

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0046794	(X3) Date Survey Completed 08/22/2024
Name of Provider or Supplier Lafene Health Center	Street Address, City, State 1105 Sunset Ave, Manhattan, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 for the McKesson Consult Combo Kit for serum beta-human chorionic gonadotropin (bHCG), vitamin D (Vit D), ferritin (FERR), free thyroxine (FT4), thyroid stimulation hormone (TSH), lack of a substantiated individualized quality control plans (IQCP), QC logs, patient test results, and interview with technical consultant (TC) #1, the laboratory failed to perform QC at least once each day of patient testing for bHCG, Vit D, FERR, FT4, and TSH. Findings: 1. The surveyor requested the laboratory's IQCPs for review. a. Review of the IQCPs found no documentation to support the stated QC interval of monthly QC for bHCG. b. Review of the IQCPs found no documentation to support the stated QC interval of weekly for: (i) Vit D (ii). FERR (iii). FT4 (iv). TSH 2. McKesson Consult Combo Kit for bHCG was placed into use for patient testing on 2/1/24. Review of for bHCG QC performance dates from QC logs and patient testing dates from 2/1/24. to 8/22/24 revealed 130 of 135 patient results were reported with no external QC performed on the date of testing. 3. Vit D, FERR, FT4, and TSH are performed on the Tosoh A1A 900. Patient testing began 5/16/23. 4. Review of QC performance dates from QC logs and patient testing dates from 5/16/23 to 8/22/24 revealed: a. Vit D: 571 of 718 patient result were reported with no QC performed the date of testing. b. FERR:</p>

662 of 819 patient result were reported with no QC performed the date of testing. c. FT4:109 of 147 patient result were reported with no QC performed the date of testing. d. TSH: 823 of 1081 patient result were reported with no QC performed the date of testing. 5. Interview with TC #1 on 8/22/24 at 12:40 p.m. confirmed, the laboratory failed to perform QC at least once each day of patient testing for bHCG, Vit D, FERR, FT4, and TSH.