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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0706889 | (X3) Date Survey Completed 02/21/2019 |
| Name of Provider or Supplier Sml Inc DbA Solis Medical Laboratory | Street Address, City, State 4200 Twelve Oaks Place, Houston, TX | |
| 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 |
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| D0000 | The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. |
| D2094 | <p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to document remedial action for PT failures for the analyte Total Iron Binding Capacity (UIBC). Findings were: 1. Review of the 2018 API proficiency testing records revealed the laboratory failed to attain an 80% for the analyte UIBC for 2 of 3 testing event for Chemistry. 2018 Event 1 UIBC (60%) lab result acceptable result CH-04 130 133 - 165 CH-05 171 176 - 207 2018 Event 2 UIBC (60%) lab result acceptable result CH-06 194 153 - 189 CH-07 124 88 - 121 2. Review of the laboratory corrective actions for the API 1st and 2nd event revealed no documentation of remedial action for the above PT failures. 3. An interview with the technical director on 2/20/19 at 1010 hours in the office confirmed the above findings.</p> |

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| <p>D2096</p> | <p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to attain 80% (passing) for the analyte Total Iron Binding Capacity (UIBC) for 2 of 3 testing events in Chemistry for 2018. Findings were: 1. Review of the 2018 API proficiency testing records revealed the laboratory failed to attain an 80% for the analyte UIBC for 2 of 3 testing event for Chemistry. 2018 Event 1 UIBC (60%) lab result acceptable result CH-04 130 133 - 165 CH-05 171 176 - 207 2018 Event 2 UIBC (60%) lab result acceptable result CH-06 194 153 - 189 CH-07 124 88 - 121 2. An interview with the technical director on 2/20/19 at 1010 hours in the office confirmed the above findings.</p> |
| <p>D3003</p> | <p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on observations and confirmed in interview, the laboratory failed to ensure contamination of patient specimens were minimized. Findings were: 1. Observations on 2/21/19 at 1045 hours revealed the following uncapped urine specimens stored in the freezer #4. Many specimens once frozen overflowed in the specimen container. 2182127U 2179801U 2179840U 2182951U 2183098U 2. Observations on 2/21/19 at 1045 hours revealed the following uncapped blood specimens stored in refrigerator #1. 2181291 2181244 2181258 2181260 2181069 3. An interview with the technical director on 2/21/19 at 1130 hours in the office confirmed the above findings. He acknowledged that the laboratory should cover the specimens once stored in the freezer/refrigerator.</p> |
| <p>D5311</p> | <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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, surveyor observations, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions</p> |

for urine specimen storage for 9 of 9 toxicology testing on the Roche Cobas chemistry analyzer. Findings were: 1. Review of the package insert for Amphetamine (2015-10, V9.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 2. Review of the package insert for Barbiturates (2013-11, V10.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 3. Review of the package insert for Benzodiazepines Plus (2016-08, V10.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 4. Review of the package insert for Cocaine (2014-03, V 7.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 5. Review of the package insert for Cannabinoids (2014-03, V 9.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 6. Review of the package insert for Methadone (2006-11, V 2) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 3 days of collection." 7. Review of the package insert for Opiates (2014-07, V 11.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 8. Review of the package insert for Phencyclidine Plus (2014-06, V 11.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 9. Review of the package insert for Propoxyphene Plus (2014-03, V 9.0) revealed under specimen collection and preparation "It is recommended that urine specimens be stored at 2 - 8 C and tested within 5 days of collection." 10. Observations on 2/20/19 at 0940 revealed the laboratory received blood specimens in a cooler with an ice pack and 1 bag of ice and a separate brown bag with urine specimens at ambient temperature. No temperature was documented to have been monitored for either the urine or blood specimens. Refer to patient alias list. 11. Review of the patient reports revealed the urine specimens above were analyzed for Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Cannabinoids, Methadone, Opiates, Phencyclidine, and Propoxyphene toxicology testing on the Roche Cobas chemistry analyzer. 12. An interview with the technical director on 2/21 /19 at 13:40 hours in the office confirmed the above findings.

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 review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to provide documentation of control procedures to include establishing acceptable control limits for PT testing on the Sysmex CA-620. Refer to D5403 2. The laboratory failed to follow the manufacturer's instructions to document the

medication history for the normal patient study for PT (Protime) testing on the Sysmex CA-600 hematology analyzer. Refer to D5411 3. The laboratory failed to ensure expired Uric Acid reagents were not used for patient testing on the Roche Cobas c501 chemistry analyzer. Refer to D5417 4. The laboratory failed to verify the reference intervals for 5 of 5 tests FDA approved tests added on the Roche Cobas chemistry analyzer in 2018 and Beckman Coulter Microscan WalkAway microbiology system for identification and sensitivities prior to testing patients. Refer to D5421-I, II 5. The laboratory failed to document complete establishment studies for the modified FDA approved Ethyl Alcohol testing on the Roche Cobas chemistry analyzer. Refer to D5423-A 6. The laboratory failed to utilize the geometric mean for International Normalized Ratio (INR) calculation for PT testing on the Sysmex CA-600 hematology analyzer. Refer to D5545 7. The laboratory failed to document required calibration per the manufacturer's instructions for the Hepatitis testing on the Roche Cobas e601 chemistry analyzer. Refer to D5437 8. The laboratory failed to follow its own policy for resolution of flagged results on the Sysmex XS-1000i hematology analyzer. Refer to D5401 9. The laboratory failed to have documentation that their policies and procedures reflected current laboratory practice for reagent preparation for Gram stains. Refer to D5407 10. The laboratory failed to follow manufacturer's instructions for monitoring over time the accuracy and precision of control material test performance for the Sysmex XS-1000i hematology analyzer for 2 of 2 lot numbers. Refer to D5441 11. The laboratory failed to document a complete IQCP for the Beckman Coulter Microscan WalkAway microbiology analyzer. Refer to D5445 12. The laboratory failed to ensure at least two levels of acceptable quality control were performed each day of patient testing for Complete Blood Counts (CBCs). Refer to D5447 13. The laboratory failed to perform and document at least two levels of acceptable quality control on the Alere HIV Combo Kit. Refer to D5449 14. The laboratory failed to perform a titered positive (reactive) quality control on the ASI RPR Card Test for Syphilis. Refer to D5451

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, manufacturer's instructions, patient final reports, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for resolution of flagged results on the Sysmex XS-1000i hematology analyzer. The findings included: 1. Review of the laboratory's policy titled, "SML Hematology Policy and Procedure" approved by the laboratory director on January 19, 2017, under "Patient Testing and Reporting" it stated: "10.3.1: For SYSMEX flagging, the system notifies the operator of the potential problem by flagging on the printout. All flagging should be addressed to ensure accuracy and reliability of results before results are reported. Refer to the SYSMEX XS-1000i Analyzer series Operator's Manual or SML's Flagging Summary." 2. Review of the manufacturer's instructions (Document Number: MKT-70-1061, Revision 1) under, "WBC Flags" it listed possible flags, their cause and possible actions as follows: WBC ABN Scattergram WBC Abnormal Scattergram Perform manual differential Neutropenia Low neutrophil count Review manual smear Neutrophilia High

neutrophil count Review manual smear Lymphopenia Low lymphocyte count Review manual smear Lymphocytosis High lymphocyte count Review manual smear Monocytosis High monocyte count Review manual smear Eosinophilia High eosinophil count Review manual smear Basophilia High basophil count Review manual smear Leukocytopenia Low leukocyte (WBC) count Review manual smear Leukocytosis High leukocyte (WBC) count Review manual smear Blasts? Presence of blasts possible Perform manual differential Immature Grans? Presence of immature granulocytes possible Perform manual differential Left Shift? Presence of "band" granulocytes possible Perform manual differential Abn Lympho/Blasts? Presence of atypical lymphocytes and/or blasts possible Perform manual differential NRBC? Presence of nucleated RBC's possible Verify presence on slide, correct WBC count if necessary Atypical Lymphocyte Presence of atypical lymphocytes possible Perform manual differential

