Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0222887	01/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
United Medical Laboratories Inc	1980 Gallows Rd - Suite 300, Vienna, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	An announced CLIA recertification survey was conducted at United Medical Laboratory on January 29 -30, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2062	VIROLOGY CFR(s): 493.831(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, procedure manual and an interview, the laboratory failed to document remedial action for one (1) unsatisfactory Viral Culture PT scores out of six (6) PT events for 2017 and 2018. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Viral Culture (VR1) PT records for three (3) events in 2017 and 3 events in 2018 (a total of 6 events) revealed no evidence of remedial action for 2017 VR1-B with an unsatisfactory score of 50%. 2. Review of the laboratory's procedure manual revealed a policy, Procedure for Proficiency Testing, which stated "Review of returned summary sheets: 4. Wrong answers will be investigated and documented for corrective action." The inspector requested documentation of the corrective action for 2017 VR1-B. The laboratory provided no corrective action documentation. 3. In an exit interview with the lab director, general supervisor and technical supervisor at 3: 30 PM, the above listed findings were confirmed.

D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a lab tour, review of policy and procedures, and interviews, the laboratory failed to follow their food storage safety policy by storing four (4) patient oral prescription glucose tolerance beverage bottles in the core laboratory's reagent and specimen refrigerator (Number 1) noted on the first date of the survey 1/29/19. Findings include: 1. During a tour of the core laboratory's testing area at approximately 11 AM on 1/29/19, the inspector noted 4 Aeromed EASYDEX 75-oral glucose tolerance beverage containers (10 ounce bottles, lot number 507237, expiration date 8/25/09) stored in a reagent and patient sample refrigerator identified as Refrigerator 1. The inspector inquired regarding the storage of the expired food item. The technical supervisor stated: "I have no idea why that is stored in the refrigerator. I will notify the lab director". 2. Review of the laboratory's policy and procedures revealed a quality assurance (QA) policy (Universal Blood and Body Fluid Precautions) that stated (under the heading Food Storage): "there will be no storage of food items in refrigerators, freezers, shelves, cabinets, or on benches in the laboratory". 3. In an exit interview with the lab director, general supervisor, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's Immunohistochemical (IHC) antibody validation records, patient test logs and interview, the laboratory failed to retain documentation of the IHC antibody validation for seven (7) of seven (7) lot numbers of IHC antibodies from 6/4/18 to 1/30/19. Findings include: 1. Review of the laboratory's IHC antibody validation records and histopathology patient logs from 6/4/18 to 1/30/19 revealed 8 lot numbers of IHC antibodies were validated and utilized for patient testing on the Leica BOND IHC stainer. The following 7 lot numbers of IHC antibodies had no validation documentation: 10131980, 20043338, 6058863, 6059089, 0025743, 6059686, 0040677. 2. During an interview with general supervisor, at approximately 12:00 PM on 1/30/19, the inspector requested to review the validation documentation. The laboratory provided no validation documentation. 3. In an exit interview with the lab director, general supervisor and technical consultant at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interview, the laboratory director failed to review and sign one (1) of six (6) Virology Culture (VR1) PT reports reviewed. Findings include: 1. Review of the College of American Pathologists (CAP) PT records for three Virology Culture (VR1) events in 2017 and 2018 (a total of 6 events) revealed that the laboratory director did not review and sign the 2017 CAP VR1-B PT results. 