Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2087711	10/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kickapoo Community Health Center	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
D0000	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant Moderate Complexity Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the manufacturer package insert for the Siemens Dimension EXL chemistry analyzer TPSA (Total Prostate Specific Antigen) reagent, review of the patient records for January 2021 to October 2021, and staff interview it was determined the laboratory failed to test samples according to manufacturer instructions for specimen acceptability. Findings included: 1. Review of the manufacturer package inserts for the Siemens Dimension EXL chemistry analyzer

	TPSA reagent revealed: "Intended use: The TPSA method for the Dimention clinical chemistry system with the heterogeneous immunoassay module is an in vitro diagnostic test intended to quantitatively measure total prostate specific antigen (PSA) in human serum and plasma: 1. As an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostate biopsy is required for diagnosis of cancer. 2. As an aid in the management (monitoring) of prostate cancer patients." 2. Review of the laboratory's patient test logs for January to October of 2021 revealed the following patients below age 50 were tested for TPSA without prior diagnosis of prostate cancer: Sample: 210428003 Collected: 04/21/2021 Tested: 04/21/2021 Patient's age: 47 Sample: 210520002 Collected: 05/20/2021 Tested: 05/20/2021 Patient's age: 49 Sample: 210528002 Collected: 05/28/2021 Tested: 05/28/2021 Patient's age: 47 Sample: 210601004 Collected: 06/01/2021 Tested: 06/01/2021 Patient's age: 45 Sample: 210601006 Collected: 06/01/2021 Tested: 06/01/2021 Patient's age: 44 Sample: 210615001 Collected: 06/15/2021 Tested: 06/15/2021 Patient's age: 49 Sample: 210618008 Collected: 06/18/2021 Tested: 06/18/2021 Patient's age: 40 Sample: 210628001 Collected: 06/28/2021 Tested: 06/28/2021 Patient's age: 40 Sample: 210721006 Collected: 07/21/2021 Tested: 07/21/2021 Patient's age: 49 Sample: 210730004 Collected: 07/30/2021 Tested: 07/30/2021 Patient's age: 43 Sample: 210811001 Collected: 08/11/2021 Tested: 08/11/2021 Patient's age: 42 Sample: 210812001 Collected: 08/12/2021 Tested: 08/12/2021 Patient's age: 43 Sample: 210812002 Collected: 08/12/2021 Tested: 08/12/2021 Patient's age: 48 Sample: 210830007 Collected: 08/30/2021 Tested: 08/30/2021 Patient's age: 45 Sample: 210902001 Collected: 09/02/2021 Tested: 09/02/2021 Patient's age: 45 Sample: 211007007 Collected: 10/07/2021 Tested: 10/07/2021 Patient's age: 48 3. In an interview on 09/29 /2021 at 1500 hours in the laboratory Testing Person number 1 (as described on CMS Form 209 and signed by the Laboratory Director on 10/20/2021) stated that she was unaware of age limitations of the test. This confirmed the findings
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's calibration records for the Sysmex XP 300 hematology analyzer, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration every six months. The findings include: 1. A review of the laboratory's policy titled "Calibration of Sysmex XP 300" revealed: "Calibration is done every 6 months." 2. A review of calibration records for the Sysmex XP 300 from 2019 to 2021 revealed calibration were performed at the following times: January 2019 December 2019 (11 months) June 2020 (6 months) April 2021 (10 months) September 2021 (5 months) 3.

