Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643851	10/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Microbial Diseases Laboratory (Mdl)	850 Marina Bay Pkwy Ste E164, Richmond, CA	

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 performed October 29, 2024, through October 30, 2024 by federal CMS surveyors. Standard level deficiencies were cited as follows:
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: I. Based on direct observation, review of reagent package insert, room temperature logs, laboratory Individual Quality Contol Plan, and staff interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for storage of 77 of 77 boxes of the Xpert Carba-R reagent cartridges used with the GeneXpert instruments in the MTB/RIF Assay section (Room A-366) and Foodborne and Waterborne Diseases section (Room A-262). Findings included: 1. A reagent package insert for the Xpert Carba-R cartridges stated, "Store the Xpert Carba-R Assay cartridges at 2-28 degrees Celsius." 2. An Individualized Quality Control Plan (IQCP) for Quality Control of GeneXpert Carba-R Assay, Version 091319, page 2 stated, "Store the Xpert Carba-R Assay cartridges at 2-28 degrees Celsius." 3. An Individualized Quality Control Plan (IQCP) for Xpert MTB/RIF Assay stated, "Store Xpert MTB/RIF Assay cartridges and reagents at 2-28 degrees Celsius. 4. Review of Room Temperature logs revealed the following room temperature ranges: a. Foodborne and Waterborne Diseases section, room A-262: Acceptable Temperature Range, 15 to 30 degrees Celsius. b. MTB/RIF Assay section, room A-366: Acceptable

	Temperature Range, 15 degrees Celsius to 30 degrees Celsius. 5. An observation during a tour of laboratory rooms A-262 and A-366 on 10/30/2024 at 2:00 pm, revealed the following: a. Room A-262: 72 boxes of Xpert Carba-R reagent cartridges stored on shelves. b. Room A-266: 5 boxes of Xpert Carba-R reagent cartridges stored in cupboard under the counter. 6. An interview on 10/30/2024 at 10:50 am with the Laboratory Director confirmed that the laboratory failed to define specified temperature requirements for the storage of Xpert Carba-R reagent cartridges on the temperature logs for room A-262 and A-366. 46043 II. Based on direct observation, review of manufacturer's instructions, lack of environmental logs, and confirmed in staff interview, the laboratory failed to ensure the manufacturer's specified conditions for storage of media preparation reagents for ten of ten months in 2024. Findings included: 1. During a tour of the laboratory on 10/30/2024 at 09:50 am in Room B101, dry reagents used for bacterial media preparation were observed stored in cabinets along two walls of the area. 2. A random review revealed the following reagents stored in Room B101 and the manufacturer's storage temperature requirements stated on the reagent label: Becton Dickinson Rhamnose; required storage temperture 2C - 25C HIMedia Lysine Decarboxylase Broth; required storage temperture 10C - 30C HIMedia DNase Test Agar Base; required storage temperture 10C - 30C Becton Dickinson Difco Gelatin; required storage temperture 2C - 25C Becton Dickinson Difco Plate Count Agar; required storage temperture 2C - 25C Becton Dickinson Difco Potato Dextrose Agar; required storage temperture 2C - 25C 3. The laboratory was asked to provide documentation of room temperature monitoring for Room B101 for 2024. No documentation was provided. 4. In an interview on 10/30/2024 at 9:55 am, the Laboratory Director confirmed that the room temperature was not monitored.
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: Based on direct observation, review of manufacturer's instructions, and confirmed in staff interview, the laboratory failed to document the manufacturer's specified revised expiration date for nine of nine vials of reconstituted Bacterial Test Standard (BTS) reagent. Findings included: 1. During a tour of the laboratory on 10/30/2024 at 10:30 am, nine vials of reconstituted and aliquoted BTS reagent were observed. The vials were stored in a larger container labeled with "Lot number 6030223009, Expiration date 05/31/2025". 2. The manufacturer's instructions titled "US IVD Bacterial Test Standard" (Document Number 5030609 Revision K April 2023) stated. " ...3.3 Storage after dissolution and aliquoting ...Aliquoted US IVD BTS solution can be stored frozen for up to 5 months at -18C/0F or below ..." 3. In an interview on 10/30 /2024 at 10:50 am, Mycology Technical Supervisor stated that the BTS reagent was reconstituted on 10/14/2024. After review of the manufacturer's instructions, the Laboratory Director confirmed that the laboratory failed to document the revised expiration date of five months from the date of preparation.
