manufacturer's specifications for the Bruker MALDI Biotyper sample preparation area. Findings included: 1. One Bruker MALDI Biotyper CA analyzer was observed during tour of room 375 at approximately 3pm on 12/04/2024. 2. Review of the room temperature monitoring logs for room 375 dated 12/04/2024 revealed alarms were set for a low of 18C and a high of 27C. 3. The operator manual for the Bruker MALDI Biotyper CA analyzer stated the following: "2.3 Environmental Requirements - Sample Preparation ...Test organism samples intended to be analyzed in the MALDI Biotyper CA System must be prepared under the following conditions. +20C/+68F to +25C/+77F ...For best results, preparation of all solutions, Standard Solvent, and the entire sample preparation process including drying steps must be performed under controlled room temperature." 4. During interview on 12/04/2024 at approximately 3pm, the General Supervisor of the Microbiology Unit confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on direct observation, review of the laboratory's procedures, and interview with testing person-4 (TP-4), the laboratory failed to ensure two of two solutions were labeled with accurate expiration dates that were used in the detection of sulfur mustard metabolites in serum by liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) method. Findings included: 1. During a tour of the chemical threats and biomonitoring department on 12/04/2024 at 1:00 pm, two glass bottles were observed stored in a refrigerator with the following information: "25 uM NH4OAC in H2O 9/4/24 [initials] exp 3/4/24" "50 uM NH4OAC in H2O [initials] 9 /16/24 exp 3/16/24" (exp - expiration) 2. Review of the "Detection of Sulfur Mustard Metabolites in Serum by LC-MS/MS method" procedure stated the above solution is used for making the LC mobile phase A and "This solution may be used for six months if stored refrigerated." 3. During an interview on 12/04/2024 at 1:06 pm, TP-4 stated the expiration dates should have been documented as 9/4/24 and 9/16/24. The laboratory failed to ensure two of two solutions were labeled with accurate expiration dates. II. Based on direct observation, review of media documents, and interview with staff, the laboratory failed to have a system in place for documenting and tracking manufacturer's expiration dates and lot numbers for 8 of 8 microorganisms used for media QC (random sampling). Findings included: 1. During a tour of the mycology department on 12/05/2024 at 2:37 pm, the following QC water stocks in glass vials

	with microorganisms and inoculated microorganism in media were observed stored in a cabinet (random sampling): T. interdigitale ATCC 9533 (no lot number or expiration date) in deionized water. T. tonsurans ATCC 28942 (no lot number), 10/31 /23 (was not labeled with the meaning of this date) in deionized water. "Asp Glaucus 14/Aug/14" (no lot number and was not labeled with the meaning of this date) in distilled water. (Asp - aspergillus) Four slants that included inoculated microorganisms Trichophytum equinum ATCC 12545 on 11/1/24 (three slants) and T. interdigitale ATCC 9533 on 11/7/24 (one slant). (no lot numbers or expiration dates) b. During a tour of the mycology department on 12/05/2024 at 2:37 pm, yeast microorganisms were observed in a 30C incubator: C. Albicans ATCC 60193 inoculated on Sabdex slant 12/2/24, C. Glabrata ATCC 66032 inoculated on Sabdex slant 12/2/24, and S. Aureus ATCC 25923 inoculated on a blood agar plate 12/2/24. (no lot numbers or expiration dates) c. During a tour of the microbiology department on 12/05/2024 at 3:00 pm, the following microorganisms in vials with glycerol (no lot numbers) were observed stored in a -76C freezer (random sampling): "C. Albicans 90028 3-5-21" "S. Aureus 25923 2/3/23" "C. Glabrata ATCC 66032" 2. Review of the mycology media documents included the above microorganisms used to QC media, as follows: Sabouraud Dextrose Agar (Emmons)-Plates -T. interdigitale ATCC 9533 and C. Albicans ATCC 60193 used for media QC 2/1/24, 4/11/24, 6/7/24, 8/13/24, and 10 /17/24. Sabouraud Dextrose Agar with Cycloheximide and Chloramhenicol - T. tonsurans ATCC 28942, C. Glabrata ATCC 66032, and S. Aureus ATCC 25923 used for media QC 1/9/24, 2/23/24, 4/9/24, 6/4/24, 7/25/24, 8/15/24, 9/27/24 and 11/26/24. 3. During an interview on 12/05/2024 at 3:00 pm, GS-6 of the mycology department was unsure what the dates on the above observed vials meant and could not provide manufacturers expiration dates. This confirmed the laboratory did not have a system in place to track and document lot numbers and expiration dates of the microorganisms used for media QC.