	An interview with testing personnel number 1 on 10/20/2021 at 1200 hours in the conference room - after her review of the records- confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's quality control records from March 2021 to August 2021, review of patient test records from March 2021 to August 2021, and staff interview, it was revealed the facility failed to have documentation of testing quality control each day of patient testing for the BioFire Film Array Respiratory Panel 2.1. The findings include: 1. A review of the laboratory's test menu revealed the laboratory performed testing utilizing the BioFire Film Array Respiratory Panel 2.1. This test kit's EUA was removed in March 2021, thus the laboratory was required to perform quality control testing each day of patient testing or develop an Individualized Quality Control Plan to modify the frequency of testing control material. 2. A review of the laboratory's quality control records from March 2021 to August 2021 revealed the laboratory had documentation of performing quality control on the following days: April 28, 2021 July 28, 2021 August 8, 2021 3. A review of patient test records from March 2021 to August 2021 revealed the laboratory performed patient testing on the following days without documentation of quality control testing being performed: a) March 2021 March 17, 2021 March 22, 2021 March 23, 2021 March 25, 2021 March 29, 2021 March 30, 2021 March 31, 2021 b) April 2021 April 4, 2021 April 6, 2021 April 7, 2021 April 8. 2021 April 9, 2021 April 12, 2021 April 14, 2021 April 20, 2021 April 26, 2021 April 27, 2021 April 29, 2021 April 30, 2021 c) May 2021 May 4, 2021 May 6, 2021 May 7, 2021 May 11, 2021 May 12, 2021 May 13, 2021 May 14, 2021 May 18, 2021 May 20, 2021 May 24, 2021 May 25, 2021 May 27, 2021 May 28, 2021 d) June 2021 June 1, 2021 June 2, 2021 June 3, 2021 June 4, 2021 June 7, 2021 June 8, 2021 June 9, 2021 June 10, 2021 June 14, 2021 June 15, 2021 June 16, 2021 June 17, 2021 June 18, 2021 June 21, 2021 June 22, 2021 June 23, 2021 June 29, 2021 e) July 2021 July 2, 2021 July 6, 2021 July 7, 2021 July 8, 2021 July 9, 2021 July 12, 2021 July 13, 2021 July 14, 2021 July 15, 2021 July 16, 2021 July 19, 2021 July 20, 2021 July 21, 2021 July 22, 2021 July 27, 2021 July 29, 2021 July 30, 2021 f) August 2021 August 2, 2021 August 3, 2021 August 4, 2021 August 5, 2021 August 9, 2021 August 10, 2021 August 11, 2021 August 12, 2021 August 13, 2021 August 16, 2021 August 17, 2021 August 18, 2021 August 19, 2021 August 20, 2021 August 23, 2021 August 24, 2021 August 25, 2021 August 26, 2021 August 27, 2021 August 30, 2021 August 31, 2021 g) September 2021 September 1, 2021 September 2, 2021 September 3, 2021 September 7, 2021 September 8, 2021 September 9, 2021 September 10, 2021 September 13, 2021 September 14, 2021 September 15, 2021 September 16, 2021 September 17, 2021 September 20, 2021 September 21, 2021 September 23, 2021 September 24, 2021 September 27, 2021 September 28, 2021 September 29, 2021 September 30, 2021 h) October 2021 October 1, 2021 October 4, 2021 October 5, 2021 October 6, 2021 October 12, 2021 October 13, 2021 October 14, 2021 October 15, 2021 October 18, 2021 4. The laboratory was asked to provide documentation of

