

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371252	(X3) Date Survey Completed 03/09/2020
Name of Provider or Supplier Donald M Birch, Md, Pc	Street Address, City, State 330 W Tienken Suite C, Rochester Hills, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant (TC) #1, the laboratory failed to monitor and document the room temperature, humidity, and the refrigerator temperature each day of patient testing for 7 months (July 2018 to January 2019) of 2 years reviewed. Findings include: 1. Review of the "Temperature/Humidity Record" log revealed the laboratory did not record the room temperature, humidity, and refrigerator temperature every day of patient testing as follows: a. room temperature, humidity, and refrigerator in 2018 i. July - 12, 19, 23, 26, and 30 ii. August -6, 9, 13, 23, and 27 iii. September - 20, 24, and 27 iv. October - 22, 25, and 29 v. November - 8, 12, and 29 vi. December - 6, 10, 13, 17, and 20 b. refrigerator in 2018 i. August - 2, and 16 ii. October - 1, 4, 8, 11, 15, and 19 iii. November - 1, 5, and 26 iv. December - 3 c. refrigerator - 2019 i. January - 7, 10, 14, 21, and 31 2. During the interview on 3/09/2020 at 10:21 am, TC1 confirmed the laboratory did not monitor and document the room temperature, humidity and the refrigerator temperatures every day of patient testing.</p>
D5803	<p>TEST REPORT CFR(s): 493.1291(b)</p>

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

. Based on document review and interview with Technical Consultant (TC) #1, the laboratory failed to have the final hematology report maintained as part of the patient's electronic medial record (EMR) for 1 (#9) of 11 patient charts audited. Findings include: 1. Record review revealed the final hematology complete blood cell count (CBC) report was not maintained as part of the patient's EMR for patient #9 tested on 7/05/2018. 2. On 3/09/2020 at approximately 11:15 am when queried, the office manager was not able to provide the surveyor the final report requested. 3. During the interview on 3/09/2020 at approximately 11:15 am, TC1 confirmed the final CBC report was not part of the patient's EMR report.

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 Technical Consultant (TC) #1, the laboratory failed to include the patient's scanned final hematology report into the electronic medical records (EMR) for 3 (#1, #4, and #5) of 11 patient charts audited. Findings include: 1. Record review revealed for 3 (#1, #4, and #5) of 11 patient charts audited the final hematology complete blood cell (CBC) report was not scanned into the patient's EMR file. 2. On 3/09/2020 at approximately 11:30 am when queried, the office manager was not able to locate the final patient report in the EMR system. 3. During the interview on 3/09/2020 at approximately 11:30 am, TC#1 confirmed the final CBC reports were not scanned into the EMR system.

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(b)(c)

(b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Technical Consultant (TC) #1, the laboratory failed to follow policy for conducting patient chart reviews for 2 (2018 and 2019) of 2 years reviewed. Findings include: 1. Review of the "Test Report

Monitoring Policy" revealed five patient charts are to be reviewed twice a year for the following: a. "The patient's name and a unique identifier." b. "The name and address of the laboratory location where the test was performed." c. "The date the sample was drawn and the date the test was performed." d. "The test performed." e. "The test results with units of measurement." f. "The initials of the person performing the test." g. "Printout has been scanned or manually enter into the Electronic Medical Record (EMR)." 2. Record review of the Quality Assurance (QA) checklist revealed the laboratory did not review the patient charts 2 times a years as follow: a. 5/no date given/2018 b. 8/26/2019 3. During the interview on 3/09/2020 at 9:34 am, TC1 confirmed the policy was not followed for patient chart reviews.