2. In an exit interview with the lab director, general supervisor and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to verify the accuracy of non-graded Thyroid Stimulating Hormone (TSH) PT results for three (3) of 3 events reviewed in calendar year 2018 and six (6) of 6 events of non-graded Rubella PT results in calendar year 2017 and 2018 due to less than ten (10) peer participants in the program. Findings include: 1. Review of the laboratory's 2018 College of American Pathologists (CAP) General Chemistry PT documentation, a total of 3 events, revealed no evaluation or verification of accuracy for the non-graded (due to less than 10 participating laboratories) TSH responses for: C-A 2018: CHM-01, CHM-02, CHM-03, CHM-04, CHM-05; C-B 2018: CHM-06, CHM-07, CHM-08, CHM-09, CHM-10; C-C 2018: CHM-11, CHM-12, CHM-13, CHM-14, CHM-15; a total of fifteen (15) non graded TSH responses. The inspectors requested to review evaluation documentation for the 3 non-graded events listed above. No additional documentation was available for review. Review of the laboratory's 2017 and 2018 CAP Diagnostic Immunology PT documentation, a total of 6 events, revealed no evaluation or verification of accuracy of the following non-graded (due to less than 10 participating laboratories) Rubella quantitative antibody responses : S- A 2017: RUB-01, RUB-02, RUB-03, RUB-04, RUB-05; S- B 2017: RUB-06, RUB-07, RUB-08, RUB-09, RUB-10; S- C 2017: RUB-11, RUB-12, RUB-13, RUB-14, RUB-15; S- A 2018: RUB-01, RUB-02, RUB-03, RUB-04, RUB-05; S- B 2018: RUB-06, RUB-07, RUB-08, RUB-09, RUB-10; S- C 2018: RUB-11, RUB-12, RUB-13, RUB-14, RUB-15; a total of thirty (30) non graded Rubella responses. The inspectors requested to review evaluation documentation for the 6 non graded events listed above. No additional documentation was available for review. 2. In an exit interview with the lab director, general supervisor, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on a review of procedures, user guides, package inserts, Quality Control (QC) logs, instrument maintenance logs, patient test logs, chemistry and hematology analyzer validation records, hematology calibration records, microbiology media invoices, and interviews, it was determined that the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems with Beckman Access' 25 Hydroxy Vitamin D (25OH- D) reagent preparation, ASI RPR Card Test needle and rotator checks, chemistry analyzer installation validation, documentation of hematology calibration, RPR QC documentation, and microbiology media visual checks during the twenty-four month review. Cross Reference- D5407, D5411, D5421, D5437, D5451, D5477.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Histology procedure manual, and interview, the laboratory failed to establish a written policy for performing and documenting positive and negative reactivity each day of use for the Leica BOND automated Immunohistochemistry (IHC) stainer. Findings include: 1. Review of the Histology procedure manual revealed no documentation of a written policy for performing and documenting positive and negative reactivity each day of use for the Leica BOND automated IHC stainer. The surveyor requested the quality control policy for the Leica BOND automated IHC stainer. The laboratory provided no documentation of the policy. 2. In an exit interview with the lab director, general supervisor and technical supervisor at at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a tour, review of analyzer validation records, policies and procedures, and interviews, the laboratory director (LD) failed to document approval and review of a procedure for Complete Blood Count (CBC) after a new analyzer and test system was installed for patient testing on March 9, 2017. Findings include: 1. During a tour of the core laboratory on 1/29/19 at approximately 9 AM, , the inspector noted a Sysmex XS 1000i , Serial Number (SN)75472, in use for patient CBC testing. 2. Review of instrument validation records revealed that a Sysmex field service representative installed the XS 1000i SN 75472 on 3/9/17. 3. Review of the laboratory's policy and procedure manual revealed a hematology CBC procedure for the Horiba ABX Pentra 6 that was approved by the LD on 6/2/15. The inspector requested to review an approved Sysmex XS 1000i. CBC procedure. No documentation was available for review. 4. In an exit interview with the lab director, general supervisor, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on a tour, review of procedures, user guide, instrument maintenance logs, patient test logs, and interviews, the laboratory failed to follow the manufacturer's instructions for the Beckman Access' 25 Hydroxy Vitamin D (25 OH- D) reagent preparation prior to performing patient testing for six hundred forty (640) patients from 2/9/18 to 1/29/19. Findings include: 1. During a tour of the core laboratory on 1 /29/19 at approximately 9 AM, the inspection noted an Elmeco Micro Mixer (Model MM50, serial number 25787) in use beside the bench top Beckman Coulter Access 2 immunoassay instrument. The inspector inquired regarding the use of the mixer and the primary testing personnel stated: "we use the mixer for our Vitamin D reagent preparation". 