

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2161467	(X3) Date Survey Completed 10/03/2019
Name of Provider or Supplier Microit Diagnostics Inc	Street Address, City, State 5117 34th Street, Suite B, Lubbock, 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	<p>The laboratory was found to be out of compliance with the CLIA regulations. The CONDITIONS not met were: D2000 - 42 C.F.R. 493.801 Condition: Proficiency Testing enrollment; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor. The laboratory ceased testing bacteriology in April 2019 and did not perform any testing for parasitology. These specialties will be removed from the certificate.</p>
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of policies and procedures, laboratory testing records, CMS 155 report, and interview of facility personnel it was revealed that the technical supervisor failed to ensure the facility enrolled in a proficiency testing program for each of the specialties and subspecialties for which it performs patient testing. The laboratory performed patient testing in the specialty of Bacteriology between issuance of the certificate of registration (February 4, 2019) and April 2019 without enrolling in a proficiency testing program for Bacteriology. The findings included: 1. Review of the</p>

laboratory's own Quality Assurance policy titled Quality Systems found on page 4 of 18, under the heading "E. Evaluation of proficiency testing performance," it stated, "1. The laboratory subscribes to commercial CMS-approved proficiency programs for all analytes, specialties, or subspecialties performed..." 2. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Bacteriology, or have any other means to verify the accuracy of their results . 3. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 4. Documentation of enrollment in a proficiency testing program for each specialty and subspecialty was requested but not provided. 5. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on October 3, 2019 at 2:36 PM confirmed that the laboratory did not enroll in a proficiency testing program for the specialty of Bacteriology or have another means to verify the accuracy of results.

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 a review of policies and procedures, the laboratory testing records, CMS 155 report, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for Virology or have another means to verify the accuracy of their results for Human Papilloma Virus (HPV). The laboratory started testing patient specimens for HPV beginning June 19, 2019 failed to enroll in a proficiency testing program or define another means to verify the accuracy of results. The findings included: 1. Review of the laboratory's own Quality Assurance policy titled Quality Systems found on page 4 of 18 under the heading "E. Evaluation of proficiency testing performance" it stated, "2. Where commercial CMS-approved proficiency programs are not available, the laboratory will use some other means of verifying the accuracy (e.g. blind testing of materials with known values, other external assessment programs, split samples with another laboratory instrument or method). This included methods that are not compatible with commercial PT matrices or emerging technologies for which PT is not yet available; verification will be performed at least twice annually." 2. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Virology, or have any other means to verify the accuracy of Human Papilloma Virus (HPV) at least twice annually. 3. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 4. Documentation of enrollment in a proficiency testing program for each specialty and subspecialty was requested but not provided. 5. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on October 3, 2019 at 2:36 PM confirmed that the laboratory did not enroll in a proficiency testing program for HPV or have another means to verify the accuracy of results.

D5300

PREANALYTIC SYSTEMS
 CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic

system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on surveyor observations, review of laboratory policies, manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to meet the minimum requirements to monitor and evaluate preanalytic systems as follows: 1. The laboratory failed to provide documentation of performing preanalytic studies to support its policies and procedures for specimen storage, transportation, and stability for its high complexity test for HPV (refer to D5311). 2. The laboratory failed to have written instructions available to its clients for HPV testing requirements (refer to D5317).

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on manufacturer's instructions, surveyor observation, review of laboratory policy, patient records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing preanalytic studies to support specimen storage, transportation, and stability procedures for its high complexity test for HPV. The findings were: 1. Review of the manufacturer's instructions for Quantbio Q Real Time PCR Cycler (version 1.0) under, "Disclaimer," it stated, "The Q instrument has been designed and is intended for research only." Therefore, the HPV test performed by the facility is a high complexity LDT (Laboratory Developed Test). 2. Review of 49 of 49 patient final reports stated, "DISCLAIMER: This test was developed and its analytical performance characteristics have been determined by Microit Diagnostics Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This assay has been validated pursuant to CLIA regulations and is used for clinical purpose." 3. Surveyor observation of previously tested patient specimens on October 3, 2019 at 09:30 hours in the laboratory revealed that the sample type for HPV testing on the Quantbio analyzer was previously tested Pap Smear specimens collected in Thin Prep Preservative retrieved from an offsite location. 4. Review of the laboratory's "Quality Assurance" policy approved by the laboratory director on October 3, 2019 stated, "Collection kits include the following information/materials where applicable: Patient preparation (e.g. for phlebotomists, Specimen collection (including suitable swabs, specimens containers with appropriate anti-coagulant, preservatives, transport media), Specimen labeling including patient name or unique patient identifier, collection date, and when appropriate specimen source, Specimen storage and preservative, Conditions for specimen transport." 5. Review of laboratory records revealed no