3. Review of the manufacturer's instructions (Document Number: MKT-70-1061, Revision 1) under, "RBC Flags" it listed possible flags, their cause and possible actions as follows: RBC ABN Distribution Interfering particles in RBC histogram, i.e. Schistocytes, large platelets, platelet clumps, RBC clumps Verify presence on slide. If RBC or platelet clumps present recollect sample if possible. Dimorphic Population Two different RBC sizes present in sample Verify RBC morphology on slide Anisocytosis RDW CV and/or SD out of defined range. Multiple sizes of RBC's in sample Verify RBC morphology on slide Microcytosis MCV lower limit range exceeded. Presence of small RBC's Verify RBC morphology on slide Hypochromia MCHC lower limit exceeded Verify RBC morphology on slide Anemia Hemoglobin lower limit exceeded Verify RBC morphology on slide Erythrocytosis RBC upper limit exceeded Verify RBC morphology on slide RBC Agglutination? Possible RBC or Platelet Clumps Verify RBC morphology on slide. Recollect sample if present. Turbidity/HGB Interference? MCHC > 36.5 Check sample of interfering substances, i.e. lipemia, icterus, cold agglutinin, and clotted sample. Iron Deficiency? Sample characteristic of iron deficiency anemia Verify RBC morphology on slide HGB Defect? Sample characteristic of hemoglobin defect Verify RBC morphology on slide Fragments? Presence of fragmented RBC's or large, clumped platelets possible Verify RBC morphology on slide. If clumped platelets are present recollect sample if possible.

4. Review of the manufacturer's instructions (Document Number: MKT-70-1061, Revision 1) under, "PLT Flags" it listed possible flags, their cause and possible actions as follows: PLT Abn. Distribution Presence of interfering particles in PLT histogram, i.e. Clumped platelets, fragmented RBC's, or microcytic RBC's. Verify presence on slide. If RBC or platelet clumps present recollect sample if possible. Perform PLT estimate to confirm count. Thrombocytopenia Low platelet count Verify on slide Thrombocytosis High platelet count Verify on slide PLT Clumps? Presence of platelet clumps possible, specifically in Diff scattergram Verify on slide. Recollect sample if present. PLT Clumps? Presence of platelet clumps possible, specifically in platelet histogram Verify on slide. Recollect sample if present.

5. Random review of patient final reports from February 2019 revealed the following patient results were reported and finalized when the patient result had flags indicated by the Sysmex analyzer. The flags were not resolved: Sample No. 2181703B Date: 02/14/2019 Morphology Flag: Positive RBC IP Message(s): Anisocytosis PLT IP Message(s): PLT Abn Distribution Sample No: 2181765 Date: 02/14/2019 Morphology Flag: Positive RBC IP Message(s): Anisocytosis PLT IP Message(s): PLT Abn Distribution Sample No: 2181821 Date: 02/14/2019 Morphology Flag: Positive RBC IP Message(s): Anisocytosis Sample No: 2181695 Date: 02/14/2019 Morphology Flag: Positive RBC IP Message(s): Anisocytosis PLT IP Message(s): PLT Abn Distribution Sample No.: 2181689 Date: 02/14/2019 Morphology Flag: Positive WBC IP Message(s): Immature Gran? Sample No.: 2181687 Date: 02/14/2019 Morphology Flag: Positive RBC IP Message(s): HGB Defect? Sample No.: 2181677 Date: 02/14/2019

Morphology Flag: Positive PLT IP Message(s): PLT ABn Distribution, Thrombocytopenia Sample No.: 2181708 Date: 02/14/2019 Morphology Flag: Positive WBC IP Message(s): Immature Gran? Sample No.: 2181765 Date: 02/24/2019 Morphology Flag: Positive RBC IP Message(s): Anisocytosis Sample No.: 2181664 Date: 02/14/2019 Morphology Flag: Positive WBC IP Message(s): Immature Gran? Sample No.: 2181715B Date: 02/14/2019 Morphology Flag: Positive WBC IP Message(s): Atypical Lympho? Sample No.: 2181649 Date: 02/14/2019 Morphology Flag: Positive RBC IP Message(s): Iron Deficiency? Sample No.: 2181814 Date: 02/14/2019 Morphology Flag: Positive RBC IP Message(s): Microcytosis Sample No.: 2181807 Date: 02/14/2019 Morphology Flag: Positive WBC IP Message(s): Immature Gran? Sample No.: 2181887 Date: 02/14/2019 Morphology Flag: Positive PLT IP Message(s): PLT Abn Distribution, Thrombocytopenia Sample No.: 2182229 Date: 02/16/2019 Morphology Flag: Positive WBC IP Message(s): Monocytosis RBC IP Message(s): HGB Defect? PLT IP Message(s): PLT Abn Distribution Sample No.: 2182268 Date: 02/16/2019 Morphology Flag: Positive RBC IP Message(s): Anisocytosis PLT IP Message(s): Thrombocytosis Sample No.: 2182287 Date: 02/17/2019 Morphology Flag: Positive WBC IP Message(s): Atypical Lympho? 6. An interview with testing personnel five (as listed on Form CMS 209) on 02/20/2019 at 15:30 hours in the laboratory confirmed the findings. After his review of the records he agreed that the results should have had a slide review or a manual differential. Key: WBC - white blood cell RBC - red blood cell PLT - platelet HGB - hemoglobin ABN - abnormal NRBC - nucleated red blood cell RDW - red cell distribution width CV - coefficient of variation SD - standard deviation CMS - Centers for Medicare and Medicaid Services

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:

A. Based on review of the laboratory's policies and procedures, review of QC (quality control) Test Batteries, and confirmed in interview of facility personnel, the laboratory's policy for "Daily Workflow Checklist" failed to include which quality control organisms should be utilized for quality control testing for microbiology AST (antimicrobial susceptibility testing). The findings included: 1. In review of the

