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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	13D0705741	02/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Nell J Redfield Memorial Hospital	150 N 200 W, Malad City, ID	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record reviews, patient worksheet reviews, and an interview with the laboratory manager, the laboratory failed to test five immunohematology proficiency samples from the American Proficiency Institute (API) in the same manner as they test patient samples during the API 2018 event 2. Findings: 1. A review of the API 2018 event 2 records revealed the laboratory failed to test immunohematology quality control for antibody detection, ABO/RH, and compatibility testing prior to testing 5 PT samples on April 11, 2018. 2. The laboratory performs approximately 180 immunohematology samples a year. 3. An interview on February 12, 2018 at 9:55 AM, with the laboratory manager, confirmed the laboratory failed to perform immunohematology quality control prior to testing PT samples.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.

	The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records review and an interview with the laboratory manager, the laboratory failed to retain instrument print-outs from PT test results from the events reviewed between October 2017 through December 2018. This is a repeat deficiency from the last survey on July 28, 2017. Findings: 1. A review of the American Proficiency Institute (API) test events for the specialties chemistry, endocrinology, toxicology, microbiology, and hematology revealed the laboratory failed to retain instrument data results or manual data results for the proficiency test samples performed during 2017 event 3 through 2018 event 3. 2. The laboratory tests approximately 61,700 analytes per year. 3. An interview on February 12, 2019 at 8:40 AM, with the laboratory manager, confirmed the PT results from the analyzers was not retained.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or 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 unacceptable analyte or testing event score, 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 an observation, a proficiency testing (PT) records reviews, and an interview with the laboratory manager, the laboratory failed to document any remedial action or corrective actions taken for an unsatisfactory Creatine kinase, total (CK, total) score from the American Proficiency Institute (API) for 2018 event 3. Findings: 1. An observation of the API 2018 event 3 results on February 12, 2019 at 9:05 AM, revealed the laboratory received a 40% for the analyte CK, total. 2. A record review of PT documents revealed the laboratory failed to document corrective actions for the failed CK, total. 3. An interview on February 12, 2019 at 9:40 AM, with the laboratory manager, confirmed the laboratory failed to document corrective actions.
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 record review and an interview with the laboratory manager, the laboratory failed to at least twice annually, verify the accuracy of microscopic urine sediment examinations and the presence of fungal elements in wet mounts with potassium hydroxide (KOH) since the last survey on July 28, 2017. Findings: 1. A record review of proficiency testing documents and laboratory documents revealed the laboratory failed to verify the accuracy, at least twice annually, of microscopic examinations of urine sediments and the presence and fungal elements using KOH since the last survey. 2. The laboratory performs approximately 5 KOH specimens and 323 urine sediment examinations a year. 3. An interview on February 12, 2019 at 9:30 AM, with the laboratory manager, confirmed the laboratory failed to verify the accuracy of the microscopic tests at least twice annually since the last survey.
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 a record review and an interview with the laboratory manager, the laboratory failed to have a written procedure that included all elements of complete blood count (CBCs) testing on the Beckman Coulter AcT Diff 5 to include the procedure for limitations in testing and flags, corrective actions for controls, calibrations, and manual differential reviews and reporting, and normal ranges for male, female, and pediatric patients since the last survey on July 28, 2017. Findings: 1. A review of the laboratory's procedure manual revealed the laboratory failed to establish the procedures for calibrations, performance of quality controls, limitations in reporting and testing CBCs, performance of manual differentials, and normal ranges for the age and sex of the patients since the last survey. 2. An interview on April 24, 2019 at 1:45 PM, with the laboratory supervisor, confirmed the laboratory failed to establish a procedure manual for the testing of CBCs.
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 the Beckman Coulter prostate-specific antigen (PSA) reagent manufacturer's instructions, patient test report reviews, and an interview with the laboratory manager, the laboratory failed to follow the Beckman Coulter Access II instructions to include the test method for PSA on the patient's test reports from the dates reviewed in April 2018. This is a repeat deficiency from the last survey on July 28, 2017. Findings: 1. A review the of Beckman Coulter Access II instruction sheet for PSA reagent revealed the laboratory failed to report the identity of the PSA assay to the physicians for patient PSA test results. 2. A review of patient #HF03156 reported on April 20, 2018 failed to include the identity of the PSA assay used. 3. An interview on February 12, 2019 at 11:40 AM, with the laboratory manager, confirmed the identity of the PSA assay was not included on patient test reports. B. Based on an observation, a review of the manufacturer's instructions, and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions to calculate a mean normal patient population (MNPT) for the current lot of RecombiPlasTin in use on February 12, 2019. Findings: 1. An observation of the laboratory on February 12, 2019 at 12:10 PM, revealed an ACL Top 300 coagulation analyzer with HemosIL RecombiPlasTin reagent, lot # 1073129, in use with an ISI of 0.99 and instrument MNPT stated as 12.0. 2. A record review revealed the laboratory failed to demonstrate how the MNPT was determined for the current lot of RecombiPlastin. 3. A review of the manufacturer's instructions for RecombiPlasTin revealed instructions to calculate the MNPT for each new lot of reagent and enter the number into the analyzer to establish the INR result. 4. An interview on February 12, 2019 at 12:40 PM, with the laboratory manager, confirmed the information on how the MNPT was determined was not available for the current lot of RecombiPlasTin reagent.
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 observation of reagents and quality control materials, record review, and an interview with the laboratory director, the laboratory failed to label or indicate the storage requirements, when applicable, and expiration dates for all chemistry and hematology reagents and quality control materials when opened for use. Findings: 1. An observation on February 12, 2019 at 10:00 AM of the refrigerator used to store chemistry and hematology reagents and quality control materials revealed the laboratory failed to label the bottles with expiration dates when opened for use according to the manufacturer's assay sheets. 2. An interview on February 12, 2019 at 3:40 PM, with the laboratory manager, confirmed the bottles of reagents and quality controls for the chemistry and hematology test systems were not labeled.

