

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0048403	(X3) Date Survey Completed 11/17/2022
Name of Provider or Supplier Hood Memorial Hospital	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Certification survey was performed at Hood Memorial Hospital, CLIA # 19D0048403, on November 14, 2022 through November 17, 2022. Hood Memorial Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and testing of samples 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency test records, test menu, and interview with personnel, the laboratory failed to enroll in an HHS approved proficiency testing program for lactate dehydrogenase (LDH). Findings: 1. Review of the laboratory's 2021 and 2022 proficiency test records revealed the laboratory was not enrolled in an HSS approved proficiency testing program for LDH. 2. Review of the laboratory's records revealed LDH testing was added in 2021. 3. In interview on November 17, 2022 at 3:45 pm , the newly hired Lab Manager confirmed the laboratory was not enrolled in proficiency testing for LDH. 4. Review of the laboratory's test menu revealed the laboratory performs twenty three (23) LDH tests annually.</p>

<p>D3031</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of coagulation quality control (QC) records, and interview with personnel, the laboratory failed to maintain instrument printouts in a manner to ensure visibility of data for at least two (2) years. Findings: 1. Observation by surveyor on November 16, 2022 at 2:32 pm and review of the laboratory's coagulation quality control records revealed the laboratory maintains the quality control thermal paper printouts in a notebook. Further observation and review of the thermal paper printouts revealed instances of faded results, clear scotch tape in location that removed the printed results, as well as, results blacked out with sharpie marker. The laboratory did not ensure the unacceptable results was still visible. 2. In interview on November 17, 2022 at 11:10 am Testing Personnel 1 stated unacceptable QC results are blacked out and acceptable results left visible. Testing Personnel 1 confirmed the laboratory's current way of maintaining the raw data for coagulation QC did not preserve the visibility of the data for at least two (2) years.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, validation records, and interview with personnel, the laboratory failed to verify the accuracy of erythrocyte sedimentation rate (ESR) and potassium hydroxide preparations (KOH) testing at least twice annually. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs ESR (utilizing the Excyte Mini) and KOH prep testing. 2. Review of the laboratory's validation records for the Excyte Mini for ESR testing revealed the laboratory began patient testing in August 2022. 3. Review of the laboratory's proficiency test records revealed the laboratory did not verify the accuracy of the ESR and KOH prep testing at least twice a year for 2022. 4. In interview on November 17, 2022 at 3:45 pm, the newly hired Laboratory Manager confirmed the laboratory did not verify the accuracy of the ESR and KOH prep testing at least twice annually.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with personnel, the laboratory failed to ensure complete documentation of review of PT results for Gentamicin in 2022. Findings: 1. Review of the laboratory's PT records</p>

for 2022 Event 2 revealed a score of 40% for Gentamicin. 2. Further review of the laboratory's PT records for the 2022 Event 2 for Gentamicin revealed the laboratory had raw data; however, did not include detailed documentation of steps taken for the assessment. 3. In interview on November 14, 2022 at 2:31 pm, the Diagnostic Services Director stated the laboratory repeated the proficiency samples. The Diagnostic Services Director confirmed the laboratory's documentation did not include specific steps/tasks performed for the unsatisfactory Gentamicin score.

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:

I. Based on review of the laboratory's policies, SARS COV-2 test logs, and interview with personnel, the laboratory failed to report SARS COV-2 results from the BioFire Film Array to the state of Louisiana as required per laboratory policy. Findings: 1. In interview on November 14, 2021 at 9:27 am, the Diagnostic Services Director stated the laboratory added the BioFire Film Array Torch for testing of respiratory pathogens including SARS COV-2 on June 2021. 2. Review of the laboratory's "Covid Reporting Results" policy revealed "All positive and negative COVID results will be reported to the state within 24 hours of being resulted." The policy had a review date of "3/15/2022." 3. In interview on November 17, 2022 at 3:30 pm Testing Personnel 3 stated on December 21, 2021 the BioFire SARS COV-2 results were no longer being reported to the state. Testing Personnel 3 further stated they were told that the BioFire COVID results did not have to be reported. 4. Review of the laboratory's BioFire test logs for SARS COV-2 revealed the laboratory tested 477 patient samples from January 3, 2022 through November 16, 2022 without reporting results to the state. II. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following: a) Written quality control procedure for blood culture bottles that included visual inspections b) Updated blood bank refrigerator alarm check policy to include frequency that matched what was in practice 2. In interview on November 16, 2022 at 1:58 pm the Diagnostic Services Director confirmed the laboratory did not have a procedure for visual inspections of blood culture bottles. 3. In interview on November 17, 2022 at 11:18 am, Testing Personnel 2 stated she began performing the blood bank high/low temperature refrigerator alarm checks monthly in September/October of 2021. Testing Personnel 2 confirmed the blood bank refrigerator alarm checks were not performed quarterly as stated in their policy. III. Based on review of the laboratory's policies and battery check logs for 2022 revealed, the laboratory failed to perform the blood bank refrigerator battery checks quarterly per laboratory policy. Findings: 1. Review of the laboratory's policies revealed the laboratory will perform blood bank refrigerator battery checks quarterly. 2. Review of the laboratory's battery check logs for 2022 revealed the laboratory performed on the following dates, not quarterly: March 28, 2022 April 15, 2022 September 1, 2022 October 3, 2022 3. In interview on November 17, 2022 at 11:18 am, Testing Personnel 2 confirmed the battery checks were not performed quarterly per policy.

