Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0660929	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kane County Hospital	355 N Main, Kanab, UT	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and confirmation by staff, the laboratory failed to retain and be able to retrieve routine chemistry instrument printouts for 2 of 5 College of American Pathology (CAP) proficiency testing events and 1 of 3 neonatal bilirubin CAP proficiency testing events reviewed. The laboratory performed proficiency testing 3 events per year for 9 proficiency testing modules. Findings include: 1. Proficiency records for EXL instrument printouts could not be located for routine chemistry testing for CAP modules C-A and C-C of 2018; or NB -A of 2019. 2. In an interview conducted on 05/15/2019 at approximately 6:45 P.M. the laboratory manager stated the laboratory recorded the date the proficiency tests were performed above the testing person's signature on the proficiency attestation statement in order to find the printouts. The dates recorded on the attestation statements were located and the complete contents of the instrument printouts were reviewed without finding proficiency test's results on the printouts for CAP events C-A and C-C of 2018 and neonatal bilirubin NB-A of 2019. The laboratory manager confirmed the printout retention did not allow for easily locating the laboratory's results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different

	concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on patient test records review, quality control records review, and interview with staff, the laboratory failed to perform two levels of quality control each day of testing for 2 of 20 test days reviewed, [on 11/01/2017 for Complete Blood Counts (CBC) and on 01/23/2019 for Low Density Lipoprotein Cholesterol (LDL)]. Findings include: 1. Patient test records review included documentation patient 57522 was tested for a CBC on 11/01/2019. The laboratory failed to document they performed at least 2 levels of CBC quality control on 11/01/2017. Patient test records review included documentation patient 13211 was tested on 01/23/2019 for LDL Cholesterol as part of a lipid profile. The patient results were reported as 59 mg/dl. The laboratory quality control records failed to include at least two levels of quality control were performed on 01/23/2019. 2. In an interview with laboratory staff on 05/15/2019 at approximately 5:50 P.M. staff confirmed CBC quality control was not recorded on 11 /01/2017 and the laboratory recorded only one (the normal) level of LDL Cholesterol control on 01/23/2019.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on immunohematology blood release records review, lack of documentation and confirmation by staff, the laboratory failed to follow Federal Food and Drug Administration (FDA) requirements and document a visual inspection of packed Red Blood Cells was performed prior to issue for 3 of 8 units issued that were reviewed for blood issued between May 15, 2017 and May 15, 2019. The laboratory issued lees than approximately 30 units per year. Findings include: 1. Immunohematology records review failed to include documentation the laboratory followed FDA requirements to perform a visual inspection of stored packed red blood cells at the time of issue for one blood unit issued on on 02/15/2019 for patient medical record number (MRN) 3701, on 11/29/2018 for patient MRN 33756, and on 03/25/2019 for patient MRN 19467. 2. In an interview with staff on 05/15/2019 at approximately 4: 00 P.M., staff confirmed they failed to document they performed a visual inspection of the packed red blood cells at the time each unit was issued.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to document 2 of 2 testing personnel were evaluated annually for 1 of 2 years of testing reviewed in 2017. Findings include: 1. The laboratory lacked documentation the technical supervisor evaluated testing personnel in 2017 for competency to perform Chemistry, Hematology, and Immunohematology testing. 2. In an interview on 05/15 /2019 at approximately 6:00 P.M., the current Hematology and Chemistry technical supervisor confirmed testing personnel were not evaluated in 2017 for competency to perform laboratory testing in any specialty.