	performing quality control testing each day of patient testing, or of developing an Individual Quality Control Plan to modify the frequency of quality control testing. No documentation was provided. 5. An interview with testing personnel number 1 on 10 /20/2021 at 1015 hours in the conference room revealed the laboratory did not perform quality control testing each day of patient testing, nor did it have an Individualized Quality Control Plan. This confirmed the findings.
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 the laboratory's chemistry analyzer's Siemens Dimension EXL with LM/EXL 200 System's Operators Guide, review of the analyzer's maintenance /function checks logs for September and October of 2021, random review of the sample testing logs for Albumin and interview with the staff it was determined the laboratory failed to document corrective action for out of limit maintenance/function checks for 14 of 14 instances corrective action was required. Findings included: 1. Review of the laboratory's chemistry analyzer's Siemens Dimension EXL with LM /EXL 200 System's Operators Guide (page 2-4) revealed: "System Temperature Specifications Cuvette System 36.8 - 37.2C" 2. Review of the Siemens Dimension EXL chemistry analyzer's maintenance/function checks logs revealed no documentation of corrective action for Daily Maintenance Cuvette Temperature out of required range of 36.8 - 37.2C on: 09/28/2021 - temperature: 36.7C 09/30/2021 - temperature: 36.7C 10/01/2021 - temperature: 36.6C 10/02/2021 - temperature: 36.6C 10/03/2021 - temperature: 36.6C 10/04/2021 - temperature: 36.6C 10/05/2021 - temperature: 36.6C 10/06/2021 - temperature: 36.6C 10/07/2021 - temperature: 36.6C 10/08/2021 - temperature: 36.6C 10/09/2021 - temperature: 36.6C 10/10/2021 - temperature: 36.6C 10/11/2021 - temperature: 36.6C 10/12/2021 - temperature: 36.6C 3. Random review of the Siemens Dimension EXL chemistry analyzer's testing records for Albumin revealed testing was performed at the time cuvette temperature was out of range as follows: 09/28/2021 samples tested: 210928001 210928005 09/30 /2021 samples tested: 210930001 210930003 210930004 210930005 210930006 10/01 /2021 samples tested: 211001001 211001002 211001004 211001007 10/04/2021 samples tested: 211004002 211004003 211004005 211004006 10/06/2021 samples tested: 211006001 211006002 211006004 10/07/2021 samples tested: 211007001 211007002 211007003 211007004 211007005 211007006 211007007 4. In an interview on 09/29/2021 at 1600 hours in the laboratory Testing Person number 1 (as described on CMS Form 209 and signed by the Laboratory Director on 10/20/2021) stated that corrective action should have been documented
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of verifying calculations. The findings include: 1. A review of the laboratory's records revealed the facility reported out the following calculated test results: LDL BUN/Creatinine ratio Cholesterol/HDL ratio VLDL eGFR Anion Gap MCV MCH MCHC Microalbumin/Urine Creatinine ratio 2. A review of the laboratory's records from 2019 and 2020 revealed the laboratory failed to have documentation of verifying calculations of the identified testing in 2020. 3. The laboratory was asked to provide documentation of verifying the calculation. No documentation was provided. 4. An interview with testing personnel number 1 on 10/20/2020 at 1420 hours in the conference room confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the verification studies performed on the BioFire Film Array Respiratory Panel 2.1, and staff interview, it was revealed the laboratory director failed to document his approval of the studies. The findings include: 1. A review of the laboratory's verification studies for the BioFire Film Array Respiratory Panel 2.1 (performed in October 2020) revealed the laboratory director failed to document his approval of the studies to ensure accuracy and precision were met. 2. The laboratory was asked to provide documentation of the laboratory director approving the studies. No documentation was provided. 3. An interview with testing personnel number 1 on 10/20/2021 at 1000 hours in the conference room - after her review of the records- confirmed the findings.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS Form 209 submitted at the time of the survey and staff interview it was determined the laboratory director failed to fill the required position of technical consultant. Findings included: 1. Review of the laboratory's CMS Form 209 revealed there was no position of technical consultant assigned to any of the laboratory personnel. 2. In an interview on 09/29/2021 at 0930 hours in the conference room Testing Person number 1 (as described on CMS Form 209 and signed by the Laboratory Director on 10/20/2021) stated that the laboratory did not have a technical consultant at the time of the survey. This confirmed the findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's CMS Form 209 submitted at the time of the survey and staff interview it was determined the laboratory failed to have the required position of technical consultant filled (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is

	responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS Form 209 submitted at the time of the survey and staff interview it was determined the laboratory failed to have a technical consultant meeting the necessary education, training and experience requirements. Findings included: 1. Review of the laboratory's CMS Form 209 revealed there was no position of technical consultant assigned to any of the laboratory personnel. 2. In an interview on 09/29/2021 at 0930 hours in the conference room Testing Person number 1 (as described on CMS Form 209 and signed by the Laboratory Director on 10/20/2021) stated that the laboratory did not have a technical consultant at the time of the survey. This confirmed the findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory staff's competency assessment records for 2019, 2020 and 2021 and staff interview it was determined the technical consultant failed to document assessment of test performance through testing previous specimens, blind test samples or external PT samples for one of one testing persons. Findings included: 1. Review of the laboratory's personnel competency assessment records for 2019, 2020 and 2021 revealed there was no documentation of assessment of test performance through testing previous specimens, blind test samples or external PT samples for Testing Person #1 for the following test systems: 2019: Hematology Sysmex XP-300 analyzer Chemistry Dimention EXL analyzer 2020: Biofire Molecular Testing 2. In an interview on 09/29/2021 at 0930 hours in the conference room Testing Person number 1 (as described on CMS Form 209 and signed by the Laboratory Director on 10/20/2021) after review of the data confirmed the findings.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

	This STANDARD is not met as evidenced by: Based on review of the laboratory staff's competency assessment records for 2019, 2020 and 2021 and staff interview it was determined the technical consultant failed to document assessment of problem solving skills for one of one testing persons. Findings included: 1. Review of the laboratory's personnel competency assessment records for 2019, 2020 and 2021 revealed there was no documentation of assessment of problem solving skills for Testing Person #1 for the following test systems: 2020: Hematology Sysmex XP-300 analyzer Chemistry Dimention EXL analyzer Biofire Molecular Testing 2. In an interview on 09/29/2021 at 0930 hours in the conference room Testing Person number 1 (as described on CMS Form 209 and signed by the Laboratory Director on 10/20/2021) after review of the data confirmed the findings.