Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2021686	03/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Perll Diagnostics Inc	5010 Ritter Road, Mechanicsburg, PA	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with Laboratory Director (LD) and Laboratory Manager (LM), the laboratory failed to enroll in PT for Parasitology from 6/21/2017 to the day of the complaint investigation. Findings include: 1. During the tour of the Microbiology laboratory on 3/9/18 at approximately 11:00 am, Surveyor A asked if the laboratory performed parasitology tests, and requested to see reference materials. The LD showed the surveyor the reference materials. 2. 2017 PT records were reviewed. There were no records for Parasitology. 3.The LM confirmed that Parasitology testing was performed (Ova and Parasite examinations), but the laboratory was not enrolled in a HHS- approved PT program. 4. The allegation of compliance submitted by the LD in 2017 stated "Parasitology test was discontinued in July 2017". Testing has not been discontinued. This is a repeat deficiency.
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 observation, review of Proficiency Testing (PT) records, and interview with the laboratory director (LD) and Laboratory Manager (LM), the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems with expired reagents and supplies, reagents not labeled with expiration dates, test system verification, equipment maintenance and control procedures as required in 493. 1251 through 493.1283. Refer to D5415, D5421, D5433, D5445, D5783, and D5791.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, tour of the laboratory, and interview with Laboratory Director (LD) and Laboratory Manager (LM), the laboratory failed to ensure all reagents, solutions, and other laboratory supplies available for patient testing, were labeled to indicate their expiration dates from June 2017 to the date of complaint investigation. Findings Include: 1. At the time of investigation on 03/09/2018, the Surveyor observed the following reagents and supplies with no expiration dates: 1 bottle of 10% Bleach Aliquot in the Chemistry section. 1 bottle of EKI Low Viscosity Immersion Oil in the Microbiology section. 1 of 1 bottle of J.T. Baker Glycerol 500 ml Lot#K13829 in the Microbiology section. 1 of 1 bottle of Sigma Aldrich Ethanol Lot # SHBB6056V in the Microbiology section. 2. Aliquots of unlabeled liquids were found in the chemistry laboratory refrigerator. According to the LD, they were aliquots for chemistry tests. 3. The LD and LM confirmed the findings above on 03/09 /2018 at approximately 10:30 am. Based on surveyor observation, tour of laboratory, interview with Laboratory Director (LD) and Laboratory Manager (LM) and laboratory policy review, the laboratory failed to ensure 9 of 9 cases of Rainin pipette tips were be labeled to indicate their expiration dates. Findings include: 1. During a tour of the Microbiology Lab, 9 cases of Raining pipette tips used for susceptibility testing, (LTS 250 L 960/10 RT-L250 Batch # 1547 Item # 17002932) were found with no expiration dates (4 in the biosafety cabinet, 5 on the bench). There were scratch marks over the expiration dates observed on each case. 2. The LM, who was interviewed on 3/9/18 at approximately 10:35am, stated that the expiration dates were scratched off as instructed by the LD. He further stated that the pipette tips had expired July, 2014. 3. The laboratory's Policy for Determining Expiration Dates, signed by the LD and accepted 06/28/2011, provided by the LD on 3/9/2018 at the time of survey states, "Supplies without manuafacturer's expiration dates should be dated upon receipt". There were no receipt dates on the Rainin pipette tips.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A Based on observation, review of the Plan of Correction (POC) submitted as a response to the February 9, 2017 complaint investigation, review of the Quality Assessment (QA) policy document submitted as part of the Allegation of Compliance (AOC) received on 1-26-2018, and interview with the laboratory director (LD) and laboratory manager (LM), the laboratory failed to ensure reagents, chemicals, control materials and other supplies were not used after exceeding the expiration date. Findings include: 1. The QA policy reviewed and signed by the LD on 7/1/2017 states on page 19, "9. Expired reagents will never be used for clinical testing. There will be no exceptions to this requirement". 