Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656701	08/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cancer Treatment Centers Of America	10109 E 79th Street, Tulsa, OK	

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	A validation survey was performed 07/30/19-08/01/19. The laboratory was found out of compliance with the following CLIA regulations: 493.1215: D5024: Condition: Hematology 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity Testing 493.1409: D6033: Condition: Technical Consultant, Moderate Complexity Testing The findings were reviewed with the vice president of general services, technical consultant #4, technical consultant #3, quality review #1, quality review #2, laboratory director, physician assistant for pathology, microbiology lead, microbiology technologist, LIS specialist, director of quality and risk management, technical consultant #6/hematology lead, and laboratory administrative director during an exit conference performed at the conclusion of the survey.
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 a review of records and interview with technical consultant #5/technical supervisor #2, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, surveyor #3 reviewed 2017, 2018 and 2019 proficiency testing records, which

	included the attestation statements. The attestation statements had not been signed by the laboratory director or designee for 4 of 92 events reviewed as follows: (a) 2018 First Ligand-Special (Y-A) Event - The attestation had not been signed by the laboratory director or designee; (b) 2018 Second Aqueous Blood Gas (AQI-B) Event - The attestation had not been signed by the laboratory director or designee; (c) 2019 First Vancomycin Resistant Enterococcus (VRE-A) Event - The attestation had not been signed by the laboratory director or designee; (d) 2019 First Fecal Lactoferrin (FLAC-A) Event - The attestation had not been signed by the laboratory director or designee. (2) Surveyor #3 reviewed the findings with technical consultant #5/technical supervisor #2 and explained that attestation statements must be signed by the laboratory director or designee.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the hematology lead/technical consultant #6, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing reagents on the Stago Compact Max and the STA Satellite coagulation analyzers. Refer to D5411; (2) The laboratory failed to test control specimens in duplicate when performing manual spinal fluid cell counts using a hemacytometer. Refer to D5543; (3) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy and interview with technical consultant #5/technical supervisor #2, the laboratory failed to have a written technical supervisor, general supervisor, and technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On the second day of the survey, surveyor #3 reviewed personnel records for competency assessments performed during 2017, 2018, and 2019. There was no evidence competencies had been performed for the technical supervisor, general supervisor, and technical consultant, based on their job responsibilities; (2) The surveyor asked technical consultant #5/technical supervisor #2 if a written policy to evaluate the technical supervisor, general supervisor, and technical consultant based on job responsibilities was available. Technical consultant #5/technical supervisor #2 stated a policy to evaluate the technical supervisor, general supervisor and technical consultant based on job responsibilities had not been written; and competencies had not been performed.

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: Based on a review of records, manufacturer's instructions, and interview with technical consultant #6, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On the first day of the survey, technical consultant #6 stated to the surveyors the laboratory performed PT /INR (Prothrombin Time/International Normalized Ratio) and APTT (Activated Partial Thromboplastin Time) testing using two analyzers (the INR was calculated using the PT reference interval geometric mean): (a) Stago Compact Max - used as the primary analyzer (b) Stago STA Satellite - used as the back-up analyzer (2) On the second day of the survey, technical consultant #6 stated the following to surveyor #2: (a) PT Reagent - STA Neoplastin CI Plus, lot #252775 was put into use on 05/31/18 and used until 05/01/19; (b) PT Reagent - STA Neoplastin CI Plus, lot #253972 was put into use on 05/02/19 and was currently in use; (c) PTT Reagent - STA PTT, lot #252853 was put into use on 05/31/18 and was currently in use. (3) Surveyor #2 reviewed the manufacturer's instructions for implementing new reagents, which stated: (a) "Normal Reference Range": (i) For PTT reagent it stated, "It is recommended that each site run a minimum of 20 normal samples with the new reagent. Use well screened samples." (ii) For PT reagent it stated, "A new Geometric mean must be verified for each new lot of PT reagent. It is recommended that each site run a minimum of 20 normal samples with the new PT reagent. Use well screened samples." (iii) For PT and PTT reagents, the "Criteria for reference range 'normal' donors" stated: (aa) "Age-Include ages that span the population your patient diversity" (bb) "Sex-Equal numbers of male and female" (cc) "Drug History-Patients excluded if taking the following drugs: -Birth control or estrogen containing products -Coumadin -Heparin (UFH, LMWH or heparinoid)" (dd) "Conditions-Patients excluded if they are pregnant or have any known immunologic diseases." (b) "Current Lot vs. New Lot Correlation": (i) "Collect 40 patient samples across the reportable range: -20 normal samples (minimum) -15 therapeutic (anti-Xa=0.3-0.7 IU/ml) -5 samples to verify the upper limits of the reported range" (c) "If there are 2 or more analyzers, the same normal samples should be run on each analyzer to account for any variability." (4) Surveyor #2 then reviewed the implementation records for the reagent lot changes for PT and PTT for both analyzers. The records showed the laboratory failed to follow the manufacturer's instructions as follows: (a) Stago Compact Max (primary analyzer) (i) PT reagent lot #252775 (put into use on 05/31/18) (aa) For the Normal Reference Range, the laboratory analyzed 25 donor samples. There was no documentation of the age, gender, medication history, and health status of the donors. Technical consultant #6 stated to surveyor #2 the donor samples used were from cancer patients. Therefore, surveyor #2 determined the donors did not meet the manufacturer's criteria for normal donors; (bb) For the Current Lot vs. New Lot Correlation, the laboratory did not utilize a minimum of 20 normal samples (since cancer patients had been used for the study). (ii) PT reagent lot #253972 (put into use on 05/02/19) (aa) For the Normal Reference Range, the laboratory analyzed 21 donor samples. There was no documentation of the age, gender, medication history, and health status of the donors. Technical consultant #6 stated to surveyor #2 the donor samples used were from

