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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D0441673 | (X3) Date Survey Completed 08/13/2024 |
| Name of Provider or Supplier Scotland County Hospital | Street Address, City, State 450 E Sigler Ave, Memphis, MO | |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D5400 | <p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of Cell-Dyn hematology procedure, calibration records for the Cell-Dyn hematology analyzer, calibration records on the Architect Plus ci4100 chemistry analyzer, Biofire quality control records, Architect Plus ci4100 chemistry analyzer quality control records, review of analytes on the Architect Plus ci4100 chemistry analyzer, hematology records, Nova Prime Plus blood gas analyzer quality control, blood gas patient results, laboratory procedures, ACL Elite coagulation analyzer quality control, blood bank patient logs, blood bank quality control logs, blood bank procedure manual, blood bank alarm check log and interview with the general supervisor (GS) #1 the laboratory failed to perform a calibration every six months (Refer to D5437), failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range (Refer to D5439), the laboratory failed to perform a negative and positive controls each date of patient testing (Refer to D5449), the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results (Refer to D5469), the laboratory failed to document the quality of staining materials each day of use for manual differentials (Refer to D5473), the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing for blood gases</p> |

(Refer D5537), the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing for blood gases (Refer to D5545), the laboratory failed to document blood bank quality control each day of patient testing (Refer to D5551), the laboratory failed to perform blood bank alarm inspections every 6 months (Refer to D5555).

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of Cell-Dyn hematology procedure, 2022, 2023 to date August 13, 2024 calibration records for the Cell-Dyn hematology analyzer and interview with general supervisor (GS) #1, the laboratory failed to perform a calibration every six months in 2022, 2023 and to date August 13, 2024. Findings: 1. Review of "Cell-Dyn Ruby System Operator's Manual" states "Calibration of the Cell-Dyn Ruby may need to be verified in the following, at least every six months". 2. Review of calibration records for the Cell-Dyn hematology analyzer for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet revealed the laboratory failed to perform a calibration every six months in 2022, 2023 and to date August 13, 2024. 2. Interview with the GS #1 on August 13, 2024 at 2:00 PM confirmed the laboratory failed to perform a Cell-Dyn hematology analyzer calibration every six months.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable

limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of 2022, 2023, and to date August 13, 2024 calibration records on the Architect Plus ci4100 chemistry analyzer for 22 of 49 analytes and interview with the general supervisor (GS) #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of Architect Plus ci4100 calibration records for 2022, 2023, and to date August 13, 2024 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analyte iron. 2. Interview with the GS #1 on August 13, 2024 at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for iron testing.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

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

This STANDARD is not met as evidenced by:

Based on review of the Biofire quality control (QC) records, and interview with the general supervisor (GS) #1, the laboratory failed to perform a negative and positive control each day of patient testing from January 2023 to date August 13, 2024. Findings: 1. Review of January 2023 to date August 13, 2024 QC records showed the laboratory failed to perform a negative and positive control each day of patient testing for the tests: adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, severe acute respiratory syndrome coronavirus 2, human metapneumovirus, human rhinovirus/enterovirus, influenza A H1-2009, influenza A H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza 4, and respiratory syncytial virus. 3. Interview with the GS #1 on August 13, 2024 at 11:30 AM confirmed the laboratory failed to perform a negative and positive control each day of patient testing.

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:

