Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642313	01/17/2019
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Through a review of the proficiency test attestation records for 2018, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to attest to the routine integration of proficiency test samples in the patient workload on eleven of fourteen proficiency testing events and the individual testing the sample failed to attest the routine integration of proficiency test samples in the patient workload in one of three Immunohematology events. Survey findings follow: A. Review of proficiency testing attestation forms showed the attestation forms for the following proficiency test events were not signed by the laboratory director: First, second and third Chemistry events 2018; First, second and third Hematology Events 2018, Second and third Microbiology Events 2018, First, second and third Immunohematology Events 2018 Chemistry Event 2015. B. Review of proficiency testing attestation forms showed that the individual performing the testing on samples SER-14 and SER-15 on the third Immunohemtology Event in 2018 did not sign the attestation form. C. In an interview, at 02:30 PM on 1/15/19, the technical consultant (as listed on the form CMS-209) confirmed the director failed to sign attestation forms for eleven proficiency testing events in 2018 and further confirmed the attestation form was not signed by the testing individual for samples SER-14 and SER-15 on the third Immunohematology event of 2018.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through a review of , manufacturer's quality control package inserts, laboratory policy and procedure, laboratory's "QC Statistics", laboratory's Levy Jennings Charts, and interview with laboratory staff, it was determined the laboratory failed to meet applicable analytic systems requirements as evidenced by: D5445- The laboratory failed to identify the external quality control materials intended for use in the laboratory's individualized quality control plan (IQCP). D5469- the laboratory failed to establish quality control acceptable range for Complete Blood Cell analyses as required according to the manufacturer's package insert recommendation .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of the Procedure for "Prothrombin Time (PT)", "Partial Prothrombin Time (APTT)", the laboratory's Individualized Quality Control Plan (IQCP) for Hemochron Signature Elite coagulation analyzer and interview it was determined that the laboratory failed to identify the external controls used for quality control of PT and PTT testing. Findings follow: A. Review of the procedures for "Prothrombin Time (PT)", "Partial Prothrombin Time (APTT)", showed that "external liquid controls" are to be performed once per month and for different lot numbers or shipment of reagent. B. Review of the"type of quality control" section of the IQCP for the Hemochron Signature Elite states "External Quality Control - 2 Levels" but does not identify the external quality control material to be used. C. In an interview on 1/17 /19 at approximately 11:15 AM the technical consultant, as identified on the CMS 209 form, confirmed that the IQCP for the Hemochron Signature Elite coagulation testing system did not specify what external quality control materials would be used.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations 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: Through review of the manufacturer's package insert for Horiba Mintrol 16 Hematology controls, the laboratory's "Quality Control Protocol", the laboratory's quality control records for 2018, and interview it was determined that the laboratory failed to determine the acceptable range for quality control of Complete Blood Cell (CBC) procedure as required by the manufacturer. Findings follow: A. Review of the manufacturer's package insert for Horiba Mintrol 16 hematology controls showed that "each laboratory should establish its own mean value and range". B. The laboratory's "Quality Control Protocol" defines an acceptable range of plus or minus 2 SD (standard deviations). C. Review of the laboratory's "QC Statistics" for 2018 revealed that the laboratory developed its own target mean but all acceptable ranges matched those published ranges for the Horiba Mintrol 16 package insert. As an example, Mintrol 16 lot # MX413H utilized by the laboratory during the month of October 2018 has a published range of 65 for platelet count which was used by the laboratory as one standard deviation (SD)) to establish its acceptable range. In October of 2018 the laboratory was actually experiencing a SD for platelet count of 24.07 which, according to manufacturer's recommendations and laboratory policy and procedure, should be used to establish an acceptable range. D. In an interview on 1/16/19 at approximately 01:15 PM the technical consultant, identified on the CMS 209 form, confirmed that the laboratory was using twice the values of the ranges published on the manufacturer's package insert for Horiba Mintrol 16 quality control material to establish the acceptable range for the laboratory.
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 laboratory policy and procedure for "Blood Bank Alarm", review of documentation of "Blood Bank Alarm Checks" and interview it was determined that the laboratory was required to perform Blood Bank refrigerator temperature checks on a quarterly basis and performed the checks twice during 2017 and three times in 2018 and only checked high temperature alarming from March 2017 to the date of the survey. Findings follow: A. Review of the laboratory procedure for "Blood Bank Alarm" revealed that "The blood bank alarm will be checked at least four times a year as stated by the Arkansas Rules and Regulations for

	Hospitals and Related Institutions" and the alarm will be checked for temperatures too cold as well as temperatures too warm. B. Review of the documentation of the "Blood Bank Alarm Check" revealed that the alarm was checked on 6/2/17, 3/1/18, 8/9/18 and 11/3/18 and the alarm was checked for only high temperature alarm on those occasions. No other temperature alarm checks were available. C. In an interview on 1 /16/19 at approximately 10:15 AM the technical consultant, as identified on the CMS 209 form, confirmed that the Blood Bank refrigerator temperature alarm checks were not accomplished with the required frequency and lacked the cold temperature checks.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Through a review of documentation for Immunohematology proficiency testing events of 2017 and 2018, performance review and corrective action forms, and interview with staff, it was determined the corrective actions documented failed to prevent the recurrence of the deficient practice. As evidenced by: A. Review of documentation for proficiency testing showed he laboratory scored 80% for the detection of unexpected antibodies on the third Immunohematology event in 2017, the first Immunohematatology event 2018, the second Immunohematology event 2018 and scored 60% for the detection of unexpected antibodies in the third Immunohematolgy event 2018. B. A review of proficiency testing corrective action forms for Immunohematology third event 2017 showed a failure for sample SER - 15 with a statement written by technical consultant "tech wrote down wrong answer" and no corrective action identified. C. A review of proficiency testing corrective action forms for Immunohematology first event 2018 showed a failure for sample SER-05 with a statement written by the technical consultant "likely cause tech testing wrong sample" and no corrective action identified. D. A review of proficiency testing corrective action forms for Immunohematology second event 2018 showed a failure for sample SER-10 with a statement written by the technical consultant "testing on # 10 must have been run on wrong sample" and a corrective action of "reviewed with tech on making sure sample is correctly identified". E. A review of proficiency testing corrective action forms for Immunohematology third event 2018 showed failures for samples SER-14 and SER-15 with a statement written by the technical consultant "tech did not verify correct sample" and a corrective action of "tech understands importance of verifying labels on specimens". C. In an interview on 1/16/19 at 11:00 AM, the technical consultant, as identified on the CMS 209 form, confirmed the corrective action taken in regard to Immunohematology proficiency testing was not effective.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Through review of the CMS 209 form, personnel records, lack of documentation and interview it was determined that the laboratory failed to document personnel competency on an annual basis for seven of ten personnel identified on the CMS 209 form. Findings follow: A. Review of the CMS 209 form provided by the laboratory identified ten personnel, identified as number one through ten inclusive, which require annual competency evaluations as testing personnel or supervisory personnel. B. Review of personnel records found that no competency evaluations for the years 2017 and 2018 were present for the technical consultant identified as number one on the CMS 209 Form, the technical supervisor identified as number four on the CMS 209 Form, or testing personnel identified as numbers two, three, five, seven, and nine on the CMS 209 form and that those employees had been employed by the laboratory for more than two years. C. Upon request, the laboratory was unable to provide documentation of the competency evaluations for the personnel identified above. D. In an interview on 1/15/19 at approximately 02:00 PM, the technical consultant identified as number one on the CMS 209 form and the technical supervisor identified as number four on the CMS 209 Form confirmed that competency evaluations had not been performed for the personnel identified above.