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:
I. Based on review of the standard operating procedure, the manufacture's operator manual, instrument maintenance records, test reports and staff interview, the laboratory failed to document daily maintenance procedures for the GeneXpert MTB /RIF Assay instrument (Serial Number: 8001139) from January 12, 2024, to October 28, 2024. Findings included: 1. A GeneXpert MTB/RIF Assay Standard Operating Procedure (6/16/2022), SOP Number: MDL-MMPDS-MPI SOP-004, Version 5.0 that stated, "Daily, weekly, and yearly preventative maintenance (PM) actions must be performed according to the manufacturer guidelines, to ensure optimal system functionality and to avoid GX failures." 2. A manufactures GeneXpert Dx System, Operator Manual, Software Version 5.3, that described the daily maintenance as "Cleaning the work area daily using good laboratory practices to avoid contamination of specimens or reagents", "Check that all module doors are closed daily to avoid contamination of the modules", and "Discard used cartridges from the GeneXpert Dx system modules and on the surrounding work surfaces." 3. A review of specimen test reports and maintenance records for the GeneXpert instrument, serial number 801139, revealed no daily maintenance procedures were documented for 8 out of 8 days (11 total specimens tested). Test Report Dates and Sample IDs: a. 01/12/24 Sample ID: M24N000047 b. 02/26/24 Sample ID: M24N000226 c. 03/15/24 Sample ID: M24N000300 Sample ID: M24N000305 d. 06/11/24 Sample ID: M24N000505_MTBR-01 Sample ID: M24N000505_MTBR-02 Sample ID: M24N000506_MTBR-03 e. 07/15/24 Sample ID: M24N000562 f. 09/09/24 Sample ID: M24N000681 g. 09/13/24 Sample ID: M24N000703_20240913 h. 10/28/24 Sample ID: M24N000799_10282024 4. An interview with the Technical Supervisor of the MTB/RIF Assay section on 10/29/2024 at 12:45 pm confirmed that daily maintenance procedures were not completed for the GeneXpert instrument for the 8 identified test days with 11 total specimens tested from January 12, 2024, to October 28, 2024. 46043 II. Based on direct observation, review of manufacturer's instructions, laboratory policy, Magna Pure 24 records (03/06/2024 - 09/11/2024) and confirmed in staff interview, the laboratory failed to ensure daily and weekly maintenance requirements were performed and documented according to manufacturer's instructions for six of six months. Findings included: 1. During a tour of the laboratory on 10/30/2024 at 09:30 am, one Magna Pure 24 automated clinical nucleic acid extraction system (Serial Number 2067) was observed. 2. The manufacturer's instructions for the Magna Pure 24 System (OS-010974-01) stated, " ...Overview of Cleaning ...Outside of the instrument Weekly; Inside of the Instrument Weekly; Reagent Rack, Sample Rack, Sample tube adapters Weekly; Processing station Adapters Weekly ...Liquid Waste inserts Daily; Tip waste container Daily; Reagent Tip Park Daily; Output adapters, Post elution adapter, Downholder frame Weekly ..." 3. The procedure titled; "Magna Pure 24 Instrument Maintenance Procedures" (Document Number MDL-MMPDS-PRS-SOP-003) stated the following: " ...5. Post-run (Daily) Maintenance 5.2 Dispose all liquid waste ...5.2.1 Clean the liquid waste insert ...5.2.2 Clean the tip waste ...5.2.3 Clean the reagent tip park ...6. Weekly Maintenance ...6.1.1 If in use, clean the reagent rack, sample racks, and sample tube adapters ...6.1.2 Clean the processing station adapter ...6.1.3 Clean the output adapter ...6.1.4 Clean the outside and inside of the instrument ..." Included with the laboratory

	procedure was the "Magna Pure 24 System Maintenance Log". 4. Review of the laboratory record titled, "Magna Pure 24 User Log" from 03/06/2024 through 09/11 /2024 revealed the laboratory failed to document performance of the specific requirements for daily and weekly maintenance. 5. In an interview on 10/30/2024 at 1: 10 pm, the Laboratory Director was asked to provide Magna Pure 24 weekly and monthly documentation as specified in the manufacturer's instructions and in the laboratory procedure. No documentation was provided. This confirmed the findings.
