

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2285073	<b>(X3) Date Survey Completed</b>  02/01/2024
<b>Name of Provider or Supplier</b>  Qc Kinetix Independence	<b>Street Address, City, State</b>  6701 Rockside Road, Suite 360, Independence, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6000</b>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. The Laboratory Director failed to ensure the NanoEnTek test systems provided quality services for all aspects of test performance through all phases of testing in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. (Refer to D6007) 2. The Laboratory Director failed to ensure the test methodologies selected had the capability of providing the quality of results required for patient care in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. (Refer to D6012) 3. The Laboratory Director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program for the prostatic specific antigen (PSA) testing performed in the subspecialty of Routine Chemistry. (Refer to D6015) 4. The Laboratory Director failed to ensure that the quality control (QC) program was maintained to assure the quality of laboratory services provided in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. (Refer to D6020) 5. The Laboratory Director failed to ensure the quality assessment program was established and</p>

maintained to assure the quality of laboratory services provided in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. (Refer to D6021) 6. The Laboratory Director failed to ensure the quality control programs were maintained to identify failures in quality as they occurred in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. (Refer to D6022) 7. The Laboratory Director failed to ensure that all remedial actions were taken and documented when significant deviations from the laboratory's established performance specification occurred in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. (Refer to D6024) 8. The Laboratory Director failed to ensure that patient test results were not reported when the system was not functioning properly in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. (Refer to D6025) 9. The Laboratory Director failed to ensure that patient test reports included the laboratory location where the tests in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing were performed. (Refer to D6026) 10. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process for prostatic specific antigen (PSA) testing and testosterone (TESTO) testing performed in the subspecialties of Routine Chemistry and Endocrinology, respectively. (Refer to D6031)

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on record review, direct observation and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure the NanoEnTek test systems provided quality services for all aspects of test performance through all phases of testing in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02 /01/2024. Findings Include: 1. Review of the laboratory's "Non-Waived Moderate Complexity CLIA Compliance Manual", unapproved by the Laboratory Director via signature and date, provided on the date of inspection revealed this was established by the manufacturer and provided to the laboratory as a general Standard Operating Procedure manual which included CLIA regulation verbiage. 2. Further review of the "Non-Waived Moderate Complexity CLIA Compliance Manual" found a section titled "Establishment and Verification of Performance Specifications" with the following statement: "When multiple FREND Systems are used to perform the same test, the laboratory must verify or establish performance specifications for each

instrument. Prior to reporting patient results, the laboratory is responsible for verifying the performance specifications. The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the laboratory's needs, as determined by the laboratory director...A laboratory may use the manufacturer's performance specifications as a guideline, but is responsible for verifying the manufacturer's analytical claims before initiating patient testing. Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data." 3. Direct observation of the laboratory found two NanoEnTek analyzers utilized for TESTO testing with serial numbers FAP220501-004 and FAP220905-027 and one NanoEnTek analyzer utilized for PSA testing with serial number FIOU220503-014. 4. The Inspector requested the laboratory's performance verification documentation for the three NanoEnTek test systems prior to patient testing from the Laboratory Director. The Laboratory Director provided two "Verification of Reportable Range/Calibration" worksheets, one each for PSA and TESTO, dated 08/31/2023, with no indication of analyzer serial number /identification and two "Verification of Accuracy/Precision" worksheets, one each for PSA and TESTO dated 09/07/2023 and 09/14/2023 with no indication of analyzer serial number/identification and without any indication of who performed the activities, any review, evaluation of results and acceptance via signature and date. 5. The Laboratory Director and Laboratory Owner, on 02/01/2024 at 8:35 AM, confirmed the Laboratory Director did not ensure the laboratory conducted performance verification studies on all analyzers utilized for patient testing, indicated what analyzer the activities were performed on, indicated who performed the activities, indicated any review, indicated evaluation of the results and indicated acceptance of the results via signature and date.

**D6012**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(i)

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) The test methodologies selected have the capability of providing the quality of results required for patient care;

This STANDARD is not met as evidenced by:  
Based on record review, direct observation and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure the test methodologies selected had the capability of providing the quality of results required for patient care in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's "Non-Waived Moderate Complexity CLIA Compliance Manual", unapproved by the Laboratory Director via signature and date, provided on the date of inspection revealed this was established by the manufacturer and provided to the laboratory as a general Standard Operating Procedure manual which included CLIA regulation verbiage. 2. Further review of the "Non-Waived Moderate Complexity CLIA Compliance Manual" found a section titled "Establishment and Verification of Performance Specifications" with the following statement: "When multiple FRENDS System are used to perform the same

