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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 06D0672142 | (X3) Date Survey Completed 01/22/2026 |
| Name of Provider or Supplier Health Center At Auraria | Street Address, City, State 955 Lawrence St, Denver, CO | |
| 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 | Based on an on-site recertification survey conducted on January 22, 2026, deficiencies were cited for Health Center at Auraria in Denver, Colorado. |
| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory Cepheid GeneXpert CT/NG control documents, an interview with the testing personnel 7 during the survey, and a review of the laboratory IQCP documents, the laboratory failed to perform control procedures for Cepheid GeneXpert CT/NG every day of testing and failed to develop a complete written IQCP. Findings include: 1. A review of the laboratory control logs on January 22, 2026, revealed that the laboratory performs control procedures for Cepheid GeneXpert CT/NG on every new lot received. 2. An interview with the testing personnel 7 on January 22, 2026, at approximately 11:30 AM confirmed that the laboratory performed control procedures on every new lot of cartridges received. 3. A review of the Cepheid verification documents on January 22, 2026, revealed that the laboratory failed to develop a complete written IQCP for the Cepheid GeneXpert CT</p> |

/NG test system. The laboratory did not have a written Risk Assessment, Quality Assessment, or a Quality Control Plan associated with the IQCP. Additionally, the IQCP did not have approval from the laboratory director.