

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0048403	<b>(X3) Date Survey Completed</b>  07/18/2018
<b>Name of Provider or Supplier</b>  Hood Memorial Hospital	<b>Street Address, City, State</b>  301 West Walnut Street, Amite, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification survey was performed at Hood Memorial Hospital-CLIA ID # 19D0048403 on July 16, 2018 through July 18, 2018. Hood Memorial Hospital was not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1215 CONDITION: Hematology 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director
<b>D5024</b>	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>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 for the specialty of Hematology. Findings: 1. The laboratory failed to ensure patient donors for Mean Prothrombin Time studies met manufacturer requirements of normal donors. Refer to D5411. 2. The laboratory failed to have complete performance specification verification studies. Refer to D5421. 3. The laboratory failed to ensure quarterly maintenance for the Beckman Coulter AU 680 was performed and documented as required. Refer to D5429. 4. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-dimer testing. Refer to D5545.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:  
 Based on record review and interview with personnel, the laboratory failed to establish written policies and procedures to assess personnel competency semi-annually. Findings: 1. Review of the laboratory's "Evaluation & Competency" policy revealed the following: a) "Each new employee is evaluated semi-annually for the first year." 2. Review of personnel records revealed the laboratory utilized the "Merit Evaluation Tool" form to assess testing personnel semi-annually during the first year of employment; however, tasks were non laboratory specific. 3. Further review of the "Merit Evaluation Tool" form revealed the following tasks were assessed: a) "Quality /accuracy of work" b) "Quantity of work" c) "Dependability" d) "Attendance /Punctuality" e) "Professional communication skills with co-workers/supervisors" f) "Customer-focused communication skills" g) "Ability to work as a member of a team; teamwork" h) "Ability to work independently" i) "Open to feedback" j) "Willingness to take on additional responsibilities" k) "Complies with company policies and procedures" l) "Exhibits effective problem solving skills" m) "Eagerness to learn new job-related skills" n) "Asks questions and seeks guidance as needed" o) "Makes progress toward professional development goals N/A" p) "Complies with hospital's annual requirements (e.g., SWANK, TB, CPR, SAFETY STORM)" q) "Actively participates in hospital activities N/A" 4. In interview on July 16, 2018 at 11:50 am, Personnel 2 confirmed she uses the "Merit Evaluation Tool" form for semi-annual competency assessments. Personnel 2 confirmed the form is not specialty or laboratory testing specific. Personnel 2 stated the laboratory uses the minimal six (6) procedures required by CLIA for annual competency assessments.

**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:  
 \*\*\* REPEAT DEFICIENCY from survey date February 6, 2017 through February 9, 2017. \*\*\* Based on record review and interview with personnel, the laboratory failed to follow their policy for documentation of Quality Control (QC) for Blood Bank testing. Findings: 1. Review of the laboratory's "Blood Bank QC" records from March 9, 2017 through July 17, 2018 revealed the following items are to be documented: a) Results for Ortho Confidence reagents: Anti-A, Anti-B, Anti-AB, Anti-D, Rh control material b) Results for Ortho Confidence Reagent Red Blood Cells: A1, B, Screen cells 1, and Screen cells 2 c) Results for DAT and Coombs d) Lot number and expiration dates for Reagents e) Visual inspection check for Diluent 2 and Saline f) RPM speed check, Timer and Incubator Checks 2. Further review of the laboratory's "Blood Band QC" records from March 9, 2017 through July 17, 2018 revealed information was not documented for the following three (3) dates: a) December 9, 2017: "QC Reagent" Lot # and Expiration Date b) May 2, 2018: RPM Check and Timer Check c) May 30, 2018: DAT Reagent Lot #s and Expiration Dates 3. In interview on July 18, 2018 at 11:40 am, Personnel 2 confirmed the identified dates did not have all QC tasks documented.

