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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>44D1075505      | <b>(X3) Date Survey Completed</b><br>08/30/2023 |
| <b>Name of Provider or Supplier</b><br>Perry County Medical Center   | <b>Street Address, City, State</b><br>7723 Clearview Church Lane, Lyles, TN |   |
| 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 recertification survey was conducted on 08/30/2023. The facility was found NOT to be in compliance with the following 42 CFR part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.1210 Condition: Routine chemistry 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor  |
| <b>D5016</b>              | <p><b>ROUTINE CHEMISTRY</b><br/>CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on observation of the laboratory, staff interviews, review of manufacturer's instructions for use, patient test reports, laboratory procedure manuals, and calibration verification studies, the laboratory failed to meet the condition of routine chemistry. The laboratory failed to have a procedure for chemistry that was approved by the laboratory director (Refer to D5407), failed to establish the performance specifications for use of the Total Bilirubin reagent outside the manufacturer's specified specimen type (Refer to D5423), failed to have an effective quality assessment in place for review of calibration verifications (Refer to D5793), and failed to ensure the final patient test report for the total bilirubin performed on neonatal samples included appropriate reference ranges (Refer to D5807).</p> |
| <b>D5293</b>              | <p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the</p>   |

effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment plan, proficiency testing policy, the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of policy, and staff interviews, the laboratory's quality assessment process was ineffective in preventing problems with the laboratory's proficiency testing in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory policy titled "Quality Assessment" revealed the following: "The laboratory director oversees the implementation of the QA plan and helps identify and correct problems as they occur. The QA process involves investigation, identification and resolution of the problem with subsequent development of policies that will prevent recurrence." 2. Review of the laboratory's quality assessment policy, under the section for proficiency testing, revealed the following statements: "Proficiency testing samples are tested exactly like patient specimens to the extent possible, i.e., the same number of times and using the same personnel and methods as for patient testing." "PT results are reviewed and retained for a period of at least two years." "Ungraded PT results"....." are self-graded by the laboratory." "A research and written explanation are required for all unacceptable results." 3. Review of the laboratory's API PT records revealed the following: No retention of the full performance evaluation for 2022 event two Hematology and 2023 event two Chemistry with no documented corrective action. The PT printout provided during the survey for 2022 event two Hematology had ungraded PT scores for Vaginal Wet Prep for sample VA-02; an unacceptable score for Red Cell Distribution Width-Standard Deviation (RDW-SD) was noted for sample XE-10. There was no evaluation of the ungraded score for VA-02, and no corrective action for the unacceptable RDW-SD score for sample XE-10. PT samples were performed multiple times for seven of eleven events reviewed (Chemistry: 2021 event three, 2022 events one, two and three, 2023 event one; Hematology: 2022 event three), with no corrective action performed. 4. There was no policy that required repeat testing of every patient test. 5. Interviews on 08/30/23 at 6 pm with the laboratory lead, testing personnel and lab director confirmed the laboratory's quality assessment process for proficiency testing was ineffective in correcting and preventing problems with proficiency testing retention, lack of evaluation of ungraded PT scores, lack of corrective action for unacceptable scores, and performance of proficiency testing samples multiple times that was inconsistent with patient testing protocol in 2021, 2022, and 2023.

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

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.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient test reports, staff interview, lack of procedures, and staff interviews, the laboratory failed to have a written procedure for performing heelstick collections. The findings include: 1. Observation of the laboratory on 08/30/23 at 8:30 am revealed the following moderately complex test systems in use for patient testing: Sysmex XN 430 Complete Blood Count (CBC) instrument Alfa Wasserman ACE Axcel Chemistry instrument Microscope in use for performing patient testing for urine microscopic and wet preps 2. Review of patient test reports revealed testing for bilirubin on neonates (five different patients from 2021, 2022 and 2023.) 3. Interview with testing person number two on 08/30/23 at 8: 30 am revealed samples collected from neonates are collected by heelstick. 4. There was no procedure for collecting samples by heelstick. 5. Interview with the laboratory lead, laboratory testing personnel and lab director on 08/30/23 at 6 pm confirmed the laboratory performs heelstick collections on neonates and infants, but failed to have a procedure for performing the collection by heelstick.