cancer patients. Therefore, surveyor #2 determined the donors did not meet the manufacturer's criteria for normal donors; (bb) For the Current Lot vs. New Lot Correlation, the laboratory did not utilize a minimum of 20 normal samples (since cancer patients had been used for the study). (iii) PTT reagent lot #252853 (put into use on 05/31/18) (aa) For the Normal Reference Range, the laboratory analyzed 25 donor samples. There was no documentation of the age, gender, medication history, and health status of the donors. Technical consultant #6 stated to surveyor #2 the donor samples used were from cancer patients. Therefore, surveyor #2 determined the donors did not meet the manufacturer's criteria for normal donors; (bb) For the Current Lot vs. New Lot Correlation, the laboratory did not utilize a minimum of 20 normal samples (since cancer patients had been used for the study). (b) Stago STA Satellite (back-up analyzer) (i) PT reagent lot #252775 (put into use on 05/31/18) (aa) The Normal Reference Range was not performed using the back-up analyzer. Technical consultant #6 stated to surveyor #2 the geometric mean obtained on the primary analyzer was programmed into the analyzer to calculate the INR; (bb) The Current Lot vs. New Lot Correlation was not performed on the back-up analyzer. (ii) PT reagent lot #253972 (put into use on 05/02/19) (aa) The Normal Reference Range was not performed using the back-up analyzer. Technical consultant #6 stated to surveyor #2 the geometric mean obtained on the primary analyzer was programmed into the analyzer to calculate the INR; (bb) The Current Lot vs. New Lot Correlation was not performed on the back-up analyzer. (iii) PTT reagent lot #252853 (put into use on 05/31/18) (aa) The Normal Reference Range was not performed using the back-up analyzer; (bb) The Current Lot vs. New Lot Correlation was not performed on the back-up analyzer. (5) Surveyor #2 reviewed the findings with technical consultant #6 who stated the following: (a) The laboratory did not follow the manufacturer's instructions for performing the new reagent lot rollover procedure for the PT and PTT reagents, as listed above; (b) The reagent lot rollover studies had not been performed on the back-up analyzer. (6) The following were examples of patient PT/INR testing performed using the Stago Compact Max (primary analyzer): (a) Patient #35-Testing performed on 05/31/18 (b) Patient #36-Testing performed on 06/02/18 (c) Patient #37-Testing performed on 06/29/18 (d) Patient #38-Testing performed on 07/16/18 (e) Patient #39-Testing performed on 07/31/18 (f) Patient #40-Testing performed on 08/06 /18 (g) Patient #41-Testing performed on 08/23/18 (h) Patient #42-Testing performed on 09/12/18 (i) Patient #43-Testing performed on 09/28/18 (j) Patient #44-Testing performed on 10/09/18 (k) Patient #45-Testing performed on 10/23/18 (l) Patient #46-Testing performed on 11/15/18 (m) Patient #47-Testing performed on 11/30/18 (n) Patient #48-Testing performed on 12/01/18 (o) Patient #49-Testing performed on 12 /14/18 (p) Patient #50-Testing performed on 12/25/18 (q) Patient #51-Testing performed on 01/10/19 (r) Patient #52-Testing performed on 01/29/19 (s) Patient #53-Testing performed on 02/06/19 (t) Patient #54-Testing performed on 02/21/19 (u) Patient #55-Testing performed on 03/07/19 (v) Patient #56-Testing performed on 03 /18/19 (w) Patient #57-Testing performed on 03/27/19 (x) Patient #58-Testing performed on 04/01/19 (y) Patient #59-Testing performed on 04/15/19 (z) Patient #60-Testing performed on 04/24/19 (aa) Patient #61-Testing performed on 04/29/19 (bb) Patient #62-Testing performed on 05/01/19 (cc) Patient #63-Testing performed on 05 /10/19 (dd) Patient #64-Testing performed on 05/22/19 (ee) Patient #65-Testing performed on 05/31/19 (ff) Patient #66-Testing performed on 06/05/19 (gg) Patient #67-Testing performed on 06/19/19 (hh) Patient #68-Testing performed on 06/27/19 (ii) Patient #69-Testing performed on 07/07/19 (jj) Patient #70-Testing performed on 07/24/19 (kk) Patient #71-Testing performed on 07/30/19 (ll) Patient #72-Testing performed on 08/01/19 (7) The following were examples of patient PTT testing performed using the Stago Compact Max (primary analyzer): (a) Patient #1-Testing performed on 06/01/18 (b) Patient #2-Testing performed on 06/17/18 (c) Patient #3-

