| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 16D0382761 | 11/26/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Guthrie County Hospital | 710 North 12th Street, Guthrie Center, IA | |

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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| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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. In addition, retain the following:<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Vitros 7600 maintenance records and confirmed by interview with General Supervisor (GS) #1 at 8:24 am on 11/26/2025, the laboratory failed to retain daily, weekly, and monthly maintenance for the Vitros 7600 chemistry analyzer for 92 out of 92 days, 14 out of 14 weeks and three out of three months from 7/1/2025 - 9/30/2025. The findings include: 1. On 7/1/2025, the laboratory started using the Vitros 7600 chemistry analyzer to perform patient testing. 2. The laboratory performed and documented daily, weekly and monthly maintenance directly on the Vitros 7600 chemistry analyzer. 3. The Vitros 7600 chemistry analyzer would only retain approximately two months worth of maintenance records. 4. At the time of the survey, GS #1 confirmed the laboratory did not realize the Vitros 7600 chemistry analyzer wouldn't store all of the maintenance records. GS #1 confirmed the laboratory did not retain daily, weekly, and monthly maintenance records for the Vitros 7600 chemistry analyzer from 7/1/2025 - 9/30/2025. |
| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score |

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| | for nonparticipation, or late return or results).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records and confirmed by interview with General Supervisor (GS) #1 at 1:32 pm on 11/25/2025, the laboratory failed to perform a self evaluation when the laboratory received ungraded PT scores from five out of six PT events from 01/01/2024- 11/26/2025. The findings include: 1. For 2024 event 1, the laboratory received ungraded PT test scores for the following: *Respiratory panel sample RSP-01 (Influenza A) *Total bilirubin samples CH-02, CH-03 and CH-05 2. For 2024 event 2, the laboratory received ungraded PT test scores for the following: *Respiratory Panel sample RSP-08 (Parainfluenza virus) *Iron sample CH-08 3. For 2024 event 3, the laboratory received ungraded PT test scores for the following: * Respiratory panel sample RSP-13 (Influenza A) 4. For 2025 event 2, the laboratory received ungraded PT test scores for the following: *Total bilirubin samples CH-07, CH-09, and CH-10 *Total iron binding capacity sample CH-06 *Folate samples IA-07 and IA-09 5. For 2025 event 3, the laboratory received ungraded PT test scores for the following: *Total bilirubin samples CH-12 and CH-15 *Low density lipoprotein samples CH-11 and CH-13 6. At the time of the survey, GS#1 confirmed the laboratory did not document a self evaluation for the above ungraded PT scores. |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records and confirmed by interview with General Supervisor (GS) #1 at 1:32 pm on 11/25/2025, the laboratory failed to take and document corrective action when they received unacceptable PT for four out of six PT testing events from 01/01/2024- 11/26/2025. The findings include: 1. For 2024 testing event 1, the laboratory received unacceptable PT test scores for the following: *Partial pressure of oxygen - 80% *Creatine kinase - 80% *Phosphorus - 80% *Total protein - 80% *Manual cell identification - 80% *Procalcitonin - 33% 2. For 2024 testing event 3, the laboratory received unacceptable PT test scores for the following: *Calcium - 80% 3. For 2025 testing event 1, the laboratory received unacceptable PT test scores for the following: *Partial pressure of oxygen - 80% *Manual cell identification - 80% *Partial thromboplastin time - 80% *International Normalized Ratio - 80% 4. For 2025 testing event 3, the laboratory received unacceptable PT test scores for the following: *Albumin - 80% *Partial pressure of oxygen - 80% *Carbon dioxide - 80% 5. At the time of the survey, GS #1 confirmed the laboratory did not have corrective action documented for the above unacceptable PT scores. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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 |

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| | 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of quality control (QC) records, laboratory policies and procedures, and patient test reports and confirmed by interview with the General Supervisor, the laboratory failed to ensure that the laboratory performed two levels of QC each day of patient testing as specified in D5447 and D5451; the laboratory failed to perform compatibility testing using procedures that demonstrate incompatibility between the donor's cell type and the recipient's serum as specified in D5551; and the laboratory failed to meet their established criteria of acceptability when performing QC as specified in D5783. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Blood Bank - MTS Dispenser procedure, MTS dispenser maintenance records and confirmed by interview with the General Supervisor (GS) #1 at 9:45 am on 11/26/2025, the laboratory failed to perform weekly maintenance on the MTS blood bank dispenser for 31 out of 42 weeks from 1/1/2025 - 10/14/2025. The findings include: 1. The Blood Bank - MTS Dispenser states, "....the dispenser be cleaned with alcohol weekly to avoid contamination." 2. The MTS Dispenser maintenance records revealed the laboratory cleaned the dispenser on: 2/3/2025, 3/5 /2025, 4/11/2025, 6/8/2025, 7/26/2025, 9/21/2025, 9/26/2025, 9/30/2025, 10/2/2025, 10/7/2025 and 10/14/2025. 3. At the time of the survey, GS #1 confirmed the laboratory did not perform weekly cleaning of the MTS dispenser. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Vitros 7600 quality controls (QC) records, the Quality Control procedure, and confirmed by interview with General Supervisor (GS) #1 at 8:24 am on 11/26/2025, the laboratory failed to perform two levels of chemistry QC for seven out of 31 days of patient testing from 7/1/2025 - 7/31/2025. The findings include: 1. The Quality Control procedure states, "Chemistry....two levels of quality control material are to be run each day of use." 2. On 7/2/2025 the laboratory performed total bilirubin testing on patients, but only ran QC level three. 3. On 7/9/2025 the laboratory performed total bilirubin testing on patients, but only ran QC level three. 4. On 7/10/2025 the laboratory performed total bilirubin testing on patients, but only ran QC level one. In addition, the laboratory performed troponin and B-type natriuretic peptide (pro-BNP), but only ran QC level three. 5. On 7/11/2025 the laboratory performed total bilirubin and direct bilirubin testing on patients, but only ran QC level one. 6. On 7/12/2025 the laboratory performed total bilirubin testing on patients, but |