2. The AOC submitted on 9/8/2017 stated "All expired reagents will be discarded and will not be permissible on the premises of the laboratory." 3. While on a tour of the laboratory with the LD and LM at the time of complaint investigation, Surveyor A and B observed 14 different expired reagents, chemicals and control materials as follows: A sampling of reagents and supplies with expiration dates includes: 1 BD Clay Adams Sedi Stain lot# 1511 02 exp. (expired) 11 /05/2017 found in the microbiology section, on the window seal near the biosafety cabinet. 1 Coulter LH series Cleaner lot# 332492F exp. 12/22/2017 behind the LH 500 analyzer. 1 bag of Conical base screw Cap Tubes Lot # 60U0211 exp. 01/2018 found where Prothrombin time tests are performed. 1 Coulter LH Series Pak lot# 110995K exp. 11/08/2017. 1 R.A Scientific Resolve oil lot# 192470 exp. 05/2013 found in the microbiology section near the microscope. 1 Remel Gram Decolorizer lot# 383689 exp. 03/02/2018 found in microbiology section. 1 Remel Gram Iodine lot# exp. 02/26/2018 found in microbiology section. 1 bottle Hardy Diagnostics Saline cat# U159 exp. 02/19/2017 found in microbiology section. 1 Coulter 5C Cell Control Normal lot# 887500 exp. 09/12/2017 found on the bench in between the 2 Hematology analyzers. 1 Coulter 5C Cell Control Normal lot#885500 exp. 04/03 /2017 found on the bench in between the 2 Hematology analyzers. 1 Coulter 5C Cell Control Abnormal 1 lot# 874900 exp. 04/01/2017 found on the bench in between the 2 Hematology analyzers. 1 Coulter 5C Cell Control Abnormal 1 lot# 885500 exp. 09 /11/2017 found on the bench in between the 2 Hematology analyzers. 1 Coulter 5C Cell Control Abnormal 2 lot# 866000 exp. 09/10/2017 found on the bench in between the 2 Hematology analyzers. 1 Coulter 5C Cell Control Abnormal 2 lot# 864000 exp. 04/02/2017 found on the bench in between the 2 Hematology analyzers. 4. During the 3/9/18 complaint investigation, the LD produced a memo signed 3/28/2017 which states that, "Laboratory supplies such as vacutainers (blood tubes) marked with an expiration date by the vendor cannot be used after that date, and should be discarded". The laboratory did not follow this memo. 5. Surveyor B observed on March 9, 2018 around 10:05 am, near the Beckman Coulter AU480 analyzer, A blue top sodium citrate vacutainer tube with expiration date 2/08/2018 containing a blood specimen labeled with the patient name, and patient specimen collected date of 03/08/2018. 6. The LM, interviewed at approximately 12:10 pm on 3/9/2018, confirmed, in the presence of the LD, that some of these expired reagents were used for patient testing and the LD was aware. 7. The LD interviewed during the 3/9/2018 complaint investigation, at approximately 11:30 pm confirmed that there were no in date QC materials available for the Beckman Coulter LH 500 and the Act diff 5 hematology

	analyzers. This is a repeat deficiency from the August 4, 2014 February 9, 2017 and June 21- 22 complaint investigations. B Based on observation, review of the Beckman Coulter (BC) AU480 analyzer quick response guide, review of the Quality Assessment (QA) policy document submitted as part of the Allegation of Compliance (AOC) received on 1-26-2018, and interview with the Laboratory Manager (LM), the laboratory failed to ensure that the BC AU480 analyzer reagent for Albumin was not used beyond the manufacturer's stability date of 90 days. Findings include: a. According to the BC AU480 analyzer Quick Response Guide, Check the ISE reagents section, "All three ISE reagents have a 90 day onboard stability that needs to be tracked by the operator. The analyzer does not track ISE reagent onboard stability. It is recommended to write the onboard expiration on the bottle when loading an ISE reagent". b. The QA policy reviewed and signed by the director on 7/1/2017 states on page 19, "8. Reagent shelf life shall be strictly observed and must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality". c. At the time of survey (3/9/18), it was observed that the onboard stability period entered in the specific test parameters section of the BC AU480 for Albumin was 120 days instead of the 90 days as instructed by the manufacturer. d. The LM interviewed on 3/9/18 at approximately 12:01pm confirmed that the LD changed the onboard stability date from 90 days to 120 days.
