

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2285485	(X3) Date Survey Completed 04/24/2024
Name of Provider or Supplier Qc Kinetix- Madison Sw	Street Address, City, State 406 Science Dr Suite 410, Madison, WI	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, a "FREND Verification Report", and interview with the laboratory owner (Staff B), the laboratory did not demonstrate that it could obtain performance specifications comparable to those established by the manufacturer for two of two analytes tested with the FREND test system prior to performing seven patient tests and did not evaluate the appropriateness of the reference ranges (normal values) for the two tests. Findings include: 1. Review of laboratory test records showed the laboratory performed testosterone and prostate specific antigen (PSA) patient tests on January 8 and 15, March 20 and 27, and April 3 and 17, 2024. The laboratory tested two patient samples on April 17, 2024. Further review of laboratory test records showed the laboratory performed portions of the verification testing on January 3, 10, 24, and 31, 2024. The records in the laboratory showed no evidence of evaluation of the results of the verification testing and showed no evaluation of reference ranges (normal values). 2. During the survey on April 24, 2024, technical support for NanoEntek, the manufacturer of the FREND test system, emailed the "FREND Verification Report" for this laboratory dated February 2, 2024. The report included results for the evaluation of accuracy, precision, and linearity (reportable range) for testosterone and PSA. The report did not include evaluation of the reference ranges for the test system. 3. Interview with Staff B on April 24, 2024, at</p>

	<p>10:00 AM confirmed the laboratory did not receive the "FREND Verification Report" prior to the survey and confirmed the director had not evaluated the report to ensure the performance specifications from the manufacturer were comparable to those obtained in this laboratory.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and manufacturer's documentation and interview with testing personnel (Staff A), the laboratory had not documented the maintenance required by the manufacturer for the FREND analyzer in three of three months when the laboratory performed patient testing. Findings include: 1. Review of laboratory records showed performance of patient tests in January, March, and April 2024. 2. Review of the instrument binder revealed a manufacturer's maintenance log showing the required maintenance. The log showed no evidence staff had performed the required maintenance. 3. Interview with Staff A on April 24, 2024, at 10:45 AM confirmed they had not used the maintenance log to document maintenance for the test system and confirmed not all required maintenance was performed.</p>
<p>D5447</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel (Staff A), the laboratory did not test two levels of external control material for testosterone and prostate specific antigen (PSA) testing performed on six of six days of patient testing. Findings include: 1. Review of patient test reports showed staff performed testing on January 8 and 15, March 20 and 27, and April 3 and 17. Further review of records showed no evidence of external liquid controls testing on any of the six days staff performed patient testing. 2. Interview with Staff A on April 24, 2024, at 10:15 AM confirmed staff did not test two control materials of different concentrations on days of patient testing and confirmed the laboratory had not developed an approved procedure that provided equivalent quality testing.</p>
<p>D5787</p>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of</p>

specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with testing personnel (Staff A), the laboratory did not maintain a record system that included the date and time of specimen receipt (collection) or the identity of the testing person who performed the tests for seven of seven patient testosterone and prostate specific antigen (PSA) tests performed. Findings include: 1. Review of seven patient reports from January to April 2024 showed no documentation of the testing person who performed the testosterone and PSA tests, or the date and time staff collected the specimen. 2. Interview with Staff A on April 24, 2024, at 10:30 AM confirmed the laboratory had not documented the date and time staff collected the specimen and the identity of the testing person responsible for test performance.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of laboratory records and policies and procedures, observation of supplies, and interviews the laboratory director did not provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The director did not ensure the laboratory enrolled in a proficiency testing program and had not developed a process for twice annual accuracy verification for the testosterone and prostate specific antigen tests. See D6015. 2. The director did not establish a quality control program for testing on the FREND analyzer. See D6020. 3. The director did not establish a quality assurance program to assure the quality of laboratory services. See D6021. 4. The director did not ensure documentation of training and the ability of staff to accurately perform testing was available. See D6029.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the laboratory owner (Staff B), the laboratory director did not ensure the laboratory enrolled in a proficiency testing program or developed a plan to evaluate accuracy twice annually