<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to ensure policies and procedures were updated to current practices. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include the following: a) Ammonia to include the manufacturer's sample stability requirements 2. In interview on November 15, 2022 at 11:47 am, the newly hired Laboratory Manager confirmed the laboratory's ammonia policy was not updated to current practices.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturer's package insert, and interview with personnel, the laboratory failed to document the visual inspection of blood culture bottles prior to use per manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on November 14, 2022 at 10:41 am revealed the laboratory utilizes BacT/ALERT Adult and Pediatric Blood Culture Collection Kits. 2. Review of the manufacturer's package insert revealed "Inspect each blood culture bottle before use to ensure integrity of bottle and sensor on bottom of bottle is intact. The sensor is normally a uniform grayish-green color and a yellow color would indicate contamination of the broth. Discard any bottle found to be damaged or with a sensor that is yellow." 3. In interview on November 16, 2022 at 1: 58 pm the Diagnostic Services Director confirmed the laboratory does not document visual inspections of the blood culture bottles received.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's performance verification</p>

records, and interview with personnel, the laboratory failed to have complete performance verification studies for erythrocyte sedimentation rate (ESR) testing. Findings: 1. Observation by surveyor during laboratory tour on November 14, 2022 at 10:41 am revealed the laboratory utilizes the Excyte Mini analyzer for ESR testing. 2. Review of the laboratory's "Excyte ESR Analyzer Verification Protocol", approved by the Laboratory Director on August 26, 2022, revealed the laboratory did not include the following: a) Reportable range b) Reference range 3. In interview on November 14, 2022 at 2:31 pm, the Diagnostic Services Director confirmed the laboratory did not address reportable and reference ranges, to include, but not limited to the clinical source utilized if applicable.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
I. Based on observation by surveyor, review of manufacturer's package insert, quality control (QC) records, test menu, and interview with personnel, the laboratory failed to establish their own means and ranges for QC material utilized for Urine Drug Screen (UDS) testing. Findings: 1. Observation by surveyor during laboratory tour on November 14, 2022 at 10:41 am revealed the laboratory utilizes the Beckman Coulter DxC 700 AU for urine drug screen testing with Bio-Rad Liquichek Qualitative Urine Toxicology controls. 2. Review of the "Bio-Rad Liquichek Qualitative Urine Toxicology Control" package insert under "Assignment of Values" section revealed " Each laboratory should use the results provided only as a reference and establish its own parameters of precision." 3. Review of the laboratory's quality control records revealed the laboratory did not have documentation of establishing their own QC means and ranges for lot # 74710. 4. In interview on November 15, 2022 at 3:40 pm, the newly hired Laboratory Manager stated per the previous Laboratory Manager the laboratory did not establish their own means and ranges due to the control being assayed. 5. Review of the laboratory's test menu revealed the laboratory performs 3,451 UDS tests annually. II. Based on observation by surveyor, review of manufacturer's package insert, quality control (QC) records, test menu, and interview with personnel, the laboratory failed to establish their own means and ranges for QC material utilized for Hemoglobin A1C testing. Findings: 1. Observation by surveyor during laboratory tour on November 14, 2022 at 10:41 am revealed the laboratory utilizes the Beckman Coulter DxC 700 AU for Hemoglobin A1C testing with extendSURE controls. 2. Review of the manufacturer's package insert under "Value Assignment, Traceability Statement and Assay Values" section revealed "Since the assay values are dependent upon assay procedures as well as several other factors and