	Testing performed on 06/30/18 (d) Patient #4-Testing performed on 07/02/18 (e) Patient #5-Testing performed on 07/18/18 (f) Patient #6-Testing performed on 07/27 /18 (g) Patient #7-Testing performed on 08/02/18 (h) Patient #8-Testing performed on 08/30/18 (i) Patient #9-Testing performed on 09/01/18 (j) Patient #10-Testing performed on 09/25/18 (k) Patient #11-Testing performed on 10/01/18 (l) Patient #12-Testing performed on 10/23/18 (m) Patient #13-Testing performed on 10/31/18 (n) Patient #14-Testing performed on 11/16/18 (o) Patient #15-Testing performed on 11 /30/18 (p) Patient #16-Testing performed on 12/02/18 (q) Patient #17-Testing performed on 12/18/18 (r) Patient #18-Testing performed on 11/20/18 (s) Patient #19-Testing performed on 01/09/19 (t) Patient #20-Testing performed on 01/28/19 (u) Patient #21-Testing performed on 02/02/19 (v) Patient #22-Testing performed on 02 /26/19 (w) Patient #23-Testing performed on 03/16/19 (x) Patient #24-Testing performed on 03/21/19 (y) Patient #25-Testing performed on 04/08/19 (z) Patient #26-Testing performed on 04/15/19 (aa) Patient #27-Testing performed on 04/24/19 (bb) Patient #28-Testing performed on 05/02/19 (cc) Patient #29-Testing performed on 05 /24/19 (dd) Patient #30-Testing performed on 06/03/19 (ee) Patient #31-Testing performed on 06/25/19 (ff) Patient #32-Testing performed on 07/05/19 (gg) Patient #33-Testing performed on 07/25/19 (hh) Patient #34-Testing performed on 08/01/19 NOTE: Technical consultant #6 stated to surveyor #2 patient PT/INR and PTT testing had not been performed using the Stago STA Satellite analyzer (back-up analyzer) during the review period of 05/2018 through the second day of the survey, but the analyzer was available for use during this time.
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 and interview with technical consultant #1, the laboratory failed to label containers with the identity, storage requirement, and lot number of the contents. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors the laboratory performed HgbA1C (Hemoglobin A1C) testing using the Roche Cobas c501 analyzer; (2) On the third day of the survey, surveyor #2 observed the refrigerator in the chemistry area and identified 2 parafilmed sample cups containing red fluid located in the tray of chemistry QC (Quality Control) materials currently in use, as follows: (a) Handwritten on the first cup: "#1 Opened 7 /25/19 Exp 8/7/19" (b) Handwritten on the second cup: "#2 Opened 7/25/19 Exp 8/7 /19" (2) Surveyor #2 asked technical consultant #1 how the contents of the sample cups were used. Technical consultant #1 stated to surveyor #2 the cups contained Level 1 and Level 2 of BioRad Liquichek Diabetes control materials used for HgbA1C testing. Surveyor #2 asked technical consultant #1 if the cups were filled from bottles of control materials and if the original bottles had been maintained. Technical consultant #1 stated to surveyor #2 the original bottles of HgbA1C control materials were stored frozen and when new control materials were needed, new bottles were thawed, poured into the sample cups, parafilmed, and stored in the refrigerator for use; (3) Technical consultant #1 escorted surveyor #2 to the freezer where the HgbA1C control materials were stored. The surveyor identified 2 boxes

