Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0978864	08/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cherokee Health Systems	6350 West Andrew Johnson Hwy, Talbott, TN	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: ========== Based on review of Proficiency Testing (PT) Attestation sheets for 2017 and 2018 and upon interview with the nurse manager, determined the laboratory failed to retain attestation sheet for 2nd event 2017 and testing personnel and laboratory director failed to document signature on attestation for 2nd event 2018. The findings include: 1. Review of 2017 attestation sheets revealed the attestation sheet for the 2nd event of 2017 had not been retained. 2. Review of 2018 attestation sheets revealed testing personnel and laboratory director failed to sign attestation sheet for the 2nd event. 3. Interview at approximately 11:00 a. m. August 6, 2018 with the nurse manager confirmed the 2nd event of 2017 attestation sheet failed to be retained and there were no signatures on the attestation sheet for the 2nd event of 2018. ==========
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: ========== Based on review of Complete Blood Count (CBC) Quality Control (QC) records for 2017 and upon interview with the nurse manager, determined the laboratory failed to retain quality control records prior to October of 2017. The findings include: 1. Review of CBC QC records for 2017 revealed QC records were not retained prior to October 2017. 2. Interview with the nurse manager at approximately 11:00 a.m. August 6, 2018 confirmed that CBC QC records failed to be retained prior to October 2017. ==========
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: ========== Based on review of the laboratory procedure manual which lacked a procedure for performing wet prep analysis and upon interview with the nurse manager, determined the laboratory failed to have a procedure for collection, performing and reporting wer prep analysis for 2017 and 2018. The findings include: 1. Review of the laboratory procedure manual lacked a procedure for collection, performing and resulting of wet prep analysis. 2. Interview at approximately 11:00 a.m. August 6, 2018 with the nurse manager confirmed the laboratory failed to have a procedure for collection, performing and reporting wet prep analysis for the 2 year period. ==========
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: ========== Based on review of annual competencies for Complete Blood Count (CBC) testing personnel 3 of 3, for Wet Prep testing personnel 2 of 2, review of quality assessment (QA) plan for competencies and upon interview with the nurse manager, determined the laboratory failed to follow policy for performing and documenting annual competencies for 2017 and 2018. The findings include: 1. Review of annual competencies for CBC testing personnel revealed 2 of 3 had no annual competency documented for 2017 and 1 of 3 had no annual competency documented for 2017 and 2018. 2. Review of 2 of 2 testing personnel performing wet prep analysis revealed no competency documentation for

	2017 and 2018. 3. Review of QA plan stated competencies are to be performed and documented annually. 4. Interview at approximately 11:00 a.m. August 6, 2018 with the nurse manager confirmed that laboratory failed to follow policy for performing annual competencies for the 2 year period. ==========
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: ========== Based on review of 2 patient CBC reports which lacked the identify of testing personnel and upon interview with the nurse manager, determined the laboratory failed to maintain a system to identify the personnel performing CBC testing. The findings include: 1. Review of CBC reports for 11/1/17 and 4/10/18 did not include the identity of the testing personnel. 2. Interview with the nurse manager at approximately 11:00 a.m. August 6, 2018 confirmed the CBC reports for review did not contain the identity of the testing personnel. ==========
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: ========== Based on the Quality Assessment (QA) policy for reviewing Quality Control (QC) results monthly and upon interview with the nurse manager, determined the laboratory director failed to follow QC review policy since 2017. The findings include: 1. The Quality Assessment policy states that laboratory director will review all QC monthly. 2. Review of quality control peer group program results from 10/4/17 to 4/8/18 failed to show documentation of director review. 3. Interview at approximately 11:00 a.m. August 6, 2018 confirmed there was no documentation of director review for QC since October 2017. ==========