Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0711468	03/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Yerington Paiute Tribal Clinic Lab	171 Cambell Ln, Yerington, NV	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on profciency testing (PT) attestation records from American Academy of Family Physicans (AAFP), the CMS-209 testing personnel form and interview with the Technical Consultant on March 10, 2020, the laboratory failed to test proficiency samples by all personnel with the laboratory's regular patient workload. The findings icluded: a. On the CMS-209 laboratory personnel form, the laboratory has listed three individual testing personnel, one (1) Medical Technologist (MT) and two (2) medical assistants. b. According to the AAFP attestation forms for the years 2018 and 2019, each AAFP testing event for waived and non-waived testing,was performed by all three testing personnel on consecutive days prior to the submission cut off dates by the PT organization. c. Review of the AAFP testing event records show that all of the testing for waived and non-waived testing results submitted by the laboratory, indicated that only the one (1) MT testing results, were submitted to the AAFP PT testing organization for the years 2018 and 2019, for all PT tests performed. d. The laboratory technical consultantant affirmed by interview that all three testing personnel performed all the PT testing (waived and nonwaived) and only the (MT) results were submitted for evaluation to the PT organization. e. The laboratory reports performing approximately 2803 nonwaived hematology specimens annually, and approximately 1997 waived tests annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on review of the laboratories Quality control quarterly Peer review records from Beckman Coulter for the AC*T DIFF2 Hematology analyzer, and interview with the laboratory technical consultant and testing personnel on March 10, 2020, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. The findings included: a. The laboratory is enrolled in the Beckman Coulter quarterly interlaboratory Quality Assurance (QA) Program for the AC*T DIFF2 Hematology analyzer. 1. During the years 2017, 2018 and 2019 the analyzer data was not submitted for assessment due to loss of the quality control disc from the analyzer. The laboratory had no documentation of corrective actions taken to ensure the QC data was maintained and evaluated by the QA program. 2. The laboratory's Quality Control (QC) for Non-Waived Testing policy states " ...daily QC results are sent to Beckman coulter at the end of the month for evaluation. The results are reviewed and signed by the tech and by the director. The laboratory documented the loss of the disc, but not the corrective actions to ensure repetition of the loss of information, or changes in policy or procedures which resulted in the subsequent reoccurrence of the loss of data card. 3. The laboratory's Quality Control for Non-Waived Testing policy states"... the laboratory is to document the corrective actions taken on the log provided." The laboratory had no documentation of corrections taken to ensure that the monthly QC results cartridge would be submitted to the QA program for analysis, nor did the laboratory have a log as indicated by the policy. b. The laboratory has implemented a laboratory information system (LIS) that tracks their hematology daily QC on a Levy-Jennings graph. Upon review of the Levy-Jennings graph for the period of February 11, 2020 through March 10, 2020, the laboratory QC results were outside of the laboratory's acceptable limits for 12 out of 29 daily runs. Feb. 14, 2020 Feb. 20, 2020 Feb. 21, 2020 Feb. 24, 2020 Feb. 25, 2020 Feb. 26, 2020 (X2) Feb. 28, 2020 Mar. 04, 2020 Mar. 08, 2020 (X2) Mar. 09, 2020 1. Of the 29 days of QC results documented on the Levy-Jennings graph, only two of the results fell on the laboratory's median as established by the manufacturer. The laboratory failed to document the corrective actions taken as established by the laboratory's QC policy, and failed to address the shift from the manufacturers established median. 2. The laboratory policy states "... Reject the run if any control result is >3 S.D. from the mean. Consult with supervisor if the control results is between 2 and 3 S.D. The supervisor will examine the control history and test parameters in evaluating the run for rejection or acceptance." The laboratory had no documentation regarding the review and acceptance of runs for the dates in which the runs were between 2 and 3 S.D. during the period of February 11, 2020 through March 10, 2020. Feb. 11, 2020: >- 2 S. D.(L2) Feb. 14, 2020: >-2 S. D. (L2), >-3 S. D. (L1) Feb. 18, 2020: > -2 S. D. (L2) Feb. 19, 2020: >-2 S. D. (2), >-3 S. D.(L2) Feb. 20, 2020: >-2 S. D. (L2). >-2 S. D. (L2), >-3 S. D.(L2) Feb. 24, 2020: -4 S. D. (L2, L1), -2 S. D.(L2) Feb. 26, 2020: >-3 S. D. (L2), >-3 S. D. ((L2) Feb. 28, 2020: -4 S. D. (L1), -2 S. D.(L2) Mar. 04, 2020: >-3 S. D. (L2) Mar. 05, 2020: >-2 S. D. (L1), >-2 S. D. (L2) Mar. 06, 2020: >--2 S. D. (L1),> -2 S. D.(L2) Mar. 09, 2020: -4 S. D., -4 S. D. (L1, L2),> -2 S. D., (L1, L2) c. The laboratory technical consultant affirmed by interview on March 10, 2020 at approximately 11:30 a.m. the lack of documentation of corrective actions taken per the laboratory's written policy. d. The

