

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0048721	(X3) Date Survey Completed 01/29/2020
Name of Provider or Supplier W O Moss Memorial Health Clinic	Street Address, City, State Main Building, 2nd Floor, Lake Charles, LA	
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 at W.O Moss Memorial Health Clinic, CLIA ID # 19D0048721 on January 27, 2020 through January 29, 2020. W.O. Moss Memorial Health Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain data for the 2018 new lot mean normal prothrombin time and quality control mean and range establishment for at least two (2) years for Coagulation testing. Findings: 1. Record request for the new lot establishment of coagulation reagents for 2018 and 2019 was requested by surveyor on January 30, 2019. The data for 2019 was provided; however, the laboratory was unable to provide the coagulation reagent data for 2018. 2. In interview on January 28, 2020, the hematology supervisor confirmed that the data for the 2018 new lot rollover was inadvertently discarded instead of the 2016 data.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of</p>

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

This STANDARD is not met as evidenced by:

I. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Ammonia testing are separated within 10 minutes according to the manufacturer for six (6) of thirty-one (31) patients reviewed. Findings: 1. Observation by the surveyor on January 27, 2020 revealed the laboratory performs Ammonia testing on the Beckman Coulter Unicel DxC 600 Chemistry analyzer. 2. Review of the Beckman Coulter Synchron Systems Chemistry Information Sheet for Ammonia revealed under "Specimen Storage and Stability" that "Tubes should be filled completely, mixed gently by inversion, placed on ice, centrifuged immediately for 10 minutes and analyzed within 30 minutes". 3. Review of patient records for Ammonia from September 1, 2019 through January 2019 revealed the laboratory did not separate the following six (6) of thirty-one (31) patients within 10 minutes: a) September 16, 2019: Patient 4917375 was collected at 11:08 am and received at 11:35 am - exceeding the ten (10) minutes required by the manufacturer by seventeen (17) minutes b) October 10, 2019: Patient 4942584 was collected at 11:24 am and received at 11:40 am - exceeding the ten (10) minutes required by the manufacturer by six (6) minutes c) October 11, 2019: Patient 4943698 was collected at 11:00 am and received at 11:19 am - exceeding the ten (10) minutes required by the manufacturer by nine (9) minutes d) October 18, 2019: Patient 4908035 was collected at 10:46 am and received at 11:08 am - exceeding the ten (10) minutes required by the manufacturer by twelve (12) minutes e) October 25, 2019: Patient 4964288 was collected at 15:25 pm and received at 15:47 pm - exceeding the ten (10) minutes required by the manufacturer by twelve (12) minutes f) December 2, 2019: Patient 4905879 was collected at 10:03 am and received at 10:21 am - exceeding the ten (10) minutes required by the manufacturer by eight (8) minutes 4. In interview on January 28, 2020 at 01:40 pm, Personnel 3 confirmed that the ammonia samples noted above were not separated within the manufacturer's requirements. 5. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 62 Ammonia tests annually. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples are separated within two (2) hours as required by laboratory policy. Findings: 1. Observation by surveyors on January 28, 2020 at 5:09 pm revealed the laboratory received uncentrifuged patient samples from three (3) outside facilities. 2. Review of the laboratory's Specimen Storage and Stability policy revealed that "Serum or plasma should be physically separated from contact with cells as soon as possible. A maximum limit of two hours from the time of collection is recommended". 3. Review of the patient samples received on January 28, 2020 revealed the laboratory received uncentrifuged samples for patient testing for the following three (3) of seven (7) samples reviewed: a) Patient DOB 02/05/1961: one (1) red BD vacutainer tube collected at 2:45 pm - exceeding the two (2) hours required by the laboratory by twenty-four (24) minutes b) Patient DOB 10/28/1994: one (1) red BD vacutainer tube collected at 11:15 am - exceeding the two (2) hours required by the laboratory by two (2) hours fifty-four (54) minutes c) Patient DOB 02/15/1999: one (1) red BD vacutainer tube collected at 9:15 am - exceeding the two (2) hours required by the laboratory by five (5) hours fifty-four (54) minutes 4. In interview on January 28, 2020 at 17:30 pm, Personnel 2 stated that the samples above were from one doctor's office which only sends their samples one time per day.