2. Review of the laboratory's chemistry procedures revealed a 25 OH-D procedure that stated: "Materials required but not supplied with reagents include: Vortex mixer with a continuous on mode and a maximum speed of 2,500 to 3,200 revolutions per minute (rpm)." The inspector requested to review the user guide for the Elmeco MM50 vortex mixer. No documentation was available for review. 3. Review of the Beckman Coulter Access 2 manufacturer's user guide revealed a reagent preparation procedure titled: "Mixing Reagent Packs for the Access 25(OH) Vitamin D Total Assay" that stated: "to ensure that the paramagnetic particles in the reagent pack are fully suspended, mix the pack with a vortex mixer immediately before loading the reagent pack on the instrument. Use a vortex mixer with a continuous ON mode (not a touch mode) and a maximum speed of between 2,500 and 3,200 rpm. Start the vortex mixer in continuous mode and set it to the maximum speed. Mix for 20-30 seconds. The requirement to mix the reagent pack by this vortex speed is unique to the Access 25(OH) Vitamin D Total assay". 4. Review of the core

	laboratory's instrument maintenance logs revealed no calibration or verification of the Elmeco MM50 vortex mixer speed. The inspector noted that the vortex mixer in use did not have a speed control. The inspector requested to review documentation of the vortex mixer speed. No records were available for review. 5. Review of the LabDaq laboratory information system patient test logs revealed that the laboratory had reported 640 25 OH- D test results from the time of the instrument installation (2/9 /18) and up to the date of the survey's review on 1/29/19. 6. In an exit interview with the lab director, general supervisor, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed. B. Based on a review of the policy and procedure manual, manufacturer's package insert, Rapid Plasma Reagin (RPR) quality control (QC) log, RPR patient logs, and an interview, the laboratory failed to follow ASI RPR Card Test for Syphilis manufacturer's package insert for needle checks prior to performing patient testing for one thousand five hundred thirteen (1513) patients from 7/6/18 to 1/29/19. Findings include: 1. Review of the policy and procedure manual revealed an RPR procedure that stated, "Assay Protocol-Qualitative: 1. Quality Control checks should be performed before every test run. This includes checking for rotator accuracy of 100 +/- 5 rpm, ensuring needle accuracy of 60 +/- 2 drops, and running control samples for all three control levels." 2. Review of the ASI RPR Card Test for Syphilis manufacturer's package insert revealed instructions that stated "Handling and Procedural Notes: 1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples... 4. The needle should deliver 60 +/- 2 drops of antigen suspension per milliliter when held in a vertical position." 3. Review of the RPR QC log revealed no documentation of the needle check from 7/6/18 to 1/29/19. The surveyor requested documentation of needle checks. The laboratory provided no documentation of the needle checks. 4. Review of the RPR patient logs revealed 1,513 patient RPR tests performed between 7/6/18 and the date of the survey on 1/29/19. 5. In an exit interview with the lab director, general supervisor and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed. C. Based on a review of the policy and procedure manual, manufacturer's package insert, Rapid Plasma Reagin (RPR) quality control (QC) log, RPR patient logs, and an interview, the laboratory failed to follow ASI RPR Card Test for Syphilis manufacturer's package insert for slide rotator checks prior to performing patient testing for one thousand five hundred thirteen (1513) patients from 7/6/18 to 1 /29/19. Findings include: 1. Review of the policy and procedure manual revealed an RPR procedure that stated, "Assay Protocol-Qualitative: 1. Quality Control checks should be performed before every test run. This includes checking for rotator accuracy of 100 +/- 5 rpm, ensuring needle accuracy of 60 +/- 2 drops, and running control samples for all three control levels." 2. Review of the ASI RPR Card Test for Syphilis manufacturer's package insert revealed instructions that stated "Handling and Procedural Notes: 1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples... 5. Place the card on automatic rotator and cover to maintain humidity. Rotate at 100 +/- 5 rpm for 8 minutes..." 3. Review of the RPR QC log revealed no documentation of the rotator check from 7/6/18 to 1/29/19. The surveyor requested documentation of the slide rotator checks. The laboratory provided no documentation of the slide rotator checks. 4. Review of the RPR patient logs revealed 1,513 patient RPR tests performed between 7/6/18 and the date of the survey on 1/29/19. 5. In an interview with the lab director, general supervisor and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
