

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2124751	<b>(X3) Date Survey Completed</b>  12/17/2020
<b>Name of Provider or Supplier</b>  Pcg Molecular Llc	<b>Street Address, City, State</b>  755 Mount Vernon Hwy, Ne, Ste 230, Atlanta, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) initial survey was completed on December 17, 2020. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780 resulting in immediate jeopardy. The following deficiencies were cited:
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and an interview with the Laboratory Director (LD), the laboratory failed to provide a flammables cabinet, shower station and eyewash for immediate emergency use within the laboratory area. The findings include: 1. The laboratory failed to have a shower station and eyewash available in the laboratory to ensure safety measures of any person's eyes or body that may be exposed to injurious corrosive materials, for quick drenching or flushing for immediate emergency use. A tour of the laboratory confirmed a shower station and eye wash was absent from the laboratory area. 2. The laboratory is using flammable reagents for RNA extractions and storing the reagents in the fume hood. The laboratory does not have a flammables cabinet to safely store the flammable reagents. 3. The LD confirmed on 12/17/2020, at 11:45 AM, in the laboratory, that a shower station, eye wash and flammables cabinet has been absent from the laboratory from September 2020 through December 2020.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on surveyor review of the procedure manual and interview with the testing personnel (TP), determined that the laboratory failed to establish a written policy that assess employee competency for all laboratory procedures performed in the laboratory from September 2020 to December 2020. The findings include: 1. The laboratory failed to have a written policy and procedure to assess competency based on the position responsibilities on an initial, semi-annual, and annual bases. 2. An initial competency was not performed for any of the testing personnel prior to patient testing from September 2020 through December 2020. 3. An interview with the Laboratory Director on 12/17/2020 at 2:30 PM, in the office, confirmed that the laboratory did not have a written policy for assessing employee competency for all test performed in the laboratory.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency test (PT) records and interview with the Laboratory Director (LD), the laboratory failed to ensure that at least twice annually the laboratory verified the accuracy of BioCode SARS-CoV-2 assay and unregulated analytes. The findings include: 1. Review of the laboratory's records revealed that there was no documentation of peer review or internal proficiency testing (PT) performed twice annually for the BioCode SARS-CoV-2 assay for unregulated analytes. 2. The laboratory does not have a policy indicating how PT for unregulated analytes is assessed. 3. The LD confirmed on 12/17/2020, at 1:30 PM, in the office, that the laboratory has not performed PT twice annually for the BioCode SARS-CoV-2 assay or unregulated analytes from September 2020 through December 2020.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual (SOP), quality assurance (QA) records, and interview with the testing personnel the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. Th findings include: 1. Review of QA records revealed that the laboratory does not have a QA policy that indicates the necessary steps to be taken to identify and correct problems, nor efforts to prevent recurrences

	<p>and necessary procedures to prevent reoccurrence of problems in the laboratory. 2. Corrective actions are being performed in the laboratory but are not being documented. The laboratory does not have a policy or log for corrective actions regarding patient testing. 3. The LD confirmed on 12/17/2020, at 12:30 PM, in the office, that the laboratory is performing corrective actions but not documenting them. The LD also confirmed that the QA policy does not adequately assess and identify problems in the laboratory.</p>
<p><b>D5311</b></p>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> 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 surveyor review of laboratory records and observation, the laboratory failed to have a written procedure for specimen rejection and the labeling of specimens. The findings include: 1. A review of the laboratory procedure manual and interview with testing personnel, the laboratory failed to have a written procedure for the criteria of specimen rejection for all test performed in the laboratory when patient testing started in September 2020. 2. An interview with the LD, in the office, on 12/17/2020 at 2:30 PM, confirmed that the laboratory did not have a written procedure for specimen rejection or labeling of specimens from September 2020 through December 2020.</p>
<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to monitor and evaluate the overall quality of the analytic systems regarding the procedure manual, maintenance and function checks, calibration verification, and control procedures for all instrumentation present in the laboratory resulting in immediate jeopardy. (Refer to D5401, D5421, and D5441)</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the laboratory's procedure manual and interview, the laboratory failed to have a written procedure for all tests, assays, and examinations performed in the laboratory. The findings include: 1. The laboratory did not have an established written procedure manual for all tests, examinations, and assays performed in the laboratory. 2. The laboratory does not have procedures for specimen labeling, handling, storage, and reportable ranges for patient test results, validations, quality assurance or patient reporting. 3. The laboratory did not have a procedure for their BioCode SARS-CoV-2 assay. 4. The laboratory failed to have an SOP that describes the practices, resources, and procedures to control the quality of a test process for their BioCode SARS-CoV-2 assay. The SOP should include all laboratory procedures including manufacturer's operator manuals, and package inserts and must reflect the director's review and approval including any modifications in the procedure. 5. There was no evidence that the laboratory has an SOP, or that it was reviewed and approved by the LD prior to the start of patient testing in September 2020. Approval of procedures and changes to procedures is the responsibility of the Laboratory Director. 6. The LD confirmed on 12/17/2020 at 2:30 PM, in the office, that the laboratory did not have a procedure manual for all test performed in the laboratory from September 2020 through December 2020.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