laboratory's policy titled, "Daily Workflow Checklist" found in the Microbiology Procedure Manual and approved by the laboratory director on February 18, 2018, under, "Outcome Standards" it stated, "2. Perform daily/weekly QC, record and sign." 2. The policy did not include which QC strains would be used for quality control testing for the Gram Negative Breakpoint Combos or the Gram Positive Breakpoint Combos. 3. On February 20, 2019, when testing personnel one (as listed on Form CMS 209) was asked how she knows which QC strains to perform, she provided the surveyor a worklist titled, "QC Test Batteries." She informed the surveyor that the Beckman Coulter representative had provided the list to her. The list had a note to the right that stated, "Weekly QC" with a dot next to it. QC organisms were listed with check-marks or dots. The document was not signed or approved by the laboratory director. 38387 B. Based on review of quality control records, laboratory policies, patient records, and confirmed in interview, the laboratory failed to provide documentation of control procedures to include establishing acceptable control limits for PT testing on the Sysmex CA-620. Findings were: 1. Review of the laboratory quality control records revealed the acceptable quality control range for PT was 9.4 - 10.9 seconds (level 1, lot 548063. exp 05/07/20) and 41.6 - 50.2 seconds (level 2, lot 548491, exp 4/4/20). 2. Review of the laboratory test records to establish the quality control for PT revealed the mean for level 1 as 10.1, with a standard deviation (SD) of 0.2; and 45.9 for level 2, with an SD of 1.4. The acceptable quality control range for level 1 with +/- 2 SD per the laboratory data documented is 9.7 - 10.5 seconds. The acceptable quality control range for level 2 with +/- 2 SD per the laboratory data documented is 43.1 - 48.7 seconds. 3. Review of the SML Coagulation Policy and Procedure revealed no documentation of control procedures to include establishing acceptable control limits for PT testing on the Sysmex CA-620. 4. Review of the quality control data for PT Level 3 from January 2019 to February 2019 revealed 3 of 25 days with QC outside of the documented acceptable range of 43.1 - 48.7 seconds. Date PT level 3 (seconds) 1/28/19 42.6 2/14/19 43.0 2/19/19 52.9 5. Review of the quality control data for PT Level 1 from January 2019 to February 2019 revealed 2 of 25 days with QC outside of the documented acceptable range of 9.7 - 10.5 seconds. Date PT level 1 (seconds) 1/24/19 9.6 1/29/19 10.6 6. Random review of the laboratory patient test records for the above dates revealed the laboratory performed patient testing with unacceptable quality control. 1/24/19: 1013137, 1016146, 1017643 1/28/19: 1016146, 1017205, 1019495 1/29/19: 1020072, 1020072 2/14/19: 1007677, 1007921, 1008449 2/19/19: 1007919, 1019373, 1022024 7. An interview with the technical director on 2/21/19 at 1345 hours in the office confirmed the above findings. He was unaware the laboratory was using 3 SD instead of 2 SD.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on surveyor observations, review of laboratory polices, and confirmed in interview of facility personnel, the laboratory failed to have documentation that their policies and procedures reflected current laboratory practice for reagent preparation for Gram stains. The findings were: 1. Surveyor observation made on February 19, 2019 at 09:30 hours in the laboratory revealed the facility performed Gram stain testing using stabilized Gram's Iodine. The surveyor observed unopened bottles of Gram's Iodine; the unopened bottles observed were of stabilized Gram's Iodine. Note:

Stabilized Gram's Iodine comes already reconstituted and does not require the laboratory to perform any reagent preparation. 2. Review of the laboratory's policy titled, "Gram Stain" approved by the laboratory director on February 18, 2018, under, "Reagents and Equipment" it stated, " ...Grams iodine-requires preparation to working solution by adding ampule to clear liquid in bottled marked iodine ..." 3. The laboratory's policy failed to reflect the laboratory's currently laboratory practice. 4. Interview with testing personnel one (as listed on Form CMS 209) on February 19, 2019 at 10:00 hours in the laboratory confirmed the findings. She confirmed that the laboratory uses stabilized Gram's Iodine Key: CMS - Centers for Medicare and Medicaid Services

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 review of the manufacturer's instructions, laboratory records, patient test reports, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to document the medication history for the normal patient study for PT (Protine) testing on the Sysmex CA-600 hematology analyzer. Findings were: 1. Review of the Reagent Lot Roll-Over Procedures (09/2012, Rev 1.1) for the Sysmex CA-600 hematology analyzer revealed under Verification of Reference Range "note medication history. After review of data, history may be used for excluding questionable results that can be attributed to medications." 2. Review of the laboratory normal patient study for the new lot of PT Innovin (lot 5497320, exp 03/22/21) revealed no documentation of medication history for 16 of 16 patients used for the study. 3. An interview with the technical director on 2/20/19 at 1240 hours in the office confirmed the above findings.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on surveyor observations and interview with facility personnel, the laboratory failed to label 4 of 4 containers with contents, preparation information, expiration dates, or storage requirements on February 19, 2019. The findings included: 1. At 09:10 hours on 02/19/2019 in the microbiology section of the laboratory, the surveyor observed 4 unlabeled containers with colored liquid in each one located by the sink. The containers did not contain labeling to include contents identification, preparation, expiration dates, or storage requirements. 2. In an interview at 10:00 hours on 02/19/2019 in the laboratory, testing personnel one (as listed on Form CMS 209) revealed

the reagents were hematology stains. She agreed the aliquots did not contain content identification, preparation dates, expiration dates, or storage requirements. She went on to say the stains were for hematology. Key: CMS - Centers for Medicare and Medicaid Services

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
A. Based on surveyor observations and interview with facility personnel, the laboratory failed to ensure 1 of 4 reagents used in Gram staining were not used beyond their expiration. The findings included: 1. At 09:15 hours in the microbiology section of the laboratory, the surveyor observed the following 1 of 4 expired Gram stain reagents: Gram's Safranin Lot # 6288 Expiration Date: 08-23-2018 Elapsed Time of Expiration: 4 months, 27 days 2. In an interview at 10:00 hours on 02/19/2019 in the laboratory, testing personnel one (as listed on Form CMS 209) revealed the expiration date on the box was different than the expiration date on the bottle and was not aware that the dates were different. 38387 B. Based on review of the manufacturer's instructions, laboratory records, patient records, and confirmed in interview, the laboratory failed to ensure expired Uric Acid reagents were not used for patient testing on the Roche Cobas c501 chemistry analyzer. Findings were: 1. Review of the package insert for Uric Acid (2016-02 V 10.0) revealed "on-board in use and refrigerated on the analyzer: 8 weeks." 2. Review of the reagent status on the Roche Cobas c501 revealed "0" stability for Uric Acid. 3. Review of the reagent detail for Uric Acid (lot 315894, exp 02/19) revealed it was placed on-board on 07/12/18, with reagent stability expiring 09/06/18. 4. Review of the tests activity report from September 2018 to February 2019 revealed the laboratory performed 150 Uric Acid patient testing with expired on-board stability reagents for Uric Acid. Refer to Uric Acid Patient alias list. 5. An interview with the testing person # 2 on 02/19/19 at 1530 hours confirmed the above findings. He acknowledged that the on-board reagent expired but since "quality control was okay," the laboratory still used the expired reagent. 6. An interview with the technical director on 02/20/19 at 1045 hours in the office confirmed the above findings.