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 a review of analyzer validation records, user guide, patient test logs, and interview, the laboratory director (LD) failed to verify the accuracy, precision, reportable and normal values (reference ranges) for 25 Hydroxy Vitamin D, (25 OH-D) and Dehyroepiandrosterone Sulfate (DHEA-S) tests performed on the Access 2 analyzer prior to reporting eight hundred seventy-four (874) patients from 2/9/18 to 1/29/19. Findings include: 1. Review of the core laboratory's analyzer records revealed a new Access 2 immunoassay instrument installation, by a Beckman Coulter applications specialist, occurred on 2/8/18. The inspector noted that the vendor's validation documentation contained no verification or approval by the LD for the new instrument (Serial Number 570428) prior to patient testing on 2/9/18. 2. Review of the Access 2 Users Guide for new instrument installation revealed the instruction: "Accuracy, precision, linearity, and patient reference range must be validated by the Lab Director". 3. Review of the LabDaq laboratory information system patient test logs from 2/9/18 to 1/30/19 revealed that the laboratory had reported: Six hundred forty (640) 25 OH- D test results; Two hundred thirty-four (234) DHEA-S test results; a total of 874 Access 2 immunoassay reports. 4. In an exit interview with the LD, general supervisor, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of policies, user guide, hematology calibration records, patient test logs, and interviews, the laboratory failed to document Sysmex XS 1000i calibration procedures according to the frequency recommended by the manufacturer prior to performing two hundred sixty-nine (269) patient Complete Blood Count (CBC) panels during the calibration lapse period of 9/9/17 through 11/3/17. Findings include: 1. Review of the laboratory's hematology quality assurance procedure manual revealed a calibration policy that stated: "calibration will be performed every six months". 2.

	Review of the Sysmex XS 1000i hematology instrument user guide revealed instructions that stated the analyzer is to be calibrated at a required interval of every six months and as needed after major service. The user guide stated: "a calibration specialist will call you 30-45 days prior to the required six month calibration to schedule a date for the calibration verification event". 3. Review of the laboratory's 2017 XS 1000i calibration records revealed calibration documentation on 3/9/17 and 11/3/17. The inspector requested to review calibration documentation in the timeframe of September 2017. No additional record was available for review. The primary testing personnel stated in an interview on 1/29/19 at approximately 2:00 PM: "our policy is to calibrate every six months but the Sysmex representative was late to do the second calibrations in 2017". 4. Review of the Lab Daq laboratory information system patient test logs revealed that 269 patient CBC test results were reported during the timeframe of the three (3) month calibration lapse outlined above. 5. In an exit interview with the lab director, general supervisor, and technical supervisor at approximately 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual, Rapid Plasma Reagin (RPR) quality control (QC) log, RPR patient log sheets and interview, the laboratory failed document QC for forty-nine (49) days while reporting seven hundred ninety-two (792) patients results from 7/6/18 to 9/18/18. Findings include: 1. Review of the laboratory's procedure manual revealed a policy, "Rapid Plasma Reagin (RPR) Procedure Manual", which stated: "Assay Protocol-Qualitative: 2. QC samples with graded reactivity should be included in each test run to confirm optimal reactivity." 2. Review of the RPR QC log revealed no documentation of QC for 49 days from 7/6/18 to 9/18/18. The surveyor requested documentation of QC. The laboratory provided no documentation. 3. Review of the RPR patient logs revealed 792 RPRs were performed from 7/6/18 to 9/18/18. 