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 laboratory records and interview with the LD, it was determined that the laboratory failed to meet analytic system requirements for their BioCode SARS-CoV-2 assay from September 2020 through December 2020. The findings include: 1. The laboratory verification process failed to provide a written description that documents all actions required to validate their BioCode SARS-CoV-2 assay with CLIA requirements. The laboratory must describe how each test is validated with statistically significant verification for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference ranges. 2. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for their SARS-CoV-2 assay. The laboratory had no records for the validation or correlation data for their BioCode SARS-CoV-2 assay. 3. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for BioCode SARS-CoV-2 assay. 4. The laboratory limits of detection are not supported by the data provided by the laboratory and failed to establish lower and upper limits of detection for their BioCode SARS-CoV-2 assay. 5. The laboratory is performing this assay off-label and outside of the Food & Drug Administration (FDA) Emergency Use Authorization (EUA) for the assay. The facility is using an MGI extraction kit to perform RNA

extractions instead of the required easyMAG or MagNA Pure 96 as required by the manufacturer for optimal assay performance. The laboratory had no documentation of correlations studies to determine if the MGI extraction kit is comparable to kits required for use by the manufacturer. 6. An interview with the LD, on 12/17/2020 at 1:00 PM, in the office, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference interval (normal range) for their BioCode SARS-CoV-2 assay from September 2020 through December 2020.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's quality control (QC) records and interview with the LD, the laboratory failed to monitor the QC failures, corrective actions, accuracy and precision of test performance for their BioCode SARS-CoV-2 assay. The findings include: 1. Review of QC records revealed no evidence that quality control pass or fail records are reviewed by the Technical Supervisor (TS) or Laboratory Director (LD) prior to reporting patient results. The laboratory does not have a method or policy for reviewing quality control values to determine shifts or trends for their BioCode SARS-CoV-2 assay. 2. An interview with the LD, on 12/17/2020 at 2:30 PM, in the office, confirmed that the laboratory is performing QC, but does not have any supporting documentation that QC records were being reviewed by the TS or LD prior to reporting patient results from September 2020 through December 2020. .

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of patient test reports and interview with the Laboratory Director, the laboratory failed to include units of measure, time of collection, reference ranges, and

	<p>normal values used for testing on patient test reports. The findings include: 1. A review of patient reports failed to include time of collection and reference ranges used for testing their BioCode SARS-CoV-2 assay. 2. An interview with the LD, in the office, on 12/17/2020 at 2:30 PM, confirmed that the laboratory's test reports failed to include and identify include units of measure, reference ranges, normal values, or specimen kit type from September 2020 through December 2020.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor record review and interview it was determined the Laboratory Director failed to ensure adequate validation and verification of test methods that were used to establish their COVID-19 assay resulting in immediate jeopardy. The Laboratory Director failed to ensure that the quality control (QC) and quality assessment (QA) programs were maintained appropriately. (Refer to D6082, D6093, D6094, D6106, and D6171)</p>
<p><b>D6082</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and an interview with testing personnel (TP), the Laboratory Director (LD) failed to provide statistical data that validated the accuracy, precision, analytical specificity, and analytical sensitivity of their BioCode SARS-CoV-2 assay. The findings include: 1. The laboratory verification process failed to provide a written description that documents all actions required to validate their BioCode SARS-CoV-2 assay with CLIA requirements. The laboratory must describe how each test is validated with statistically significant verification for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference ranges. 2. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for their COVID-19 assay. The laboratory had no records for the validation or correlation data for their BioCode SARS-CoV-2 assay. 3. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for BioCode SARS-CoV-2 assay. 4. The laboratory limits of detection are not supported by the data provided by the laboratory and failed to establish lower and upper limits of detection for their BioCode SARS-CoV-2 assay. 5. The LD failed to verify and establish validation and quality control data for their BioCode SARS-CoV-2 assay prior to performing patient testing. 6. The laboratory is performing this assay off-label and outside of the Food &amp; Drug Administration (FDA) Emergency Use Authorization (EUA) for the assay. The facility is using an MGI</p>