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on direct observation, interview with testing person-2 (TP-2), review of the laboratory's procedure, and extension request document, the laboratory used expired blank blood for one of one test method in chemical threat and biomonitoring department. Findings included: 1. During a tour of the chemical threats and biomonitoring department on 12/04/2024 at 1:00 pm, four expired 30 ml bottles of Defib Sheep Blood by HemoStat Laboratories were observed stored in a refrigerator, as follows: "Lot #773366- 1, expires Aug 21, 2023" "Lot #773366 - 2, expires Aug 21, 2023" "Lot #832628 - 1, expires Sept 23, 2024" - two bottles 2. During an interview on 12/04/2024 at 1:06 pm, TP-2 stated the sheep blood was used on the high-resolution accurate mass qualitative targeted screening method by orbitrap Identification-X Liquid Chromatography - High Resolution Mass Spectrometry (ID-X LC-HRMS). He stated the expiration date had been extended just not documented on the bottle. 3. Review of the "Extraction Procedure for Multiple Drugs in Blood and Urine" SOP 1002 stated, "Drug free blood (HemoStat Laboratories) or equivalent - Used for blank quality controls and for spiking standards; Store at 2 to 6C; Expires one year after opening or when noticeable clotting is observed." 4. The laboratory

provided a "Blank Blood Extension Request" to the laboratory director for extending the expired blank blood to 08/21/2025 and it stated " ...the manufacturer extended the expiration to 8/21/2024." The laboratory could not provide this documentation and there was no documentation from the manufacturer extending the expiration to 08/21 /2025. The laboratory failed to ensure blank blood for quality control and spiking standards were not used past their expiration dates. II. Based on direct observation, interview with TP-16, review of the laboratory's procedure, and extension request document, the laboratory used expired blank blood for one of one test method in the metals department. Findings included: 1. During a tour of the metals department on 12 /05/2024 at 11:21 am, there were 59 small plastic vials of blank blood observed stored in "Metals 202 FRZ" freezer labeled as "Human Whole Blood 5E19043 Expires 03/31 /17." 2. During an interview on 12/05/2024 at 11:21 am, TP-16 provided the following information "UTAK B0734, received 05/19/2015, expiration date 03/31 /2029" from their laboratory information system. (UTAK was the manufacturer) Documentation from the manufacturer extending the expiration date was not provided. 3. Review of Determination of Metals in Whole Blood by (Inductively coupled plasma mass spectrometry) ICP-MS SOP 1001 stated, "The batch connects with the calibration curve standards at the sequence level. The IBL is the initial blood blank, the ICB is the blood blank check run immediately after the calibration curve, and the CCB is the aqueous blank run at the end of the batch ...Blank samples are run at least four times during a sequence, two blood blanks and two aqueous blanks: blood blank immediately before the first calibrator (IBL), blood blank immediately after the calibration curve (ICB), aqueous blank before the batch and an aqueous blank at the end of the batch (CCB)." 4. The laboratory provided a "Blank Blood Expiration Request" to the laboratory director for extending the expired blank blood to 03/31 /2029 and with "Blank data from Jan 1, 2019." Documentation from the manufacturer extending the expiration date was not provided. The laboratory failed to ensure blank blood was not used past the expiration date. III. Based on direct observation, media documents, and interview with staff, the laboratory failed to ensure microorganisms were not used past the manufacturer's expiration date and water stock expiration dates when used for media QC for 24 of 24 days in 2024. Findings included: 1. During a tour of the mycology department on 12/05/2024 at 2:37 pm, the following expired QC water stocks in glass vials with microorganisms were observed stored in a cabinet (random sampling): T. rubrum ATCC 28188, lot 444-86-4, expiration date 10/31/23 and the sterilized water it was in had a label with a made date of "Jan 24, 2022" and an expiration date of "July 24, 2022." T. interdigitale ATCC 9533 (no lot number or expiration date) in deionized water with a label that stated, made date of "3/11/24" and an expiration date of "9/11/24." T. tonsurans ATCC 28942 (no lot number), 10/31 /23 (was not labeled with the meaning of this date) in deionized water with a label that stated, made date of "6/1/23" and an expiration date of "12/1/23." 