

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2271743	(X3) Date Survey Completed 05/18/2023
Name of Provider or Supplier Qc Kinetix	Street Address, City, State 18707 Hardy Oak Blvd #445, San Antonio, 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	An initial survey was performed on May 18, 2023. The laboratory was found to be out of compliance with the CLIA regulations based on the following CONDITION level deficiency: 493.1415 Clinical Consultant, (moderate complexity)
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records, and confirmed in staff interview, the laboratory failed to ensure patient criteria for testing was met as specified by the manufacturer's instructions for 2 of 2 patients in 2023. Findings included: 1. A review of the manufacturer's instructions for FRENDA PSA Plus (version 0.6) stated, "This device is indicated for the serial measurement of total Prostate Specific Antigen (PSA) to be used as an aid in the management of patients with prostate cancer." 2. Review of patient testing records for 2023 revealed the following 2 patients had PSA testing and did not have a history of prostate cancer: Patient ID Date of Service 3/14/65 04/21/2023 8/14/55 05/04/2023 3. During an interview on 05/18/2023 at 1125 hours in the break room, after the above records were reviewed, testing person number 1 (as listed on CMS 209 form) confirmed the findings.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, the laboratory's FRENED verification studies, patient records, and confirmed in staff interview, the laboratory failed to complete patient normal range studies and failed to approve the assay performance prior to performing patient testing for 2 of 2 unmodified FDA-approved assays. Findings included: 1. A review of the laboratory's test menu revealed the following 2 analytes were tested on the FRENED analyzer in 2023: Prostate Specific Antigen (PSA) Total Testosterone 2. The laboratory was asked to provide documentation of performing the required normal range studies. No documentation was provided. 3. A review of the laboratory's FRENED verification studies performed in 2023 revealed the laboratory director approved the studies on 05/15/2023. 4. A review of patient testing records for 2023 revealed the following 3 patients were tested on the FRENED analyzer: Patient ID Date of Service Analyte(s) 3/29/71 03/09/2023 Testosterone 3/14/65 04/21/2023 Testosterone and PSA 8/14/55 05/04/2023 Testosterone and PSA The laboratory failed to approve the FRENED test system prior to performing patient testing. 5. During an interview on 05/18/2023 at 1125 hours in the break room, after review of the above records, testing person number 1 (as listed on CMS 209 form) confirmed the above findings.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient reports and confirmed in staff interview, the laboratory failed to provide normal range values for 2 of 2 patient records. Findings included: 1. Review of the following patient electronic medical records revealed the following: a) Patient PRN: WT342150 Result: "Initial: Baseline 5/4/2023: TT: 112 PSA: 0.50" b) Patient PRN: Gj802643 Result: "Initial: Baseline 4/21/2023: TT: 211 PSA: 2.24 " The laboratory failed to indicate normal range values on the test report. 2. In an interview on 05/18/2023 at 1125 hours in the break room, after review of patients records, testing person number 1 (as listed on CMS 209 form) confirmed the findings. Word key: TT = Testosterone PSA = Prostate specific antigen

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 review of manufacturer's instructions, laboratory records, and confirmed in staff interview, the laboratory director failed to develop a quality control plan to establish statistical limits of quality control for 2 of 2 unmodified FDA-approved assays. Findings included: 1. A review of the manufacturer's instructions titled "Cliniqa Liquid QC Immunoassay Control (32928_07 8/24/18)" stated, "The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation." 2. A review of the laboratory's document titled "NanoEntek FREND Controls, Tubes, AMR, and Normal Range Guide" stated the following: Cliniqa Control Material - Lot #2008122A, Expiration 10/2023 a) PSA Mean Range Level 1 1.7 0.98 - 2.42 Level 2 14.95 9.55 - 20.35 b) Testosterone Mean Range Level 1 193.45 86.08 - 300.83 Level 2 947.56 585.36 - 1309.77 3. The laboratory was asked to provide documentation for establishing Cliniqa quality control material means and standard deviations. No documentation was provided. 4. In an interview on 05/18/2023 at 1125 hours in the break room, after review of the above records, testing person number 1 (as listed on CMS 209 form) confirmed the findings. Word key: AMR = Analytical Measurement Range QC = Quality Control ng/mL = nanograms per milliliter ng/dL = nanograms per deciliter

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 review of laboratory records and confirmed in staff interview, the laboratory director failed to establish a quality assessment program to ensure the quality of laboratory services provided. Findings included: 1. The laboratory was asked to provide documentation indicating a quality assessment program has been established. No documentation was provided. 2. In an interview on 05/18/2023 at 1000 hours in the break room, testing person number 1 (as indicated on CMS 209 form) was asked to provide policies and procedures related to the laboratory's quality assessment program. Testing person number 1 stated none were established. This confirmed the findings.

D6056

CLINICAL CONSULTANT
CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:
Based on review of the laboratory Centers for Medicare and Medicaid (CMS) 209 form, laboratory records, and confirmed in interview, the facility failed to have documentation available for review to qualify the clinical consultant for his position as clinical consultant of a moderate complexity laboratory. Refer to D6057

D6057

CLINICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's personnel records and confirmed in staff interview, the designated Clinical Consultant failed to meet the qualification requirements for a Clinical Consultant. Findings included: 1. The laboratory was asked to provide the designated Clinical Consultant's qualifications. No documentation was provided. 2. During an interview on 05/18/2023 at 1000 hours in the break room, testing person number 1 (as listed on CMS 209 form) confirmed that no qualification documentation was available.