Personnel 2 further stated that the red collection tubes were normally drawn as an extra and were not used for patient testing. 5. In further interview, Personnel 2 confirmed the above samples were received uncentrifuged exceeding the laboratory's specimen storage and stability requirements.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system.

Findings: 1. The laboratory failed to ensure patient samples for Ammonia testing are separated within 10 minutes according to the manufacturer for six (6) of thirty-one (31) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure patient samples are separated within two (2) hours as required by laboratory policy. Refer to D5311 II.

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, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 2. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for four (4) of one hundred fifteen (115) patient reviewed. Refer to D5411 II. 3. The laboratory failed to perform a normal donor study as required by manufacturer to verify reference intervals and establish their own normal Prothrombin Time (PT) mean. Refer to D5411 III. 4. The laboratory failed to ensure patient samples for Erythrocyte Sedimentation Rate (ESR) are performed within four (4) hours as required by the manufacturer for thirty-two (32) of three hundred twenty eight (328) patients reviewed. Refer to D5411 IV. 5. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 6. The laboratory failed to document monthly instrument maintenance for the Instrumentation Laboratory ACL Top CTS 500 Coagulation analyzer. Refer to D5429. 7. The laboratory failed to perform Analytical Measurement Range (AMR) Validation on the Beckman Coulter Unicel DxC 600 Synchron chemistry analyzer every 6 months according to laboratory policy. Refer to D5439. 8. The laboratory failed to perform reactive and non reactive quality controls for Rapid Plasma Reagin

(RPR) testing for one (1) of four (4) patients reviewed. Refer to D5449 I. 9. The laboratory failed to perform positive and negative quality controls for Mononuclear Spot testing. Refer to D5449 II. 10. The laboratory failed to perform positive and negative quality controls for Lateral Flow Cryptococcus Antigen testing. Refer to D5449 III. 11. The laboratory failed to perform Low/High blood bank refrigerator alarm checks quarterly. Refer to D5555. 12. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.

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:

I. Based on observation, record review, and interview with personnel, the laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Findings: 1. Observation by surveyor during laboratory tour on January 27, 2020 revealed the laboratory utilizes the following BacT/ALERT blood culture bottles: BacT/ALERT, Lot # 4053910 BacT/ALERT, Lot # 4053838 2. Review of the BacT/ALERT package insert revealed "Prior to use, visually inspect all BacT/ALERT bottles for evidence of damage or contamination. A bottle should not be used if any evidence of leakage is notes. Do not use a bottle which contains media exhibiting turbidity, excess gas pressure, or a yellow sensor; these are signs of possible contamination." 3. In interview on January 27, 2020 at 03:00 pm, Personnel 2 stated the laboratory received blood culture bottles from the main campus but does not document visual inspections of culture bottles prior to use. II. Based on observation, record review and interview with personnel, the laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for four (4) of one hundred fifteen (115) patient reviewed. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory utilized the Instrumentation Laboratory ACL Top CTS 500 Coagulation analyzer for Partial Thromboplastin Time (PTT) testing. 2. Review of the Instrumentation Laboratory ACL Top CTS 500 operator's manual revealed under specimen storage states for APTT testing that "samples should be analyzed within four (4) hours of collection". 3. Review of patient reports from October 15, 2019 through January 15, 2020 revealed the following four (4) of one hundred fifteen (115) patients were not tested within four hours of collection as required by the manufacturer: a) Patient 4990872 collected on November 27, 2019 at 07:48 am, received at 11:46 am, completed test at 12:09 pm - exceeding the four (4) hours required by the manufacturer by twenty one (21) minutes b) Patient 4939186 collected on October 7, 2019 at 09:45 am, recieved at 14:49 pm, completed test at 15:21 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour thirty-six (36) minutes c) Patient 5024016 collected on January 7, 2020 at 10:50 am, received at 14:55 pm, completed test at 15:59 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour nine (9) minutes d) Patient 4967200 collected on November 4, 2019 at 14:35 pm, received at 18:41 pm, completed test at 19:26 pm - exceeding the four (4) hours required by the manufacturer by fifty-one (51) minutes 4. Interview with the hematology supervisor