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 record review and an interview with the laboratory manager, the laboratory failed to verify the performance specifications of 17 out of 17 endocrinology analytes performed on the Beckman Coulter Access II before reporting patient test results since major maintenance in June 2018. Findings: 1. A record review revealed the laboratory failed to perform verification activities for prostate-specific antigen, folate, vitamin D/B-12, ferritin, human choriogonadotropin, free triiodothyronine, free thyroxine, thyroid stimulating hormone, follicular stimulating hormone, luteinizing hormone, estradiol, testosterone, progesterone, insulin, troponin, and prolactin after major maintenance was performed on the Access II. 2. The laboratory performs approximately 1500 endocrinology tests per year. 3. An interview on February 12, 2019 at 2:15 PM, with the laboratory manager, confirmed the laboratory failed to perform verification of performance activities on analytes after major maintenance on the Access II.
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 a record review and an interview with the laboratory manager, the laboratory failed to establish and document maintenance activities for the Beckman Coulter Access II, Beckman Coulter AU480, Beckman Coulter AcT Diff 5, and the ACL Top 300 analyzers since the last survey on July 28, 2017. Findings: 1. A review of the Access II daily start-up reports revealed on 12/6/2017, the laboratory failed to perform and document corrective actions when the daily start-up failed twice before reporting patient test results. 2. A record review revealed the laboratory failed to document unscheduled maintenance activities. 3. An interview on February 12, 2019 at 4:45 PM, with the laboratory manager, confirmed the laboratory failed to establish a system and document maintenance activities for the analyzers.
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 a record review and an interview with the laboratory manager, the laboratory failed to establish, perform, and document calibration procedures for the Beckman Coulter AcT Diff 5 hematology analyzer since April 2017. Findings: 1. A review of the complete blood count (CBC) procedure revealed the laboratory failed to establish a calibration procedure for the continued accuracy of test performance on the AcT Diff 5. 2. The laboratory performs approximately 5400 complete blood counts per year. 3. An interview on February 12, 2019 at 1:45 PM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration procedure activities on the AcT Diff 5 since April 2017.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification procedures for D-Dimer assay performed on the ACL Top 300; alkaline phosphatase, amylase, potassium, alanine aminotransferase, aspartate aminotransferase, direct/total bilirubin,

	sodium, chloride, creatine phosphokinase performed on the Beckman Coulter AU480; and blood gases performed on the i-Stat since the last survey on July 28, 2017. Findings: 1. A record review revealed the laboratory failed to perform and document calibration verification procedures for the listed analytes since the last survey. 2. The laboratory performs approximately 52,000 chemistry tests per year. 3. An interview on February 12, 2019 at 12:05 PM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration verification procedures.
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 an observation, a record review, and an interview with the laboratory manager, the laboratory failed to establish a quality control system to monitor and detect immediate errors for blood gases performed on the i-Stat and microbiology media used for throat and urine cultures the last survey on July 28, 2017. Findings: 1. An observation on February 12, 2019 at 4:50 PM, revealed the laboratory refrigerator stored microbiology media for throat (Strep Select Agar) and urine cultures (Tryptic Soy agar and MacConkey agar). 2. A review of laboratory documents revealed the laboratory failed to establish a quality control plan to include the number, type, and frequency of quality control reagents used to perform blood gases and throat and urine cultures, as well as monitor the performance of the tests over time. 3. An interview on February 12, 2019 at 4:55 PM, with the laboratory manager, confirmed the laboratory failed to establish and identify quality control procedures or write an Individualized Quality Control Plan for the i-Stat or microbiology media.
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: Based on record review and an interview with the laboratory manager, the laboratory failed to ensure two levels of quality control material were performed and/or were within acceptable limits for the analytes reviewed: troponin, vitamin D, folate, and chloride. Findings: 1. A quality control record review from 09/01/2018 through 09/21

