Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0874568	12/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Multnomah County Health Department Sti Clinic	619 Nw 6th Avenue, 2nd Floor Sti Clinic, Portland, OR	

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
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 review of competency records and interview with the General Supervisor (GS)/Technical Supervisor (TS) the laboratory failed to perform annual competency for the GS/TS. Findings include: 1. The laboratory had one individual identified as the GS and the TS. 2. Review of competency records for 2021 and 2022 revealed there were no competency assessment performed for the GS and the TS. 3. Interview with the GS/TS on 12/14/2022 @ 10:20 AM confirmed these findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) results and interview with the Technical Supervisor (TS) the laboratory failed to follow the PT corrective action plan (CAP) procedure for failed or missed PT results. Finding includes: 1. Review of the API 1st Event 2022 Parasitology revealed the laboratory failed to identify correctly one (1) out of five (5) parasites. A CAP was written 03/22/2022, however, the CAP was not signed by the Testing Personnel (TP), the TS, and the Laboratory Director (LD). 2. The PT CAP procedure clearly states "

	the corrective action plan must be signed by the performing TP, the TS, and the LD". 3. Interview with the TS on 12/14/2022 @ 11:20 AM confirmed these findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) policies and procedures and interview with the Technical Supervisor (TS) the laboratory failed to document QA monitoring. Findings include: 1. Review of the QA Calendar Report 2022 revealed the laboratory lack documentation of QA monitoring for the following threshold. a) Critical laboratory results b) Turn around times c) Accuracy of manual entry of patients results from analyzer printout to EPIC Laboratory Information System (LIS). 2. The laboratory performed 15, 394 test for the year 2022. 3. Interview with the TS on 12/14/2022 @ 10:45 AM confirmed these findings.
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: Based on random observation of reagents and culture media from the bacteriology section of the laboratory and interview with the Testing Personnel (TP) and the Technical Supervisor (TS) the laboratory had expired reagents and culture media. Findings include: 1. The following reagents and culture media were expired at the time of survey. a) Desoxycholate dropper, lot# B0IB287M, expired 07/31/2021. b) Vogues Proskauer A dropper, lot# B0IB135M, expired 01/31/2022. c) Vogues Proskauer B dropper, lot# B0IB195M, expired 02/28/2022. d) Remel Campylobacter Blood Agar media, lot# 562354 expired 12/13/2022. 2. Review of bacteriology worksheet and workups from 07/31/2021 to 12/14/2022 revealed the following expired reagents and culture media were used beyond the expirations dates. a) Desoxycholate dropper, lot# B0IB287M, expired 07/31/2021. = Zero (0) b) Vogues Proskauer A dropper, lot# B0IB135M, expired 01/31/2022. = Sixteen (16) c) Vogues Proskauer B dropper, lot# B0IB195M, expired 02/28/2022. = One (1) d) Remel Campylobacter Blood Agar media, lot# 562354 expired 12/13/2022. = Zero (0) 3. The laboratory performed a total of 1,546 culture workups from 07/31/2021 to 12/14/2022. 4. Interview with the TP and the TS on 12/14/2022 @ 11:45 AM confirmed these findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document 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 observations of the laboratory equipments and interview with Technical Supervisor (TS) revealed the laboratory failed to perform 2022 preventive maintenance for equipments used in the laboratory. Findings include: 1. Urinalysis and Bacteriology microscopes last preventive maintenance were done 09/2021. The laboratory performed 372 urine microscopic examinations and 109 gram stains from 01/03/2022 to 12/14/2022. 2. The Axion Biosafety cabinet and Biosafety incubator last preventive maintenance were done on 06/01/2021 and 01/23/2021 respectively. The laboratory participates in the Laboratory Response Network for the State of Oregon and are given bioterrorism organisms to identify three (3) times per calendar year, every January, April and June. 3. Interview with the TS on 12/14/2022 @ 11:45 AM confirmed these findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observations of the laboratory timers and interview with Technical Supervisor (TS) revealed the laboratory failed to perform function checks for the timers used in the laboratory. Findings include: 1. VWR timers in the parasitology workbench and BBL Crystal workbench function checks were performed on 02/20 /2019 and 06/20/2013 respectively. 2. The laboratory performed a total of 681 test in parasitology and 1546 test in bacteriology from 01/03/2022 to 12/14/2022. 3. Interview with the TS on 12/14/2022 @ 11:45 AM confirmed these findings.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of Bacteriology Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to perform weekly QC for Gram Stain. Findings includes: 1. Review of the Patients Culture Logs from January 3, 2022 to December 14, 2022 revealed the laboratory performed a total of 109 gram stains. 2.

	There were no documentation that weekly Grams Stain QC were performed from January 3, 2022 to December 14, 2022 at the time of survey. 3. Interview with the TS on 12/14/2022 @ 11:45 AM confirmed these findings.