

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406035	(X3) Date Survey Completed 01/16/2020
Name of Provider or Supplier Centracare Clinic St Joseph	Street Address, City, State 1360 Elm St E, Saint Joseph, MN	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document function checks for a refrigerator thermometer in 2018. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 01/16/20, at 8:05 a.m. 2. A Whirlpool refrigerator (asset tag = SJ00034) with a Stanley Mobileview thermometer (serial number = 6W3 PY071617) was observed as present and available for use during the tour of the laboratory. 3. The Policy for Equipment Maintenance Checks procedure found in the CentraCare - St Joseph - Lab QA Manual indicated that thermometers are factory calibrated / certified to NIST standards. 4. Documentation of the thermometer function check for the equipment noted above was not found in laboratory records for 2018. The laboratory was unable to provide this documentation upon request. 5. In an email dated 1/20/20, the LD confirmed that the 2018 documentation could not be located, as the information entered in tracking software for 2019 had overwritten that from 2018, rendering it unretrievable. 6. In an interview at 11:15 a.m. on 01/16/20, the LD confirmed the above finding.</p>

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure a reference interval was consistent between a Hematology procedure and a patient test report. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 01/16/20, at 8:05 a.m. 2. An PolyMedco Sedimat 15 ESR (*) analyzer was observed as present and available for use during the tour. 3. The ESR reference intervals listed in the Erythrocyte Sedimentation Rate (ESR) procedure, located in the CentraCare - St Joseph - Lab QA Manual #2 were not consistent with those included on patient test reports reviewed on date of survey, as indicated below. Patient #00166678 - adult male tested on 5/28/18 Patient #00235549 - adult female tested on 9/16/19 Sex Procedure Report Males = 0 - 15 mm/Hr 0 - 22 mm/Hr Females = 0 - 20 mm/Hr 0 - 18 mm/Hr 4. In an interview at 12:30 p.m., on 01/16/20, the LD confirmed the above finding. (*) ESR = erythrocyte sedimentation rate

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