and technical consultant on January 28, 2020 confirmed that the above samples were outpatient testing referred to the laboratory but not tested within 4 hours as required by the manufacturer. 5. Review of the Task 1 & 3 provided to surveyors revealed the laboratory performs 386 PTT tests annually. III. Based on observation, record review and interview with personnel, the laboratory failed to perform a normal donor study as required by manufacturer to verify reference intervals and establish their own normal Prothrombin Time (PT) mean. Findings: 1. Observation by surveyor during laboratory tour on January 27, 2020 revealed the laboratory utilizes the Instrumentation Laboratory ACL Top CTS 500 Coagulation analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the ACL Top CTS 500 installation manual under "Establishing a normal reference interval" revealed the following donor requirements: a) minimum of 20 donors should be used b) Donors should be healthy and have no known pathological conditions c) Donors should not be on medications, including aspirin, aspirin related products, oral contraceptives, and estrogen therapy d) Donors should span the adult age range. Pediatric ranges should be established separately. e) Study should include a fairly even number of males and females 3. Review of the laboratory policy and procedure manual revealed the laboratory did not have a written criteria for normal donors that qualify for the reference interval study. 4. Review of the laboratory's normal mean PT study records revealed the laboratory did not have record of the participants included in the reference interval study or if they qualified as normal donors as required by the manufacturer. 4. Interview with the hematology supervisor on January 28, 2020 confirmed the laboratory did not record the individuals utilized for the reference interval verification for the current lot of thromboplastin. 5. Review of the Task 1&3 form provided to surveyors revealed the laboratory performs 2,465 PT/INR tests annually. IV. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Erythrocyte Sedimentation Rate (ESR) are performed within four (4) hours as required by the manufacturer for thirty-two (32) of three hundred twenty eight (328) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory utilizes the Sediplast System for Erythrocyte Sedimentation Rate (ESR) patient testing. 2. Review of the Sediplast package insert under "General Guidelines" revealed that "test should be set up within 4 hours". 3. Review of patient records for ESR testing from November 1, 2019 through December 31, 2019 revealed the laboratory did not perform ESR testing according to the manufacturer for the following thirty-two (32) of three hundred twenty-eight (328) patients reviewed: a) December 17, 2019: Patient 5008498 was collected at 12:10 pm and received at 17:26 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour sixteen (16) minutes b) December 9, 2019: Patient 5000510 was collected at 08:50 am and received at 17:45 pm - exceeding the four (4) hours required by the manufacturer by four (4) hours fifteen (55) minutes c) December 12, 2019: Patient 5004253 was collected at 12:23 pm and received at 17:27 pm - exceeding the four (4) hours required by the manufacturer by one (1) hours four (4) minutes d) December 18, 2019: Patient 5009635 was collected at 12:13 pm and received at 17:34 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour twenty-one (21) minutes e) November 12, 2019: Patient 4975828 was collected at 07:57 am and received at 17:20 pm - exceeding the four (4) hours required by the manufacturer by five (5) hours twenty-three (23) minutes f) December 10, 2019: Patient 5001890 was collected at 12:24 pm and received at 17:31 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour seven (7) minutes g) December 3, 2019: Patient 4994878 was collected at 07:30 am and received at 17:19 pm - exceeding the four (4) hours required by the manufacturer by five (5) hours forty-nine (49) minutes h) December 4, 2019: Patient 4995923 was collected at 08:25 am and received at 15:20 pm - exceeding the four (4) hours