4. In an exit interview with the lab director, general supervisor and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the Microbiology procedure manual, patient log book, Microbiology media invoices, and an interview, the laboratory failed to document the visual check of media from 7/1/18 to 1/24/19 while utilizing the media for five thousand six hundred sixty-one (5661) patient cultures. Findings include: 1. Review of the Microbiology procedure manual revealed a policy, "Quality Control and Improvement Program", which stated "5. Media-Upon arrival all media is visually inspected." 2. Review of the laboratory's Microbiology media invoices revealed no documentation of visual inspection of media for lot numbers utilized from 7/1/18 to 1 /24/19. The inspector requested to review the documentation of the media's visual inspection. The laboratory provided no documentation. 3. Review of the Microbiology patient logs from 7/1/18 to 1/24/19 revealed 5,661 patient cultures utilizing commercially prepared media. 4. In an exit interview with the lab director, general supervisor and technical supervisor at 3:30 PM on 01/30/19, the above listed findings were confirmed.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of histology patient logs, patient reports, and interview, the laboratory failed to document the testing personnel who performed the grossing of tissue for two (2) of six (6) pathology reports reviewed. The findings include: 1. Review of the histopathology patient logs revealed testing personnel N (TP N) performed the grossing for cases 1901-306 and 191-250. 2. Review of the pathology reports for cases 1901-306 and 191-250 revealed no documentation that TP N performed the grossing for 1901-306 and 191-250. 3. In an exit interview with the laboratory director, general supervisor, technical supervisor, the above listed findings were confirmed.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a tour, review of Standard Operating Procedure (SOP) manuals, user guides, quality assurance (QA) policies, temperature and humidity logs, and an interview, the laboratory failed to document corrective action when the humidity was recorded outside the acceptable limits in the core laboratory (Room 304) on seventy-seven (77) days from 4/1/17 to the date of survey on 1/29/19. Findings include: 1. During a tour of Room 304 on 1/29/19 at approximately 9 AM, the inspector noted a pre-assay

	checklist attached to the front of the Gen Probe Panther System analyzer. The first instruction on the checklist for instrument daily maintenance was to verify room humidity (acceptable range of 20-85 percent). 2. Review of the core laboratory's SOP manuals and analyzer manufacturer's user guides revealed: "Panther System- patient and reagent preparation guidelines for room humidity requirement to be between 20-85 percent (%). Beckman Access 2 Immunoassay - analyzer specification guidelines for room humidity requirement to be between 20-85 %. Sysmex XS 1000i - operating performance specifications for room humidity acceptable limitations to be 30-85%." 3. Review of the QA manual revealed a Temperature Policy that stated: "Temperature and humidity ranges will be recorded daily with verified certified thermometers. Failure to fall within the acceptable range will constitute a corrective action". 4. Review of the daily temperature and humidity logs for the core lab from 4/1/17 to the date of the survey on 1/29/19 (a total of twenty-two months reviewed) revealed that the following dates that the humidity readings were outside of the charted acceptable ranges: November 2017 - 11/24; December 2017 - 12/7 to 12/9, 12/11 to 12/16, 12/18 to 12/23, 12/26 to 12/30; January 2018 - 1/2 to 1/6, 1/8 to 1/12, 1/14, 1/16 to 1/21, 1 /23 to 1/27; February 2018 - 2/1 to 2/4, 2/6; March 2018 - 3/1 to 3/2, 3/4, 3/6 to 3/9, 3 /11, 3/13 to 3/14, 3/17, 3/24, 3/27; December 2018 - 12/2, 12/4, 12/6, 12/7, 12/9, 12 /11 to 12/15, 12/17 to 12/19; January 2019 - 1/4 to 1/1/6, 1/8 to 1/13, 1/15 to 1/20, 1 /25 to 1/27; a total of 77 days. The inspector requested to review corrective action for the testing days recorded with unacceptable humidity readings. No corrective action documentation was available for review. 5. In an exit interview with the lab director, general supervisor, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of policies and procedures, onboard instrument logs, Quality Control (QC), and an interview, the laboratory failed to follow their policy for monthly QC review in order to monitor, assess and correct problems with the Beckman Coulter Access immunoassay analyzer for ten (10) of 10 months reviewed in calendar year 2018. Findings include: 1. Review of the laboratory's policies and procedures revealed a quality assurance (QA) plan to monitor and assess QC on a monthly basis. The policy stated: "the QC data will be reviewed monthly by the Lab Director to assess problems, shifts, and trends" . 