Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2036231	08/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Medical Center-Op Depts(Surgery,Mri,Pain Ctr	3101 Se 14th St, Bentonville, AR	

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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Through observation, review of the manufacturer's system manual, lack of documentation and interview it was determined that the laboratory failed to document room temperature and room humidity level on two of two rooms in which instruments with operating temperature and humidity requirements were used for testing. Findings follow: A) During a tour of the laboratory on 8/25/21 at 08:45 AM, I Stat instruments used for patient testing were observed in the Radiology suite and the separate Pain Management suite. B) Review of the manufacturer's system manual for the I Stat instruments revealed an operating temperature required range of 16 degrees C. to 30 degrees C. and an operating humidity required range of below 90%. C) Upon request, the laboratory was unable to provide room temperature or humidity documentation for the Radiology suite or Pain Management suite in which the I Stat instruments are used. D) In an interview on 8/25/21 at 08:45 AM, the laboratory staff member, identified as number 11 on the CMS 209 form, confirmed that room temperature and humidity were not monitored and documented in the Radiology or Pain Management suites.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records for ten laboratory testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director did not give written authorization for testing personnel to perform testing without direct supervision for three of ten personnel reviewed. Survey findings include: A. Through a review of personnel records for the ten laboratory testing personnel it was determined that the written authorization to test, which was a part of competency assessment, was signed by the laboratory staff member (listed as #11 on the form CMS-209) for the personnel , identified as number three on the CMS 209 form, and not the laboratory director and there was no authorization to test presented for testing personnel, identified as numbers 6 and 10 on the CMS 209 form. There were no other written authorizations in the personnel records. B. In an interview, at 10: 07 AM on 8/25/21, laboratory personnel #11 (as listed on the form CMS-209) confirmed the laboratory director had not signed written authorizations stating the tests each employee was approved to perform or whether direct supervision was required for the testing personel identified above.