

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2169553	(X3) Date Survey Completed 09/22/2020
Name of Provider or Supplier Mohammed Ogaily, Md	Street Address, City, State 19727 Allen Rd, Suite 12, Brownstown, MI	
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: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform and document daily shutdown maintenance for the Beckman Coulter DxH 520 hematology analyzer for 27 days of 11 months reviewed. Findings include: 1. A review of the laboratory's "DxH Instrument Maintenance Checklist" revealed the following days when daily shutdown maintenance was not documented: a. 10/10/19 b. 10/11/19 c. 10/14/19 d. 10/15/19 e. 10/21/19 f. 11/4/19 g. 11/6/19 h. 11/12/19 i. 11/15/19 j. 11/26/19 k. 12/13/19 l. 12/19/19 m. 12/23/19 n. 12/27/19 o. 2/19/20 p. 2/26/20 q. 3/20/20 r. 4/21/20 s. 4/30/20 t. 5/13/20 u. 5/29/20 v. 6/10/20 w. 6/23/20 x. 7/2/20 y. 7/31/20 z. 8/12/20 aa. 8/18/20 2. A review of the laboratory's established "Performing Shutdown" procedure revealed a section stating, "Beckman Coulter recommends a shutdown once every 24 hours. Shutdown removes diluent and replaces it with cleaner for 30 minutes. It also checks the expiration date and volume of the reagents." 3. A review of the laboratory's quality assurance documentation revealed a lack of documentation of corrective action for the days daily shutdown maintenance was not recorded for the Beckman Coulter DxH 520 hematology analyzer. 4. An interview on 9/22/20 at 12:30 pm with the TC confirmed the laboratory did not document daily shutdown maintenance for the Beckman Coulter DxH 520 hematology analyzer.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p>

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform and document background counts of the Beckman Coulter DxH 520 hematology analyzer for 5 (7/2/20, 6/25/20, 5/19/20, 4/1/20 and 3/5/20) of 12 patient testing days reviewed. Findings include: 1. The surveyor requested background counts for the Beckman Coulter DxH hematology analyzer on 9/22/20 at 11:20 am and they were not made available for the following dates patient testing was performed: a. 7/2/20 b. 6/25/20 c. 5/19/20 d. 4/1/20 e. 3/5/20 2. A review of the laboratory's established "Daily Checks" procedure revealed a section stating, "Running Daily Checks ensures that the instrument is operational and ready to process samples. Daily Checks must be run every 24 hours either after shutdown or at the beginning of the day before specimen processing. Daily Checks includes background counts." 3. An interview on 9/22/20 at 12:30 pm with the TC confirmed the laboratory did not have documentation of performing background counts on the Beckman Coulter DxH 520 hematology analyzer.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to include the address of the laboratory location where hematology testing was performed for 11 (October 2019 to September 2020) of 11 months reviewed. Findings include: 1. A review of records revealed a lack of address on the hematology test reports for patients tested on the following days: a. 10/18/19 b. 11/22/19 c. 12/23/19 d. 1/16/20 e. 2/3/20 f. 3/5/20 g. 4/1/20 h. 5/19/20 i. 6/25/20 j. 7/2/20 k. 8/17/20 l. 9/3/20 2. An interview on 9/22/20 at 12:07 pm with TP1 confirmed the laboratory did not include the address of the laboratory on patient test reports.