	/2018, for troponin performed on the Beckman Coulter Access II, analyzer revealed 13 out of 15 days no quality control was performed, and 32 patient test results reported. 2. A quality control record review from 02/01/2018 through 03/01/2018, for troponin performed on the Access II analyzer, revealed 2 out of 16 days of patient testing where 1 out of 2 levels of quality control results were not acceptable and 31 patient test results reported. 3. A quality control record review from 09/01/2018 through 09/21/2018, for vitamin D performed on the Access II analyzer, revealed 4 out of 8 days of patient testing where no quality control was performed, and 9 patient test results reported. 4. A quality control record review from 04/02/2018 through 04/30 /2018, for vitamin D performed on the Access II analyzer, revealed 3 out of 9 days of patient testing where no quality control was performed, and 4 patient test results reported. 5. A quality control record review from 10/18/2018 through 10/21/2018, for chloride performed on the Beckman Coulter AU480, analyzer revealed 2 out of 3 days of patient testing where 1 out of 2 levels of quality control results were not acceptable and 13 patient test results reported. 6. An interview on February 12, 2019 at 11:45 AM, with the laboratory manager, confirmed the laboratory failed to identify quality control failures before reporting patient test results.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with the laboratory manager, the laboratory failed to ensure the temperature of the refrigerator where blood products were stored was monitored over a 24-hour period from March 14, 2018 through May 28, 2018. This is a repeat deficiency from the last survey on July 28, 2017. Findings: 1. An observation on February 12, 2019 at 2:45 PM, of the blood bank refrigerator temperature logs, revealed the laboratory failed to ensure the blood storage refrigerator temperature was monitored over a 24-hour period between March 14, 2018 through March 28, 2018. 2. A record review of the temperature logs revealed the laboratory failed to ensure the blood storage refrigerator temperature was monitored over a 24-hour period. 3. An interview on February 12, 2019 at 2:45 PM, with the laboratory manager, confirmed the laboratory failed to ensure the blood storage refrigerator temperature was monitored over a 24-hour period.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to establish a system that evaluates the relationship between complete blood counts (CBC) performed on the Beckman Coulter AcT Diff 5 analyzer and microscopic manual differentials at least twice a year since the last survey on July 28, 2017. Findings: 1. A record review revealed the laboratory failed to establish a system to evaluate the comparison of the manual differentials and the CBC analyzer since the last survey. 2. An interview on February 12, 2019 at 1:55 PM, with the laboratory manager, confirmed the laboratory failed to evaluate the relationship between the CBC analyzer and manual differentials at least twice a year.
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 records review and an interview with the laboratory manager, the laboratory failed to follow the laboratory's Quality Assessment Plan and failed to monitor, assess, and correct problems identified in chemistry, endocrinology, hematology, microbiology, and immunohematology since the last survey. This is a repeat deficiency from the last survey on July 28, 2017. Findings: 1. A review of the Quality Assessment Plan revealed the laboratory failed to follow the written policy to perform, monitor, and correct problems identified in calibration and calibration verification procedures for chemistry, endocrinology, and hematology test systems. See D5437 and D5439. 2. A review of quality control records for chemistry revealed the laboratory failed to identify, monitor over time, and correct problems when quality controls for chemistry and endocrinology were not acceptable or not performed. See D5441 and D5447. 3. A review of proficiency testing records and laboratory records revealed the laboratory failed to establish and follow a system to monitor the accuracy at least twice a year for urine and fungal microscopic tests, as well as the evaluation of manual differentials. See D5217 and D5775. 4. An interview on February 12, 2019 at 5:15 PM, with the laboratory manager, confirmed the laboratory failed to identify and correct problems with the test systems.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a record review of final patient reports and an interview with the laboratory manager, the laboratory failed to determine the different reference ranges for sex and age of patients for complete blood count (CBC) analytes performed on the Beckman Coulter AcT Diff 5 since the last survey on July 28, 2017. Findings: 1. A review of 5 patient CBC test reports from 02/9/2018 through 04/21/ 2018 revealed the reference

