

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0525341	(X3) Date Survey Completed 09/07/2022
Name of Provider or Supplier Moab Regional Hospital	Street Address, City, State 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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Standard Operating Procedures (SOP), instrument maintenance logs, and an interview with the Lab Supervisor, the laboratory failed to document performance of monthly function checks established for the Renok Rehydrator unit to verify the dispensed volume, for 4 of 12 months reviewed from August 2021 - August 2022. The Renok Rehydrator is used to simultaneously rehydrate and inoculate MicroScan panels for the identification and antimicrobial susceptibility testing of bacteria isolated from a microbiology culture. Findings include: 1. In the laboratory SOP titled, "Maintenance of Renok," it states: "The RENOK unit dispense volume is checked on a monthly basis." 2. A review of the monthly MicroScan Instrument Maintenance Checklist, at approximately 11:30 AM on 9/7/22, revealed that the monthly maintenance item listed for "Check Renok Dispense Volume" was not documented for January, March, July, and August of 2022. 3. An interview with the Lab Supervisor, at approximately 11:40 AM on 9/7/22, confirmed that the monthly maintenance item listed for "Check Renok Dispense Volume" was not documented for January, March, July, and August of 2022.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must</p>

have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on laboratory record review and interview with the general supervisor (GS), the laboratory failed to ensure the twice a year evaluation of two coagulation analyzers (Sysmex CA-600 series and Sysmex CS-2500 series) and two hematology analyzers (Sysmex XN-350 and Sysmex XN-550) that compared the relationship between instruments. The laboratory performs approximately 49,000 hematology tests annually. Findings include: 1. The laboratory quality assessment procedure failed to include a system that twice a year evaluates and defines the relationship between test results using different instruments. 2. The laboratory records review failed to include instrument to instrument comparison. 3. In an interview conducted on 09/07/2022 at 9: 20 AM, the GS stated the laboratory did not have a system in place that twice a year evaluates and defines the relationship between test results using different instruments.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of patient test reports, laboratory procedure manual, and an interview with the general supervisor (GS), the laboratory failed to include the correct normal ranges for chemistry and hematology analytes. Findings include: 1. Review of the patient reports revealed nine female ranges and six male ranges did not correctly match those reference ranges for the chemistry and hematology in the procedure manual. 2. The procedure manual showed: Parameter Reference Range Troponin 0.0 - 0.056 (male and female) Vancomycin, Trough 5 - 10 (female) Alanine Transaminase 30 - 65 (female) Alkaline Phosphatase 50 - 136 (female) White Blood Count 4.00 - 10.50 (male) Red Blood Count 4.00 - 6.00 (female) Hemoglobin 13.5 - 18.0 (male and female) Hematocrit 40.0 - 54.0 (male and female) Red Cell Distribution Width 11.5 -17.5 (female) # Basophils 0.2 - 1.0 (male and female) # Immature Granulocytes 0 - 1.0 (male and female) 3. The patient report showed: Parameter Reference Range Troponin 0.0 - 34.0 (female) & 0.0 - 53.0 (male) Vancomycin, Trough 10.0 - 20.0 (female) Alanine Transaminase 12 - 78 (female) Alkaline Phosphatase 46 - 116 (female) White Blood Count 4.00 - 12.00 (male) Red Blood Count 3.50 - 5.80 (female) Hemoglobin 11.5 - 16.0 (female) & 13.0 -16.0 (male) Hematocrit 37.0 - 47.0 (female) & 36.0 - 50.0 (male) Red Cell Distribution Width 11.5 -14.5 (female) # Basophils 0.0 - 0.1 (male and female) # Immature Granulocytes 0.0 - 0.1 (male and female) 4. In an interview on 09/07/2022 at 3:00 PM, the GS confirmed the lab failed to provide pertinent normal ranges on the test report.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least

semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with the General Supervisor (GS), the laboratory failed to evaluate the performance at least twice during the first year testing personal (TP) performed patient testing in the specialties of microbiology, chemistry, hematology, and immunohematology. Findings include: 1. Record review revealed that 2 of 7 TP were not evaluated at least two times during the first year the TP performed patient testing. 2. The in an interview on 09/07/2022 at 10:20 AM with the General Supervisor, it was confirmed that 2 of 7 TP did not receive competency assessment at least two times during their first year of patient testing.