

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1052514	(X3) Date Survey Completed 07/30/2021
Name of Provider or Supplier Sherwood Urgent Care-Searcy,Ar	Street Address, City, State 610 Shepherd Way, Searcy, AR	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the 2020 Daily Maintenance Log for the Medonics M Series Hematology Analyzer, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform daily maintenance as specified by the manufacturer. As evidence by: A. A review of the Daily Maintenance Log for the Medonic M Series Hematology Analyzer revealed the following required daily maintenance: Check reagent levels, check printer paper, background count, clean probes with alcohol and perform quality controls. B. A review of the Medonic Hematology daily maintenance log revealed daily maintenance was not documented on three of thirty-one days in October 2020 (one of twelve months reviewed). C. A review of the Medonic Hematology daily maintenance log revealed daily maintenance was not documented on eleven of thirty-one days in November 2020 (two of twelve months reviewed). D. In an interview on 7/30/2021 at 10:30, the technical consultant confirmed the lack of documented daily maintenance for the Medonic M Series Hematology Analyzer.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document</p>

all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

. Through review of Technical Consultant's quality assurance reports, Medonics Hematology quality control and patient results, lack of documentation and interviews with staff, it was determined that the laboratory failed to employ effective corrective action to prevent recurrence of using quality control material after the expiration date. Survey finding follow: A. A review of the technical consultant's quality assurance report for October 2020 revealed the technical consultant noted the laboratory used Hematology quality control material lot #'s 2200621, 2200621, and 2200623 past the expiration date of October 27, 2020. Corrective action cited testing personnel is no longer employed. B. A review of the Medonic Hematology Summary report revealed on October 28th and October 29th the laboratory analyzed and resulted a total of nine patients for Complete Blood Counts (CBC). C. A review of the technical Consultant report revealed "A Quality Assurance report was completed for the patients test." D. The surveyor requested the Technical Consultant's Quality Assurance report. None was provided. E. In an interview on 7/30/21 at 1300 the technical consultant confirmed the laboratory reported patient CBC results on expired Quality Control and confirmed that the corrective action employed was not effective in preventing recurrence.