**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 observation, record review, and interview with personnel, the laboratory failed to ensure patient donors for Mean Prothrombin Time studies met manufacturer requirements of normal donors. Findings: 1. Observation by surveyor during laboratory tour on July 16, 2018 revealed the laboratory utilizes the Stago Satellite for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the laboratory's "Establishing Patient Normal Range" policy revealed the following: "The donors should be screened using the following guidelines: a) A minimum of 20 donors should be used b) The donors should be healthy and have no known pathological conditions c) The donors should not be on medication, including oral contraceptives and estrogen therapy d) Donors should span the adult age range. (Employees are used when available). e) The study should include a fairly even number of males and females. Reference: NCCLS H21-A3 December 1998" 3. Review of the laboratory's donor questionnaires from October 23, 2017 through November 1, 2017 for Thromboplastin lot # 251655 revealed the laboratory utilized two (2) questionnaires. 4. Further review of the laboratory's donor questionnaires revealed on October 24, 2017 through November 1, 2017 the laboratory utilized the "Prothrombin Time Normal Mean Study Questionnaire." The laboratory documented responses from twenty one (21) donors (Patients 54-73) for the following questions: "Are you currently taking any of the following? a) Alcohol b) Antibiotics c) Anti-coagulants d) Vitamin K e) Aspirin 5. Review of the laboratory's donor questionnaires revealed the laboratory did not include the following criteria: a) Healthy and have no known pathological conditions donors b) Not be on medication, including oral contraceptives and estrogen therapy 6. In interview on July 18, 2018 at 11:40 am, Personnel 2 stated the questionnaire was changed after she spoke to the manufacturer and was told oral contraceptives should not interfere with PT results. Personnel 2 further stated it was unknown if donors (Patients 54-73) were on birth control (oral contraceptives). 7. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 1,002 PT/INR tests annually.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

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

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to ensure Blood Bank reagents were not used beyond their expiration date. Findings: 1. Observation by surveyor during laboratory tour on July 16, 2018 revealed the laboratory utilizes Micro Typing Systems Gel cards for Antibody Screen and Crossmatch testing. 2. Review of the laboratory's Blood Bank Quality Control and

patient test records from March 9, 2017 through July 17, 2018 revealed the following expired reagent: On January 28, 2018 Gel Card Lot # 032717001-05, Documented Expiration Date: 1-19-18 3. Further review of the laboratory's patient test records revealed the following patient was reported on January 28, 2018: Patient 48 4. Review of the laboratory's Blood Bank Quality Control form for January 28, 2018 revealed the form was reviewed on January 29, 2018 5. In interview on July 18, 2018 at 11:40 am, Personnel 3 stated the testing personnel transcribed the expiration date of the gel cards incorrectly. Personnel further stated that he was unable to find a packing slip or insert from the manufacturer verifying the identified gel cards expiration date.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies. Findings: 1. Observation by surveyor during the laboratory tour on July 16, 2018 revealed the laboratory utilizes the Sysmex XN 550 for Complete Blood Count (CBC) and Reticulocyte (Retic) testing. 2. In interview on July 16, 2018 at 9:05 am, Personnel 2 stated the laboratory began patient testing on the new hematology analyzer in February 2018. 3. Review of the laboratory's "Validating New Methodologies" policy under section "IV. Reference Range Studies" revealed the following: "The laboratory may begin patient testing using the manufacturer suggested reference ranges or published reference ranges from a textbook or a journal publication. The Reference ranges may vary based on the type of patient (e.g. pediatric, male, female). Be sure to verify that the manufacturer's reference ranges (normal values) are appropriate for your laboratory's patient population by performing the study below. In addition, Reference ranges will be monitored as part of the quality assessment program. If published ranges are used, document published 'source' with method validation studies." 4. Further review of the laboratory's "Validating New Methodologies" policy under section "SUMMARY OF TEST METHOD VALIDATION" revealed "All documented data must be reviewed and approved by the lab director prior to initiating patient testing." 5. Review of the laboratory's performance verification studies revealed the following information was not included: a) Reference Range b) Laboratory Director approval/signature 6. In interview on July 16, 2018 at 3:20 pm, Personnel 2 stated the Laboratory Director reviewed the performance studies but did not sign. Personnel 2 further stated she could not locate data for reference range study. 7. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performed 43,953 CBC and forty (48) Retic tests on the Sysmex XN 550 analyzer.