for two of two non-waived test systems performed in the laboratory since testing started in January 2024. Findings include: 1. Review of laboratory records showed no evidence of proficiency testing enrollment or records, or a process for twice annual accuracy verification for the testosterone or prostate specific antigen testing performed on the FRENDA analyzer. 2. Interview with Staff B on April 24, 2024, at 9:30 AM confirmed the director did not ensure the laboratory was enrolled in a proficiency testing program and did not have a process in place for twice annual accuracy verification of the testosterone or PSA assays.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records, observation of supplies in the laboratory, and interview with testing personnel (Staff A), the laboratory director did not establish a quality control program that met the regulatory requirements for two of two non-waived analytes. Findings include: 1. Review of laboratory records showed no evidence staff tested two levels of external quality control samples on each day of testosterone or prostate specific antigen (PSA) patient testing. See D5447. 2. Further review of laboratory records showed no evidence the laboratory had developed an individualized quality control plan (IQCP) as an equivalent quality testing program. Review of quality control logs showed staff had not recorded any information on the logs. The logs included a statement directing staff to perform two levels of liquid quality control testing monthly, with new lot numbers, and new testing personnel. 3. Observation of supplies in the laboratory on April 24, 2024, at 11:00 AM showed no evidence the laboratory had external quality control samples available for testing. 4. Interview with Staff A on April 24, 2024, at 10:45 AM confirmed the laboratory had not developed an IQCP and confirmed personnel did not test quality control samples each day of testing. Further interview at 11:00 AM confirmed the laboratory did not have external liquid controls available to test.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory policies and procedures and interview with the laboratory owner (Staff B), the laboratory director had not established a quality

assessment program that monitors and assures the quality of laboratory services throughout the laboratory including pre-analytic, analytic, and post-analytic processes. Findings include: 1. Review of laboratory policies showed no evidence of a quality assessment program to monitor the laboratory operations and assure continued quality throughout the laboratory. 2. Interview with Staff B on April 24, 2024, at 11:00 AM confirmed the laboratory director had not established or implemented a quality assessment program to monitor the quality of laboratory operations.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview with testing personnel (Staff A), the laboratory director did not ensure three of three testing personnel had documented training for the FRENDA analyzer or had demonstrated performance of all testing operations reliably to provide and report accurate results prior to performing patient testing. Findings include: 1. Review of laboratory records showed no evidence of training on the FRENDA analyzer for the three testing personnel and no documented evidence the testing personnel had demonstrated that they could perform the tests reliably before they performed patient testing. 2. Interview with Staff A on April 24, 2024, at 9:30 AM confirmed there was no documentation of the training provided by the technical service representative on the FRENDA analyzer that included demonstration of testing samples.

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 surveyor review of submitted Centers for Medicare and Medicaid Services (CMS) forms and personnel records and interviews, the technical consultant, who is also the laboratory director, did not show they met the qualification requirements of 493.1411. Findings include: 1. The technical consultant did not show they had the required training or experience in non-waived testing to meet the qualification requirements. See 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 surveyor review of the submitted Centers for Medicare and Medicaid Services (CMS) Form, CMS-209 'Laboratory Personnel Report (CLIA)' and personnel records, and interview with the owner (Staff B) and email with the laboratory director, one of one technical consultant did not meet the laboratory training or experience requirements to qualify as a technical consultant. Findings include: 1. Review of the submitted CMS-209 form signed by the laboratory director on April 16, 2024, showed the laboratory director also identified as the technical consultant. The form did not identify any other technical consultant. 2. Review of provided records showed no evidence the laboratory director had received training or had experience performing non-waived testing. 3. Interview with Staff B on April 24, 2024, at 9:30 AM revealed the owner could not confirm the director had the required training or experience to meet the qualification requirements for technical consultant. 4. The laboratory director did not respond by May 2, 2024, to email correspondence sent April 30 and May 1, 2024, requesting documentation showing training or experience in non-waived clinical chemistry testing.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on surveyor review of CMS (Centers for Medicare and Medicaid Services) forms and personnel records, and interview with the owner (Staff B), the laboratory did not provide credentials for three of three testing personnel to show they were qualified to perform moderate complexity testing. Findings include: 1. The laboratory did not show three of three testing personnel met the qualification requirements for moderate complexity testing. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 'Laboratory Personnel Report (CLIA)' and personnel records, and interview with the owner (Staff B), three of three non-waived testing personnel did not have documented evidence showing they met the qualification requirements to perform moderate complexity testing. Findings include: 1. Review of the Form CMS-209 submitted for this survey and signed by the laboratory director on April 16, 2024, showed the laboratory had three non-waived testing personnel. 2. Review of personnel records showed no evidence three of the three testing personnel met the academic requirements for non-waived testing personnel. 3. Interview with Staff B on April 24, 2024, at 09:30 AM confirmed credentials were not available to show the three testing personnel met the regulatory requirements for moderate complexity testing personnel.