| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 03D0057138 | 04/20/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Maricopa County Public Health Lab | 1645 East Roosevelt Street, Phoenix, AZ | |

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 |
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| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Control (QC) documentation and interview with the technical consultant, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the subspecialty of Mycobacteriology. Findings include: 1. The laboratory began testing for the MTB/RIF assay on the Cepheid GeneXpert analyzer in May 2020, under the subspecialty of Mycobacteriology. The laboratory's approximate annual test volume for this test is 458. 2. On the date of the survey, April 20, 2023, review of the laboratory's quality control policy for the Cepheid GeneXpert MTB/RIF assay indicated external controls will be performed once per month and for each new lot /batch/shipment of GeneXpert MTB/RIF cartridges. 3. No daily QC documentation was provided for review during the survey for the Cepheid GeneXpert MTB/RIF assay, to indicate the laboratory performed external control material of different concentrations each day of patient testing as required. The laboratory had not established an Individualized Quality Control Plan (IQCP) for this test at the time of the survey. 4. The number of patients tested from May 2020 through 4/20/2023 could not be determined at the time of the survey. 5. The technical consultant interviewed on 4/20/23 at 2:25pm confirmed that the laboratory did not perform and document |

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| | external controls each day of patient testing as required and confirmed the laboratory did not have an approved IQCP in place for this test at the time of the survey. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality control records for the MTB/RIF assay performed on the Cepheid GeneXpert analyzer, the technical consultant failed to establish a quality control program appropriate for the testing performed and failed to establish the parameters for acceptable levels of analytic performance to ensure that these levels are maintained throughout the entire testing process. See D5445 for findings. |