**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 observation, record review and interview with personnel, the laboratory failed to ensure quarterly maintenance for the Beckman Coulter AU 680 was performed and documented as required. Findings: 1. Observation by surveyor during laboratory tour on July 16, 2018 revealed the laboratory utilizes the Beckman Coulter AU 680 for Chemistry and D-dimer testing. 2. Review of the "AU680 ANALYZER QUARTERLY & AS NEEDED MAINTENANCE LOG" indicated the following quarterly maintenance tasks: a) "Clean Air Filters" b) "Replace Detergent Rolling Tube" c) "Replace Roller Tubes for MID soln Depense & Mixture Aspiration" d) "Replace Pinch Valve Tubing" 3. Further review of the "AU680 ANALYZER QUARTERLY & AS NEEDED MAINTENANCE LOG" for 2017 and 2018 revealed the laboratory did not document quarterly maintenance for the following four (4) quarters: 2017: 3rd Quarter, due September 2017 2017: 4th Quarter, due December 2017 2018: 1st Quarter, due March 2018 2018: 2nd Quarter, due June 2018 4. In interview on July 16, 2018 at 2:40 pm Personnel 2 stated the laboratory did not document quarterly maintenance for the identified dates.

**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 observation, record review, and interview with personnel, the laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-dimer testing. Findings: 1. Observation by surveyor during laboratory tour on July 16, 2018 revealed the laboratory utilizes the Beckman Coulter AU 680 for D-dimer testing. 2. Review of the laboratory's "D-dimer" procedure under the "Quality Control" section revealed "Bio-Rad D-Dimer Controls Level 1 & Level 3 should be tested a minimum of once a day. In addition, these controls should be tested after calibration, with each new lot of reagent and after specific maintenance or troubleshooting steps described in the appropriate User's Guide." 3. Review of the manufacturer's package insert under the "Quality Control" section revealed "During operation of the Beckman Coulter AU analyzer at least two levels of appropriate control material, such as D-Dimer Control ODC0029, should be tested a minimum of once a day. In addition, these controls should be tested after calibration, with each new lot of reagent and after specific maintenance or troubleshooting steps described in the appropriate Beckman Coulter AU analyzer User Guide/Instructions For Use (IFU). Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure." 4. In interview on July 17, 2018 at 10:39 am, Personnel 2 stated D-Dimer controls are tested once a day since the AU has been in use. 5. In further interview on July 17, 2018 at 11:30 am, Personnel 2 stated the laboratory did not perform an Individualized Quality Control Plan (IQCP). Personnel 2 further stated she thought they could go by the manufacturer requirements. 6. Review of D-dimer Quality Control (QC) and patient test records for

July 2017 and June 2018 revealed the laboratory did not perform two (2) levels of QC each eight (8) hours of patient testing for the following forty-seven (47) patients:

Patient 1 reported on July 5, 2017 at 20:39, QC reported on July 5, 2017 at 06:30  
Patient 2 reported on July 20, 2017 at 19:07, QC reported on July 20, 2017 at 05:26  
Patient 3 reported on July 4, 2017 at 01:23, QC reported on July 4, 2017 at 05:37  
Patient 4 reported on July 4, 2017 at 14:25, QC reported on July 4, 2017 at 05:37  
Patient 5 reported on July 5, 2017 at 19:08, QC reported on July 5, 2017 at 06:30  
Patient 6 reported on July 8, 2017 at 14:09, QC reported on July 8, 2017 at 05:12  
Patient 7 reported on July 8, 2017 at 15:33, QC reported on July 8, 2017 at 05:12  
Patient 8 reported on July 8, 2017 at 18:38, QC reported on July 8, 2017 at 05:12  
Patient 9 reported on July 9, 2017 at 21:47, QC reported on July 9, 2017 at 05:35  
Patient 10 reported on July 12, 2017 at 04:43, QC reported on July 12, 2017 at 06:24 and 09:10  
Patient 11 reported on July 12, 2017 at 19:49, QC reported on July 12, 2017 at 06:24 and 09:10  
Patient 12 reported on July 13, 2017 at 23:30, QC reported on July 13, 2017 at 05:39  
Patient 13 reported on July 15, 2017 at 12:52, QC reported on July 15, 2017 at 04:07  
Patient 14 reported on July 16, 2017 at 08:09, QC reported on July 16, 2017 at 12:11  
Patient 15 reported on July 17, 2017 at 22:56, QC reported on July 17, 2017 at 04:54  
Patient 16 reported on July 18, 2017 at 02:51, QC reported on July 18, 2017 at 05:51  
Patient 17 reported on July 18, 2017 at 16:08, QC reported on July 18, 2017 at 05:51  
Patient 18 reported on July 20, 2017 at 19:18, QC reported on July 20, 2017 at 05:26  
Patient 19 reported on July 21, 2017 at 22:04, QC reported on July 21, 2017 at 05:26  
Patient 20 reported on July 21, 2017 at 22:56, QC reported on July 21, 2017 at 05:26  
Patient 21 reported on July 22, 2017 at 20:00, QC reported on July 22, 2017 at 04:13  
Patient 22 reported on July 22, 2017 at 19:33, QC reported on July 22, 2017 at 04:13  
Patient 23 reported on July 24, 2017 at 17:36, QC reported on July 24, 2017 at 05:34 and 06:57  
Patient 24 reported on July 26, 2017 at 16:10, QC reported on July 26, 2017 at 06:56  
Patient 25 reported on July 28, 2017 at 14:23, QC reported on July 28, 2017 at 05:40  
Patient 26 reported on July 28, 2017 at 14:43, QC reported on July 28, 2017 at 05:40  
Patient 27 reported on July 29, 2017 at 14:31, QC reported on July 29, 2017 at 05:51  
Patient 28 reported on July 29, 2017 at 21:00, QC reported on July 29, 2017 at 05:51  
Patient 29 reported on July 29, 2017 at 22:12, QC reported on July 29, 2017 at 05:51  
Patient 30 reported on July 31, 2017 at 02:34, QC reported on July 31, 2017 at 02:34  
Patient 31 reported on June 3, 2018 at 22:24, QC reported on June 3, 2018 at 04:09  
Patient 32 reported on June 7, 2018 at 23:40, QC reported on June 7, 2018 at 03:33  
Patient 33 reported on June 1, 2018 at 14:00, QC reported on June 1, 2018 at 04:05  
Patient 34 reported on June 3, 2018 at 13:37, QC reported on June 3, 2018 at 04:09  
Patient 35 reported on June 3, 2018 at 13:36, QC reported on June 3, 2018 at 04:09  
Patient 36 reported on June 4, 2018 at 00:18, QC reported on June 4, 2018 at 03:45  
Patient 37 reported on June 4, 2018 at 17:58, QC reported on June 4, 2018 at 03:45  
Patient 38 reported on June 6, 2018 at 22:01, QC reported on June 6, 2018 at 03:31  
Patient 39 reported on June 8, 2018 at 19:37, QC reported on June 8, 2018 at 03:31  
Patient 40 reported on June 8, 2018 at 19:36, QC reported on June 8, 2018 at 03:31  
Patient 41 reported on June 10, 2018 at 23:26, QC reported on June 10, 2018 at 03:44  
Patient 42 reported on June 14, 2018 at 23:06, QC reported on June 14, 2018 at 03:57  
Patient 43 reported on June 15, 2018 at 22:58, QC reported on June 15, 2018 at 04:07  
Patient 44 reported on June 19, 2018 at 20:46, QC reported on June 19, 2018 at 03:39  
Patient 45 reported on June 26, 2018 at 20:22, QC reported on June 26, 2018 at 04:03  
Patient 46 reported on June 26, 2018 at 21:51, QC reported on June 26, 2018 at 04:03  
Patient 47 reported on June 29, 2018 at 19:58, QC reported on June 29, 2018 at 07:09

7. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs three hundred eighty nine (389) D-dimer tests annually.