2. Review of the mycology media documents included the above microorganisms used to QC media, as follows: Sabouraud Dextrose Agar (Emmons)-Plates -T. interdigitale ATCC 9533 (water expiration date 9/11/24) inoculated in the media 10/17/24 and read for growth on 10/21/24. Sabouraud Dextrose Agar with Cycloheximide and Chloramhenicol - T. rubrum ATCC 28188 (expiration date 10/31/23, water expiration date 7/24/22) and T. tonsurans ATCC 28942 (water expiration date 12/1/23) used for media QC 1/9/24, 2 /23/24, 4/9/24, 6/4/24, 7/25/24, 8/15/24, 9/27/24 and 11/26/24. Potato Flake Agar - T. rubrum ATCC 28188 (expiration date 10/31/23, water expiration date 7/24/22) used for media QC 1/4/24, 3/5/24, 5/3/24, 6/14/24, 6/25,24, 6/28/24, 7/8/24, 8/15/24, 9/27 /24, and 11/26/24. Pablum Agar - T. rubrum ATCC 28188 (expiration date 10/31/23, water expiration date 7/24/22) used for media QC 2/15/24, 4/11/24, 5/7/24, 7/8/24, 8 /16/24, 10/9/24, and 12/5/24. V8 Agar - T. rubrum ATCC 28188 (expiration date 10 /31/23, water expiration date 7/24/22) used for media QC 2/15/24, 4/15/24, 5/7/24, 6/6

	/24, 8/7/24, 8/16/24, 9/27/24, and 11/26/24. The mycology media documents did not include expiration dates of the in-use ATCC microorganisms. The laboratory was unable to provide manufacturer's instructions for the ATCC microorganisms used for media QC. Refer to D3031. 3. During an interview on 12/05/2024 at 2:37 pm, general supervisors of the mycology department stated the ATCC microorganisms observed above were used until they were no longer viable. For T. interdigitale ATCC 9533, they were unable to provide the manufacturer's expiration date and for T. tonsurans ATCC 28942 they were unsure what the date 10/31/23 meant.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and laboratory microscopy maintenance policies and procedures record review on December 5, 2024 at 10:45 am, the laboratory failed to document daily microscopy maintenance procedures as established by the laboratory's microscopy maintenance protocol. Findings included: a. In the Parasitology Section, it was the practice of the laboratory to use a microscope to examine patient specimen parasitology slides. According to the laboratory's written protocol titled "Microscope - Lietz, Operation and Maintenance," daily maintenance is to be performed according to Section 9.0, Maintenance Procedures. b. Laboratory personnel confirmed on December 5, 2024 at 10:45 am that the laboratory maintained no documentation to indicate that daily microscopy maintenance had been performed pursuant to the laboratory's written protocol. c. According laboratory parasitology records, from January 1, 2024 to December 5, 2024, the laboratory reported approximately 16 patient parasitology results that would have involved the use of the microscope.
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 laboratory personnel interviews and RPR (Rapid Plasma Reagin) titer quality control record review on December 5, 2024 at 09:30 am, the laboratory, which used unassayed RPR titer quality control materials, failed to established statistical parameters for the unassayed control materials through concurrent testing of control materials having previously determined statistical parameters. Findings included: a. In the Syphilis Serology Section, it was the practice of the laboratory to titer patient specimens that had positive RPR screening test results. The laboratory used unassyaed positive RPR titer quality control materials to monitor patient RPR titer tests. b. Laboratory personnel confirmed on December 5, 2024 at 09:30 am that the laboratory maintained no documentation to indicate that the statistical parameters of the unassayed positive RPR titer quality control material used to monitor patient RPR titer testing had been established through concurrent testing of control materials having previously determined statistical paramters. c. According to laboratory RPR titer patient testing records, from August 5, 2024 to September 30, 2024, the laboratory performed and reported approximately 23 patient RPR titer test results.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and virology culture media quality control record review on December 5, 2024 at 11:45 am, the laboratory failed to check each batch of antibiotic media for its ability to inhibit specific organism growth before or concurrent with initial use. Findings included: a. In the Virology Section, it was the practice of the laboratory to included an in-house made penicillin/streptomycin antibiotic additive to their viral culture media. This additive was to enhance viral growth and inhibit bacterial growth. b. Laboratory personnel confirmed on December 5, 2024 at 11:45 am that the laboratory maintained no documentation to indicate that each batch of penicillin/streptomycin antibiotic additive had been checked, before or concurrent with initial use, for its ability to inhibit bacterial growth. c. According laboratory records, from December 1, 2024 to December 5, 2024, the laboratory performed and reported approximately 16 patient viral cultures to which the antibiotic additive had been added to the viral culture media.