because other assay systems may produce different values it is recommended that each laboratory should establish its own control limits from day-to-day use of the test." 3. Review of the laboratory's quality control records revealed the laboratory did not have documentation of establishing their own QC means and ranges. 4. In interview on November 15, 2022 at 3:40 pm, the newly hired Laboratory Manager stated per the previous Laboratory Manager the laboratory did not establish their own means and ranges due to the control being assayed. 5. Review of the laboratory's test menu revealed the laboratory performs 2,867 Hemoglobin A1C tests annually.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's blood bank refrigerator circular charts, alarm check logs, and interview with personnel, the laboratory failed to ensure the high/low temperature alarm checks were visible on the blood bank refrigerator's circular charts in 2021 (June through December) and 2022 (January through December). Findings: 1. Review of the laboratory's policies revealed the laboratory will perform blood bank high/low temperature alarm checks quarterly. 2. Review of the laboratory's alarm check logs for 2021 and 2022 revealed the laboratory performed alarm checks more frequently than quarterly. The alarm checks were documented on the log for the following dates: a) 2022: January 20, 2022 February 28, 2022 March 28, 2022 April 5, 2022 June 1, 2022 July 12, 2022 September 1, 2022 October 3, 2022 b) 2021: June 2, 2021 September 3, 2021 October 12, 2021 December 1, 2021 3. Review of the laboratory's blood bank refrigerator circular charts for 2021 and 2022 revealed the high /low temperature alarm checks were not visible on the charts. 4. In interview on November 17, 2022 at 11:18 am, Testing Personnel 2 stated she started performing the blood bank refrigerator's high/low alarm checks monthly in September/October 2021. Testing Personnel 2 further stated a button is pushed to initiate the alarm check. Testing Personnel 2 confirmed the alarm checks are not visible on the blood bank refrigerator's circular charts.

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 observation by surveyor, 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 performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed

to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D6015. 4. The Laboratory Director failed to ensure the laboratory documented complete corrective actions for unacceptable proficiency testing results. Refer to D6019. 5. The Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6020. 6. The Laboratory Director failed to ensure one (1) of eight (8) Testing Personnel had appropriate training documentation prior to patient testing. Refer to D6029. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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;

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to maintain instrument printouts in a manner to ensure visibility of data for at least two (2) years. Refer to D3031. 1. The laboratory failed to report SARS COV-2 results from the BioFire Film Array to the state of Louisiana as required per laboratory policy. Refer to D5401 I. 2. The laboratory failed to document the visual inspection of blood culture bottles prior to use per manufacturer's requirements. Refer to D5411.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D2000.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory documented complete corrective actions for unacceptable proficiency testing results. Refer to D5221.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

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

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5469 I and D5469 II.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel

have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure one (1) of eight (8) Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of personnel records for Testing Personnel 5, hired September 2022, revealed the Laboratory Director did not sign off on the initial training documents approving her for patient testing. 2. In interview on November 15, 2022 at 8:45 am , the Diagnostic Services Director confirmed the Laboratory Director did not sign off/approve the identified Testing Personnel for patient testing.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 II. 2. The laboratory failed to ensure policies and procedures were updated to current practices. Refer to D5407.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

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

This STANDARD is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to maintain instrument printouts in a manner to ensure visibility of data for at least two (2) years. Refer to D3031. 2. The laboratory failed to verify the accuracy of erythrocyte sedimentation rate (ESR) and potassium hydroxide preparations (KOH) testing at least twice annually. Refer to D5217. 3. The laboratory failed to ensure complete documentation of review of PT results for Gentamicin in 2022. Refer to D5221. 4. The laboratory failed to report SARS COV-2 results from the BioFire Film Array to the state of Louisiana as required per laboratory policy. Refer to D5401 I. 5. The laboratory failed to establish

	<p>a complete policy and procedure manual. Refer to D5401 II. 6. The laboratory failed to document the visual inspection of blood culture bottles prior to use per manufacturer's requirements. Refer to D5411.</p>
D6040	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.</p>
D6041	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)</p> <p>(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure enrollment in an HHS approved proficiency testing program. Refer to D2000.</p>
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5469 I and D5469 II.</p>
D6087	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 II. 2. The laboratory failed to perform the blood bank refrigerator battery checks quarterly per laboratory policy. Refer to D5401 III. 3. The laboratory failed to ensure the high/low temperature alarm checks were visible on the blood bank refrigerator's circular charts in 2021 (June through December) and 2022 (January through December). Refer to D5555.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure one (1) of eight (8) Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of personnel records for Testing Personnel 5, hired September 2022, revealed the Laboratory Director did not sign off on the initial training documents approving her for patient testing. 2. In interview on November 15, 2022 at 8:45 am , the Diagnostic Services Director confirmed the Laboratory Director did not sign off/approve the identified Testing Personnel for patient testing.