Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0651409	09/15/2022
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
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 2020 and 2021 personnel competency records and interview with the quality assurance officer (QA) #1, the laboratory failed to ensure 46 of 46 general supervisor (GS) and 13 of 13 technical supervisor (TS) competency assessments included specific position responsibilities listed in Subpart M. Findings include: 1. Review of competency records showed the laboratory failed to include documentation of evaluations of specific GS and TS responsibilities. 2. In an interview conducted on 09/13/2022 at approximately 2:30 P.M. QA #1 confirmed that competency assessments for GS and TS failed to include specific position responsibilities.
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 a review of the mycology procedure manual, media agar log documentation, and interview with testing personnel (TP) #6, the laboratory failed to follow the procedure for failed media quality control (QC) for one of the five set-ups reviewed

for cornmeal agar. Findings include: 1. Review of document MDH Public Health Laboratory Division DOC -282 Revision 8, Quality Control of Media and Reagents section C 5 states "If media and reagents do not perform as expected when QC'd, troubleshooting should be employed and if media/reagents are unsatisfactory after assessment, they should not be put into use. The manufacturer or Media Services should be notified accordingly. Enter any failure in the Corrective Action Log and notify the Unit Supervisor." 2. Review of the Cornmeal agar log, version 1/21/2021, states at the bottom of the page, "Evaluate and record results. Deviations from the expected (acceptable) results require documentation of corrective action taken." 3. Review of the Cornmeal agar log entries for five setups between 1/21/22 and 7/22/22 revealed one control failed to thrive on 6/10/2022 with no corrective action. QC was set up on 5/24/22 and a failure to thrive was entered on 6/10/2022 with no corrective action documented. 4. Interview with TP #6 confirmed on 9/14/22 at approximately 11:00 AM that they did not repeat the control or complete the corrective action report for the failure to thrive Trichophyton rubrum on 6/10/2022. B. Based on a review of DOC-1140, DPC-1080 policies, communication log, and interview with the technical supervisor (TS) #1, the laboratory failed to follow the procedure for clinical acceptance and rejection of specimens received in the laboratory processing area for seven of the fifteen specimens reviewed from 9/6/2022 through 9/12/2022. Findings: 1. Review of document MDH Public Health Laboratory Division DOC -1140, Revision 0, Clinical Specimen Acceptance and Rejections Policy indicated in section 5.4.1.1, "Verbal resolution should be documented on the laboratory report or communication log with the name of contact, date, and time of the call." 2. Review of document MDH Public Health Laboratory Division DOC-1080, Revision 2, Specimen Problem and Resolution in the Infectious Disease Laboratory indicated in section 9.3.1.4 "Direct the submitter to fax a corrected MDH Infectious Disease Submission Form or other signed traceable documentation (e.g. cover letter, letterhead), or information from an official electronic source such as the medical record or vital records." 3. Record review of the communication log from 9/6/2022 through 9/12 /2022 showed that seven of the fifteen entries were missing the contact name. 4. TS #1 confirmed on 9/14/2022 at approximately 10:00 AM that the names were not documented and there was no follow-up fax with a corrected submission form. C. Based on a review of DOC-451 policy, internal challenges, and interview with the quality assurance officer (QA) #1, the laboratory failed to follow the procedure for intra-laboratory challenges in 2021 and 2022 for 14 of 28 documents reviewed. Findings: 1. Review of document MDH Public Health Laboratory Division DOC-451, Revision 6, Proficiency Testing in the Clinical Laboratories section 3.1 defines "Blind test specimen: Specimens of known values or concentrations. These specimens can be intra-laboratory challenges previously tested patient specimens, analyte spiked into appropriate matrix material or external specimens sent for another laboratory for inter-laboratory challenge set exchange." 