Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384646	08/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Buchanan County Health Center	1600 First Street East, Independence, IA	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based upon review of personnel records and the Lab Quality Management Plan and confirmed by laboratory personnel identifiers #1 and #7 (refer to the Laboratory Personnel Form) at 8:31 am on 8/5/2024, the laboratory failed to follow written policies and procedures to document training, six month competencies, and annual competencies for nine out of 14 testing personnel. The findings include: 1. The Lab Quality Management Plan stated, "Upon hire, training in each area of the laboratory for the new employee will be provided using policy manuals, direct observation and training by competent staff. This training will be monitored and signed off utilizing the departmental orientation sheets and training documents relevant to the instrumentation." 2. Testing personnel identifier #2 did not have completed training documents. Several sections did not indicate training had occurred. 3. The Lab Quality Management Plan stated, "Staff will be assessed for competency initially, 6 months after the completion of training, and then annually thereafter." 4. Testing personnel identifiers #1 and #2 did not have six month competency documented. 5. Testing personnel identifiers #7 - #13 did not have 2022 annual competency documented. 6. Testing personnel identifiers #8 & #12 did not have 2023 annual competency documented.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: A. Based on review of quality control records and the Stool Panel PCR procedure and confirmed by laboratory personnel #1 and #7 (refer to the Laboratory Personnel Report) at 12:15 pm on 8/5/2024, the laboratory failed to follow their quality control policy for one out of two lot number of stool panels performed on the Biofire analyzer from 2/19/2024 - 8/8/2024. The findings include: 1. The Stool Panel PCR procedure states, "External quality control testing is done with every new lot of Biofire Stool cartridge. 3 levels of control: Cary Blair Media green top empty (negative), Control L1 and Control L2." 2. On 2/19/2024 the laboratory only performed Control L1 and Control L2 for lot number 2ZL323 of stool cartridges. The laboratory did not perform the Cary Blair Media green top empty (negative) quality control. B. Based on lack of quality control (QC) records, review of the Gram Stain procedure and confirmed by laboratory personnel #1 and #7 (refer to the Laboratory Personnel Report) at 1:41 pm on 8/5/2024, the laboratory failed to follow their quality control policy for performing gram stain QC for one out of one day of patient testing in March 2024. The findings include: 1. The Gram Stain procedure states, "Each day a gram stain is performed quality control should be performed." 2. On 3/23/2024 Patient identifier A had a gram stain performed. 3. The laboratory did not document gram stain QC had been performed on this date.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the Blood Bank Maintenance procedure, blood bank system alarm check records, and confirmed by laboratory personnel identifier #1 and #7 (refer to the Laboratory Personnel Report) at 3:44 pm on 8/5/2024, the laboratory failed to perform quarterly alarm system checks for the blood bank refrigerator for three out of six quarters and the blood bank freezer for four out of six quarters from 01/01/2023- 8/5 /2024. The findings include: 1. The Blood Bank Maintenance Procedure stated that the alarms on the blood storage refrigerator and plasma freezer would be checked quarterly. 2. The laboratory performed blood bank refrigerator alarm checks on 10/23 /23, 2/9/2024, and 6/19/2024. 3. The laboratory performed plasma freezer alarm checks on 2/9/2024 and 7/11/2024. 4. At the time of the survey, the laboratory did not have additional blood bank refrigerator and freezer alarm system check records.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (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 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 upon review of the laboratory test list, observations made during the survey and confirmed by laboratory personnel #1 and #7 (refer to the Laboratory Personnel Report) at 1:24 pm on 8/5/2024 the laboratory failed to perform twice annual comparison testing for the analytes: influenza A, influenza B, respiratory syncytial virus (RSV), SARS-CoV-2, and Clostridioides difficile (C diff) toxin for one out of one time period from 2/1/2024 - 8/8/2024. The findings include: 1. In February 2024 the laboratory implemented new testing on the Biofire analyzer. The laboratory performed a respiratory panel on the Biofire which included influenza A, influenza B, RSV and SARS-CoV-2 testing. The laboratory also performed a stool panel which include C diff toxin testing. 2. The laboratory also performs influenza A, influenza B, RSV and SARS-CoV-2 testing using the Cepheid analyzer and C diff toxin testing using the Quick Check test kit. 3. At the time of the survey, the laboratory had not performed comparison testing between the Biofire and Cepheid for influenza A, influenza B, RSV and SARS-CoV-2 testing. In addition, the laboratory had not performed comparison testing between the Biofire and the Quick Check test kit for the C diff toxin.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifiers #1 and #7 (refer to the Laboratory Personnel Report) at 9:28 am on 8/5/2024, the laboratory director failed to ensure that the laboratory reviewed and documented corrective action for unacceptable PT scores for two out of five testing events from 8/5/2022 - 8/5/2024. The findings include: 1. For 2023 testing event 1, the laboratory received unacceptable PT scores for the following analytes: 80% for anti-human immunodeficiency virus, 66% for ammonia, and 33% for urine creatinine. 2. For 2023 testing event 3, the laboratory received an unacceptable PT scores of 80% for the analyte, low density lipoproteins-measured. 3. At the time of the survey, the laboratory did not have corrective action for the above unacceptable PT scores.