

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0918200	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Moore County Hospital Respiratory Svcs	Street Address, City, State 224 East 2nd Street, Dumas, 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	An onsite validation survey conducted on March 20-23, 2023, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Review of laboratory records, policies and procedures, and interview of facility personnel found that the laboratory director failed to approve, sign, and date 5 of 5 procedures reviewed from November 2022 to March 2022. The findings included: 1. Review of laboratory records found the laboratory changed laboratory director in November 2022. 2. Random review of 5 policies and procedures found no documentation of the current laboratory director's approval to include signature and date. 3. The findings were confirmed in an interview with the Laboratory Manager on March 21, 2022, at 16:05 hours in the hallway.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p>

This STANDARD is not met as evidenced by:
Review of laboratory records, policies and procedures, and interview of facility personnel found that the laboratory director failed to ensure that all procedures available to testing personnel had been approved, signed, and dated by the current laboratory director (refer to D5407).

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:
Based on review of laboratory policies, review of the laboratory's personnel records, and confirmed in staff interview, the technical consultant failed to perform annual competency assessments on 3 of 3 testing personnel in 2022. The findings included: 1. A review of the laboratory's policy titled, "Laboratory Competency Assessment Plan" (no laboratory director approval date provided) under, "Responsibilities" it stated, "The Laboratory Director/Manager, Pathologist-Medical Director, and the Senior Technologists are responsible for the review and documentation of competencies for all laboratory personnel. These individuals are responsible for the training and assessment of technical and phlebotomy skills as outlined by CLIA and NCCLS guidelines ..." a. The laboratory's policy failed to include that competency assessments must be performed by a qualified Technical Consultant. 2. A review of the laboratory's personnel files found 3 of 3 competency assessments performed in 2022 were performed by someone other than the technical consultant. They were (as listed on Form CMS 209): Testing personnel number 1 annual competency performed May 2022 Testing personnel number 3 annual competency performed May 4, 2022 Testing personnel number 5 annual competency performed May 4, 2022 3. The laboratory was asked to provide documentation of the technical consultant performing the identified competency assessments. No documentation was provided. 4. An interview with the laboratory manager on March 20, 2022 at 15:30 hours in the conference room her review of the records- confirmed the findings. Key: CLIA - Clinical Laboratory Improvement Amendments NCCLS - National Committee for Clinical Laboratory Standards CMS - Centers for Medicare and Medicaid Services