

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453227	(X3) Date Survey Completed 09/25/2024
Name of Provider or Supplier Kearny County Hospital	Street Address, City, State 500 E Thorpe Street, Lakin, KS	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation and lack of QC data for an unsubstantiated Individualized Quality Control Plans (IQCP)s, the Rupture of Membrane (ROM) test, Gene Xpert Chlamydia trachomatis and Neisseria gonorrhoeae (CTNG) test, Gene Xpert Clostridioides difficile (C.diff) test, Gene Xpert Group B test, Gene Xpert Trichomonas vaginalis (TV), Gene Xpert methicillin-resistant Staphylococcus aureus (MRSA) test, QuickVue+ Infectious mononucleosis (mono) test and BD Affirm vaginitis panel for patient testing, and interview, the laboratory failed to have acceptable QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency or monthly and failed to perform a negative and positive control on each day of patient testing at time of survey. Findings: 1. Review of the facility's IQCP documents of the Rupture of Membrane (ROM) test revealed the laboratory performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Only 20 days of QC data was performed and no risk assessment could be presented. Two levels of QC were not performed every day of patient testing from 9/18/2019 to date of survey. 2. Review of the facility's IQCP documents of the Gene Xpert Chlamydia trachomatis and Neisseria gonorrhoeae (CTNG) test revealed the laboratory performed QC new lot or new shipment or every thirty (30) days. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Two levels of QC were not performed every day of patient</p>

testing from 2/2/2018 to date of survey. 3. Review of the facility's IQCP documents of the Gene Xpert Clostridioides difficile (C.diff) test revealed the laboratory performed QC new lot or new shipment or every thirty (30) days. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Only 20 days of QC data could be presented. Two levels of QC were not performed every day of patient testing from 2/2/2018 to date of survey. 4. Review of the facility's IQCP documents of the Gene Xpert Group B test revealed the laboratory performed QC new lot or new shipment or every thirty (30) days. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Two levels of QC were not performed every day of patient testing from 2/2/2018 to date of survey. 5. Review of the facility's IQCP documents of the Gene Xpert Trichomonas vaginalis (TV) test revealed the laboratory performed QC new lot or new shipment or every thirty (30) days. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Only 10 days of QC data could be presented. Two levels of QC were not performed every day of patient testing from 2/2/2018 to date of survey. 6. Review of the facility's IQCP documents of the Gene Xpert methicillin-resistant Staphylococcus aureus (MRSA) test revealed the laboratory performed QC new lot or new shipment or every thirty (30) days. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Only 20 days of QC data could be presented. Two levels of QC were not performed every day of patient testing from 2/2/2018 to date of survey. 7. Review of the facility's IQCP documents of the QuickVue+ Infectious mononucleosis (mono) test revealed the laboratory performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Only 10 days of QC data could be presented. Two levels of QC were not performed every day of patient testing from 2/2/2018 to date of survey. 8. Review of the facility's IQCP documents of the BD Affirm vaginitis panel revealed the laboratory performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Two levels of QC were not performed every day of patient testing from 4/8/2020 to date of survey. 8. Interview with technical consultant #4 on 9/25/2024 at 1:30 p.m. confirmed the laboratory failed to have acceptable QC data for IQCP documentation to allow QC to be performed at the manufacturer's number, frequency or monthly and failed to perform a negative and positive control on each day of patient testing at time of survey.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:
 Review of eight (8) Individual Quality Control Plans (IQCP)s, and interview with the technical consultant #4 (TC#4), the laboratory director (LD) failed to ensure reviewing of quality control (QC) for analytical performance on eight (8) of eight (8) IQCPs. Findings: 1. Review of IQCPs performed from 2/2/2018 to time of survey revealed no documentation of review was performed at the time of survey. 2. The following IQCPs have not be reviewed for QC analytical performance at any time: a. Rupture of Membranes test b. BD Affirm Vaginitis Panel (includes Candida (C.) albicans, C. tropicalis, C. galbrata, C. kefyri, C. krusei, C. parapsilosis, Gardnerella vaginalis and Trichomonas vaginalis) c. QuickVue+ Infectious Mononucleosis test d. Gene Xpert methicillin-resistant Staphylococcus aureus (MRSA) test e. Gene Xpert

Clostridioides difficile (C. diff) test f. Gene Xpert Trichomonas vaginalis (TV) test g. Gene Xpert Group B test h. Gene Xpert Chlamydia trachomatis and Neisseria gonorrhoeae (CTNG) test 3. Interview with the technical consultant #4 (TC#4) on 9/25/2024 at 1:30 p.m. confirmed, the laboratory director failed to ensure reviewing of QC for analytical performance on eight (8) of eight (8) IQCPs.