required by the manufacturer by two (2) hours fifty-five (55) minutes i) November 5, 2019: Patient 4968490 was collected at 10:07 am and received at 17:33 pm - exceeding the four (4) hours required by the manufacturer by three (3) hours twenty-six (26) minutes j) November 14, 2019: Patient 4978479 was collected at 08:30 am and received at 17:38 pm - exceeding the four (4) hours required by the manufacturer by five (5) hours eight (8) minutes k) December 12, 2019: Patient 5004278 was collected at 12:05 pm and received at 17:35 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour thirty (30) minutes l) December 18, 2019: Patient 5009641 was collected at 13:08 pm and received at 17:41 pm - exceeding the four (4) hours required by the manufacturer by thirty-three (33) minutes m) November 18, 2019: Patient 4981759 was collected at 12:55 pm and received at 18:05 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour ten (10) minutes n) November 4, 2019: Patient 4967175 was collected at 12:24 pm and received at 18:11 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour forty-seven (47) minutes o) November 14, 2019: Patient 4978515 was collected at 12:07 pm and received at 18:01 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour fifty-four (54) minutes p) December 9, 2019: Patient 5000486 was collected at 12:41 pm and received at 17:15 pm - exceeding the four (4) hours required by the manufacturer by thirty-four (34) minutes q) November 20, 2019: Patient 4984407 was collected at 12:44 pm and received at 17:23 pm - exceeding the four (4) hours required by the manufacturer by thirty-nine (39) minutes r) November 13, 2019: Patient 4977127 was collected at 12:27 pm and received at 17:28 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour one (1) minute s) December 5, 2019: Patient 4997552 was collected at 13:04 pm and received at 17:44 pm - exceeding the four (4) hours required by the manufacturer by forty (40) minutes t) November 18, 2019: Patient 4981758 was collected at 13:02 pm and received at 18:04 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour two (2) minutes u) November 26, 2019: Patient 4990226 was collected at 08:00 am and received at 17:38 pm - exceeding the four (4) hours required by the manufacturer by five (5) hours thirty-eight (38) minutes v) November 19, 2019: Patient 4983150 was collected at 12:20 pm and received at 17:22 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour two (2) minutes w) November 26, 2019: Patient 4990230 was collected at 08:15 am and received at 17:48 pm - exceeding the four (4) hours required by the manufacturer by five (5) hours thirty-three (33) minutes x) December 16, 2019: Patient 5007430 was collected at 12:39 pm and received at 17:41 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour two (2) minutes y) December 2, 2019: Patient 4993594 was collected at 12:50 pm and received at 17:36 pm - exceeding the four (4) hours required by the manufacturer by forty-six (46) minutes z) December 30, 2019: Patient 5017309 was collected at 12:30 pm and received at 17:29 pm - exceeding the four (4) hours required by the manufacturer by fifty-nine (59) minutes aa) December 2, 2019: Patient 4993605 was collected at 10:13 am and received at 17:48 pm - exceeding the four (4) hours required by the manufacturer by three (3) hours thirty-five (35) minutes bb) November 14, 2019: Patient 4978480 was collected at 12:28 pm and received at 17:33 pm - exceeding the four (4) hours required by the manufacturer by one (1) hour five (5) minutes cc) December 23 2019: Patient 5013233 was collected at 09:30 am and received at 17:26 pm - exceeding the four (4) hours required by the manufacturer by three (3) hours fifty-six (56) minutes dd) November 12, 2019: Patient 4976596 was collected at 16:28 pm and received November 13, 2019 at 12:32 pm - exceeding the four (4) hours required by the manufacturer by sixteen (16) hours three (3) minutes ee) December 10, 2019: Patient 5001893 was collected at 12:49 pm and received at 17:23 pm - exceeding the four (4) hours required by the manufacturer by thirty-four (34) minutes 4. Interview with the

	<p>hematology supervisor and technical consultant on January 28, 2020 confirmed that the above samples were outpatient testing referred to the laboratory but not tested within 4 hours as required by the manufacturer. 5. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs 2,471 ESR tests annually.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration date. Findings: 1. Observation by surveyor during laboratory tour on January 27, 2020 revealed the following expired items: Located in Fisher Scientific Isotemp Laboratory Refrigerator #2 a) Beckman Coulter Access Free T3 Calibrator: Lot 989911, Expiration date 01/17/2020, Quantity 1 box with 6 vials 2. In interview on January 27, 2020 at 2:30 pm, Personnel 6 confirmed the identified supplies from the refrigerator were expired.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation and record review, the laboratory failed to document monthly instrument maintenance for the Instrumentation Laboratory ACL Top CTS 500 Coagulation analyzer. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory utilizes the Instrumentation Laboratory ACL Top CTS 500 analyzer for Prothrombin Time (PT), International Normalized Ratio (INR), and Activated Partial Thromboplastin Time (APTT) testing. 2. Review of the laboratory's ACL TOP 500 maintenance log revealed the following monthly maintenance: a) Clean Air Filter b) Every 5000 Piercings Replace CTS Filter 3. Further review of the laboratory's maintenance logs for January 2019 through December 2019 revealed the laboratory did not perform the monthly maintenance for the following six (6) of twelve (12) months: a) January 2019 b) February 2019 c) March 2019 d) May 2019 e) July 2019 f) August 2019</p>
<p>D5439</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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</p>