2. Review of records from Micro Unit Internal Challenges 2021, 2022 binder revealed no signed attestations or supervisory review available in hard copy for the following 14 of 28 reviewed Micro Unit Internal Challenges: a. Minnesota Antifungal Susceptibility PT #2 (2020) b. OXA PCR 11/18 /21 c. CACUL/CACOL 12/13/21 d. CPOCX 3/1/22 e. CPOCX 12/31/21 f. MALPCR 1/31/22 g. C Auris PCR 5/20/22 h. C Auris PCR 1/31/22 i. Fungal Accuprobe 6/25/21 j. Fungal Accuprobe 12/31/21 k. MAC PCR 11/29/21 l. MCR PCR 11/23/21 3. Interview with QA #1 on 9/15/2022 at 8:15 AM confirmed there was no evidence of attestations or supervisory reviews within Master Control for the 14 of 28 Micro Unit Internal Challenges. QA#1 also confirmed that the intra-laboratory challenges are to be treated the same way as all PT testing and require an Attestation that is signed by an appropriate designee. D. Based on a review of DOC-1170 policy, one of one patient test report, and an interview with QA #1, the laboratory failed to follow the

	procedure for correcting and revising a test report in Harvest. Findings: 1. Review of document MDH Public Health Laboratory Division DOC-1170, Revision 1 Correcting and Revising a Test Report in Harvest section 6.9.10.3 states, "Document the date /time and the person you contacted about the revised report." 2. Record review of patient test report A for Campylobacter Culture- Stool had no documentation of date /time and person contacted about the revised report. 3. Interview with QA #1 on 9/14 /2022 at 3:15 PM and 9/15/2022 at 9:15 AM confirmed no contact information for the revised result was documented for sample H22-08154 Campylobacter Culture- Stool as required by reviewed document DOC-1179 Correcting and Revising a Test Report in Harvest.
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: Observation of one of one diluted aliquot of Merck Measles, Mumps, and Rubella Virus Vaccine Live (M-M-R II) used for the positive control stored in the freezer, review of the manufacturer's storage instructions and laboratory procedure for M-M-R II, patient test volumes, and interview with the quality assurance officer (QA) #1, the laboratory failed to follow the manufacturer's instructions for storage of control material. Findings include: 1. Observation of the "Viro UC Baymax" freezer showed one bottle of diluted aliquot of M-M-R II used for the positive control being stored at -60 to -80 degrees Celsius (C). 2. Review of the Merck M-M-R II manufacturer's instructions stated, "to maintain potency M-M-R II must be stored between -50 and +8 degrees C. Reconstituted vaccine may be stored between 2 to 8 degrees C for up to 8 hours." 3. Review of the M-M-R II procedure showed to "store the diluted PXC aliquots at -85 to -65 degrees C. Expiration: 1 year from the date of aliquot preparation." 4. The laboratory performs approximately 145 measles, mumps, and rubella tests annually. 5. Interview with QA #1 on September 15, 2022, at 10:30 a.m. confirmed the laboratory failed to store the M-M-R II used as the positive control material per the manufacturer's instructions. Based on observation of the Newborn Screening (NBS) extraction and polymerase chain reaction (PCR) room, review of the manufacturer's operating conditions, and interview with the quality assurance officer (QA) #1, the laboratory failed to monitor the humidity to ensure proper operation of instrumentation. Findings: 1. Observation of the NBS molecular room used for extraction and PCR testing showed the laboratory failed to monitor and document the humidity. 2. Review of the Quant Studios manufacturer's instructions for proper operating conditions revealed "15-80% relative humidity (noncondensing)." 3. The laboratory performs approximately 267,600 NBS PCR tests annually. 4. Interview with the QA #1 confirmed the laboratory failed to monitor the humidity in the NBS extraction and PCR laboratory rooms.