**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:  
Based on observation of the laboratory, review of the laboratory procedure manual and staff interviews, the procedures used for chemistry testing performed on the Alfa Wasserman ACE Axcel instrument did not include calibration verification. The findings include: 1. Observation of the laboratory on 08/30/23 at 8:30 am revealed the Alfa Wasserman ACE Axcel chemistry instrument in use for patient testing. 2. Review of the laboratory's procedures for chemistry revealed calibration verification was not included. 3. Interview on 08/30/23 at 6 pm with the laboratory lead, testing personnel and lab director confirmed the following: The laboratory uses the manufacturer operator's manual and package inserts as their procedures to follow. Calibration verification requirements were not addressed in any of the procedures.

**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 observation of the laboratory, interview with the laboratory lead, review of chemistry procedures, and staff interviews, the laboratory director failed to approve the procedures being used by the laboratory for the Alfa Wasserman ACE Axcel chemistry instrument. The findings include: 1. Observation of the laboratory on 08/30/23 at 8:30 am revealed the Alfa Wasserman ACE Axcel chemistry instrument in use for patient testing. 2. Interview with the laboratory lead on 08/30/23 at 4 pm revealed the laboratory uses the manufacturer operator's manual and package inserts for their procedures to follow. 3. Review of the manufacturer operator's manual revealed no approval of the lab director; the manufacturer reagent package inserts used by the laboratory were not part of the procedure manual and had not been approved by the lab director. 4. Interviews on 08/30/23 at 6 pm with the laboratory lead, testing personnel and the lab director, confirmed the procedures used for the Alfa Wasserman ACE Axcel chemistry instrument had not been approved by the laboratory director.

**D5413**

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory's environmental records, the manufacturers' operating manuals, and staff interviews, the laboratory failed to ensure it monitored environmental conditions in a manner that was consistent with manufacturers' requirements in 2022 and 2023. The findings include: 1. Observation of the laboratory on 08/30/2023 at 8:30 am revealed the Sysmex XN 430 CBC instrument and the Alfa Wasserman ACE Axcel chemistry instrument in use for patient testing. 2. Review of the laboratory's environmental monitoring records revealed the laboratory used a room temperature range of 16-35 degrees Celsius (61-86 degrees Fahrenheit), and a humidity range of up to 85%. These ranges were noted in use from review of monthly environmental records from 03/2022, 05/2022, 04/2023, 07/2023. 3. Review of the manufacturers' manuals revealed the following humidity and temperature ranges: Humidity: Sysmex XN430: 20 to 85% Ace Axcel: 20 to 80% Room temperature range: Sysmex XN 430: 15 to 35 degrees Celsius Ace Axcel 15 to 27 degrees Celsius 4. Interviews with the laboratory lead, testing personnel and the lab director on 08/30/23 at 6 pm confirmed the laboratory failed to ensure monitoring of environmental conditions that was consistent with manufacturer's requirements in 2022 and 2023.

**D5423**

**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:

Based on observation of the laboratory, staff interview, review of manufacturer package inserts, lack of documentation, patient test reports and staff interview, the laboratory failed to establish performance specifications for the performance of total bilirubin (TBIL) on specimens collected from neonates on the Alfa Wasserman Ace Axcel total bilirubin chemistry reagent with patient testing performed on a total of five patients since 10/28/2021. The findings include: 1. Observation of the laboratory on 08/30/2023 at 8:30 am revealed the Alfa Wasserman ACE Axcel chemistry instrument (serial #16110350) in use for patient testing. 2. During an interview with testing person number two, conducted during the observation on 08/30/2023 at 8:30 am, testing person two stated the laboratory performs patient testing for TBIL on neonates. 3. Review of the manufacturer's package insert for the TBIL reagent revealed the following under the section titled "Conditions for Use": "The ACE Total Bilirubin Assay is not indicated for use on neonates, as its performance has not been validated using neonatal samples." 4. The laboratory was unable to provide any evidence that establishment studies had been performed for use of the TBIL reagent on neonatal samples. 5. Review of patient test reports revealed a total of eight TBIL results had been reported since 10/28/21 on five different neonatal patients as follows: H35509 on 10/28/2021 (age 19 days) H36238 on 08/11/2022 (age 5 days) H36369 on 10/06/2022 (age 22 days) H36591 on 01/13/2023 (age 5 days) and 01/17/2023 (age 9 days) H37193 on 08/09/2023 (age 3 days), 08/11/2023 (age 5 days), and 08/14/2023 (age 8 days) 6. Interview with laboratory lead, testing personnel and lab director on 08/30/23 at 6 pm confirmed the laboratory performed total bilirubin testing on neonates in 2021, 2022, and 2023 using the Alfa Wasserman TBIL reagent. They further confirmed the laboratory did not establish performance specifications for use of the TBIL reagent on neonatal samples.