test, the laboratory must verify or establish performance specifications for each instrument. Prior to reporting patient results, the laboratory is responsible for verifying the performance specifications. The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the laboratory's needs, as determined by the laboratory director...A laboratory may use the manufacturer's performance specifications as a guideline, but is responsible for verifying the manufacturer's analytical claims before initiating patient testing. Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data." 3. Direct observation of the laboratory found two NanoEnTek analyzers utilized for TESTO testing with serial numbers FAP220501-004 and FAP220905-027 and one NanoEnTek analyzer utilized for PSA testing with serial number FIOU220503-014. 4. The Inspector requested the laboratory's performance verification documentation for the three NanoEnTek test systems prior to patient testing from the Laboratory Director. The Laboratory Director provided two "Verification of Reportable Range/Calibration" worksheets, one each for PSA and TESTO, dated 08/31/2023, with no indication of analyzer serial number /identification and two "Verification of Accuracy/Precision" worksheets, one each for PSA and TESTO dated 09/07/2023 and 09/14/2023 with no indication of analyzer serial number/identification and without any indication of who performed the activities, any review, evaluation of results and acceptance via signature and date. 5. Review of the laboratory's "Quality Control (QC) Log - PSA Plus" and "Quality Control (QC) Log - Testosterone" found the laboratory, due to the routine QC material failing, utilized linearity material as QC with no documentation of lot numbers, expiration dates and acceptable ranges for the following days of QC testing: 11/03/2023, 12/07/2023, 12/14/2023, 12/21/2023, 01/04/2024, 01/11/2024 and 01/18 /2024 6. Further review of the laboratory's QC logs revealed the following documented QC acceptable ranges and the laboratory's QC results indicated as "pass". "Quality Control (QC) Log - PSA Plus" Lot# 303077 Level 1 Lab result 0.98-2.42 3.05 on 02/01/2024 "Quality Control (QC) Log - Testosterone" Lot # 353004 Level 2 Lab result 585.36-1309.77 1500 on 01/25/2024 1500 on 02/01/2024 7. The Laboratory Director and Laboratory Owner, on 02/01/2024 at 8:35 AM, confirmed the Laboratory Director did not review, evaluate the results and indicate acceptance of the results via signature and date and failed to accurately document the capability of providing the quality of results required for patient care.

**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 record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing (PT) program for the prostatic specific antigen (PSA) testing performed in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect four out of four patient PSA testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include:

1. Review of the laboratory's "Proficiency Testing (PT)" policy and procedure provided to the laboratory by the manufacturer, unapproved by the Laboratory Director via signature and date and provided on the date of the inspection, found CLIA regulation text along with the following statement: "NanoEnTek recommends 'American Proficiency Institute' to gather all our customers to increase the number of population to enable better statistical assessment." 2. The Inspector requested the laboratory's 2023 and 2024 PT enrollment confirmation documents and all PT event documentation since the implementation of PSA testing on 10/12/2023 from the Laboratory Director and Laboratory Owner. The Laboratory Director confirmed the laboratory did not enroll with a PT provider for the regulated PSA testing performed in this laboratory and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 02/01/2024 at 9:45 AM.

**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 record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure that the quality control (QC) program was maintained to assure the quality of laboratory services provided in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's "Quality Control (QC) Procedures" policy and procedure provided to the laboratory by the manufacturer and unapproved by the Laboratory Director found the following statements: "Results of control materials must meet the laboratory's and the manufacturer's criteria for acceptability before reporting patient test results..." 2. Review of the laboratory's "Quality Control (QC) Log - PSA Plus" and "Quality Control (QC) Log - Testosterone" found the laboratory, due to the routine QC material failing, utilized linearity material as QC with no documentation of lot numbers, expiration dates and acceptable ranges for the following days of QC testing: 11/03/2023, 12/07/2023, 12/14/2023, 12/21/2023, 01/04/2024, 01/11/2024 and 01/18/2024 3. Further review of the laboratory's QC logs revealed the following documented QC acceptable ranges and the laboratory's QC results indicated as "pass". "Quality Control (QC) Log - PSA Plus" Lot# 303077 Level 1 Lab result 0.98-2.42 3.05 on 02/01/2024 "Quality Control (QC) Log - Testosterone" Lot # 353004 Level 2 Lab result 585.36-1309.77 1500 on 01/25/2024 1500 on 02/01/2024 4. The Laboratory Director and Laboratory Owner, on 02/01/2024 at 8:56 AM, confirmed the Laboratory Director did not ensure the laboratory reviewed, evaluated and indicated acceptance of the QC results via signature and date, prior to patient testing.

**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 record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure the quality assessment program was established and maintained to assure the quality of laboratory services provided in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the inspection and unapproved by the Laboratory Director via signature and date did not find any mention of a quality assessment program. 2. The Inspector requested the laboratory's quality assessment policy and procedure, approved by the Laboratory Director via signature and date, from the Laboratory Director and Laboratory Owner. The Laboratory Director confirmed the Laboratory Director did not ensure the laboratory established a quality assessment policy and procedure, documented quality assessment activities and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 02/01/2024 at 11:23 AM.