**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 observation, record review, and interview with personnel, the laboratory failed to perform corrective action when quality control was unacceptable for Acetaminophen testing. Findings: 1. Observation by surveyor during laboratory tour on July 16, 2018 revealed the laboratory utilizes the Beckman Coulter AU 680 with Bio-Rad Multiquel controls for Acetaminophen testing. 2. Review of the laboratory's Quality Control (QC) records for July 2017 revealed the laboratory did not take corrective action when QC was not acceptable for the following date: July 21, 2017: Control Level 2: reported value "172.0 EXCLUDE RESULT" at 23:51 3. In interview on July 18, 2018 at 9:05 am, Personnel 2 stated the Acetaminophen QC was excluded and not repeated on the identified date. 4. Review of patient test records for Acetaminophen testing in July 2017 revealed the following patient was reported without corrective action: Patient 49 reported July 21, 2017 at 23:51

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (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's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. Review of the laboratory's "Quality Assurance" plan revealed the following monitors: a) "Assure that analyzer maintenance is done each day of use b) Assure that Blood Bank reagent lot # & exp date is documented each day of patient testing c) Assure Autocontrol is done each time Selectogens are performed d) Assure internal & external QC for SPT is performed and documented on each day of use e) Assure that QC for Ketone testing is performed and documented on each day of use f) Assure the temp is checked and in range daily in BB room, Drawing room & ER g) Assure QC in routine Chemistry is performed as per policy h) Neg Strep A cultures following Neg Strep A screen i) Assure that QC for Beta HCG is performed each day of testing" 2. Review of the laboratory's records revealed the laboratory did not identify the following issues: a) The laboratory failed to follow their policy for documentation of Quality Control (QC) for Blood Bank testing. Refer to D5401. b) The laboratory failed to ensure patient donors for Mean Prothrombin Time studies met manufacturer requirements of normal donors. Refer to D5411. c) The laboratory failed to ensure

	<p>Blood Bank reagents were not used beyond their expiration date. Refer to D5417. d) The laboratory failed to have complete performance specification verification studies. Refer to D5421. e) the laboratory failed to ensure quarterly maintenance for the Beckman Coulter AU 680 was performed and documented as required. Refer to D5429. f) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-dimer testing. Refer to D5545. g) The laboratory failed to perform corrective action when quality control was unacceptable for Acetaminophen testing. Refer to D5783.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, 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 that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 5. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6023. 6. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 7. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030.</p>
<p><b>D6013</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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: Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b></p>

	<p>CFR(s): 493.1407(e)(3)(iii)</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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</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 laboratory personnel performed testing as required. Refer to D5411.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D5545.</p>
<p><b>D6022</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 and quality assessment programs are established and maintained to identify failures in quality as they occur.</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 and to identify failures as they occur. Refer to D5793.</p>
<p><b>D6023</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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</p>

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;

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 the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(7)

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,

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5783.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test

methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow their policy for documentation of Quality Control (QC) for Blood Bank testing. Refer to D5401. 2. The laboratory failed to ensure Blood Bank reagents were not used beyond their expiration date. Refer to D5417.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to establish written policies and procedures to assess personnel competency semi-annually. Refer to D5209. 2. The Technical Supervisor failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of thirteen (13) testing personnel reviewed. Refer to D6127.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Supervisor failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of thirteen (13) testing personnel reviewed. Findings: 1. Review of the laboratory's "Evaluation & Competency" policy revealed the following: a) "Each new employee is evaluated semi-annually for the first year." 2. Review of personnel records revealed the laboratory did not have documentation of performance of a semi-annual competency assessment for Blood Bank testing for the following personnel: Personnel 9: Date of Hire 03-21-17; Assessment due: September 2017 3. Further review of Personnel 9's competency assessment records revealed for Blood Bank specialty assessments were documented on April 13, 2017 and June 30, 2017. 4. In interview on July 17, 2018 at 9:05 am, Personnel 2 confirmed the laboratory did not perform a six (6) month competency assessment for Personnel 9 for Blood Bank section.