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:
I. Based on review of manufacturer's instructions, instrument verification records, and

confirmed in interview of facility personnel, the laboratory failed to perform a complete instrument performance verification on the Beckman Coulter Microscan WalkAway microbiology system for identification and sensitivities prior to testing patients. The findings included: 1. Interview of testing personnel one (as listed on Form CMS 209) on February 19, 2019 at 10:00 hours in the laboratory revealed the instrument performance verification for the Beckman Coulter Microscan WalkAway (Serial Number 0407230) analyzer had been performed at an off-site location (facility name redacted) then relocated to its current location at 7501 Fannin Street, Floor 8 (Suite 800), Houston, Texas 77054. The laboratory failed to verify the accuracy, precision, reportable range, and normal range of the instrument once the instrument was moved to its current location. 2. Review of manufacturer "Technical Support Bulletin: 166c, replaces TSB 166b, Date released: 2016-01) under, "Verification Recommendations" it stated: "Verification is the one-time process performed when a new system is first introduced into a laboratory or when that system is updated by the introduction of new identification substrates, antimicrobial agents, updated databases, software or hardware. This documents that a new or updated test system meets the manufacturer's product claims. Per CLIA, when changing to a new test system you should perform an in-house verification study. The new method should be performed in parallel with your current method. When changing to a new method such as a new antimicrobial agent added to an existing panel type, the verification study should be performed in parallel with a reference method. The reference method used for comparison may be a disk diffusion, gradient diffusion, or another microdilution method. A limited verification study may be designed for the new antimicrobial agent (s) only. Each laboratory must define the extent of testing needed to demonstrate that the system is functioning in the laboratory as claimed by Beckman Coulter." 3. Review of quality control records from January 2018 revealed that once the analyzer was relocated to its current location it immediately had quality control failures for Arginine on multiple consecutive days. To troubleshoot the failure, the laboratory: - performed repeat testing -re-subcultured quality control organism -re-subcultured stock quality control organism -deployed field service engineer for technical service 4. Continued interview of testing personnel one (as listed on Form CMS 209) on February 19, 2019 at 13:30 hours in the laboratory confirmed the findings. She revealed that she had questioned the Arginine failures and was concerned that they could have been related to the move and had voiced such concerns. She confirmed that the failures resolved after onsite service. She continued to perform weekly quality control for antimicrobial susceptibility testing. 5. On February 19, 2019 the surveyor made a phone call to Beckman Coulter. When asked what recommendations Beckman Coulter would make for laboratories performing an off-site verification study then relocating an analyzer, he confirmed that Beckman Coulter would not make any such recommendations and that those decisions were left to discretion of the laboratory. 6. According to the CMS 116, the laboratory performs 4770 microbiology tests annually. Key: CLIA - Clinical Laboratory Improvement Amendment CMS - Centers for Medicare and Medicaid Services 38387 II. Based on review of the laboratory verification records and confirmed in interview, the laboratory failed to verify the reference intervals for 5 of 5 tests FDA approved tests added on the Roche Cobas chemistry analyzer in 2018. Findings were: 1. Review of the 2018 laboratory verification studies for the Roche Cobas chemistry analyzer revealed no documentation of the reference intervals for 5 of 5 tests added: Lipase, Vitamin D, Iron, Vancomycin, and TIBC. 2. Review of the patient final reports for the above tests revealed the laboratory used the following reference intervals for the following tests. Lipase: 0 - 59 U/L Vitamin D: 30 - 100 ng/mL Iron: 37 - 145 ug/dL Vancomycin: 10 - 20 mcg/mL TIBC: 250 - 450 ug/dL 3. An interview with the technical director on 2/19 /19 at 1055 hours in his office confirmed the above findings.

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

A. Based on review of the manufacturer's instructions, laboratory verification records, patient final reports, and confirmed in interview, the laboratory failed to document complete establishment studies for the modified FDA approved Ethyl Alcohol testing on the Roche Cobas chemistry analyzer. Findings were: 1. Review of the Roche Cobas Ethyl Alcohol package insert () revealed "for use in the quantitative analysis of ethyl alcohol (ethanol) in human urine, serum, or plasma...quantifies alcohol concentration in human urine, serum, or plasma containing 10-600 mg/dL (0.01-0.60%, 0.1-6.0 g/L) alcohol." 2. Random review of laboratory patient final reports from February 2019 revealed 10 of 10 patient final reports that the laboratory reported Ethyl Alcohol as Negative with a cut-off value of 100 mg/mL. The laboratory modified the intended use; thus making the Ethyl Alcohol testing high complexity. Patient ID 1003043, Ethyl Alcohol Negative Patient ID 1021858, Ethyl Alcohol Negative Patient ID 1020394, Ethyl Alcohol Negative Patient ID 1007335, Ethyl Alcohol Negative Patient ID 1021485, Ethyl Alcohol Negative Patient ID 1021856, Ethyl Alcohol Negative Patient ID 1021855, Ethyl Alcohol Negative Patient ID 1021162, Ethyl Alcohol Negative Patient ID 1021851, Ethyl Alcohol Negative Patient ID 1009635, Ethyl Alcohol Negative 3. Review of the laboratory verification records revealed documentation of the precision, accuracy, and linearity studies. No documentation was available for review of the laboratory performing sensitivity, specificity, carryover, interfering substances, and any other pertinent studies. 4. An interview with the technical consultant on 2/20/19 at 1020 hours in the office confirmed the above findings. B. Based on review of the manufacturer's instructions, laboratory patient final reports, laboratory verification records, and confirmed in interview, the laboratory failed to document complete establishment studies for 3 of 9 toxicology testing on the Roche Cobas chemistry analyzer. (Cannabinoids, Benzodiazepine, Cocaine) Findings were: 1. Review of the package insert for Benzodiazepines Plus (2016-08, V10.0) revealed under intended use "Benzodiazepines is an in vitro diagnostic test for the qualitative and semiquantitative detection of benzodiazepines in human urine..." 2. Review of the package insert for Cocaine (2014-03, V 7.0) revealed under intended use "Cocaine is an in vitro diagnostic test for the qualitative and semisemiquantitative detection of benzoylecgonine, the primary metabolite of cocaine in human urine..." 3. Review of the package insert for Cannabinoids (2014-03, V 9.0) revealed under intended use "Cannabinoids is an in vitro diagnostic test for the qualitative and semiquantitative detection of cannabinoids in human urine..." 4. Random review of patient test results from September 2018 to february 2019 revealed 14 of 50 toxicology reports that the laboratory reported quantitative values for Cannabinoids, Benzodiazepine, Cocaine.

The laboratory modified the intended use; thus making the Cannabinoids, Benzodiazepine, Cocaine testing high complexity. Date: 09/04/18, Patient # 1007377, Cannabinoids 345 ng/mL Date: 10/10/18, Patient # 1008676, Cannabinoids 536 ng/mL Date: 10/16/18, Patient # 1012317, Cannabinoids 51 ng/mL Date: 10/27/18, Patient # 1013207, Cannabinoids 59 ng/mL Date: 12/13/18, Patient # 1016566, Cannabinoids 174 ng/mL Date: 01/17/19, Patient # 1016566, Cannabinoids 486 ng/mL Date: 9/4/18, Patient # 1007377, Cannabinoids 345 ng/mL Date: 1/29/19, Patient #1018998, Cannabinoids 430 ng/mL Date: 2/12/19, Patient #1019485, Cocaine 3020 ng/mL Date: 11/21/18, Patient 1015198, Cocaine 4493 ng/mL Date: 11/21/18, Patient 1015198, Benzodiazepine 402 ng/mL Date: 1/23/19, Patient 1019485, Cocaine 4520 ng/mL Date: 1/29/19, Patient 1019485, Cocaine 312 ng/mL Date: 2/5/19, Patient 1020593, Cannabinoids 148 ng/mL 5. Review of the laboratory verification records revealed documentation of the precision, accuracy, and linearity studies. No documentation was available for review of the laboratory performing sensitivity, specificity, carryover, interfering substances, and any other pertinent studies. 6. An interview with the technical consultant on 2/20/19 at 1020 hours in the office confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:
 Based on review of laboratory policy, review of manufacturer's instructions, review of laboratory maintenance records, and confirmed in interview of facility personnel, the laboratory failed to perform maintenance according to the manufacturer's instructions for the Sysmex XS-1000i hematology analyzer. The findings included: 1. Review of the laboratory's policy titled, "SML Hematology Policy and Procedure" approved by the laboratory director on January 19, 2017, under, "12. General Laboratory Functions that all Tester Personnel Should be Responsible For" stated, "12.1.5: Ensuring that all applicable maintenance log documentation are complete ..." 2. Review of the manufacturer's instructions for the XS-1000i Automated Hematology Analyzer (Code No. 461-2629-2, revision 2007) under, "9.3 Monthly Maintenance" it stated, "Carry out Monthly maintenance every month, or after every 1200 analyses." 3. Review of Sysmex XS-1000i maintenance records from January 2018 to December 2018 revealed the following 4 of 12 months when monthly maintenance was not documented as being performed. March 2018 April 2018 May 2018 December 2018 4. An interview with testing personnel five (as listed on Form CMS 209) on February 20, 2019 at 15:30 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