2. Review of the Beckman Coulter Access 2 immunoassay instrument's onboard report log revealed the following two (2) test kits were assayed from February 2018 to December 2018: Access 25 Hydroxy Vitamin D, Total (25 OH- D), Access Dehyroepiandrosterone Sulfate (DHEA-S). 3. Review of the Access 2 immunoassay QC reports in calendar year 2018 (a total of 10 months) revealed no record that the lab director (LD) reviewed the monthly QC data. The inspector requested documentation of the QC statistics review. No documentation was available upon request. 4. In an exit interview with the LD, general supervisor, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D5801	TEST REPORT

	CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a tour, review of policy and procedures, and interviews, laboratory failed to document the verification of a newly installed laboratory information system's (LIS) accuracy of patient results transmission from March 2017 to the date of the survey on 1/30/19. Findings include: 1. During an initial facility tour at approximately 9 AM on 1/29/19, the inspectors observed the work flow of the core laboratory's primary testing personnel and it was revealed that patient results were transmitted from the chemistry and hematology analyzers through LabDaq LIS instrument interfaces. The primary testing personnel stated: "we have a new LIS that was installed after our last laboratory inspection". 2. Review of the laboratory's policies and procedures revealed no approved LabDaq LIS validation or transmission verification study. The inspectors requested the documentation during an interview with the general supervisor (GS) on 1 /29/19 at approximately 1 PM. The GS stated: "we do not have the documentation when the LIS was verified, but I will contact LabDaq to request a copy. The new system was installed in March 2017". 3. In an exit interview with the lab director, GS, and technical supervisor at 3:30 PM on 1/30/19, the above listed findings were confirmed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on a review of procedures, Proficiency Testing (PT) record, user guides, package inserts, Quality Control logs, instrument maintenance logs, patient test logs, chemistry and hematology analyzer validation records, hematology calibration records, microbiology media invoices, and interviews, it was determined that the laboratory director failed to: ensure corrective actions for unsatisfactory PT; and ensure quality control and quality assessment programs were maintained. Cross Reference- D6092, D6093 and D6094.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing (PT) records, procedure manual and an interview, the laboratory director (LD) failed to ensure a corrective action plan was followed and remedial action documented for one (1) unsatisfactory Viral Culture PT score out of six (6) PT events for 2017 and 2018. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Viral Culture (VR1) PT records for three events in 2017 and three events in 2018, a total of 6 events, revealed no evidence of LD review or remedial action for 2017 VR1-B with an unsatisfactory score of 50%. 2. Review of the laboratory's procedure manual revealed a policy, "Procedure for Proficiency Testing", which stated "Review of returned summary sheets: 2. The Laboratory Director reviews the final report.... 3. These sheets will be signed off as reviewed. 4. Wrong answers will be investigated and documented for corrective action." The surveyor requested documentation of the corrective action. The laboratory provided no corrective action documentation. 3. In an exit interview with the laboratory director, general supervisor and technical supervisor at approximately 3:30 PM, the above listed findings were confirmed.
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 the review of procedures, quality control (QC) records and interviews, the lab director failed to ensure: that quality control was documented for forty-nine (49) days of Rapid Plasma Reagin (RPR) testing; and media visual checks were documented from 7/1/18 to 1/24/19. Cross Reference D5451, D5477.
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 the review of procedure manuals, user guides, quality assurance (QA) policies, temperature and humidity logs, instrument quality control (QC), onboard instrument logs and interviews, the laboratory director failed to ensure that the established quality assurance plan identified and addressed issues in the analytic systems of Hematology, and Chemistry. Cross Reference D5437, D5785, D5791.