

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2043987	(X3) Date Survey Completed 11/02/2021
Name of Provider or Supplier First Choice Urgent Care	Street Address, City, State 472 West Poplar Ave, Suite 201, Collierville, TN	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory procedure manual and staff interview, the laboratory failed to test proficiency testing samples the same number of times it would a patient sample in 2019, 2020 and 2021 (five of thirty proficiency testing samples). The findings include: 1. Review of proficiency testing records revealed proficiency testing samples were performed in duplicate for the following: 2019 event three--Sample number HSY-11 2020 event two--Sample number HSY-10 2020 event three--Sample number HSY-13 2021 event one--Sample number HSY-04 2021 event two--Sample number HSY-06 No flags were present on any of the samples that were repeated. 2. Review of the laboratory's procedure titled "PATIENT CBC ANALYSIS-MEDONIC-M SERIES" revealed that patient samples are repeated if flags are present. 3. Interview with the technical consultant on 11/02/2021 at approximately 3pm confirmed the laboratory did not test proficiency testing samples in the same manner as patient samples in 2019, 2020 and 2021.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p>

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and staff interview, testing personnel failed to sign attestation statements for two of seven proficiency testing events. The findings include: 1. Review of the laboratory's proficiency testing records revealed the following attestation statements were not signed by testing personnel: 2019 event two and 2019 event three. 2. Interview with technical consultant on 11/02/2021 at approximately 3pm confirmed testing personnel failed to sign attestation statements for two of seven proficiency testing events.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(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 review of laboratory records and staff interview, the laboratory director failed to ensure proficiency testing reports were reviewed for 2019 event three (one of seven proficiency testing events). The findings include: 1. Review of the laboratory's proficiency testing records revealed no review of the performance evaluation report for 2019 event three. 2. Interview with the technical consultant on 11/2/2021 at approximately 3pm confirmed the laboratory director failed to ensure the proficiency testing performance evaluation was reviewed for 2019 event three.

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 review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory records and staff interview, the laboratory director failed to ensure proof of highest level of education for five of nine testing who perform patient Complete Blood Count (CBC) testing. The findings

include 1. Review of the form CMS-209 revealed nine personnel who perform patient testing for CBC. 2. Review of testing personnel records revealed no documentation of the highest level of education for testing personnel numbers two, four, five, eight and nine. 3. Interview with the technical consultant on 11/02/2021 at approximately 3pm confirmed the lab director failed to ensure testing personnel have proof of highest level of education prior to performing patient testing (five of nine testing personnel).