	with 6 bottles each, of BioRad Liquichek Diabetes QC materials, Level 1, Lot #38571 and Level 3, Lot #38573 (expiration date 07/31/20) stored inside; (4) Surveyor #2 explained aliquots of reagents, solutions, control materials, and other supplies must be labeled with the identity of the materials, storage requirements, and other pertinent information required for the proper use of the materials. Therefore, surveyor #2 could not verify the identity and lot numbers of the contents of the 2 sample cups stored in the chemistry refrigerator.
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: Based on a review of records and interview with technical consultant 2, the laboratory failed to ensure testing materials were not used beyond the expiration date. Findings include: (1) On the first day of the survey, technical consultant #2 stated to the surveyors the laboratory performed identification of fungal isolates from cultures (i.e. Urine, Wound, Sputum,Throat, Blood, Tissues, Body fluids, Cerebral spinal fluid, etc.); (2) Surveyor #2 reviewed the Daily Microbiology QC (Quality Control) Logs from 01/01/2019 through 07/30/19. Documentation showed Rapid Trehalose Assimilation broth, Lot #423484, with an expiration date of 04/18/19, had been used on 3 of 9 days for QC testing. The days were: (a) 04/19/19 (b) 04/21/19 (c) 04/22/19 (3) Surveyor #2 asked technical consultant #2 how the Rapid Trehalose Assimilation broth was used. Technical consultant #2 stated to surveyor #2, the broth was used to identify yeast colonies as Candida glabrata; (4) Surveyor #2 then reviewed the records with technical consultant #2 and asked if the expired Rapid Trehalose Assimilation broth had been used for patient testing on the days listed above. Technical consultant #2 stated to surveyor #2 the expired Rapid Trehalose Assimilation broth had been removed from use on 04/26/19 but had been available for use on 04/19/19, 04/21/19, and 04/22/19; (5) The following were examples of patient testing performed using the expired Rapid Trehalose Assimilation broth for identification of Candida glabrata: (a) Patient #1: Testing performed on 04/19/19 (b) Patient #2: Testing performed on 04/21 /19
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 review of records and interview with technical consultant #4 and the administrative laboratory director, the laboratory failed to perform calibration verification every six months. Findings include: (1) On the second day of the survey, technical consultant #4 stated the following to surveyor #1: (a) Sodium, Potassium, Ionized Calcium, Hemoglobin, Hematocrit pH, pCO2, and pO2 testing were performed using the EG7+ cartridge and 4 iSTAT 1 analyzers; (b) Analyzer serial number 338451 was the primary analyzer and serial numbers 344853, 326074, and 378932 were the back-up analyzers; available for use in the event the primary analyzer was not available or inoperable. (2) Surveyor #1 reviewed calibration verification records for the test system performed during 2018 and to date in 2019 and identified calibration verification had not been performed on the 3 back-up analyzers (serial numbers 344853, 326074, and 378932) during the review period; (3) Surveyor #1 reviewed the records with technical consultant #4 and the administrative laboratory director and asked if calibration verification had been performed on the 3 back-up analyzers at least once every six months and if the back-up analyzers could be used at any time. Both stated to surveyor #1 calibration verification had not been performed on the 3 back-up analyzers and any one of the analyzers could be used at any time if needed; (4) Surveyor #1 then asked technical consultant #4 if the back-up analyzers had been used for patient testing during the review period. Technical consultant #4 stated to surveyor #1 the back-up analyzers had not been used for patient testing during the review period.
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: Based on a review of records and interview with technical consultant #4 and the administrative laboratory director, the laboratory failed to perform quality control as stated in the IQCP. Findings include: (1) On the second day of the survey, technical consultant #4 stated the following to surveyor #1: (a) Sodium, Potassium, Ionized Calcium, Hemoglobin, Hematocrit pH, pCO2, and pO2 testing were performed using the EG7+ cartridge and 4 iSTAT 1 analyzers; (b) Analyzer serial number 338451 was the primary analyzer and serial numbers 344853, 326074, and 378932 were the back-

