

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0984477	(X3) Date Survey Completed 07/25/2024
Name of Provider or Supplier Roosevelt Co Hospital District	Street Address, City, State 42121 Us Hwy 70, Portales, NM	
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 offsite paper revist conducted on August 9, 2024 , for Roosevelt General Hospital found the laboratory to be in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvement Amendments (CLIA) 116 application for certification, laboratory policy, patient reports, Quality Control (QC) data logs, and interview with Technical Supervisor #2 and General Supervisor #2, the laboratory failed to follow their polices for repeating quality control when analytes were out of range for urinalysis for 4 of 122 days reviewed in 2023 Findings included: 1. A review of the CLIA 116 form listed the laboratory performing urine dipsticks on the Siemens Clinitek Novus, serial number: 19291. The following analytes are being tested and resulted by the laboratory: - Bilirubin - Blood - Clarity - Color - Glucose - Ketones - Leukocytes - Nitrite - pH - Protein - Urobilinogen 2. A review of laboratory policy titled "Quality Control Program", under section 14.1 stated: Corrective actions include: 1.Repeat controls. If still out 2. Change reagents and repeat controls: If still out 3. Recalibrate: If still out. 3. A review of quality control data logs from April of 2023 through July of 2023 revealed the laboratory failed to repeat unacceptable QC on the following dates: 1. 04/16/2023: Bilirubin: Control 2 Result = Negative, Expected result: Small - Large Glucose: Control 2 Result = >=1000, Expected result: 100-500 2. 04/17/2023: Bilirubin: Control 2 Result = Negative, Expected result: Small - Large Glucose: Control 2 Result = >=1000, Expected result: 100-500 3. 07/15/2023:</p>

Bilirubin: Control 2 Result = Negative, Expected result: Small - Large 4. 07/23/2023: Bilirubin: Control 2 Result = Negative, Expected result: Small - Large 4. A review of patient reports revealed the following patients were resulted with unacceptable QC: 4/16/2023: - M000274700 - M000157490 - M000019350 4/17/2023: - M000190100 - M000054320 - M000318930 - M000456687 - M000175241 - M00448273 - M000263470 - M000178792 - M000296780 - M000460171 - M000460603 - M000163950 07/15/2023 - M000034780 - M000184780 5. An Interview on 07/24/2024 at 12:10 pm with Technical Supervisor #2 and General Supervisor #2 confirmed the above findings. 6. The laboratory reported performing 4367 urinalysis tests annually.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, lack of documentation, and interview with Technical Supervisor #2 and General Supervisor #2, the laboratory failed to follow policies by not documenting corrective actions for quality control (QC) failures in urinalysis for 4 of 122 days reviewed in 2023. Findings included: 1.A review of quality control data logs from April of 2023 through July of 2023 for the Siemens Clinitek Novus, serial number:19291, revealed the QC was rerun multiple times and the laboratory failed to document corrective actions for the following dates: - 04/09/2023 @ 4:12 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/09/2023 @ 4:32 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/09/2023 @ 4:43 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/09/2023 @ 4:50 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/09/2023 @ 5: 40 am: Control 2 Glucose result = 500, Expected Result = 100-500 - 04/18/2023 @ 1:54 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/18/2023 @ 1:57 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/18/2023 @ 2:39 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/18/2023 @ 2:46 am: Control 2 Glucose result = >=1000, Expected Result = 100-500 - 04/18/2023 @ 3: 06 am: Control 2 Glucose result = 500, Expected Result = 100-500 - 04/26/2023 @ 1:20 am: Control 2 Bilirubin result = Negative, Expected Result = small - large - 04/26/2023 @ 1:24 am: Control 2 Bilirubin result = Negative, Expected Result = small - large - 04/26/2023 @ 1:28 am: Control 2 Bilirubin result = Negative, Expected Result = small - large - 04/26/2023 @ 1:31 am: Control 2 Bilirubin result = Negative, Expected Result = small - large - 04/26/2023 @ 2:06 am: Control 2 Bilirubin result = Negative, Expected Result = small - large - 07/23/2023 @ 1:01 am: Control 2 pH result = 7.5, Expected Result = 8 - >= 9.0 - 07/23/2023 @ 1:05 am: Control 2 pH result = 7.5, Expected Result = 8 - >= 9.0 - 07/23/2023 @ 1:09 am: Control 2 pH result = 8, Expected Result = 8 - >= 9.0 2. Laboratory was asked to provide documentation that corrective actions were done

for the above dates. None were provided. 3. Interview on 07/24/2024 at 2:30 pm with Technical Supervisor #2 and General Supervisor #2 confirmed the above findings. 4. The laboratory reported performing 4367 urinalysis tests annually.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory policies, competency assessment records, education records, and interview with Technical Supervisor #2 and General Supervisor #2, a qualified Technical Supervisor failed to sign off on competency assessments for immunohematology for 5 of 5 testing personnel in 2023. Findings included: 1. A review of the CMS -209 personnel form listed 6 testing personnel 5 of which performed immunohematology testing. The Laboratory Director was also listed as Technical Supervisor #1 over immunohematology. 2. A review of the facility's policy titled "Competency Assessment", under the responsibilities section stated: Laboratory Medical Director: -Technical Supervisor for immunohematology -Ensure that all testing personnel are competent and maintain their competency in order to perform and report accurate and reliable test results. 3. A review of competency assessments for immunohematology in 2023 revealed Technical Supervisor #3 signed off on competencies for 5 of 5 testing personnel. 4. Review of education records for Technical Supervisor #3 revealed they did not meet the education requirements to be assigned as technical supervisor over immunohematology 5. An interview on 07/23 /2024 at 10:00 am with Technical Supervisor #2 and General Supervisor #2 confirmed the above findings. 6. The laboratory reported performing 727 immunohematology tests annually.