

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1001265	(X3) Date Survey Completed 03/25/2019
Name of Provider or Supplier Winding Cross Urgent Care	Street Address, City, State 5930 Frederick Crossing Lane, Frederick, MD	
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 review of the proficiency testing (PT) records and interview with the testing person, the laboratory did not ensure that the testing personnel documented the PT results in the same manner as patient specimens and that the attestation worksheets were saved. Findings: 1. The chemistry, hematology and microbiology PT records for 2017 and 2018 were reviewed. 2. The PT records for the first microbiology event in 2017 showed that the testing person failed to document the microbiology PT testing results on the patient log along with the patient test results as required by the procedure. 3. Review of the PT records for microbiology in 2018 showed that the laboratory failed to maintain the attestation worksheet for the first event in 2018. 4. During the survey on 03/06/2019 at 12:00 PM the testing person confirmed that the microbiology testing results for the first PT event of 2017 were not documented on the patient log along with the patient test results as required and the attestation worksheet from the first microbiology event in 2018 was not saved.</p>
D6016	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

The laboratory director did not ensure that the proficiency testing samples were tested as required. Cross refer to D2015 for details.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

I. Based on review of the quality assessment (QA) records and interview with the testing person, the laboratory director (LD) failed to ensure that QA records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. Findings: 1. The "Monthly Quality Assurance Checklist" worksheets for 2017 and 2018 were reviewed. 2. Review of the "Monthly Quality Assurance Checklist" worksheet for October 2017 showed that the LD did not sign the worksheet until 11/29/17; the worksheet for November 2017 was signed by the LD but there was no date to indicate when the review was performed; and the worksheets from January through March 2018 were not signed by the LD until 04/18/18. 3. During the exit interview on 03/06/19 at 12:00 PM the testing person confirmed that the "Monthly Quality Assurance Checklist" was not being reviewed in a timely manner. II. Based on review of the quality control (QC) records and interview with the testing person, the laboratory director (LD) failed to ensure that "Monthly QC Summary Report" was being reviewed by the qualified, bachelor's degree and 2 years documented experience, technical consultant. Findings: 1. The "Monthly QC Summary Report" forms from 2017 and 2018 were reviewed. The documentation includes and evaluation of the Levy-Jennings charts looking for systemic trends and shifts. The testing person confirmed that she performed the review and presented the worksheet to the LD for review. The testing person was not qualified with a bachelor's degree and 2 years documented experience as required by the regulations. 2. The "Monthly QC Summary Report" worksheet lists the actual date of the review. The worksheet does not identify the time period that was reviewed. 3. During the exit interview on 03/06/19 at 12:00 PM the testing person confirmed that the QC data on the Levy-Jennings graphs in the computer was not being reviewed by the LD and being documented on the "Monthly QC Summary Report" and the worksheet did not identify the time period that was reviewed. III. Based on review of the quality control (QC) records and interview with the testing person, the laboratory director (LD) failed

to ensure that "Monthly QC Summary Report" was updated to include the correct name of the laboratory. Findings: 1. The "Monthly QC Summary Report" worksheets for 2017 and 2018 were reviewed. 2. The "Monthly QC Summary Report" worksheets currently in use list the name of the laboratory as "Advanced Urgent Care of Frederick." The Name of the laboratory being surveyed is "Winding Cross Urgent Care." 3. During the exit interview on 03/06/19 at 12:00 PM the testing person confirmed that the "Monthly QC Summary Report" did not list the current name of the laboratory.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview with the testing personnel, the laboratory director acting as the technical consultant failed to ensure scientific oversight of the laboratory (D6036). Note: This deficiency was cited during the previous recertification survey on 01/25/2017.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 01/25/2017 for not ensuring that quality control (QC) and quality assessment (QA) records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. The plan of correction stated that the QC would be reviewed and the QA would be documented as required. Based on review of the quality control (QC) and quality assessment (QA) records and interview with the testing person, the laboratory director (LD) acting as the technical consultant (TC) failed to ensure that QC and QA records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. Findings: 1. The LD acting as the TC failed to ensure that QA records were reviewed in a timely manner. Cross refer to Tag D6022 #1. 2. The LD acting as the TC failed to ensure that QC records were reviewed by the LD. Cross refer to Tag D6022 #2. 3. The "Monthly Quality Assurance Checklist" worksheets for 2017 and 2018 were reviewed. 4. Review of the "Monthly Quality Assurance Checklist" worksheet for October 2017 showed that the LD did not sign the worksheet until 11/29/17; the worksheet for November 2017 was signed by the LD but there was no date to indicate when the review was performed; and the worksheets from January through March 2018 were not signed by the LD until 04/18/18. 5. Review of the credentials showed that the testing person documenting the reviews on the "Monthly QC Summary Report" did not meet the minimum educational requirement for technical consultant, e.g., a bachelor's degree and 2 years documented experience. 6 During the telephone exit interview on 03/25/19 at 2:20 PM the laboratory director confirmed that the "Monthly

Quality Assurance Checklist" was not being reviewed in a timely manner and that the "Monthly QC Summary Report" was being documented by an unqualified technical consultant.