Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642313	07/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Izard Regional Hospital	61 Grasse Street, Calico Rock, 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 temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature on each day of operation in one of two rooms in which supplies with storage temperature requirements were stored. . Findings follow: A) During a tour of the laboratory on 7/11 /23 at 12:50 p.m. two separate rooms (main lab, phlebotomy blood drawing room) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the phlebotomy blood drawing area. C) During a tour of the laboratory on 7/13/23 at 9:10 a.m. 24 five ml. Vacuette heparin blood collection tubes lot # 822113QY expiration date 2024-05-05, 195 two ml. Vacuette EDTA blood collection tubes lot # 82211328 expiration date 2024-03-06 , 91 two ml. Vacuette Na Citrate blood collection tubes lot # 82302359 expiration date 2024-02-01 , 64 eight ml. BD Serum Separation blood collection tubes lot # 8109767 expiration date 2024-04-30 , all with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed in the phlebotomy blood collection room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the

	supplies identified above were stored. E) In an interview on 7/13/23 at 8:30 a.m. , the laboratory staff member (# 3 on the CMS 209) stated " no we don't have temperatures for the phlebotomy blood drawing room".
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of the blood bank refrigerator temperature recording chart, lack of documentation and interview it was determined that the laboratory did not document proper storage temperature requirements were maintained on one of one occasions when the storage temperature for blood and blood components could not be confirmed on the temperature recording charts. Findings follow: A) Review of the temperature recording chart for the blood storage refrigerator revealed that temperature records were not recorded on 5/11/22 12:00 p.m. until 5/12/22 09:00 a.m. with no notation explaining the lack of recording. B) Upon request, the laboratory was unable to provide documentation of hourly temperature recordings for 5/11/22 at 12:00 PM until 5/12/22 at 09:00 a.m.for the blood storage refrigerator. C) In an interview on 7/12 /23 at 03:03 p.m. the laboratory staff members, (# 3 on the CMS 209 form) , confirmed that the laboratory did not document proper storage temperatures for the blood storage refrigerator for the twenty-one hour period identified above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of the laboratory's policy and procedure for quality control (QC), March 2023 quality control results, a review of corrective action notes. lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to evaluate patient test results back to the last successful QC when Complete Blood Count (CBC) quality control failed to meet the laboratory's criteria for acceptability. Survey findings follow: A) Through a review of QC policy and procedure it was determined that QC was unacceptable with a 2/2s failure (the same control material was outside of 2 standard deviation index (SD) on successive attempts) and "all prior results should be evaluated". B) Through a review of quality control documentation for March 2023 it was determined that on 3/15/23 Minitrol 16

	Tri-level high Hematology control lot # 440 expiration date 5/5/23 was reported as greater than 2 SD on two successive attempts . C) Review of corrective action documentation revealed that "troubleshooting included bleach clean, prime/drain, changed lyse reagent" which represented a change in the test system. D) Upon request the laboratory was unable to provide documentation that prior results back to the last successful QC were evaluated. E) In an interview on 7/12/23 at 9:45 a.m., the laboratory staff member (# 3 on the CMS 209 form) confimed that the results prior to the QC failure on 3/15/23 back to the last successful QC had not been evaluated and should have been.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Through review of instrument print-outs, lack of documentation and interviews with staff members it was determined that the laboratory could not produce patient records on ten of ten patients requested for review of required elements on the final report. Findings follow: A) In an interview on 7/11/23 at 1:20 p.m. laboratory staff member (#3 on the CMS 209 form) stated that the electronic medical record (EMR) system had changed to a new provider and system on 1/17/23 and no records of patient final result reports or physician orders are available prior to that date as the contract with the previous EMR system had not been renewed. B) In an interview on 7/11/23 at 1: 40 p.m. medical records staff member (#1 on a separate staff identification list) stated that a paper medical record system was established in August of 2022 and maintained until the installation of the EMR system on 1/17/23 but no records of final result reports or physician orders were available prior to August 2022. C) Through review of instrument print-outs it was determined that laboratory testing was performed on ten patients selected at random between the dates of 1/1/22 and 8/12/22 (patient identification and tests performed are listed as numbers one through ten on a separate patient identification list). D) Upon request the laboratory was unable to provide records of the physician orders and final reports of the patients and testing identified above. E) In an interview on 1/12/23 at 3:20 p.m., the laboratory staff member (# 3 on the CMS 209 form) confirmed that the testing was performed and reported on the patients identified above and no records of final reports and physician orders were available.