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 observation, record review and interview with personnel, the laboratory failed to perform Analytical Measurement Range (AMR) Validation on the Beckman Coulter Unicel DxC 600 Synchron chemistry analyzer every 6 months according to laboratory policy. Findings: 1. Observation by surveyors during the laboratory tour on January 27, 2020 revealed the laboratory utilizes the following two (2) Beckman Coulter Unicel DxC 600 Synchron Clinical Systems analyzers for Chemistry testing: a) Beckman Coulter Unicel DxC 1 b) Beckman Coulter Unicel DxC 2 2. Review of the AMR validation policy for the chemistry analyzers revealed the laboratory performs AMR verification upon initial startup of a method, at least every six (6) months thereafter, and following changes in critical system components. 3. Further review of the AMR validation policy revealed the laboratory performs the following AMR Validation Schedule on both Chemistry analyzers: a) JAN/JULY - GC3: Enzymes b) FEB/AUG - GC2: CO₂-URIC-ETOH-NH₃ c) FEB/AUG - LP: HDL-LDL d) MARCH/SEPT - GC4, TDM1: TBIL-DBIL-SAL e) APRIL/OCT - UC1: Urine Chemistries f) MAY/NOV - UC4, UC5: Urine Chemistries g) JUNE/DEC - GC1: GLU, BUN, NA,K, CL, CA, CRET, PO₄ h) JUNE/DEC - GC1: LI, CHOL, TRIG, MG, TP, ALB, LACT 4. Review of the laboratory's AMR records revealed the laboratory did perform the GC4 AMR verification on the Beckman Coulter DxC 2 in March 2018, October 2018, and October 2019; however, the laboratory did not perform the GC4 verification in March 2019. 5. In interview on January 29, 2020 at 09:04 am, Personnel 3 stated the AMR verification was not performed on the DxC 2 due to the analyzer being out of service at the time. Personnel 3 further stated that when the analyzer was put back into use the laboratory did not perform the required verification.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

I. Based on observation, record review and interview with personnel, the laboratory

failed to perform reactive and non reactive quality controls for Rapid Plasma Reagin (RPR) testing for one (1) of four (4) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory performs Rapid Plasma Reagin (RPR) testing utilizing the Sure-Vue Signature Fisher Healthcare test kit. 2. Review of the laboratory's "RPR QC" log revealed the laboratory performs Quality Control (QC) with each day of patient testing. 3. Review of QC and patient logs from October 14 2019 through October 15, 2019 revealed the laboratory reported patient results without performance of reactive and non reactive QC for the following one (1) of four (4) patients reviewed: a) October 15, 2019: Patient 4945733 4. Interview with the serology supervisor on January 29, 2020 confirmed the above patient did not have acceptable quality control documented the day of patient testing. II. Based on observation, record review, and interview with personnel, the laboratory failed to perform positive and negative quality controls for Mononuclear Spot testing. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory performs Mononuclear Spot testing utilizing the Fisher Healthcare Sure-Vue Mono test kit. 2. Review of the laboratory's "MONOSPOT QC" log revealed the laboratory performs Quality Control (QC) with each day of patient testing. 3. Review of QC and patient logs from December 2019 revealed the laboratory reported patient results without performance of positive and negative QC for the following patients reviewed: a) December 18, 2019: Patient 5008735 4. Further review of the "MONOSPOT QC" log revealed the laboratory performed a weekly review of QC performance on December 18, 2019. 5. Interview with the serology supervisor on January 29, 2020 confirmed that the above patient was tested without acceptable quality control the day of patient testing. III. Based on observation, record review and interview with personnel, the laboratory failed to perform positive and negative quality controls for Lateral Flow Cryptococcus Antigen testing. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory performs Cryptococcus Antigen testing utilizing the 2. Review of the laboratory's "Lateral Flow Cryptococcus Antigen Test" log revealed the laboratory performs quality control (QC) on each day of use. 3. Review of QC and patient logs from December 2019 revealed the laboratory reported patient results without performance of positive and negative QC for the following patients reviewed: a) December 18, 2019: Patient 5005120 4. Further review of the "Lateral Flow Cryptococcus Antigen Test" log revealed the laboratory performed a weekly review of QC performance on December 18, 2019. 4. Interview with the serology supervisor on January 29, 2020 confirmed the above patient was testing without acceptable quality control the day of patient testing.

