

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2087711	(X3) Date Survey Completed 09/05/2023
Name of Provider or Supplier Kickapoo Community Health Center	Street Address, City, State 2192 Rosita Valley Road, Eagle Pass, TX	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of a policy for or of performing a competency assessment on 1 of 1 technical consultants. The findings include: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 9/1/2023) revealed the laboratory identified 1 technical consultant. 2. A review of the personnel records for the technical consultant revealed the laboratory failed to have documentation of a competency being performed. 3. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy which addressed competency assessments of the technical consultant and the required frequency. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 09/05/2023 at 1405 in the conference room confirmed the findings.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Individualized Quality Control Plan for the BioFire analyzer, review of the laboratory's verification records, and staff interview, it was revealed the laboratory failed to have documentation of developing Individualized Quality Control Plans when current instrumentation was replaced for 2 of 2 analyzers. The findings include: 1. A review of the laboratory's Individualized Quality Control Plan for the BioFire analyzer revealed the plan was developed for the analyzer with the serial number 2FA0502 in 2021. 2. A review of the laboratory's verification studies for the BioFire analyzer revealed the laboratory replaced the analyzer in use twice since the initial Individualized Quality Control Plan was developed. Serial number 2FA07850 In use: 07/2022 to 05/2023 Serial number FA2252 In use: 05/2023 to 8/2023 3. The laboratory was asked to provide documentation of developing a new Individualized Quality Control Plan for each of the new analyzers. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 09/05/2023 at 15000 hours in the conference room revealed the facility was not aware new Individualized Quality Control Plans needed to be developed with each new analyzer. This confirmed the findings.