

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0367679	(X3) Date Survey Completed 12/13/2022
Name of Provider or Supplier Downriver Internist Pc	Street Address, City, State 21801 Goddard Rd, Taylor, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</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 include the units of measurement for the hematology and chemistry testing in the electronic medical records (EMR) system for nine of nine patient charts audited. Findings include: 1. A record review revealed for nine of nine patient charts audited, the final testing results in the EMR did not include the units of measurement for the complete blood count (CBC- excluding the hemoglobin and hematocrit), thyroid stimulating hormone (TSH), and the lipid panel (cholesterol, triglycerides, high density lipoprotein, and low density lipoprotein [calculation]), as follows: a. 404 tested on 6/25/2021 - CBC TSH, and lipid panel b. 3987 tested on 8/22/2021 - CBC, TSH, and lipid panel c. 2367 tested on 10/08/2021 - CBC and lipid panel d. repeat testing for JL on 12/06/2021 - TSH e. 2303 tested on 2/08/2022 - CBC and lipid panel f. 3440 tested on 4/22/2022 - lipid panel g. 360 tested on 6/17/2022 - TSH h. 5578 tested on 8/05/2022 - CBC, TSH, and lipid panel i. 194 tested on 10/14/2022 - CBC, TSH, and lipid panel 2. During the interview on 12/06/2022 at 12:15 pm, the TC confirmed the final test results in the EMR do not contain the units of measurement.</p>

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

. Based on record review and interview with the Technical Consultant j(TC), the laboratory failed to provide the educational requirements for 1 (testing personnel #2 [TP2]) of 2 testing personnel performing moderately complex hematology testing. Refer to D6065

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure personnel performing Complete Blood Count (CBC) testing were qualified for 1 (Testing Personnel [TP] #2) of 2 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of the laboratory's testing personnel records revealed a lack of qualification documentation for TP2. 2. An interview on 12/06/2022 at 10:578 am, the TC confirmed qualification documentation was not available for TP2. 3. The laboratory was given an additional 7 days to supply the necessary education documents. The documents were not received.