**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 of the laboratory, review of calibration verification reports, review of an audit journal and instrument screen shots, interview with the lead testing person, and staff interviews, the laboratory's quality assessment process was ineffective when it did not ensure all calibration verification levels tested were

included in evaluation of the laboratory's reportable range for tests performed on the ACE Axcel chemistry instrument for the calibration verification performed in July 2023. The findings include: 1. Observation of the laboratory on 08/30/2023 at 8:30 am revealed the Alfa Wasserman ACE Axcel chemistry instrument (serial #16110350) in use for patient testing. 2. Review of the laboratory's ACE Axcel calibration verification report from the calibration verification performed on 07/31/2023 revealed the following: Potassium - Level A and E not evaluated. Chloride - Level E not evaluated. Carbon Dioxide - Level A not evaluated. Blood Urea Nitrogen - Level A not evaluated. Alkaline Phosphatase - Level A not evaluated. Cholesterol - Level E not evaluated. High Density Lipoprotein (HDL) Cholesterol - Level D and Level E not evaluated. Direct Bilirubin - Level D and Level E not evaluated. 3. Review of the an audit journal and screen shots from the Alfa Wasserman ACE Axcel instrument revealed that testing for Level A was performed for Alkaline Phosphatase, Carbon Dioxide, Blood Urea Nitrogen, and Potassium; testing for Level D was performed for HDL Cholesterol and Direct Bilirubin; and testing for Level E was performed for Potassium, Chloride, Cholesterol, HDL cholesterol and Direct Bilirubin. 4. Interview with the lead testing person on 08/30/2023 at 2:30 pm revealed the following statements: The laboratory uses the manufacturer analytic measurement ranges as define in the package inserts for all tests performed on the ACE Axcel chemistry instrument. The laboratory ran all five levels of the calibration verification materials on all analytes. If results return a less than or greater than result, the laboratory does not submit those results to the data processing program to be evaluated. The laboratory did not perform a self-evaluation of those results. 5. Review of the laboratory policy titled "Quality Assessment" revealed the following: "The laboratory director oversees the implementation of the QA plan and helps identify and correct problems as they occur. The QA process involves investigation, identification and resolution of the problem with subsequent development of policies that will prevent recurrence." 6. Interviews on 08/30/23 at 6 pm with the laboratory lead, testing personnel and lab director confirmed the laboratory's quality assessment process was ineffective when it did not submit results to the calibration verification data evaluation program, did not perform a self-evaluation of results that were not submitted, and did not perform corrective action for the missing data evaluation points.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on review of final patient test reports and staff interview, the reference range on the final patient test report for Total Bilirubin was not appropriate for testing performed on neonate samples for eight of eight reports reviewed from 10/28/2021 to 08/14/2023. The findings include: 1. Review of final patient test reports for total bilirubin performed on samples from neonates revealed that eight of eight reports did not include appropriate reference ranges. Reports reviewed were from 2021, 2022, and 2023. 2. Interview on 08/30/23 at 6 pm with the lab director confirmed the Total Bilirubin reference range included on the final report for neonates was not appropriate for the age group.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on observations, review of manufacturer instructions for use, patient test reports, personnel records and staff interviews the laboratory director failed to meet the regulatory requirements for directing high complexity testing (Refer to D6078).