preanalytic studies were available for review to determine specimen storage, transportation, and stability. 6. According to the laboratory's submitted Form CMS-116, the laboratory performs 400 tests annually. 7. Review of patient final reports from June 2019 to September 2019 revealed the following patients were tested and finalized when the laboratory failed to complete pre-analytic studies for specimen storage, transportation, and stability: Sample ID: 40013 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40014 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40015 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40016 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40017 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40018 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40019 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40020 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40021 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40022 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40023 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40024 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40025 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40026 High-Risk HPV Types PCR: DNA Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40027 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40028 High-Risk HPV Types PCR: DNA Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40029 High-Risk HPV Types PCR: DNA Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40030 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40031 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40032 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40025 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40033 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40034 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not Detected HPV 45 PCR: DNA Not Detected Sample ID: 40035 High-Risk HPV Types PCR: DNA Not Detected HPV 16 PCR: DNA Not Detected HPV 18 PCR: DNA Not

	<p>Director on October 3, 2019 at 10:30 hours in the front office confirmed the findings. Key: PCR - polymerase chain reaction DNA - deoxyribonucleic acid</p>
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of</p>
D5400	<p>ANALYTIC SYSTEMS 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: Based on surveyor observation, review of laboratory policy, manufacturer's instructions, quality control records, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate the overall quality of its analytics systems as evidenced by: 1. The laboratory failed to monitor the room humidity of the laboratory (refer to D5413). 2. The laboratory failed to complete validation studies prior to patient testing for its high complexity LDT for Human Papilloma Virus (refer to D5423). 3. The laboratory failed to establish and follow procedures to detect errors over time (refer to D5441). 4. The laboratory failed to follow its own policy for verifying quality control materials prior to being put into use (refer to D5469).</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, manufacturer's instructions, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to monitor the humidity of the laboratory. The findings were: 1.</p>

Surveyor observation made on October 3, 2019 at 09:25 hours during the initial tour of the facility found no means to monitor the humidity of the laboratory. 2. Review of the manufacturer's instructions for the QuantaBio qPCR analyzer revealed the operating humidity was, "20-80% humidity." 3. Review of the laboratory's environmental records from June 2019 to September 2019 revealed no records that the laboratory monitored and documented the humidity of the laboratory. 4. The findings were confirmed in interview of the Laboratory Director on October 3, 2019 at 14:00 hours in the office.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's test menu, performance specification documentation, and confirmed in interview of the laboratory director, the laboratory failed to perform complete establishment studies prior to patient testing for its high complexity test HPV (Human Papilloma Virus). The findings included: 1. Review of the laboratory's submitted test menu revealed the laboratory performs high complexity testing for HPV. 2. A review of the laboratory's establishment studies for HPV revealed that the facility: a. Failed to perform studies to determine specimen storage and preservation conditions; b. Failed to perform studies to determine specimen transport conditions; c. Failed to perform studies to determine specimen stability; d. Failed to perform studies to determine reagent and buffers stability; e. Failed to complete accuracy studies (no final statistical analysis); f. Failed to complete precision studies (no final statistical analysis); g. Failed to complete specificity studies (no final statistical analysis); h. Failed to perform carry-over studies; i. Failed to complete limits of detection (no final statistical analysis); 2. The laboratory was asked for documentation of the missing or incomplete portions of the establishment study. No documentation was provided. 3. An interview with the laboratory director 10:30 hours in the office confirmed the findings.

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 a review of the laboratory's quality control plan, review of quality control records from June 2019 to September 2019, and confirmed in interview of facility personnel, the laboratory quality control plan failed to detect errors over time. The findings were: 1. Review of the "Quality Systems" procedure approved by the laboratory director on February 4, 2019 revealed no policy for monitoring quality control (QC) statistics. 2. Review of quality control records from June 2019 to September 2019 revealed no documentation of the laboratory monitoring QC statistics at intervals to assess the analytical process. 3. In an interview of the Laboratory Director on October 3, 2019 at 14:00 hours in the front office, the above finding were confirmed.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's own written procedure, the manufacturer's instructions for the Microbiologic Control lot 8214-02 expiration 02-29-2020 (which was in use at the time of the survey), review of the laboratory's quality control records from June 2019 to present, and staff interview, it was revealed the laboratory failed to establish its own means and limits as defined in it's own procedure. The findings included: 1. Review of the laboratory's written policy for establishing the acceptability of quality control material found " The laboratory will test quality control material 5 times within the same run and 5 times on consecutive days and establish means and calculate 3 Standard deviation range of acceptability." 2. Review of the manufacturer's instructions for the Microbiologic controls (PL2198 Rev. C), under, "Principles" it stated, "Helix Elite Molecular Standards (Inactivated Pellet) Products are compromised of cultured organisms inactivated by chemical, radiological, or heat treatments. Each pellet is packaged in a single-use foil pouch. Users should follow assay manufacturer or laboratory procedures for processing controls." 3. Review of the laboratory's establishment studies for the range of acceptability for quality control material lot 8214-02 found that quality control materials were tested 4 times each on April 27, 2019. There were no other studies available for review. 4. Interview of Testing Person one listed on the CMS report 209 Laboratory Personnel Report