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 direct observation, review of the Individual Quality Control Plan (IQCP) specimen test worksheets, quality control records and staff interview, the laboratory failed to follow their IQCP quality control procedures during the months of patient specimen testing for two of three Cepheid GeneXpert Carba-R Assay instruments from March 5, 2024, to July 2, 2024. Findings included: 1. An IQCP for Quality Control of GeneXpert Carba-R Assay, Version 091319, Page 14 stated "External QC must be performed monthly." 2. An observation during a tour of the Foodborne and Waterborne Diseases section on 10/30/2024 at 9:30 am revealed 3 individual Cepheid GeneXpert test systems in use: Cepheid GeneXpert (Serial Number 110019063), Cepheid GeneXpert System 2 (Serial Number 819594), and Cepheid GeneXpert System 4 (Serial Number 815607). 3. A review of patient specimen test worksheets and external quality control records revealed external quality control procedures were not completed for 6 of 6 specimen test runs (27 total specimens) on the GeneXpert Instruments, ID 815607 and Instrument ID 819594. Test Dates and Sample ID's: a. 03 /05/24 Sample IDs: M24R000220, M24R000234, M24R000269, M24R000271, M24R000274 b. 03/12/24 Sample IDs: M24R000255, M24R000293, M24R000298, M24R000255 c. 03/19/24 Sample IDs: M24R000300, M24R000302, M24R000303, M24R000304, M24R000305, M24R000310 d. 03/26/24 Sample IDs: M24R000319, M24R000330, M24R000331, M24R000333, M24R000335 e. 03/27/24 Sample ID: M24R000205 f. 07/02/24 Sample IDs: M24R000733, M24R000737, M24R000741, M24R000746, M24R000751, M24R000756 4. An interview with the Laboratory Director on 10/30/24 at 3:15 PM confirmed there were no external QC procedures completed for 6 of 6 patient specimen test runs using instrument ID 815607 and instrument ID 819594.
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 review of laboratory policy, media quality control (QC) records, and confirmed in staff interview, the laboratory failed to perform quality control checks on each batch of media to include its ability to support growth for six of six lot numbers of Blood microbiological media slants. Finding included: 1. The laboratory policy titled, "Receipt and Quality Control Testing of Media and Reagents" (Document number MDL-BDS-QA-010) stated, " ...1.6.8 Test the medium or reagent for performance and sterility ... 2. Review of the laboratory's media quality control record for Blood Slants (03/26/2024 through 10/16/2024) revealed the laboratory failed to perform quality control check to ensure the media's ability to support growth (performance) for the following six lot numbers: Lot numbers 777599, 777585, 777571, 777564, 777557, and 777550 The record documented sterility checks only for each lot number. 3. In an interview on 10/30/2024 at 1:50 pm, the Laboratory Director confirmed the findings.
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 direct observation, review of correlation verification worksheets, and staff interview, the laboratory failed to evaluate and define, twice per year, the relationship between test results among the three individual Cepheid GeneXpert instruments used for the same analyte testing for eight of eight months (12/08/2023 to 07/02/2024). Findings included: 1. An observation during a tour of the Foodborne and Waterborne Diseases laboratory, room A-262, identified three individual GeneXpert instruments used for qualitative testing of gene sequences, blaKPC, blaNDM, blaVIM, blaOXA-48 and blaIMP. The three instruments are as follows: a. Cepheid GeneXpert Serial number: 110019063 b. Cepheid GeneXpert System 2, Serial Number: 819594 c. Cepheid GeneXpert System 4, Serial Number: 815607 2. A review of the laboratory's GeneXpert CARBA-R Correlation Verification Worksheet revealed the laboratory failed to evaluate and compare all three individual Cepheid GeneXpert instruments. Instead, the laboratory compared two instrument results, serial number 110019063 and serial number 815607/819594 (two instruments combined). 3. An interview on 10 /30/2024 at 1:30 pm with the Laboratory Director confirmed the laboratory failed to evaluate and define, twice per year, the relationship between test results among the three Cepheid GeneXpert instruments in use.