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 complete blood count (CBC) patient results, and interview with Laboratory director (LD) at the time of complaint investigation, the laboratory failed to verify the performance specifications of the LH 500 Hematology analyzer that had been out-of-service for about a year, before reporting patient results. Findings include: 1. The LD, interviewed on 3/9/18 at approximately 10:45 am, revealed that the LH 500 Hematology analyzer had been out-of-service for about a year. The analyzer was used to perform patient testing on March 5, March 7 and March 8, 2018 without verification of performance specifications. 2. CBC test was performed on 30 patients on 3/5/18, 3/7/18 and 3/8/18. These patients results were reported.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policy, observation, and interview with the laboratory director (LD) and the Laboratory manager (LM), the laboratory failed to follow the maintenance protocol written in the QA policy (effective date January 02/2014) for the 2 of 2 microscopes and 1 of 1 Unico Power Spin HX centrifuge used for the urine sediment tests performed from July 2016 through the date of survey. Findings include: 1. The QA policy (effective date January 02/2014), Page 19 (#7 & #8), reviewed at the time of the complaint investigation stated that, "Microscopes are examined and cleaned annually, centrifuges are cleaned weekly by staff. Annual calibration is performed". 2. Leonhard Instrument Co. stickers observed at the time of the complaint investigation showed that the Amscope & Premiere microscopes were last checked on 07/16. The laboratory was unable to produce documentation of examination and cleaning performed on the microscopes between 07 /16 and the day of survey, 03/09/2018. 3. The laboratory was unable to produce the documentation for the calibration performed on the Unico Power Spin HX centrifuge. 4. According to the LD at the time of investigation, 300 urine specimens were examined in 2017. 5. The LD confirmed the findings above. 6. The LD submitted the QA policy (effective date January 02/2014) as part of the AOC received on 1-26-2018 for the June 2017 complaint investigation. This is a repeat deficiency.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A Based on Syphilis serology quality control (QC) record review and interview with the Laboratory Director (LD) at the time of complaint investigation, March 9, 2018, the laboratory failed to perform the RPR control procedures using the number of materials specified by the manufacturer on 2/8/18. Findings: 1. The package insert for Impact RPR Rapid Plasma Reagan Card Test states, "RPR controls with established patterns of reactivity should be included in each day of testing", and "#2. If IMPACT RPR Liquid controls are used, use a Reactive, minimally reactive and non - reactive control as described under "Test Procedure". 2. The QC records revealed that the LD, who performed the test, ran 2 of 3 levels of QC materials. The LD did not run the weakly reactive control with the patient specimen on 2/8/2018 as specified by the manufacturer. The patient result was reported. 3. LD interview at 11:00 am on March 9, 2018 confirmed the findings above. B Based on review of Urinalysis Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to include a negative and positive control material in the urine sediment tests at least each day of patient testing. Findings include: 1. Records reviewed at the time of complaint investigation revealed that QC was performed once a week, instead of daily as required, for the urine sediment tests. 2. The LD interviewed on 3/9/2018 at 11:45

	am confirmed that QC was performed using the Biorad quantify control materials weekly. 3. According to the LD at the time of complaint investigation, urine sediment tests were performed on 300 specimens in 2017.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A Based on review of ITC Hemochron Jr Quality Control (QC) records, patient test logs and interview with laboratory director (LD), the laboratory failed to include two control materials of different concentrations in the Prothrombin time (PT) tests performed on the ITC Hemochron Jr Signature Elite analyzer (1of 1), at least once each day of patient testing from 6/26/17 through the date of complaint investigation. Findings include: 1. The Hemochron Signature Elite QC log reviewed at the time of complaint investigation revealed that the laboratory did not perform external QC since 6/26/17. 2. The laboratory director interviewed on 03/09/2018 at approximately 9:40 am confirmed that external QC was not performed each day of patient testing. 3. The March 2018 patient log reviewed at the time of the complaint investigation revealed that the PT test was performed on 73 patient specimens from 3/6/18 - 3/7/18. B Based on review of urinalysis Quality Control (QC) records and interview with laboratory director (LD), the laboratory failed to include two control materials of different concentrations in the urinalysis tests performed using the Clinitek Advantus analyzer (non-waived) at least once each day of patient testing. Findings include: 1. The Laboratory performs urinalysis tests with a Siemens Multistix 10 SG and a Clinitek Advantus analyzer (non-waived). 