D5431

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, review of the laboratory maintenance records, and confirmed in interview, the laboratory failed to document the manufacturer required LED calibration for the Sysmex CA-600 hematology analyzer. Findings were: 1. Review of the Sysmex CA-600 instructions for use (September 2011) revealed "quarterly [LED] calibration is required." 2. Review of the laboratory maintenance records from 2018 revealed the laboratory documented 2 of 4 LED calibration in 2018 (7/6/18 and 11/13/18). No documentation was provided for 2 of 4 LED calibration for 2018. 3. An interview with the technical director on 2/21/19 at 1000 hours in the office confirmed the above findings. He was unaware the LED calibration was required quarterly.

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:
I. Based on review of the manufacturer's instructions, laboratory calibration records, patient records, and confirmed in interview, the laboratory failed to document required calibration per the manufacturer's instructions for the Hepatitis testing on the Roche Cobas e601 chemistry analyzer. a) HBsAg b) anti-HBc IgM c) anti- HCV
Findings were: a) HbsAG 1. Review of the application sheet for the Roche Hepatitis B surface antigen (HBsAg) (Ref 2016-03 V 13.0) revealed under calibration "Renewed calibration is recommended as follows: after 1 month when using the same reagent lot after 7 days (when using the same reagent kit on the analyzer)" 3. Review of the calibration records for the Roche Cobas e601 revealed the laboratory performed calibrations on the following dates. HBsAG calibration documented on 1/23/19 4. Review of patient testing from 02/2019 revealed the laboratory performed HBsAg testing with no documentation of the required calibration on 1/30/19, 2/6/19, 2/13/19. Refer to Hepatitis patient alias list. 5. An interview with the technical direcotr on 02/20/19 at 1045 hours in the office confirmed the above findings. b) anti-HBc IgM 1. Review of the application sheet for the Roche Hepatitis B core IgM (anti-HBc IgM) (Ref 2016-04 V7.0) revealed under calibration "Renewed calibration is recommended as follows: after 1 month when using the same reagent lot after 7 days (when using the same reagent kit on the analyzer)" 3. Review of the calibration records for the Roche Cobas e601 revealed the laboratory performed calibrations on the following dates. anti-HBc IgM calibration documented on 12/24/18 4. Review of patient testing from 02/2019 revealed the laboratory performed 67 anti-HBc IgM testing with no documentation of the required calibration on 12/31/18, 1/7/19, 1/14/19, 1/21/19, 1/28/19, 2/4/19, 2/18/19. Refer to Hepatitis patient alias list. 5. An interview with the technical direcotr on 02/20/19 at 1045 hours in the office confirmed the above

findings. c) anti- HCV 1. Review of the application sheet for the Roche Hepatitis C (anti- HCV) (Ref 2019-01 V1.0) revealed under calibration "Renewed calibration is recommended as follows: after 1 month when using the same reagent lot after 7 days (when using the same reagent kit on the analyzer)" 3. Review of the calibration records for the Roche Cobas e601 revealed the laboratory performed calibrations on the following dates. anti- HCV calibration documented on 01/31/19 4. Review of patient testing from 02/2019 revealed the laboratory performed 43 anti- HCV testing with no documentation of the required calibration on 2/7/19, 2/14/19. Refer to Hepatitis patient alias list. 5. An interview with the technical director on 02/20/19 at 1050 hours in the office confirmed the above findings.

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 review of laboratory policies and procedures, review of manufacturer's instructions, review of quality control records, and interview with facility personnel, the laboratory failed to follow manufacturer's instructions for monitoring over time the accuracy and precision of control material test performance for the Sysmex XS-1000i hematology analyzer for 2 of 2 lot numbers. The findings included: 1. Based on review of the laboratory procedure "SML Hematology Policy and Procedure" approved by the laboratory director on January 19, 2017, stated under, "8.10 QC results are stored in the Sysmex Analyzer. At the time designated on the SYSMEX QC insert, the results are printed and filed in the appropriate monthly QC binder. Results are also submitted to the appropriate SYSMEX Peer Group Program for evaluation. If unable to utilize the program, an alternative method shall be decided by the Laboratory Manager, such as internal evaluation." 2. Review of manufacturer's instructions (Product Notification for Sysmex Evidence-Based Control Limits, Document Number: 62-1339, 07/2017) under, "Action" it stated, "Most deeming organizations recommend that laboratories employ statistical quality control and verify control policies to meet clinical requirements. Sysmex has completed the statistical analysis for you. Sysmex recommends the following actions:" "6. Participate in peer comparison using Insight program." "7. Take corrective actions when Insight comparison indicates. a. Parameter bias exceeding +/- 3SDI. b. Parameter CV significantly higher than historic or group recovery. 3. Review of quality control records from January 2018 to January 2019 revealed that the laboratory was using evidence-based Sysmex limits. However, beginning in August 2018, the facility stopped submitting data to Insight, the peer review program for Sysmex as required by the manufacturer. 4. Further review of quality control materials for the Sysmex XS-1000i hematology analyzer, the following 2 of 2 lots were used to monitor test performance between September 2018 to January 2019: Lot: 82960 Lot:

82408 5. In an interview at 10:00 hours in the technical consultant's office, the technical consultant stated that the laboratory was not currently submitting to peer group (Insight).

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:

I. Based on review of the laboratory's Individualized Quality Control Plan (IQCP) procedure for the Beckman Coulter Microscan WalkAway microbiology analyzer, and interview with facility personnel, the laboratory's IQCP was incomplete. The findings included: Note: A laboratory IQCP must include 1) a risk assessment, 2) a quality control plan, and 3) a quality assurance assessment. 1. The laboratory's IQCP was not signed or approved by the laboratory director. 2. Conducting the Risk Assessment: To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality. A. Review of the Risk Assessment portion of the IQCP for the Beckman Coulter WalkAway analyzer included potential sources of error and mitigation strategies. B. The Risk Assessment did not include the frequency with which the laboratory defined potential sources of error had occurred or were likely to occur. For example, as a potential preanalytic risk, the laboratory identified under "Specimen" the following potential risk: Patient Identification. The laboratory did not document the frequency the laboratory had incorrectly identified a patient or evaluate how likely this event would occur. C. The Risk Assessment did not include an assessment of the potential impact on patient results for each laboratory defined potential source of error. For example, the lab defined "QC strain storage /prep" as a potential risk of error. The laboratory did not define the potential impact on patient testing and test quality when QC strains were improperly stored or incorrectly prepared. 3. Quality Control Plan A. Review of the QCP (Quality Control Plan) revealed the plan was incomplete. The plan did not include policies or procedures to instruct testing persons as to which strains of quality control organisms to use, how frequently quality control would be performed, and did not define acceptability criteria for quality control performance. B. Review of the QCP under, "QCP for Streamlined QC of Microscan Identification System" it stated: "Based on our risk assessment the QCP consists of the following instructions that are provided in SOP.xxx (Microscan ID System). The policies section was blank and no policies were listed. C. Review of the QCP under, "QCP for Streamlined QC of Microscan Identification System" it stated: "Testing of appropriate QC strains for streamlined QC on each new lot/shipment of panels before or concurrently with placing these materials into use for patient testing." And; "Testing of appropriate QC strains on each panel type after major system maintenance or software upgrade before or concurrently with placing the instrument back into service. The QCP did not list what QC strains would be utilized for quality control testing. D. Review of the QCP under,