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| | failed to run two levels of QC. 7. On 7/13/2025 the laboratory performed total bilirubin testing on patients, but failed to run two levels of QC. 8. On 7/16/2025 the laboratory performed procalcitonin and thyroid stimulating hormone testing on patients, but only ran QC level three. In addition, the laboratory performed free thyroxine testing on patients, but only ran QC level two. 9. At the time of the survey, GS #1 confirmed the laboratory did not perform two levels of QC for the above dates of patient testing. |
| **D5451** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(iii)(g)<br><br>(d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Blood Bank - Antibody Screen by (GEL) procedure, blood bank quality control records and confirmed by interview with General Supervisor (GS) #1 at 9:45 am on 11/26/2025, the laboratory failed to perform a negative control each day of patient testing for one out of one patient that had an unexpected antibody screen performed on 7/27/2025. The findings include: 1. Patient A had an unexpected antibody screen performed on 7/27/2025. 2. The Blood Bank - Antibody Screen by (GEL) procedure states, "To recognize reagent deterioration and to confirm the specificity and reactivity of the gel system, the Ortho Confidence Control System will be used each day of testing. The MTS control microtube should be negative." 3. On 7 /27/2027, the laboratory performed positive (graded) QC for the undetected antibody screen, but not a negative control. 4. At the time of the survey, GS #1 confirmed the laboratory did not perform a negative control for the undetected antibody screen. |
| **D5551** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(a)(f)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Blood Bank Crossmatch procedure, patient compatibility records and confirmed by interview with General Supervisor (GS) #1 at approximately 9:45 am on 11/26/2025, the laboratory failed to perform compatibility testing using procedures that demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type for one out of one patient that had compatibility testing performed on 7/27/2025. The findings include: 1. Patient identifier A had compatibility testing performed on one unit of packed red blood cells on 7/27/2025. 2. The Blood Bank Crossmatch procedure only specified using the MTS Anti-Human Globulin Anti-IgG gel card for performing a patient crossmatch, the Blood Bank Crossmatch procedure did not include performing an immediate spin |

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| | crossmatch. 3. An immediate spin crossmatch is necessary to detect IgM antibodies and ensure ABO compatibility. 4. At the time of the survey, GS #1 confirmed the laboratory did not perform compatibility testing using a method that specifically demonstrated incompatibility between the donor's cell type and the recipient's serum or plasma. |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Blood Bank Quality Assurance policy, blood bank system alarm check records, and confirmed by interview with General Supervisor (GS) #1 at 9:45 am on 11/26/2025, the laboratory failed to inspect, perform, and document semi-annual alarm system checks for the blood storage refrigerator for one out of two time periods from 01/01/2025 - 11/26/2025. The findings include: 1. The Blood Bank Quality Assurance policy states, "Blood bank refrigerator:...Every six months the high and low range of the alarm is checked." 2. On 11/24/2025, the laboratory performed and documented an alarm check on the blood bank refrigerator. 3. At the time of the survey, GS #1 confirmed the laboratory did not perform blood bank refrigerator alarm checks every six months. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Vitros 7600 quality control (QC) records, the Quality Control policy and confirmed by interview with General Supervisor #1 (GS #1) at 8:24 am on 11/26/2025, the laboratory failed to take corrective action when the QC failed to meet their established critieria of acceptability for 28 out of 31 days of patient testing from 7 /1/2025 - 7/31/2025. The findings include: 1. The Quality Control policy states, "Chemistry - Westgard rules as defined below will be used to determine acceptability. The following outlines Westgard's rules: Reject run if any of the following criteria are met: One control exceeds control limits set at plus or minus 3 SD (Standard Deviation) from the mean. Two controls exceed control limits set at plus or mius 2 SD two times in a row." 2. The laboratory did not take corrective action when the following QC fell outside the their established criteria of acceptability: *7/1/2025: total cholesterol level 1 = 2.53 SD; and total cholesterol level 3 = 2.56 SD *7/2/2025: total cholesterol level 1 = 3.19 SD; total cholesterol level = 3.42 SD; carbon dioxide |