2. Urinalysis records reviewed at the time of survey revealed that QC was performed weekly instead of daily, as required. 3. The LD confirmed the findings above. C Based on review of the Complete Blood Count (CBC) Quality Control (QC) patient report and interview with the laboratory Director (LD), the laboratory failed to perform quality control on the LH 500 Hematology analyzer, at least once each day of patient testing. (3 of 3 days patient results reviewed at the time of complaint investigation). Findings include: 1. Two CBC analyzers (LH 500 and Act diff 5 Beckman Coulter) were observed during a tour of the laboratory on March 9, 2018. 30 CBC patient results were found on the bench next to these analyzers. (Tests performed 3/5/18, 3/7/18, 3/08/18). 2. The LD interviewed at the time of survey 3/9/18 at approximately 10:00 am, stated that the Act diff 5 analyzer broke, so the laboratory switched to the LH 500. The LD also stated that the LH 500 had not beeen used for about a year. The LD stated that no QC was performed before patient testing on the 3 days listed above because the laboratory ran out of QC reagents. 3. The laboratory was unable to produce QC records for the LH 500 analyzer. 4. CBC tests performed: 1 patient on March 5, 2018 23 patients on March 7, 2018 6 patients on March 8, 2018 5. According to QA policy (page 5 of 38 effective date January 02, 2014) reviewed at the time of complaint investigation, which was also submitted as part of the AOC received on 1-26-2018 for the June 2017 complaint, "QC must be acceptable before testing and/or reporting of results is permitted. Any results obtained when QC is unacceptable or not performed are invalid and must be repeated. There are no exceptions"'. This policy was not followed.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of humidity logs and interview with Laboratory Director (LD) and Laboratory Manager (LM), the laboratory failed to document all corrective actions taken when acceptable humidity range (3 of 3 months reviewed) was exceeded from January - March 9, 2018. Findings include: 1. Review of the chemistry and hematology laboratory humidity log revealed that the acceptable humidity range of 20 - 60 % degrees was exceeded in: 17 of 21 days in January, 2018 - humidity below 20%. 12 of 14 days in February, 2018 - humidity below 20%. 3 of 10 days in March, 2018 - humidity below 20%. 2. No documented corrective action was available at the time of inspection. The LD and LM interviewed on March 9, 2018 at the time of complaint investigation, confirmed that the laboratory did not document the corrective action taken. Based on surveyor review of temperature logs and interview with Laboratory Director (LD) and Laboratory Manager (LM), the laboratory failed to document all corrective actions taken when acceptable temperature range (1 of 21 days) was exceeded in January, 2018. Findings include: 1. Review of the chemistry and hematology laboratory temperature log revealed that the acceptable temperature range of 65 -78 degrees Fahrenheit (F), was exceeded or not recorded. January 12, 2018 temperature was 82 degrees F February 21 - 28, 2018 - No temperature taken. 2. No documented corrective action was available at the time of investigation. The LD and LM interviewed on March 9, 2018 confirmed that the laboratory did not document the corrective action taken.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policy document submitted as part of the Allegation of Compliance (AOC) received on 1-26-2018, review of February 2018 Quality Control (QC) records and interview with the laboratory director (LD) and Laboratory Manager (LM) on 3/9/2018, the laboratory failed to document the

	corrective actions taken for 1 of 1 control for Magnesium (Mg) test performed on the Beckman Coulter AU480 analyzer that was outside of acceptable ranges in February 2018. Findings include: 1. The QA policy reviewed and signed by the director on 7/1 /2017 states on page 32, "19. O.A "Corrective action must be initiated whenever the laboratory suspects that errors in laboratory testing has occurred. This includes the pre-analytic, analytic, and postanalytic phases of testing. Specific instances which require corrective include, but are not limited to, the following: - Quality control results are out-of-range and cannot be corrected on repeat testing". 2. A review of the Routine Chemistry QC records revealed the following: Mg Control 2 was more than 2 standard deviations outside of the mean for Mg on 2/16/18. 3. There was no documented correction action for the out-of-range QC. 4. Interview with the LM on 3 /9/18 at approximately 10:00 am confirmed there was no repeat testing or other documented corrective action taken for the out-of-range QC.