"QCP for Streamlined QC of Microscan Identification System" it stated: "QC acceptability criteria is defined in SOP.xxx (Quality Control for Microscan ID). Any abnormal result is immediately investigated. The acceptability criteria was blank and therefore, incomplete. 4. Quality Assessment Plan A. The laboratory's IQCP failed to have a QAP (Quality Assessment Plan) that included policies and procedures for the ongoing monitoring of the IQCP. B. Interview with the technical supervisor on February 21, 2019 at 13:30 hours in the technical consultant's office confirmed the findings. II. Based on review of the laboratory's Individualized Quality Control Plan (IQCP) procedure for "CLSI-Exempt Media", and interview with facility personnel, the laboratory's IQCP for media was incomplete. Note: A laboratory IQCP must include 1) a risk assessment, 2) a quality control plan, and 3) a quality assurance assessment. The findings included: 1. The laboratory's IQCP was incomplete and was not signed by the laboratory director. 2. Conducting the Risk Assessment: To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality. A. Review of the Risk Assessment portion of the IQCP for "Commercially Prepared CLSI-Exempt Media included potential sources of error and mitigation strategies. B. The Risk Assessment did not include the frequency with which the laboratory defined potential sources of error had occurred or were likely to occur. For example, as a potential preanalytic risk, the laboratory identified under "Test System (Media)" the following potential risk: Contamination. The laboratory did not document the frequency the laboratory had identified contamination of media or evaluate how likely this event would occur. C. The Risk Assessment did not include an assessment of the potential impact on patient results for each laboratory defined potential source of error. For example, the lab defined "Visual Inspection" as a potential risk of error. The laboratory did not define the potential impact on patient testing and test quality when the visual inspection of media was unacceptable. 3. Quality Control Plan A. Review of the QCP revealed it referenced an IQCP for an AST system. It stated, "Final QCP for AST System XYZ." B. Interview with the technical supervisor on February 21, 2019 at 13:30 hours in the technical consultant's office confirmed the findings.

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 review of laboratory policy, review of quality control records, review of patient reports, and confirmed in interview of facility personnel, the laboratory failed to ensure at least two levels of acceptable quality control were performed each day of patient testing for Complete Blood Counts (CBCs). The findings were: 1. In review of the laboratory's policy titled, "SML Hematology Policy and Procedure" approved by the laboratory director on January 19, 2017 under, "Quality Control and Reagent Processing" it stated: "8.4 Patient results must not be reported until a minimum of two controls are within SML's established reference range or the manufacturer's reference range, if performing parallel testing for a new lot of control. Do not perform multiple control runs for controls that are outside of the established normal reference range

without notifying the General Supervisor. In addition, if only one out of three levels is out, testing personnel shall ensure that that particular level is not consistently out. If a particular level is out more than two times across different shifts, it shall be investigated." And; "8.8 In the event of a QC failure, such as QC being out of the normal reference range, and patient specimens were run, all patient specimens in that run must be re-tested to validate the accuracy and reported again as a corrected report which must be communicated to the applicable facility." 2. Review of quality control records from November 2018 to January 31, 2019 revealed the following days when the laboratory failed to ensure at least two levels of quality control were performed prior to patient testing. Lot 829608 Level 1 Range PLT = 45 - 73 Level 2 Range PLT = 202 - 258 Level 3 Range PLT = 476 - 578 Date: 11/30/2018 QC Run Time: 06:22 a.m. PLT Level 1: 81 (out of control) PLT Level 2: 250 (in control) PLT Level 3: 575 (in control) Summary: QC was acceptable (2 of 3 passed) Date: 11/30/2018 QC Run Time: 16:13 p.m. PLT Level 1: 77 (out of control) PLT Level 2: 264 (out of control) PLT Level 3: 570 (in control) Summary: QC was unacceptable (only 1 of 3 passed) Date: 12/01/2018 QC Run Time: 07:09 am. PLT Level 1: not documented (out of control) PLT Level 2: 265 (out of control) PLT Level 3: 553 (in control) Summary: QC was unacceptable (only 1 of 3 passed) Date: 12/01/2018 (no patients in afternoon) Date: 12/02/2018 QC Run Time: 06:56 a.m. PLT Level 1: not documented PLT Level 2: 266 (out of control) PLT Level 3: 570 (in control) Summary: QC was unacceptable (only 1 of 3 passed) Date: 12/02/2018 (no patients in afternoon) Date: 12/03/2018 QC Run Time: 07:39 a.m. PLT Level 1: not documented PLT Level 2: 253 (in control) PLT Level 3: 584 (out of control) Summary: QC was unacceptable (only 1 of 3 passed) Date: 12/03/2018 QC Run Time: 17:00 p.m. PLT Level 1: not documented PLT Level 2: 281 (out of control) PLT Level 3: 578 (in control) Summary: QC was unacceptable (only 1 of 3 passed) Date: 12/04/2018 QC Run Time: 12:45 p.m. PLT Level 1: 82 (out of control) PLT Level 2: 283 (out of control) PLT Level 3: 575 (in control) Summary: QC was unacceptable (only 1 of 3 passed) Date: 12/04/2018 QC Run Time: 18:54 p.m. PLT Level 1: 40 (out of control) PLT Level 2: 204 (in control) PLT Level 3: 505 (not documented) Summary: QC was unacceptable (only 1 of 3 passed) 3. Based on review of the quality control records, it was determined that from the period of November 30, 2018 to December 4, 2018, the last acceptable QC (quality control) run was the morning of November 30, 2018. 4. Review of patient records from November 30, 2018 to December 4, 2018 revealed the laboratory performed 454 CBCs (see patient alias list). 5. Interview with testing personnel five (as listed on Form CMS 209) on February 21, 2019 at 11:00 hours confirmed the findings. After his review of the records, he agreed there were quality control failures and patients were still tested. Key: QC - quality control PLT - platelet CMS - Centers for Medicare and Medicaid Services