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the quality assurance officer (QA) #2, the laboratory failed to follow written quality control policies for two of eight months. Findings include: (1) On 09/15/22 at 09:15 am, QA #2 stated the following: (a) Gastrointestinal testing was performed using the Biomerieux BioFire FilmArray GI Panel; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the IQCP (DOC-548 dated as effective on 05/27/2020) stated the QCP (Quality Control Plan) required two levels of external QC (Quality Control) materials to be performed when greater than 30 days from last control run; (3) A review of QC records from May 2021 through December 2021 revealed the laboratory failed to follow the written QCP of performing quality control testing greater than 30 days from the last control run. Two levels of quality control testing had not been performed between: (a) 05/18/21 and 07 /08/21; (b) 10/29/21 and 12/10/21. (4) The findings were reviewed with QA #2 who confirmed on 09/15/22 at 09:45 am, the laboratory had not performed QC testing as required by the QCP.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality assurance officer (QA) #2 and general supervisor (GS) #10, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for: (a) Three of three Thermofisher ABI 7500 analyzers; (b) Two of two Thermofisher ABI 7500 analyzers; (c) Five of five Illumina MiSeq analyzers; (d) Two of two Qiagen QiaCube analyzers. Findings include: (1) On 09/14/22 at 10:00 am, QA #2 stated: (a) Influenza SARS-CoV-2 (FluSc2) testing was performed on three Thermofisher ABI 7500 (Chewie, Obi, Luke) analyzers; (b) Enterovirus (EVD68), Haemophilus influenzae, MMR (Measles, Mumps, Rubella), Measles Vaccine Strain (MeVa), Neisseria meningitidis, Streptococcus pneumoniae, Varicella-zoster Virus, and West Nile Virus testing using two Thermofisher ABI 7500 (Obi and Luke) analyzers; (c) Salmonella and Streptococcus pneumoniae testing was performed using five Illumina MiSeq (#1, #2, #3, #4, #5) analyzers; (d) Bordetella, Haemophilus influenzae, Streptococcus pneumoniae, Neisseria meningitidis, and MMR (Measles, Mumps, Rubella) using two

	Qiagen Qiacube (Grommitt and Wallace) analyzers. (2) A review of records from 02 /01/2021 through the third day of the survey (09/14/2021) revealed no indication the relationship between the testing performed using the different analyzers had been evaluated twice annually; (3) The records were reviewed with QA #2 and GS #10 who confirmed on 09/14/2022 at 02:55 pm a comparison between the analyzers could not be produced during the survey.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality assurance officer (QA) #2, the laboratory failed to have a policy for monitoring the effectiveness of their Individualized Quality Control Plan (IQCP) for commercially prepared media. Findings include: (1) On 09/15/22 at 09:10 am, QA #2 stated: (a) The laboratory used the following media: (i) Cefsulodin-Irgasan-Novobiocin (CIN) Agar, Hektoen Enteric Agar, Salmonella Shigella Agar, and Thiosulfate-citrate-bile salts-sucrose (TCBS) Agar plates to perform enteric testing; (ii) Lowenstein-Jensen Medium Slants and Mycobacteria Growth Indicator (MGIT) Tubes to perform Tuberculosis (TB) testing; (iv) Trypticase soya agar (TSA) II Sheep Blood Agar to perform Microbiology testing. (b) IQCP's had been developed for the commercially prepared media. (2) A review of the IQCP's (DOC-282 dated as approved on 01/04/16) revealed the Quality Assessment section of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) The findings were reviewed with QA #2 who confirmed on 09/15/22 at 09:35 am, the quality assessment plan did not include an evaluation of the QCP, and the frequency of the reviews.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of a hard copy DRAFT Quality Policy and interview with the quality assurance officer (QA) #1 and the laboratory director (LD), the LD failed to ensure that a quality assessment program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. Review of a hard copy of a DRAFT Quality Policy on 9/14/2022 at 8:45 AM showed that it was neither signed by the LD, under document control, nor fully implemented as described in the DRAFT document. 2. Interview with QA #1 and the LD on 9/14/2022 at 11:10 AM confirmed the DRAFT document did not constitute a written Quality System procedure and the DRAFT document had not been fully implemented.