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 observation, review of Proficiency Testing (PT) records, patient results, and interview with the laboratory director (LD) and Laboratory Manager (LM), the laboratory's quality assessment mechanism failed to correct problems with expired reagents and monitor for test system verification and equipment maintenance as required in 493.1251 through 493.1283. Findings include: 1. expired reagents and supplies without expiration dates were present in the laboratory at the time of the survey. Refer to D5415. 2. Failure to verify the performance specifications of the LH 500 hematology analyzer before reporting patient test results. Refer to D5421. 3. Failure to follow the established maintenance protocol for microscopes and the centrifuge used in the Microbiology laboratory. Refer to D5433. 4. The plan of correction submitted for the deficiencies cited at the February 9, 2017 investigation, signed by the LD 3/31/17 stated, "The Laboratory Director will now oversee the inventory list every month and make sure all expired supplies are discarded appropriately". Expired reagents and laboratory supplies were found onsite during the March 9, 2018 investigation. The laboratory failed to monitor the effectiveness of its quality assessment program. This is a repeat deficiency.
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 observation, and record review, and interview with the laboratory director (LD), the laboratory director failed to provide overall management and direction in accordance with 42 CFR 493.1445. Findings include: 1. Failure to ensure that the

	laboratory enrolled in an HHS - approved proficiency testing program for Parasitology testing performed. Refer to D6088. 2. Failure to ensure corrective actions were taken for unacceptable proficiency testing results. Refer to D6092. 3. Failure to ensure that the quality assessment programs were maintained. Refer to D6094.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) record review, observation, and interview with Laboratory Manager (LM), at the time of the survey, the Laboratory Director failed to ensure that the laboratory enrolled in an HHS-approved PT program for the Parasitology testing performed from June 22, 2017 to the day of the complaint investigation. Refer to D2000. This is a repeat deficiency.
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 review of American Proficiency Institute (API) Proficiency Testing (PT) records, and interview with the laboratory director (LD), the laboratory director failed to ensure that an approved corrective action was followed for the 2017 Urine Sediment PT unsuccessful performance (2 of 3 events). Findings include: 1. Urine sediment failure of 2017 API PT 1st event - 0% score. 2. Urine sediment failure of 2017 API PT 2nd event - 50% score. 3. Corrective action reviewed at the time of the inspection did not address patient outcome for the unsuccessful performance. 4. During an interview on the day of complaint investigation, March 09, 2018 at approximately 12:10 pm, the LD confirmed the findings above.
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 direct observation, review of Quality Control (QC) records, procedure manual, manufacturer's package insert,Quality Asessment policy (effective date January 02/2014) and interview with laboratory director (LD), the laboratory director and laboratory manager (LM) failed to maintain a quality assessment program that identified failures in quality. Refer to D5417, D5421, D5433, D5445, D 5447 and D 5491. This is a repeat deficiency.