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 record review and interview with personnel, the laboratory failed to perform Low/High blood bank refrigerator alarm checks quarterly. Findings: 1. Observation during laboratory tour identified the laboratory utilized an on site refrigerate to hold

blood for patient transfusion. 2. Review of the laboratory's records for blood bank revealed the laboratory did not perform and document quarterly alarm checks for the years of 2018 and 2019. 2. In interview with the hematology supervisor and technical consultant on January 28, 2020 confirmed that the laboratory stores blood provided by the main campus laboratory for patient transfusion on site but had not previously performed alarm checks.

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, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 2. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for four (4) of one hundred fifteen (115) patient reviewed. Refer to D5411 II. 3. The laboratory failed to perform a normal donor study as required by manufacturer to verify reference intervals and establish their own normal Prothrombin Time (PT) mean. Refer to D5411 III. 4. The laboratory failed to ensure patient samples for Erythrocyte Sedimentation Rate (ESR) are performed within four (4) hours as required by the manufacturer for thirty-two (32) of three hundred twenty eight (328) patients reviewed. Refer to D5411 IV. 5. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 6. The laboratory failed to document monthly instrument maintenance for the Instrumentation Laboratory ACL Top CTS 500 Coagulation analyzer. Refer to D5429. 7. The laboratory failed to perform Analytical Measurement Range (AMR) Validation on the Beckman Coulter Unicel Dx C 600 Synchron chemistry analyzer every 6 months according to laboratory policy. Refer to D5439. 8. The laboratory failed to perform reactive and non reactive quality controls for Rapid Plasma Reagin (RPR) testing for one (1) of four (4) patients reviewed. Refer to D5449 I. 9. The laboratory failed to perform positive and negative quality controls for Mononuclear Spot testing. Refer to D5449 II. 10. The laboratory failed to perform positive and negative quality controls for Lateral Flow Cryptococcus Antigen testing. Refer to D5449 III. 11. The laboratory failed to perform Low/High blood bank refrigerator alarm checks quarterly. Refer to D5555.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

acceptability.

This STANDARD is not met as evidenced by:

I. Based on observation, record review and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer.

Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory utilizes the Beckman Coulter Unicel Dx C 600 Synchron Chemistry System for Urine Drug Screen (UDS) testing. 2. Review of the Beckman Coulter Synchron Systems Chemistry Information Sheet under the "Intended Use" section revealed "This assay provides only a preliminary analytical result; a positive result by this assay should be confirmed by another generally accepted non-immunological method such as thin layer chromatography (TLC), gas chromatography (GC), or gas chromatography/mass spectrometry (GC/MS). GC/MS is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used". 3. Review of the UDS final report for Patient 5034169 revealed the following comment: "Screen For Medical Purposes". 4. In interview on January 28, 2020 at 03:02 pm, Personnel 2 confirmed the laboratory did not report UDS as stated by the manufacturer. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 487 UDS tests annually. II. Based on observation, record review and interview with personnel, the laboratory failed to report Anti-Nuclear Antibody (ANA) results as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on January 27, 2020 revealed the laboratory utilizes the Bio-Rad PhD System for Anti-Nuclear Antibody (ANA) testing which includes the following: a) Anti-dsDNA, quantitative b) Anti-Sm antibody, quantitative c) Anti-Sm/RNP antibody, quantitative d) Anti-SS-A antibody, quantitative e) Anti-SS-B antibody, quantitative 2. Review of the Bio-Rad PhD system operator manual and the FDA website for medical devices revealed the Bio-Rad PhD system is not an FDA approved medical device. 3. Review of the laboratory ANA patient reports revealed the laboratory did not state "This test is not FDA approved. The performance specifications have been established by WO Moss Memorial". 4. In interview on January 29, 2020, the technical consultant stated the laboratory was not aware the test was not FDA approved. The technical consultant confirmed the laboratory did not report the test with this disclaimer.

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 record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 2. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure that

the laboratory performed required maintenance and calibration to ensure acceptable levels of analytical performance. Refer to D6023. 5. The Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D6026.

