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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 06D0672142 | (X3) Date Survey Completed 03/06/2023 |
| 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 |
|---------------------------|--|
| D2015 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the Laboratory Director, the laboratory failed to document the handling and each step in the testing and reporting of microscopic urinalysis results for The American Academy of Family Physicians (AAFP) proficiency testing in all events of 2021 and 2022. Findings include: 1. Record review of proficiency testing documentation from AAFP revealed the laboratory failed to document who performed the testing and reporting, as well as the date of test performance for all events in 2021 and 2022. 2. An interview with the laboratory director on March 6, 2023, at 2:00 p.m. confirmed the lab failed to document who performed the proficiency testing, reporting and the date testing was performed for microscopic urinalysis in all events in 2021 and 2022.</p> |
| D6018 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p> |

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the Laboratory Director, the laboratory failed to document corrective actions for the American Academy of Family Physicians (AAFP) proficiency testing in microscopic urinalysis for events A and C in 2021. The laboratory performed approximately 100 microscopic urinalysis per year. Findings include: 1. A record review of proficiency testing documentation from AAFP revealed the laboratory failed to document corrective actions for unacceptable microscopic urinalysis performed during 2021 events A and C. 2. An interview with Laboratory Director on March 6, 2023, at 2:00 p.m. confirmed the laboratory failed to document corrective actions for proficiency testing in events A and C in 2021.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the Laboratory Director, the laboratory failed to document three out of four testing personnel training prior to patient testing for microscopic urinalysis since the last survey on 10/16/2020. The laboratory performed approximately 100 microscopic urinalysis per year. Finding include: 1. A record review of personnel documents revealed the laboratory failed to document initial training for three out of four testing personnel for microscopic urinalysis. 2. An interview with the laboratory director on March 6, 2023, at 2:15 p.m. confirmed the laboratory failed to document personnel training for microscopic analysis.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the Laboratory Director, the

laboratory failed to evaluate and document competency assessment at least twice annually for three out of four testing personnel for microscopic urinalysis since the last survey on 10/16/2020. Findings include: 1. A record review of personnel documents revealed the laboratory failed to perform competency assessment for three out of four testing personnel during the first year of hire for microscopic urinalysis. 2. An interview with the laboratory director on March 6, 2023, at 3:00 p.m. confirmed failure to perform competency assessment at least twice annually for three out of four testing personnel.