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:
Based on review of manufacturer's instructions, review of quality control documentation, patient records, and interview with facility personnel, the laboratory

failed to perform and document at least two levels of acceptable quality control on the Alere HIV Combo Kit. The findings included: 1. Review of the manufacturer's instructions for the Alere HIV-1/2 Ag/Ab Combo Controls (PN: TBD.01) under, "Intended Use" it stated, "Perform the Kit Controls under the following circumstances" -Each new operator prior to performing tests on patient specimens, - When opening a new test kit lot, -Whenever a new shipment of test kits is received, - At periodic intervals as indicated by the user facility. 2. The laboratory did not develop an IQCP (Individualized Quality Control Plan) for the Alere HIV Combo Kit. The laboratory is required to perform at least two levels of acceptable quality control each day of patient testing. Random review of patient records from January, February, and December 2018 and January 2019 revealed the following patients were tested when at least two levels of quality control were not performed: Batch Date: 01/15/2018 Last 3 Digits of Patient ID: 282 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/15/2018 Last 3 Digits of Patient ID: 737 HIV-1/2 Abs Result: Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/15/2018 Last 3 Digits of Patient ID: 17.3 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/15/2018 Last 3 Digits of Patient ID: 739 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/15/2018 Last 3 Digits of Patient ID: 198 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/15/2018 Last 3 Digits of Patient ID: 738 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/17/2018 Last 3 Digits of Patient ID: 284 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/17/2018 Last 3 Digits of Patient ID: 754 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/17/2018 Last 3 Digits of Patient ID: 110 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/17/2018 Last 3 Digits of Patient ID: 63.1 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/17/2018 Last 3 Digits of Patient ID: 196 HIV-1/2 Abs Result: Reactive HIV1 P24 Ag Result: Non Reactive Batch Date: 01/17/2018 Last 3 Digits of Patient ID: 733 HIV-1/2 Abs Result: Non Reactive HIV1 P24 Ag Result: Non Reactive 3. An interview with testing personnel five (as listed on Form CMS 209) on February 20, 2019 at 13:30 hours in the laboratory confirmed the findings. He agreed the logsheets were missing quality control documentation.

D5451

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(iii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, review of manufacturer's instructions, review of quality control documentation, patient records, and interview with facility personnel, the laboratory failed to perform a titered positive (reactive) quality control on the ASI RPR Card Test for Syphilis. The findings included: 1. Review of the laboratory's policy titled, "ASI RPR Card Test for Syphilis" under, "Quality Control" it stated, "Controls with graded reactivity should be included daily to confirm optimal reactivity of the antigen ..." 2. Review of the manufacturer's instructions for the ASI

RPR Card Test for Syphilis (Document No. 6004-900, 11-2016) under, "Quality Control" it stated, "Quality Control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included ..." 3. Review of patient records from October, November, and December 2018 revealed the following patient results were resulted semi-quantitatively when a positive quality control titer was not performed: Date: 10/16/2018 Specimen ID: 2156429 Patient Titer: 1:2 Date: 10/17/2018 Specimen ID: 2156361 Patient Titer: 1:2 Date: 10/24/2018 Specimen ID: 2158090 Patient Titer: 1:2 Date: 10/25/2018 Specimen ID: 2158659 Patient Titer: 1:4 Date: 11/07/2018 Specimen ID: 2160881B Patient Titer: 1:2 Date: 11/08/2018 Specimen ID: 2161104 Patient Titer: 1:8 Date: 11/08/2018 Specimen ID: 2161340 Patient Titer: 1:2 Date: 11/09/2018 Specimen ID: 2161865 Patient Titer: 1:2 Date: 11/26/2018 Specimen ID: 2163642B Patient Titer: 1:2 Date: 12/20/2018 Specimen ID: 2169697 Patient Titer: 1:2 4. Interview with testing personnel five (as listed on Form CMS 209) on February 20, 2019 at 15:30 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, laboratory records, patient test reports, and confirmed in interview, the laboratory failed to utilize the geometric mean for International Normalized Ratio (INR) calculation for PT testing on the Sysmex CA-600 hematology analyzer. Findings were: 1. Review of the Reagent Lot Roll-Over Procedures (09/2012, Rev 1.1) for the Sysmex CA-600 hematology analyzer revealed under Verification of Reference Range "MNPT for INR calculation must be the geometric mean." 2. Review of the geometric mean used on the Sysmex CA-620 for PT Innovin lot 5497320, exp 03/22/21 on 02/20/19 was input as 9.7 seconds. 3. Review of the laboratory normal patient study for the new lot of PT Innovin (lot 5497320, exp 03/22/21) revealed the geometric mean as 9.7. Surveyor calculated the documented data on 02/20/19 and found the geometric mean as 9.8 seconds. 4. Review of the patient test records for January to February 2019 revealed the laboratory performed patient testing using the incorrect geometric mean of 9.7. Refer to PT patient alias list. 5. An interview with the technical director on 2/21/19 at 1100 hours in the office confirmed the above findings. He was unaware the laboratory was using the incorrect geometric mean.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The

laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy, quality control records, patient final records, and confirmed in interview, the laboratory failed to evaluate test results obtained in the unacceptable test run and since the last acceptable test run for chemistry testing on the Roche Cobas 6000 chemistry analyzer. Findings were: 1. Review of the laboratory policy SML Chemistry, Immunochemistry, Toxicology Procedure revealed "during troubleshooting in the event that the control value is within reference range following calibration, remediation may be required to the last successful QC run. A sample of specimen (approximately 10%) of patient samples from the last successful QC must be re-tested to validate the accuracy of the test performed before the QC failure. Results of the re-testing must be within 10% of the results previously obtained or justified and approved by the laboratory supervisor or manager." 2. Random review of the quality control checklist for November and December 2018 revealed the laboratory had quality control failures for Level 1 for the following analytes Carbon Dioxide (CO2), Glucose (GLU), Direct Bilirubin (DBili), Sodium (NA), Cholesterol (CHOL), and Digoxin on the Roche Cobas 6000 chemistry analyzer. 11/01/18 Level 1 CHOL - Recal and QC 11/04/18 Level 1 NA - Cal and QC 11/06/18 Level 1 NA - Cal and QC 12/14/18 Level 1 CO2 - Cal and QC CO2 12/18/18 Level 1 GLU, DBili - Cal and QC CO2 12/22/18 Level 1 CO2 - Cal and QC 12/30/18 Level 3 Digoxin - Cal and QC 3. Review of the laboratory corrective actions for the above dates for the corresponding analytes revealed no patient evaluation since the last acceptable quality control run. 4. An interview with the technical director on 2/21/18 at 1135 hours in the office confirmed the above findings. He was unaware the laboratory was required to evaluate test results since the last acceptable quality control.

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:

I. Based on review of the laboratory quality control, laboratory policy, and confirmed in interview, the laboratory quality assurance policy failed to detect and correct errors in control procedures. (shifts for the laboratory quality control for the analyte ALP on the Roche Cobas chemistry analyzer) Findings were: 1. Random review of the laboratory quality control data form October 2018 to December 2018 revealed the laboratory had a shift of their quality control for Multiquel Level 3 (47973) for the analyte Alkaline Phosphatase (ALP) for 2 of 3 months (October and November 2018). Multiquel Level 3 (47973) ALP with established mean of 395, but actual mean of 414 from the following documented data from November 2018 Date ALP (U/L) 11/01/2018 419 11/02/2018 413 11/03/2018 423 11/04/2018 420 11/05/2018 429 11/06/2018 416 11/07/2018 411 11/08/2018 413 11/09/2018 403 11/10/2018 409 11/11/2018 413 11/12/2018 419 11/13/2018 414 11/14/2018 405 11/15/2018 408 11/16/2018 417 11/17/2018 416 11/18/2018 405 11/19/2018 406 11/20/2018 411 11/21/2018 416 11/22/2018 416 11/23/2018 425 11/24/2018 417 11/25/2018 409 11/26