**D6022**

**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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure the quality control programs were maintained to identify failures in quality as they occurred in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's "Verification of Control Materials" policy and procedure provided to the laboratory by the manufacturer and unapproved by the Laboratory Director found the following statements: "The laboratory must demonstrate that each reagent performs within the specifications established by the laboratory for the test procedure...Results of control materials must meet the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient test results..." 2. Review of the laboratory's "Quality Control (QC) Log - PSA Plus" and "Quality Control (QC) Log - Testosterone" found the laboratory, due to the routine QC material failing, utilized

linearity material as QC with no documentation of lot numbers, expiration dates and acceptable ranges for the following days of QC testing: 11/03/2023, 12/07/2023, 12/14/2023, 12/21/2023, 01/04/2024, 01/11/2024 and 01/18/2024 3. Further review of the laboratory's QC logs revealed the following documented QC acceptable ranges and the laboratory's QC results indicated as "pass" with no documentation of the failures and corrective action. "Quality Control (QC) Log - PSA Plus" Lot# 303077 Level 1 Lab result 0.98-2.42 3.05 on 02/01/2024 "Quality Control (QC) Log - Testosterone" Lot # 353004 Level 2 Lab result 585.36-1309.77 1500 on 01/25/2024 1500 on 02/01/2024 4. The Laboratory Director and Laboratory Owner, on 02/01/2024 at 8:56 AM, confirmed the Laboratory Director did not ensure the laboratory reviewed, evaluated and documented any corrective action for the failed QC results prior to patient testing.

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:  
Based on record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure that all remedial actions were taken and documented when significant deviations from the laboratory's established performance specification occurred in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's "Split Sample Analysis /Method Comparison" log revealed the following four out of four patient results: Date Lab Result Reference Lab Result TESTO 10/12/23 392.1 318 12/21/23 171.4 578 12/21/23 193.7 466 01/25/24 42.66 235 PSA 10/12/23 1.42 1.1 12/21/23 0.88 0.8 12/21/23 4.47 4.0 01/25/24 0.26 0.3 2. The Inspector requested the laboratory's review and evaluation documentation of the split sample comparison studies from the Laboratory Director and Laboratory Owner. The Laboratory Director confirmed the result discrepancies and that the laboratory did not review and document any evaluation of the comparison studies performed, did not take remedial action, as necessary, and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 02/01/2024 at 11:42 AM.

**D6025**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:  
 Based on record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure that patient test results were not reported when the system was not functioning properly in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's "Quality Control (QC) Log - PSA Plus" and "Quality Control (QC) Log - Testosterone" found the laboratory, due to the routine QC material failing, utilized linearity material as QC with no documentation of the lot numbers, expiration dates and acceptable ranges on 12/21/2023 with two patient PSA and TESTO results reported. 2. Review of the laboratory's quality control documentation found the following unacceptable result with one patient TESTO result reported: "Quality Control (QC) Log - Testosterone" Lot # 353004 Level 2 Lab result 585.36-1309.77 1500 on 01/25/2024 3. The Laboratory Director and Laboratory Owner confirmed test results were reported on 12/21/2023 and 01/25/2024. The interviews occurred on 02/01/2024 at 11:50 AM.

**D6026**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:  
 Based on record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure that patient test reports included the laboratory location where the tests in the subspecialties of Routine Chemistry for prostatic specific antigen (PSA) testing and Endocrinology for testosterone (TESTO) testing were performed. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of four out of four of the laboratory's QC Kinetix Non-Surgical Regeneration" hand written final test reports, with the NanoEnTek result print-out taped on it, did not find the laboratory address, where the testing was performed included on the report. 2. Interviews with the Laboratory Director and Laboratory Owner revealed the laboratory scans the hand written final test report into the patient's medical record when completed and confirmed the final test report did not include the address of the laboratory location where the testing was performed. The interviews occurred on 02/01/2024 at 10:43 AM.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Director and Laboratory Owner, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process for prostatic specific antigen (PSA) testing and testosterone (TESTO) testing performed in the subspecialties of Routine Chemistry and Endocrinology, respectively. This deficient practice had the potential to affect four out of four patient PSA and TESTO testing procedures performed in this laboratory from 10/12/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's "Non-Waived Moderate Complexity CLIA Compliance Manual", unapproved by the Laboratory Director via signature and date, provided on the date of inspection revealed this was established by the manufacturer and provided to the laboratory as a general Standard Operating Procedure manual which included CLIA regulation verbiage. 2. Review of the laboratory's "QC Kinetix Non-Surgical Regeneration Policies and Procedures", provided on the date of the inspection, found it unapproved by the Laboratory Director via signature and date. This five-page document included the laboratory's policy, procedure, patient preparation, blood collection, post procedure, lab processing, specimen acceptability and rejection, specimen storage and preservation and specimen referral. 3. The Laboratory Director and Laboratory Owner confirmed that the Laboratory Director did not indicate their approval of any of the laboratory's policies and procedures via signature and date. The interviews occurred on 02/01/2024 at 9:20 AM.