	ranges for pediatric, male, and female patients was not determined or available. 2. An interview on February 12, 2019 at 1:55 PM, with the laboratory manager, confirmed the laboratory did not establish reference ranges for adult and pediatric, sex-specific patient populations.
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 the lack of quality assessment activities (D5791 and D6094), deficiencies found in the analytic test systems (D6086, D6093, and D6095), and the lack of documentation of reviews and corrective actions for proficiency samples and ensuring proficiency samples were tested as required in Subpart H (D6089 and 6092).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record reviews and interview with the laboratory manager, the laboratory director failed to ensure that verification procedures to determine the performance specification for the Beckman Coulter Access II immunoassay analyzer was performed prior to reporting patient test results (5421), failed to ensure twice a year verification of accuracy was performed for urine sediment and fungal microscopic examinations and manual differentials (D5217 and D5775), and failed to ensure the reporting of Protime INR calculations was accurate (D5411).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records and interview with the laboratory manager, the laboratory director failed to ensure that PT samples from the American Proficiency Institute (API) were tested as required by Subpart H. Refer to D2006 and D2015.
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 proficiency testing (PT) records and interview with the laboratory manager, the laboratory director failed to ensure unsatisfactory or unacceptable PT results were evaluated and corrected. Refer to D2094.
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 quality control records and interview with the laboratory manager, the laboratory director failed to ensure the quality control program was established and monitored to detect errors in the analytic test systems. Refer to D5411, D5415, D5441, and D5447. This is a repeat deficiency from the last survey on July 28, 2017.
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 a review of the laboratory's Quality Assessment Plan, lack of corrective actions, and an interview with the laboratory manager, the laboratory director failed to ensure the laboratory followed the written policy and failed to ensure the laboratory was maintained for the analytic test systems. Refer to D5791. This is a repeat deficiency from the last survey on July 28, 2017.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on quality control records and interview with the laboratory manager, the laboratory director failed to ensure that corrective actions are taken and documented when quality control or calibrations occur. Refer to D5437, D5439, D5441, and D5447.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)

	The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on quality control records, lack of documentation, and an interview with the laboratory manager, the laboratory director failed to ensure that chemistry and hematology test systems were functioning properly before reporting patient samples. Refer to D5411, D5415, D5439, and D5447. This is a repeat deficiency from the last survey on July 28, 2017.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a record review of personnel competency assessments and an interview with the laboratory manager, the technical supervisor failed to evaluate the competency for 1 out of 3 testing personnel who performs complete blood counts (CBC), immunohematology, microscopic examinations for urine sediment and manual differentials, chemistry, endocrinology, toxicology, immunology, and microbiology since the last survey on July 28, 2017. Findings: 1. A review of personnel documents revealed the technical supervisor failed to evaluate the competency for the laboratory manager who is also a testing personnel who performs all specialties in the laboratory since the last survey in 2017. 2. An interview on February 12, 2019 at 10:30 AM, with the laboratory manager, confirmed the technical supervisor failed to assess and document the competency for the laboratory manager who is also a testing personnel.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a record review of personnel competency assessments and an interview with the laboratory manager, the laboratory personnel competency assessment forms failed to include direct observation of routine patient testing, specimen handling, processing, and testing since the last survey on July 28, 2017. Findings: 1. A review of the competency documents for 2 out of 3 testing personnel from 2017 and 2018 revealed the evaluation forms failed to include direct observation of patient specimen handling,

	processing, and testing as applicable. 2. An interview on February 12, 2019 at 8:50 AM, with the laboratory manager, confirmed the competency assessment forms did not include the direct observation requirement.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on a record review of personnel competency assessments and an interview with the laboratory manager, the laboratory personnel competency assessment forms failed to include the direct observation of performance of instrument maintenance for the analyzers in laboratory since the last survey on July 28, 2017. Findings: 1. A review of the competency documents for 2 out of 3 testing personnel from 2017 and 2018 revealed the evaluation forms failed to include the direct observation of performance of instrument maintenance for the analyzers in the laboratory since the last survey. 2. An interview on February 12, 2019 at 8:50 AM, with the laboratory manager, confirmed the competency assessment forms did not include the direct observation of instrument maintenance.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a record review of personnel competency assessments and an interview with the laboratory manager, the laboratory personnel competency assessment forms failed to include the assessment of problem solving skills for the tests performed in laboratory since the last survey on July 28, 2017. Findings: 1. A review of the competency documents for 2 out of 3 testing personnel from 2017 and 2018 revealed the evaluation forms failed to include the assessment of problem solving skills for the tests performed in laboratory since the last survey. 2. An interview on February 12, 2019 at 8:50 AM, with the laboratory manager, confirmed the competency assessment forms did not include the assessment of problem solving skills.