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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure patient samples for Ammonia testing are separated within 10 minutes according to the manufacturer for six (6) of thirty-one (31) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure patient samples are separated within two (2) hours as required by laboratory policy. Refer to D5311 II. 3. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 4. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for four (4) of one hundred fifteen (115) patient reviewed. Refer to D5411 II. 5. The laboratory failed to perform a normal donor study as required by manufacturer to verify reference intervals and establish their own normal Prothrombin Time (PT) mean. Refer to D5411 III. 6. The laboratory failed to ensure patient samples for Erythrocyte Sedimentation Rate (ESR) are performed within four (4) hours as required by the manufacturer for thirty-two (32) of three hundred twenty eight (328) patients reviewed. Refer to D5411 IV. 7. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 8. The laboratory failed to perform Low /High blood bank refrigerator alarm checks quarterly. Refer to D5555 9. The laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Refer to D5805 I. 10. The laboratory failed to report Anti-Nuclear Antibody (ANA) results as required by the manufacturer. Refer to D5805 II.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory

	<p>Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform reactive and non reactive quality controls for Rapid Plasma Reagin (RPR) testing for one (1) of four (4) patients reviewed. Refer to D5449 I. 2. The laboratory failed to perform positive and negative quality controls for Mononuclear Spot testing. Refer to D5449 II. 3. The laboratory failed to perform positive and negative quality controls for Lateral Flow Cryptococcus Antigen testing. Refer to D5449 III.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.</p>
<p>D6023</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)</p> <p>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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance and calibration to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to document monthly instrument maintenance for the Instrumentation Laboratory ACL Top CTS 500 Coagulation analyzer. Refer to D5429. 2. The laboratory failed to perform Analytical Measurement Range (AMR) Validation on the Beckman Coulter Unicel DxC 600 Synchron chemistry analyzer every 6 months according to laboratory policy. Refer to D5439.</p>
<p>D6026</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D5805 I.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
I. Based on record review and interview with personnel, the Laboratory Director failed to specify in writing the duties and responsibilities for all personnel serving as Technical Consultant. Findings: 1. Review of the laboratory's personnel records revealed the laboratory had multiple individuals serving as technical consultants with varying responsibilities. 2. Further review of laboratory personnel records as well as policy and procedure manual revealed the no specifications for duties of each individual technical consultant. 2. In interview on January 28, 2020, the Laboratory Manager confirmed the was no written specification of the individual duties and responsibilities of each technical consultant. II. Based on record review and interview with personnel, the Laboratory Director failed to designate and specify in writing the duties and responsibilities for all Testing Personnel. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory did not have a written, detailed description for each duty and responsibility to be performed in the laboratory and who was to perform each of those duties. 2. Further review of competency assessments of testing personnel revealed incomplete assessments for testing personnel. 3. In interview on January 28, 2020 with Technical Consultants and Laboraotry Manager revealed not all testing personnel perform certain maintenance functions or perform all testing. The laboratory manager confirmed specific delegations for each testing personnel were not detailed in writing.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
 Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Ammonia testing are separated within 10 minutes according to the manufacturer for six (6) of thirty-one (31) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure patient samples are separated within two (2) hours as required by laboratory policy. Refer to D5311 III. 3. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 4. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for four (4) of one hundred fifteen (115) patient reviewed. Refer to D5411 II. 5. The laboratory failed to perform a normal donor study as required by manufacturer to verify reference intervals and establish their own normal Prothrombin Time (PT) mean. Refer to D5411 III. 6. The laboratory failed to ensure patient samples for Erythrocyte Sedimentation Rate (ESR) are performed within four (4) hours as required by the manufacturer for thirty-two (32) of three hundred twenty eight (328) patients reviewed. Refer to D5411 IV. 7. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 8. The laboratory failed to document monthly instrument maintenance for the Instrumentation Laboratory ACL Top CTS 500 Coagulation analyzer. Refer to D5429. 9. The laboratory failed to perform Analytical Measurement Range (AMR) Validation on the Beckman Coulter Unicel DxC 600 Synchron chemistry analyzer every 6 months according to laboratory policy. Refer to D5439.

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 observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform reactive and non reactive quality controls for Rapid Plasma Reagin (RPR) testing for one (1) of four (4) patients reviewed. Refer to D5449 I. 2. The laboratory failed to perform positive and negative quality controls for Mononuclear Spot testing. Refer to D5449 II. 3. The laboratory failed to perform positive and negative quality controls for Lateral Flow Cryptococcus Antigen testing. Refer to D5449 III.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the establishment and documentation of maintenance procedures as required. Refer to D6095.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805 II.