**D6078**

**LABORATORY DIRECTOR QUALIFICATIONS**

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of manufacturer package inserts, staff interview, review of patient test reports, personnel records and staff interview, the laboratory director failed to meet the qualifications for directing high complexity testing. The findings include: 1. Observation of the laboratory on 08/30/2023 at 8:30

am revealed the Alfa Wasserman ACE Axcel chemistry instrument (serial #16110350) in use for patient testing. 2. Review of the manufacturer package insert for the Total Bilirubin reagent revealed the following under the section titled "Conditions for Use": "The ACE Total Bilirubin Assay is not indicated for use on neonates, as its performance has not been validated using neonatal samples." 3. Staff interview with testing person number two, conducted during the observation on 08/30/2023 at 8:30 am, revealed the laboratory performs patient testing for TBIL on neonates using the manufacturer's Total Bilirubin reagent, resulting in a laboratory-developed high-complexity assay. 4. Review of patient test reports revealed a total of eight TBIL results had been reported since 10/28/21 on five different neonatal patients as follows: H35509 on 10/28/2021 (age 19 days) H36238 on 08/11/2022 (age 5 days) H36369 on 10/06/2022 (age 22 days) H36591 on 01/13/2023 (age 5 days) and 01/17/2023 (age 9 days) H37193 on 08/09/2023 (age 3 days), 08/11/2023 (age 5 days), and 08/14/2023 (age 8 days) 5. Review of the laboratory's personnel records revealed no evidence that the laboratory director met the regulatory requirements for directing high complexity testing. 6. Interview with the laboratory lead, testing personnel and the lab director on 08/30/23 at 6 pm confirmed the laboratory performed bilirubin testing on neonates in 2021, 2022, and 2023 using the Alfa Wasserman TBIL reagent, which was outside the manufacturer conditions for use, resulting in a laboratory-developed, high-complexity assay. The director confirmed he did not meet the regulatory requirements for directing high-complexity testing.

**D6108**

**LABORATORY TECHNICAL SUPERVISOR**  
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:  
Based on observation of the laboratory, review of manufacturer package inserts, staff interviews, review of patient test reports and personnel records, the laboratory director failed to meet the regulatory requirements for providing technical supervision of high complexity chemistry testing (Refer to D6111).

**D6111**

**TECHNICAL SUPERVISOR QUALIFICATIONS**  
CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in

clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which

the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which

the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must-- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is

located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a

training program leading to certification specified in paragraph (b) or (1)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (1)(2) For tests in dermatopathology, meet one of the following requirements: (1)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (1)(2)(i)(B) Meet one of the following requirements: (1)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (1)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (1)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (1)(2)(ii) An individual qualified under 493.1449(b) or paragraph (1)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (1)(3) For tests in ophthalmic pathology, meet one of the following requirements: (1)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (1)(3)(i)(B) Must meet one of the following requirements: (1)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (1)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (1)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or

experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high

complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of manufacturer package inserts, staff interview, review of patient test reports, personnel records and staff interview, the laboratory director failed to meet the qualifications for providing technical supervision of high complexity testing in chemistry. The findings include: 1. Observation of the laboratory on 08/30/2023 at 8:30 am revealed the Alfa Wasserman ACE Axcel chemistry instrument (serial #16110350) in use for patient testing. 2. Review of the manufacturer package insert for the Total Bilirubin reagent revealed the following under the section titled "Conditions for Use": "The ACE Total Bilirubin Assay is not indicated for use on neonates, as its performance has not been validated using neonatal samples." 3. Staff interview with testing person number two, conducted during the observation on 08/30/2023 at 8:30 am, revealed the laboratory performs patient testing for TBIL on neonates using the manufacturer's Total Bilirubin reagent, resulting in a laboratory- developed high-complexity assay. 4. Review of patient test reports revealed a total of eight TBIL results had been reported since 10/28/21 on five different neonatal patients as follows: H35509 on 10/28/2021 (age 19 days) H36238 on 08/11/2022 (age 5 days) H36369 on 10/06/2022 (age 22 days) H36591 on 01/13/2023 (age 5 days) and 01/17/2023 (age 9 days) H37193 on 08/09/2023 (age 3 days), 08/11/2023 (age 5 days), and 08/14/2023 (age 8 days) 5. Review of the laboratory's personnel records revealed no evidence that the laboratory director met the regulatory requirements for performing technical supervisor duties. 6. Interview with the laboratory lead, testing personnel and the lab director on 08/30/23 at 6 pm confirmed the laboratory performed bilirubin testing on neonates in 2021, 2022, and 2023 using the Alfa Wasserman TBIL reagent, which was outside the manufacturer conditions for use, resulting in a laboratory-developed, high-complexity assay. The director confirmed he did not meet the regulatory requirements for performing technical supervisor duties.