extraction kit to perform RNA extractions instead of the required easyMAG or MagNA Pure 96 as required by the manufacturer for optimal assay performance. The laboratory had no documentation of correlations studies to determine if the MGI extraction kit is comparable to kits required for use by the manufacturer. 7. An interview with the LD, on 12/17/2020 at 1:00 PM, in the office, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference interval (normal range) for their BioCode SARS-CoV-2 assay from September 2020 through December 2020.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's quality control (QC) records and interview with the LD, the laboratory director (LD) failed to monitor the QC failures, corrective actions, accuracy and precision of test performance for their BioCode SARS-CoV-2 assay . The findings include: 1. Review of QC records revealed no evidence that quality control pass or fail records are reviewed by the Technical Supervisor (TS) or Laboratory Director (LD) prior to reporting patient results. The laboratory does not have a method or policy for reviewing quality control values to determine shifts or trends for their BioCode SARS-CoV-2 assay. 2. An interview with the LD, on 12/17 /2020 at 2:30 PM, in the office, confirmed that the laboratory is performing QC, but does not have any supporting documentation that QC records were being reviewed by the TS or LD prior to reporting patient results from September 2020 through December 2020.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory records and interview with the LD, the laboratory director failed to establish a written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment. The findings include: 1. The LD did not have a written and approved quality assessment policy that encompasses all facets of the laboratory's technical and non-technical functions. 2. The LD failed to have a QA to assess patient confidentiality, specimen integrity and identification, complaint, corrective actions, proficiency test performance, and personnel competency. 3. An interview with the LD, on 12/17/2020 at 1:00 PM, in the office, confirmed that the laboratory failed to have a written and established QA policy from September 2020 through December 2020.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(14)

The laboratory director must 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 surveyor review of the laboratory's procedure manual and interview, the laboratory failed to have a written procedure for all tests, assays, and examinations performed in the laboratory. The findings include: 1. The laboratory did not have an established written procedure manual for all tests, examinations, and assays performed in the laboratory. 2. The laboratory does not have procedures for specimen labeling, handling, storage, and reportable ranges for patient test results, validations, quality assurance or patient reporting. 3. The laboratory did not have a procedure for their BioCode SARS-CoV-2 assay. 4. The laboratory failed to have an SOP that describes the practices, resources, and procedures to control the quality of a test process for their BioCode SARS-CoV-2 assay. The SOP should include all laboratory procedures including manufacturer's operator manuals, and package inserts and must reflect the director's review and approval including any modifications in the procedure. 5. There was no evidence that the laboratory has an SOP, or that it was reviewed and approved by the LD prior to the start of patient testing in September 2020. Approval of procedures and changes to procedures is the responsibility of the laboratory director. 6. The LD confirmed on 12/17/2020 at 2:30 PM, in the office, that the laboratory did not have a procedure manual for all test performed in the laboratory from September 2020 through December 2020.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor review of personnel records and interview with the Laboratory Director (LD), the Technical Supervisor failed to assess the six competency assessment criteria for testing personnel for their BioCode SARS-CoV-2 assay. The findings include: 1. A review of testing personnel records revealed that the LD did not perform an initial competency assessment laboratory procedures and skills evaluation prior to patient testing, the laboratory does not have a competency assessment that addresses the six competency assessment criteria as required by CLIA for their BioCode SARS-CoV-2 assay procedure. 2. An interview with the LD in the office, on 09/09/20 at 11:30 AM, confirmed that annual competencies were not performed and did not contain the six competency assessment criteria for testing personnel for all assays performed in the laboratory from September 2020 through December 2020.

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of personnel documentation, three out of four testing personnel (TP) failed to meet the high complexity personnel educational qualifications as required by Clinical Laboratory Improvement Amendments (CLIA) 493.1489 (b)(2). The findings include: 1. A review of personnel records indicated that 3 out 4 testing personnel had foreign degrees with no equivalency documentation. 2. No further records were identified which showed a bachelor's or associates degree in a chemical, physical, biological, clinical laboratory science or medical technology as required by CLIA. 3. An interview with the LD on 12/17/2020 at 2:00 PM, in the office, confirmed that 3 out of 4 testing personnel had foreign degrees with no equivalency documentation.