Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0525341	09/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Moab Regional Hospital	450 W Williams Way, Moab, 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
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel record review, training record review, and interview with staff, the laboratory director failed to ensure that training and competency assessment was completed for testing personnel prior to testing patients' specimens for 1 of 2 new testing personnel in Bacteriology. The laboratory peforms approximately 20 Bacteriology tests per week. Findings include: 1. Personnel record review for testing personnel F included incomplete training and competency records for Bacteriology. 2. Personnel record review for testing personnel F included partial training completed and signed off by personnel G. Test personnel G lacked documentation to qualify as a technical consultant or supervisor authorized to evaluate training completion or competency. 3. Personnel record review for testing personnel F included a written warning dated 2/25/20 citing incorrect isolation techniques and improper workup of a urine culture on a patient specimen dated 2/18/20. 4. Personnel record review for testing personnel F included 4 written warnings dated 2/25/20 for improper processing and workup of Bacteriology patient specimens. In an interview with the Technical Supervisor on 9/21/20 at approximately 2:30 pm the Technical Supervisor stated that testing personnel F did not perform any laboratory testing alone.
D6168	TESTING PERSONNEL CFR(s): 493.1487

	The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on lack of documentation, patient test records review, and confirmation by staff, 2 of 2 new testing personnel records review failed to include educational benchmarks to qualify as moderate complexity testing personnel. (See D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the

	factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on personnel records review, lack of documentation and confirmation by staff, 2 of 4 high competency testing personnel lacked documentation of educational credentials to qualify to perform high complexity testing in Microbiology and Immunohematology. Findings include: 1. Personnel records review showed testing persons B and D lacked education documentation to qualify as a high complexity testing personnel. 2. In an interview conducted on 09/21/2020 at approximately 3:15 P. M. the laboratory manager confirmed testing personnel B and D did not have education documentation present in the laboratory personnel record system.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on immunohematology test records review, immunohematology procedure review and confirmation by staff, laboratory testing personnel failed to follow laboratory instructions to perform compatibility testing for 2 of 47compatiblity tests reviewed from January 2, 2020 to February 12, 2020. Findings include: 1. Immunohematology test record review failed to include documentation the laboratory performed an immediate spin cross match for compatibility testing on 02/03/2020 for patient #2781 previously tested on 02/01/2020 patient ID #2002020030 and for patient # 2002140119 on 02/14/2020 . 2. Immunohematology procedure manual review included instruction s to perform an immediate spin cross match for compatibility. 3. In an interview conducted on 09/21/2020 at approximately 2:50 P M. the Laboratory manger confirmed the laboratory procedure included instructions for staff to perform immediate spin cross match.