

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0726047	(X3) Date Survey Completed 07/26/2018
Name of Provider or Supplier Roper St Francis Physicians Lab At Inlet Medical	Street Address, City, State 912 Inlet Square, Suite B, Murrells Inlet, SC	
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: During an onsite recertification certification survey on 07/26/2018, based on the HmX hematology analyzer operator's guide, laboratory temperature records, and testing personnel interview, the laboratory failed to document an acceptable room temperature and humidity for 1 out of 7 months reviewed in 2018 (July). Findings include: 1. The HmX hematology analyzer operator's guide stated that the instrument should be operated in an ambient room temperature between 60 to 90 degrees fahrenheit and humidity between 0 and 95%.. 2. Review of the laboratory's temperature records revealed 1 out of 7 months in 2018 (July) during which room temperature and humidity was not documented. There was no corrective action for the missing temperature and humidity values. 3. Testing personnel confirmed during an onsite interview on 07/26/2018 at 2:30pm that the laboratory failed to document an acceptable room temperature and humidity for 1 out of 7 months reviewed in 2018 (July).</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

During an onsite recertification survey on 07/26/2018, based on procedure manual review, hematology quality control (QC) record review, and confirmation by testing personnel, the laboratory failed to verify the stated assay values of hematology QC materials prior to testing for twenty four of twenty four months reviewed (July 2016 through July 2018). Findings include: 1. The laboratory procedure manual stated that prior to the use of any new control material used for moderate testing, the performance of such new control must be verified to meet the manufacturer's recommendations of acceptability. 2. Review of the laboratory's hematology QC records revealed that the laboratory failed to verify the stated assay values of hematology QC materials prior to testing for twenty four of twenty four months reviewed (July 2016 through July 2018). There was no corrective action for the missing lot verification available for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 07/26/2018 at 2:30 pm that the laboratory failed to verify the stated assay values of QC materials prior to testing.

D5777

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(b)(c)

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

During an onsite recertification survey on 07/26/2018, based on laboratory procedure manual review, lack of documentation and testing personnel interview, the laboratory failed to ensure that a system to identify and assess patient test results that appear inconsistent was followed in the laboratory for 2 of 2 years reviewed (2016 and 2017). Findings include: 1. The laboratory's procedure manual stated that 5 random patient requisitions would be selected semi-annually and evaluated for consistency with the following criteria: a: Patient age. b: Sex. c: Diagnosis or pertinent clinical data. d: Distribution of patient test results. e: Relationship with other test parameters 2. Documentation of the laboratory's system to identify and assess patient test results that appear inconsistent with the stated criteria for the years 2016 and 2017 was unavailable for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 07/26/2018 at 2:30pm that the laboratory had failed to ensure that a system to identify and assess patient test results that appear inconsistent

with the relevant criteria was followed in the laboratory for 2 of 2 years reviewed (2016 and 2017).