	up analyzers; available for use in the event the primary analyzer was not available or inoperable; (c) An IQCP (Individualized Quality Control Plan) had been developed for the test system and external QC (quality control) was performed each 30 days and with new lot numbers of cartridges. (2) Surveyor #1 reviewed QC records for 2019 and identified that QC had not been tested using the 3 back-up analyzers (serial numbers 344853, 326074,and 378932). QC had only been performed, as stated in the IQCP, on the primary analyzer (serial number 338451); (3) Surveyor #1 reviewed the records with technical consultant #4 and the administrative laboratory director and asked if QC had been performed on the 3 back-up analyzers and if the back-up analyzers could be used at any time. Both stated to surveyor #1 QC had not been performed on the 3 back-up analyzers and any one of the analyzers could be used if needed; (4) Surveyor #1 then asked technical consultant #4 if the back-up analyzers had been used for patient testing during the review period. Technical consultant #4 stated to surveyor #1 the back-up analyzers had not been used for patient testing during the review period.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the chemistry lead and administrative laboratory director, the laboratory failed to follow the manufacturer's specifications for quality control materials. Findings include: (1) On the second day of the survey, the chemistry lead stated the following to surveyor #1: (a) The laboratory performed qualitative serum pregnancy testing using the SP Brand Rapid Test hCG Combo test kit; (b) Positive and negative QC (quality control) was performed each day of patient testing; (c) For the positive control, the laboratory used Bio-Rad Lyphochek Immunoassay Plus Control level 2. Once reconstituted, the control material was aliquoted and stored frozen for 30 days. (2) Surveyor #1 reviewed the manufacturer's storage and stability instructions for the control material. Under the heading "Reconstituted and Frozen", the instructions stated, "When reconstituted and stored tightly capped at -20 to -70 C, this product will be stable as follows: -All analytes: 20 days"; (3) Surveyor #1 observed the QC materials currently stored in the freezer, which had the date of 06/19/19 documented on the aliquots, which the chemistry lead stated to surveyor #1 was the date the controls had been reconstituted and frozen. Based on that date, surveyor #1 determined the 20 day expiration date would be 07/09/19; (4) Surveyor #1 then reviewed the serum pregnancy test log and identified the positive control had been used for testing beyond the 20 day expiration date on 07/15/19, 07/25/19, and 07/30/19; (5) The findings were reviewed with the chemistry lead who was not aware of the manufacturer's 20 day expiration date once the controls were reconstituted and frozen.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and

	control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the hematology lead/technical consultant #6, the laboratory failed to test control specimens in duplicate when performing manual spinal fluid cell counts using a hemacytometer. Findings include: (1) On the second day of the survey, the hematology lead/technical consultant #6 stated to surveyor #1 CSF (Cerebral Spinal Fluid) cell counts were performed using a hemacytometer; (2) Surveyor #1 reviewed records for patient CSF cell counts performed in 2019. There was no evidence control materials had been tested in duplicate for 14 of 14 days of patient testing (the days of testing were 01/15,25/19; 02 /19,21,22/19; 03/06,08,22/19; 04/08,29/19; and 05/03,08,31/19; (3) Surveyor #1 reviewed the records with the hematology lead/technical consultant #6 who stated that, although it was the policy of the laboratory to test control materials in duplicate, it had not been documented.
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 a review of records, manufacturer's instructions,observation, and interview with technical consultant #1, technical consultant #2, technical consultant #4, technical consultant #6, administrative laboratory director, and the chemistry lead, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment due to the following issue identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411. (b) The laboratory failed to label containers with the identity, storage requirement, and lot number of the contents. Refer to D5415; (c) The laboratory failed to ensure testing materials were not used beyond the expiration date. Refer to D5417; (d) The laboratory failed to perform calibration verification every six months. Refer to D5439; (e) The laboratory failed to perform quality control as stated in the IQCP. Refer to D5445; (f) The laboratory failed to follow the manufacturer's specifications for quality control materials. Refer to D5479; (g) The laboratory failed to test control specimens in duplicate when performing manual spinal fluid cell counts using a hemacytometer. Refer to D5545.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #6, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for the testing performed. Refer to D6014.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #6, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for the testing performed. Refer to D5411.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant #6, the technical consultant failed to provide technical oversight for the moderate complexity testing performed in the laboratory. Findings include: (1) The technical consultant failed to the manufacturer's instructions were followed for the testing performed. Refer to D6042.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with

	technical consultant #6, the technical consultant failed to establish and maintain a quality control program appropriate for the testing performed to ensure acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions for the testing performed. Refer to D5411.