	<p>conducted on October 3, 2019 at 12:08 PM confirmed that the laboratory did not follow their own procedure for establishing acceptable means and limits for each of the quality control materials used to verify the accuracy of results for HPV.</p>
D6076	<p>LABORATORY DIRECTOR 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 review of laboratory policies, review of manufacturer's instructions, high complexity validation studies, quality control records, environmental records, patient results, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction to the laboratory (refer to D6082, D6086, D6088, and D6093).</p>
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 review of laboratory policy, high complexity establishment studies, patient records, and confirmed in interview of facility personnel, the laboratory director failed to ensure testing systems provide quality lab service for all aspects of test performance (refer to D5311 and D5423).</p>
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, performance specification documentation, and confirmed in interview of the laboratory director, the laboratory failed to perform complete establishment studies prior to patient testing for its high complexity test HPV (Human Papilloma Virus) (refer to D5423).</p>
D6088	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p>

This STANDARD is not met as evidenced by:
 Based on a review of policies and procedures, laboratory testing records, CMS 155 report, and interview of facility personnel it was revealed that the laboratory director failed to ensure the facility enrolled in a proficiency testing program for each of the specialties and subspecialties for which it performs patient testing. The laboratory performed patient testing in the specialty of Bacteriology between issuance of the certificate of registration (February 4, 2019) and April 2019 without enrolling in a proficiency testing program for Bacteriology. The findings included: 1. Review of the laboratory's own Quality Assurance policy titled Quality Systems found on page 4 of 18, under the heading "E. Evaluation of proficiency testing performance," it stated, "1. The laboratory subscribes to commercial CMS-approved proficiency programs for all analytes, specialties, or subspecialties performed..." 2. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Bacteriology, or have any other means to verify the accuracy of their results . 3. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 4. Documentation of enrollment in a proficiency testing program for each specialty and subspecialty was requested but not provided. 5. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on October 3, 2019 at 2:36 PM confirmed that the laboratory did not enroll in a proficiency testing program for the specialty of Bacteriology or have another means to verify the accuracy of results.

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 laboratory policy, review of manufacturer's instructions, quality control records, patient results, and confirmed in interview of facility personnel, the laboratory director failed to ensure a quality control program is established and maintained (refer to D5441 and D5469).

D6108

LABORATORY TECHNICAL SUPERVISOR
 CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:
 Based on review of laboratory policies, review of manufacturer's instructions, high complexity validation studies, quality control records, environmental records, patient results, and confirmed in interview of facility personnel, the technical supervisor failed to provide technical supervisor for each speciality and subspeciality for high complexity testing (refer to D6115, D6116, and D6117).

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's test menu, performance specification documentation, and confirmed in interview, the technical supervisor failed to perform complete establishment studies prior to patient testing for its high complexity test HPV (Human Papilloma Virus) (refer to D5423).

D6116

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(3)

The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.

This STANDARD is not met as evidenced by:

Based on a review of policies and procedures, laboratory testing records, CMS 155 report, and interview of facility personnel it was revealed that the technical supervisor failed to ensure the facility enrolled in a proficiency testing program for each of the specialties and subspecialties for which it performs patient testing. The laboratory performed patient testing in the specialty of Bacteriology between issuance of the certificate of registration (February 4, 2019) and April 2019 without enrolling in a proficiency testing program for Bacteriology. The findings included: 1. Review of the laboratory's own Quality Assurance policy titled Quality Systems found on page 4 of 18, under the heading "E. Evaluation of proficiency testing performance," it stated, "1. The laboratory subscribes to commercial CMS-approved proficiency programs for all analytes, specialties, or subspecialties performed..." 2. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Bacteriology, or have any other means to verify the accuracy of their results. 3. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 4. Documentation of enrollment in a proficiency testing program for each specialty and subspecialty was requested but not provided. 5. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on October 3, 2019 at 2:36 PM confirmed that the laboratory did not enroll in a proficiency testing program for the specialty of Bacteriology or have another means to verify the accuracy of results.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, review of manufacturer's instructions, quality control records, patient results, and confirmed in interview of facility personnel, the technical supervisor failed to ensure a quality control program is established and maintained (refer to D5441 and D5469).