

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0882223	(X3) Date Survey Completed 08/23/2022
Name of Provider or Supplier Comanche County Hospital Dist D/B/A	Street Address, City, State 10201 Highway 16 North, Comanche, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D6143	<p>GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461</p> <p>(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(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 or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on</p>

Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on the review of patient reports from January 25, 2021 to August 22, 2022, the laboratory's records and policies, CMS 209, and confirmed in an interview found the general supervisor failed to ensure the laboratory document the testing personnel (TP) who performed grossing for 20 of 20 patient reports reviewed for MOHS procedure. The findings were: 1. Review of CMS 116 application signed by the laboratory director (LD) on 08/22/2022 revealed the laboratory performed MOHS procedure. 2. An interview with the testing personnel 2 (TP#2) on 8/23/2022 at 9:10 am in the office revealed the TP#2 and the technical supervisor (TS) both performed grossing of patient samples. 3. Random review of patient reports from January 25, 2021 to August 22, 2022 revealed no documentation of identity of who grossed the patient samples for 20 of 20 patient reports reviewed. 1/25/2021 Accession# C21-01 3/30/2021 Accession# C21-07 4/26/2021 Accession# C21-12 5/24/2021 Accession# C21-24 6/14/2021 Accession# C21-28 7/26/2021 Accession# C21-37 8/9/2021 Accession# C21-40 8/9/2021 Accession# C21-41 11/8/2021 Accession# C21-43 12/13/2021 Accession# C21-50 12/27/2021 Accession# C21-57 12/27/2021 Accession# C21-61 2/14/2022 Accession# C22-12 4/25/2022 Accession# C22-42 4/25/2022 Accession# C22-44 4/25/2022 Accession# C22-50 6/13/2022 Accession# C22-63 6/13/2022 Accession# C22-66 7/11/2022 Accession# C22-81 8/22/2022 Accession# C22-100 4. An interview with the laboratory manager on 8/23/22 at 9:40 am in the office confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services