Based on review of the Architect Plus ci4100 chemistry analyzer quality control (QC) records, review of 3 of 49 analytes on the Architect Plus ci4100 chemistry analyzer, and interview with the general supervisor (GS) #1, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results. Findings: 1. Review of the Architect Plus ci4100 QC records showed the laboratory used assayed Thermo Scientific MAS ChemTrak QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative chemistry QC when they had to change the ranges from the manufacturer's established ranges. 2. Review of assayed QC on the Architect Plus ci4100 analyzer showed alkaline phosphatase level 3 QC range of 317-476 U/L. Thermo Scientific MAS ChemTrak manufacturer's package insert level 3 for alkaline phosphatase revealed an assayed value range of 249-373 U/L. The laboratory could not provide documentation for how alkaline phosphatase QC range was established. 3. Review of assayed QC on the Architect Plus ci4100 analyzer showed total bilirubin level 1 QC range of .54-.82 mg/dL. Thermo Scientific MAS ChemTrak manufacturer's package insert level 1 for total bilirubin revealed an assayed value range of .66-.98 mg/dL. The laboratory could not provide documentation for how total bilirubin QC range was established. 4. Review of assayed QC on the Architect Plus ci4100 analyzer showed total bilirubin level 3 QC range of 5.16-7.74 mg/dL. Thermo Scientific MAS ChemTrak manufacturer's package insert level 3 for total bilirubin revealed an assayed value range of 4.49-6.73 mg/dL. The laboratory could not provide documentation for how total bilirubin QC range was established. 5. Interview with the GS #1 on August 13, 2024 at 1:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of hematology records and interview with the general supervisor (GS) #1, the laboratory failed to document the quality of staining materials each day of use for manual differentials for August 1, 2024 to date August 13, 2024. Findings: 1. Review of stain quality records, the laboratory failed to document stain quality on

August 1 and August 6, 2024 2. Interview with GS #1 on August 13, 2024 at 1:00 PM confirmed the laboratory failed to document the quality of the manual differential stain each day of use.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of Nova Prime Plus blood gas analyzer quality control (QC), patient results and interview with the general supervisor (GS) #1, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing for 135 of 498 days. Findings: 1. Review of the Nova Prime Plus blood gas analyzer QC showed no documentation of QC each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing from April 2023 to August 13, 2023 for the analytes pH, pCO₂, pO₂ and lactic acid. 2. The laboratory was unable to provide the volume of patient tests performed on the Nova Prime Plus testing while QC was not performed. 4. Interview with the GS #1 on August 13, 2024 at 11:30 AM confirmed the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

D5545

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

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

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, ACL Elite coagulation analyzer quality control (QC), bioMerieux Vidas analyze QC, patient results and interview with general supervisor (GS) #1, the laboratory failed to include two levels of control materials each 8 hours of patient testing for Prothrombin time (PT) and activated partial thromboplastin time (APTT) from June 12 to June 30, 2024 and D-Dimer from January 1, 2024 to date August 12, 2024. Findings: 1. Review of laboratory procedure, "Quality Assurance Plan for the Clinical Laboratory" states "has 2 levels of QC performed at least every 8 hours of patient testing." 2. Review of ACL Elite coagulation analyzer QC showed QC was not performed every 8 hours on the following days: June 12, June 19, June 26 and June 30. 3. Review of PT patient results showed 4 patient were resultd while QC was not performed. 4. Review of APTT patient results showed 2 patient results were while QC was not performed. 5. Review of bioMerieux Vidas analyzer showed D-Dimer QC was not performed every 8 hours for 103 of 224 days 6. Review of D-Dimer patient testing showed 152 out of 191 patients were resultd while QC was not performed every 8 hours. 7. Interview with

GS #1 on August 13, 2024 at 11:00 AM confirmed the laboratory failed to perform two levels of control materials each 8 hours of patient testing for PT, APTT, and D-Dimer.

D5551

IMMUNOHEMATOLOGY

CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 blood bank procedures, blood bank patient logs, blood bank quality control (QC) logs, and interview with the general supervisor (GS) #1, the laboratory failed to document QC for one patient testing day from March 2023 to date August 13, 2024. Findings: 1. Review of the laboratory's procedure "Quality Assurance Plan for the Clinical Laboratory" states "Blood Bank quality control is performed once per each day of patient testing". 2. Review of blood bank patient testing logs showed ABO grouping and Rh typing patient testing was performed on March 19, 2023. 3. Review of blood bank QC logs showed no documented QC on March 19, 2023. 4. Interview with the GS #1 on August 13, 2024 at 12:30 PM confirmed the laboratory failed to document quality control each day of patient testing. 47802 Based on review of blood bank procedures, blood bank patient log, blood bank quality control (QC) log, and interview with the general supervisor (GS) #1, the laboratory failed to document QC for the tube method from May 1, 2024 to date August 13, 2024. Findings: 1. Review of the blood bank procedures showed there was no procedure for performing and documenting QC for the tube method used for compatibility testing. 2. Review of blood bank patient testing log showed tube method compatibility testing was performed on the following days: May 2024: 7, 18, 24, 28, 30, and 31 June 2024: 1, 18, and 20 July 2024: 8, 10, 15, 19, 22, 24, and 27 3. Review of blood bank patient log showed 34 units were tested for compatibility by tube method from May 1, 2024 to date August 13, 2024. 4. Review of blood bank QC log showed no documented QC from May 1, 2024 to date August 13, 2024. 5. Interview with GS #1 on August 13, 2024 at 10:30 AM confirmed the laboratory failed to perform and document QC for tube method each day of patient testing.