/2018 412 11/27/2018 413 11/28/2018 414 11/29/2018 422 11/30/2018 417 Multiqua
 Level 3 (47973) ALP with established mean of 395, but actual mean of 415.8 from the
 following documented data from October 2018 Date ALP 10/01/2018 426 10/02/2018
 414 10/03/2018 418 10/04/2018 415 10/05/2018 421 10/06/2018 418 10/07/2018 422
 10/08/2018 423 10/09/2018 427 10/10/2018 427 10/11/2018 403 10/12/2018 417 10
 /13/2018 423 10/14/2018 414 10/15/2018 425 10/16/2018 425 10/17/2018 402 10/18
 /2018 409 10/19/2018 407 10/20/2018 412 10/21/2018 413 10/22/2018 417 10/23
 /2018 417 10/24/2018 413 10/25/2018 410 10/26/2018 419 10/27/2018 423 10/28
 /2018 425 10/29/2018 416 10/30/2018 419 10/31/2018 420 4. An interview with the
 technical director on 2/21/19 at 1140 hours in the office confirmed the above findings.
 He acknowledged that there was a shift in the quality control mean and the laboratory
 should change the mean. 36914 II. Based on surveyor observations, review of
 manufacturer's instructions, review of policies and procedures, quality control records,
 patient records, and confirmed in interview of facility personnel, the laboratory failed
 to establish written policies and procedures for an ongoing mechanism to monitor,
 asses, and correct problems in analytic systems as evidenced by: 1. The laboratory
 failed to have a policy that would identify and correct when the laboratory failed to
 follow its own policy for resolving flags on CBC results. (refer to D5401) 2. The
 laboratory failed to have a policy that would identify and correct when the laboratory's
 Quality Control policy for daily workflow in microbiology did not include which
 quality control organisms should be used QC testing. (refer to D5403) 3. The
 laboratory failed to have a policy that would identify and correct when the laboratory's
 policy for Gram stains failed to provide correct steps for reagent preparation. (refer to
 D5407) 4. The laboratory failed to have a policy that would identify and correct when
 the laboratory failed to ensure reagents were properly labeled with identifying
 information, lot number, and expiration date. (refer to D5415) 5. The laboratory failed
 to have a policy that would identify and correct when the laboratory failed to ensure
 that items were not used beyond their expiration date. (refer to D5417) 6. The
 laboratory failed to have a policy that would identify and correct when the laboratory
 failed to perform complete verification studies. (refer to D5421) 7. The laboratory
 failed to have a policy that would identify and correct when the laboratory failed to
 ensure maintenance procedures were performed according to the manufacturer's
 instructions. (refer to D5429) 8. The laboratory failed to have a policy that would
 identify and correct when the laboratory failed to follow the manufacturer's
 instructions for monitoring quality control over time. (refer to D5441) 9. The
 laboratory failed to have a policy that would identify and correct when the laboratory
 failed to have complete IQCP studies to reduce the frequency of quality control. (refer
 to D5445) 10. The laboratory failed to have a policy that would identify and correct
 when the laboratory failed to have at least two acceptable levels of quality control on
 each day of patient testing. (refer to D5447) 11. The laboratory failed to have a policy
 that would identify and correct when the laboratory failed to have a least two
 acceptable levels of quality control on each day of patient testing. (refer to D5449) 12.
 The laboratory failed to have a policy that would identify and correct when the
 laboratory failed to include a titered qualilty control result each day of patient testing
 when patients were reactive for RPR. (refer to D5451)

D5801

TEST REPORT
 CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported

from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of patient log sheets, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to ensure patient results were accurately inputted into the laboratory's electronic medical record for 1 of 20 patient reports. The findings were: 1. Review of RPR (Rapid Plasma Reagin for Syphilis) logsheets from October, November, and December 2018 revealed that on the date, 10/26/2018 specimen number 2158658 for (patient ID redacted) the RPR result was reactive and had a titer of 1:4. 2. Review of the final patient report for specimen number 2158658 revealed the patient report was resulted as "Non Reactive." 3. It should be noted that this patient had a Reactive RPR 10 days prior on 10/16/2018. 4. Interview with testing personnel five (as listed on Form CMS 209) on February 20, 2019 at 15:30 hours confirmed the findings. He agreed the patient result that was manually entered in to the computer was incorrect. He agreed that the result should have been entered as reactive. Key: ID - identification CMS - Centers for Medicare and Medicaid Services

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on surveyor observations, review of policies and procedures, review of manufacturer's instructions, quality control records, patient records, and confirmed in interview of facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in post-analytic systems as evidenced by: 1. The laboratory failed to have a quality assurance policy that would identify and correct when patient results are manually entered into the electronic medical record incorrectly. (refer to D5801)

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 review of the laboratory's policies and procedures, quality control records, quality assessment records and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. (Refer to D6012, D6013-A, B, D6020-A, B, D. 6021, D6024)

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| <p>D6012</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i)</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)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care;</p> <p>This STANDARD is not met as evidenced by: Based on review of patient logsheets, review of patient final reports, and confirmed in interview of facility personnel, laboratory director failed to ensure the manual entry of patient results into the LIS (laboratory information system) were accurate. (refer to D5801)</p> |
| <p>D6013</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: A. Based on review of instrument verification records and confirmed in interview of facility personnel, the laboratory director failed to ensure a complete instrument verification study was performed on the Beckman Coulter MicroScan WalkAway prior to patient testing. (refer to D5421-I) 38387 B. Based on a review of the laboratory's test system records and interview of facility personnel it was revealed that the laboratory director failed to ensure verification and establishment studies were complete for chemistry and toxicology testing on the Roche Cobas chemistry analyzer before reporting patient test results. (Refer to D5421-II, D5423)</p> |
| <p>D6020</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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: A. Based on review of manufacturer's instructions, review of quality control records, and confirmed in interview of facility personnel, the laboratory director failed to</p> |

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| | <p>ensure the quality control plan was maintained. (refer to D5441, D5445, D5447, D5449, and D5451) 38387 B. Based on review of the manufacturer's instructions, laboratory quality control (QC) records, and confirmed in interview, the laboratory failed to ensure the laboratory established and maintained a quality control program. Refer to D5783</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 review of laboratory policies, review of quality assurance records, review of quality control records, review of maintenance records, review of finalized patient results, and confirmed in interview of facility personnel, the laboratory director failed to ensure a quality assurance program was established and maintained. (refer to D5791 and D5891)</p> |
| <p>D6024</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,</p> <p>This STANDARD is not met as evidenced by: Based on a review of Roche Cobas chemistry analyzer quality control reports for 2018, corrective action logs, patient test logs, and confirmed in interview, the laboratory director failed to ensure the laboratory evaluated all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Refer to D5783</p> |
| <p>D6054</p> | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records for 2018 and verified by</p> |

interview, the Technical Consultant failed to perform the annual competency evaluations for 3 of 16 testing personnel (TP) in the year 2018. Findings were: 1. Review of the CMS form 209 revealed the laboratory had 16 testing personnel. 2. A review of the laboratory competency assessments for 2018 revealed the technical consultant failed to document the annual competencies for 3 of 16 testing personnel: TP #3, TP#5, TP#6. Testing person # 3, hired 11/6/15. 2018 annual competencies performed on 7/2/18 performed by TP #12, who does not qualify as a technical consultant. TP# 12 has an associates degree. Testing person # 5, hired 10/14/15. 2018 annual competencies performed on 10/12/18 performed by TP #12, who does not qualify as a technical consultant. TP# 12 has an associates degree. Testing person # 6, hired 05/26/17. 2018 annual competencies performed on 5/3/18 performed by TP #12, who does not qualify as a technical consultant. TP# 12 has an associates degree. 3. An interview with the technical director on 2/20/19 at 0945 hours in the office confirmed the above findings. key: CMS - Centers for Medicaid and Medicare Services