	laboratory reports performing approximately 2803 hematology tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS- 116 and the laboratory's current procedure manual on March 10, 2020, the laboratory failed to ensure that the policy and procedures and changes in procedures had been approved, signed, and dated by the current laboratory director before use. Findings included: a. On the day of survey the new laboratory director had not reviewed or signed off the laboratory procedures and changes in procedures. The previous laboratory director had been terminated on December 31, 2019 and upon submission of the signed CMS-116 on January 21, 2020 a new laboratory director had been appointed. b. On the day of survey it was determined that the appointed laboratory director listed on the signed CMS 116 dated January 21, 2020, had rejected the appointment due to qualifications requirements for laboratory experience or continued education requirements as defined in 493.1407 and the laboratory currently did not have a laboratory director meeting the qualificartions for non-waived testing. See DTag 6000. c. The laboratory technical consultant affirmed by interview on March 10, 2020 at approximately 11:00 a.m., that the new appointed laboratory director had not reviewed, approved and dated the current laboratory procedures for use. d. The laboratory reports performing approximately 2803 non-waived tests, and approximately 1997 waived test annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a random review of the laboratory's hematology complete blood count (CBC) test results, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. The findings included: a. The laboratory performs automated CBC's Beckman Coulter AcT DIFF2 hematology analyzer. The laboratory's information system (LIS) is not integrated with the automated analyzer and the three (3) testing personnel must manually enter the patients results into the LIS system. b. Upon random selection and review of 10 patient test reports from January 2018- March 10, 2020, revealed one patient test results had been entered incorrectly. Patient ID requisition 880 date 11/19.19: WBC Reported result 7.1, analyzer report 7.2. c. Upon random selection and review of 10 patient test reports from January 2018- March 10, 2020, revealed one patient CBC test was ran as a female and reported as female in the laboratory LIS system, with the Normal ranges in system reported for female although it was a male patient. Patient ID requisition 975 date 01/08/20. System records identified as male. d. The laboratory's technical consultant affirmed by interview on March 10, 2020 at

	approximately 11:30 a.m., that the laboratory does not have a mechanism or policies or procedures in place for performing post-analytical testing systems quality assessment. e. The laboratory reports performing approximately 1997 waived tests, and 2803 non-waived tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS-209 personnel report and interview with the laboratory technical consultant and testing personnel on March 10, 2020, the laboratory failed to have a laboratory director that qualified for moderate complexity testing. The findings included: a. The laboratory performs moderate complexity Complete Blood Count (CBC) on a Beckman AcT Diff2 automated hematology analyzer, along with urine sedimentation examinations. b. The CMS 116 application for change of director submitted on January 24, 2020 along with the new laboratory directors resume and license as well as signature dated January 21, 2020, did not include one year of qualified laboratory experience or 20 hours CME as listed in 493.1407. See DTag 6003. c. The laboratory was given two (2) months to meet this criteria, and on the date of survey the laboratory notified the survey team that the laboratory did not have a current laboratory director. d. The technical consultant affirmed by interview on March 10, 2020 at approximately 10:00 a.m. that the laboratory director on file had resigned due to lack of qualified training.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory

science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination

	conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on interview with the laboratory consultant and laboratory testing personnel on March 10, 2020 and review of the CMS-116 application for change of laboratory director received on January 25, 2020 at the regional CMS CLIA office in San Francisco, the laboratory failed to have a qualified laboratory director for moderate complexity testing in accordance to the testing complexity for which the laboratory has been performing. Findings included: a. The laboratory submitted a change of laboratory director on January 25, 2020, at which time a request was made by CMS CLIA SF office, for the laboratory to provide additional information regarding the qualification/experience of the new proposed laboratory director. The proposed laboratory directors resume failed to provide evidence of laboratory training or experience consisting of at least one year experience directing or supervising non-waived laboratory testing, or completion of a 20 hour continuing medical education (CME) program commensurate with the director responsibilities as defined in 493. 1407. The laboratory was given till next the survey scheduled date (March 10, 2020) to meet that requirement. b. On the day of survey (March 10,2020) the laboratory testing personnel informed the surveyors that the laboratory did not have a laboratory director. The previous laboratory director's contract had been terminated on December 31, 2019 and the proposed laboratory director had turned down the position. c. The laboratory performs all waived testing except for Complete Blood Counts (CBC) which it performs a three (3) part diff on a Beckman Coulter AcT DIFF2 moderate complexity analyzer and urine sediment examinations. d. The laboratory consultant affirmed by interview on March 10,2020 at approximately 10:30 a.m. that the laboratory did not have a qualified laboratory director for moderate complexity testing. e. The laboratory reported 46 patients CBC results in January 2020, and 50 patients CBC results in February 2020.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the laboratories testing personnel competency records and interview with the laboratory technical consultant on March 10, 2020, the laboratory failed to include policies and procedures for evaluation of the competency of the staff that included direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. Findings

	included: a. The laboratory has three testing personnel which include the technical consultant (MT) and two medical assistants (MA). b. The laboratory consultants competency included direct observation by the laboratory director, but the two MA did not include direct observation as part of the competency assessments for 2018 or 2019. c. The laboratory consultant affirmed by interview on March 10, 2020 at approximately 11: 20 a.m., the direct observation portion of competency had not been performed for the two MA testing personnel. d. The two MA's perform the bulk of the patient preperaation, specimen handling, processing, testing, QC and maintanence for the laboratory. d. The laboratory performs approximately 4,800 patient tests annually.