D5555

IMMUNOHEMATOLOGY

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

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

This STANDARD is not met as evidenced by:
Based on review of the blood bank procedure manual, blood bank alarm check log, and interview with the general supervisor (GS) #1, the laboratory failed to perform blood bank refrigerator alarm inspections every 6 months from October 2021 to date August 13, 2024 according to the laboratory's established procedure. Findings: 1. Review of blood bank procedure "BB Temperature Alarm Checks" states, "To be completed every 6 months". 2. Review of the laboratory's blood bank alarm check log showed blood bank refrigerator alarm inspections were not completed every 6 months from October 2021 to date August 13, 2024. 3. Interview with the GS #1 on August 13, 2024 at 11:00 AM confirmed, the laboratory failed to perform blood bank refrigerator alarm inspections according to the laboratory's established procedure.

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 review of blood gas analyzer verification procedures, review of College of American Pathologists (CAP) immunohematology proficiency testing (PT) records for 2024, personnel records, laboratory blood bank procedures, and interview with general supervisor #1, the laboratory director failed to ensure the verification procedure for the Nova Prime Plus blood gas analyzer verified the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population (Refer to D6086), the laboratory director failed to ensure return of the PT results to CAP within the timeframe specified resulting in unsatisfactory performance with a score of zero percent for the testing event (refer to D6090), the laboratory director failed to ensure one of five testing personnel (TP) received appropriate training prior to testing patient specimens for high complexity testing (Refer to D6102), and the laboratory failed to provide an approved written procedures for the blood bank department (Refer to D6106).

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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 review of Nova Prime Plus blood gas analyzer verification procedures and interview with the general supervisor (GS) #1, the laboratory director failed to ensure the verification procedure for the Nova Prime Plus blood gas analyzer verified the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Findings: 1. Review of the Nova Prime Plus blood gas analyzer verification procedure showed no verification for normal values for the analytes pH, pCO₂, pO₂ and lactic acid. 2. Interview with the GS #1 on August 13, 2024 at 1:00

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| | <p>PM confirmed the laboratory director failed to verify normal values pH, pCO₂, pO₂ and lactic acid are appropriate for the laboratory's patient population.</p> |
| <p>D6090</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii)</p> <p>The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) immunohematology proficiency testing (PT) records for 2024 and interview with the general supervisor (GS) #1 revealed the laboratory director failed to ensure return of the PT results to CAP within the timeframe specified, resulting in unsatisfactory performance with a score of zero percent for the testing event. Findings: 1. Review of the J-A event of 2024 for immunohematology PT records showed a score of zero percent for ABO group and D typing, unexpected antibody detection, and compatibility testing. 2. Interview with the GS on August 13, 2024 at 2:00 PM confirmed the laboratory director failed to ensure return of the PT results to CAP within the timeframe specified and scored an unsatisfactory performance of zero percent.</p> |
| <p>D6102</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the general supervisor (GS), the laboratory director failed to ensure one of five testing personnel (TP) received appropriate training prior to testing patient specimens for high complexity testing. Findings: 1. Review of personnel records, showed the laboratory could not provide documentation for annual training prior to testing patient specimens for TP #5. 2. Interview with the GS on August 13, 2024 at 9:30 AM confirmed the laboratory director failed ensure TP received appropriate training prior to testing patient specimens for high complexity testing.</p> |
| <p>D6106</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory blood bank procedures and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to provide an approved written procedures for the blood bank department. Findings: 1. Review of the laboratory</p> |

procedures showed no approved procedure in the blood bank department for checking patient history, weak D, and quality control procedures for weak D and tube method testing. 2. Interview with the GS #1 on September 13, 2023 at 10:00 PM confirmed the LD could not provide an approved written procedure for the blood bank department.