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| | (CO2) level 1 = -4.73 SD; and CO2 level 3 = -4.53 SD *7/5/2025: CO2 level = -3.39 SD *7/7/2025: total cholesterol level 1 = 3.87 SD; and total cholesterol level 3 = 2.50 SD *7/8/2025: total cholesterol level 1 = 3.46 SD *7/9/2025: total cholesterol level 1 = 3.22 SD; and total cholesterol level 3 = 2.27 SD *7/10/2025: total cholesterol level 1 = 3.17 SD; and total cholesterol level 3 = 2.25 SD *7/11/2025: total cholesterol level 1 = 3.70 SD; chloride level 3 = 4.43 SD; sodium level 3 = -7.96 SD; potassium level 3 = -5.78 SD; urea nitrogen level 3 = -12.17 SD; creatinine level 3 = -4.91 SD; CO2 level 3 = -4.32 SD; alkaline phosphatase level 3 = -21.88 SD; creatine kinase level 3 = -14.47; triglycerides level 3 = -33.51 SD; total cholesterol = -15.96 SD; iron level 3 = -29.62; phosphorus level 3 = -7.60 SD; glucose level 3 = -26.14 SD; calcium level 3 = -19.20 SD; lactic acid level 3 = 25.70 SD; and total iron binding capacity level 3 = -21.86 SD *7/12/2025: albumin level 1 = -4.69 SD; albumin level 2 = -6.27 SD; and vancomycin level 1 = 3.18 *7/13/2025: albumin level 1 = -5.17 SD; albumin level 2 = -5.78 SD *7/14/2025: albumin level 1 = -4.84 SD; albumin level 2 = -5.70 SD; total cholesterol level 1 = 3.31 SD; total cholesterol level 3 = 3.57 SD; and vancomycin level 1 = 4.46 SD *7/15/2025: total cholesterol level 1 = 3.18 SD; and total cholesterol level 3 = 2.73 SD *7/16/2026: albumin level 1 = -4.62 SD; albumin level 2 = -4.70 SD; total cholesterol level 1 = 3.13 SD; glucose level 3 = -5.53 SD; and procalcitonin level 3 = 3.50 SD *7/17/2025: total cholesterol level 1 = 3.42 SD; total cholesterol level 3 = 2.30 SD; and albumin level 2 = -5.09 SD *7/18/2025: albumin level 1 = -4.37 SD; albumin level 2 = -4.47 SD; total cholesterol level 1 = 4.64 SD; total cholesterol level 3 = 2.70 SD; CO2 level 1 = -3.33 SD; and CO2 level 3 = -5.35 SD. *7/19/2025: albumin level 1 = -4.54 SD; and albumin level 2 = -4.81 SD *7/20/2025: albumin level 1 = -4.27 SD; and albumin level 2 = -3.27 SD *7/21/2025: albumin level 1 = -4.69 SD; albumin level 2 = -5.68 SD; total cholesterol level 1 = 3.05 SD; total cholesterol level 3 = 2.16 *7/22/2025: albumin level 1 = -4.54 SD; albumin level 2 = -4.57 SD; total cholesterol level 1 = 2.40 SD; and total cholesterol level 3 = 2.52 SD; glucose level 1 = 2.38 SD; and glucose level 3 = 4.45 SD *7/23 /2025: albumin level 1 = -4.32 SD; albumin level 2 = -4.50 SD; urea nitrogen level 1 = 3.36 SD; glucose level 1 = 2.97 SD; and glucose level 3 = 3.37 SD; total cholesterol level 1 = 3.19 SD; and total cholesterol level 3 = 2.09 SD *7/24/2025: albumin level 1 = -4.58 SD; albumin level 2 = -3.21 SD; glucose level 1 = 2.59 SD; and glucose level 3 = 3.18 SD; total cholesterol level 1 = 3.06 SD; and total cholesterol level 3 = 2.50 SD *7/25/2025: albumin level 1 = -4.79 SD; albumin level 2 = -4.99 SD; total cholesterol level 1 = 3.41 SD; and total cholesterol level 3 = 2.67 SD *7/26/2025: albumin level 1 = -4.26 SD; albumin level 2 = -4.55 SD; urea nitrogen level 1 = 5.20 SD; and urine nitrogen level 3 = 2.93 SD *7/27/2025: albumin level 1 = -4.26 SD; albumin level 2 = -5.45 SD; urea nitrogen level 1 = 3.20 SD; and urine nitrogen level 3 = 2.93 SD *7/28/2025: albumin level 1 = -4.75 SD; albumin level 2 = -6.84 SD; urea nitrogen level 1 = 2.72 SD; and urine nitrogen level 3 = 2.69 SD *7/29/2025: albumin level 1 = -4.16 SD; albumin level 2 = -6.55 SD; glucose level 1 = 2.99 SD; and glucose level 3 = 3.89 SD *7/30/2025: albumin level 1 = -4.39 SD; albumin level 2 = -5.36 SD; glucose level 1 = 3.09 SD; glucose level 3 = 3.89 SD; and urine microalbumin level 1 = 82.39 SD *7/31/2025: albumin level 1 = -4.71 SD; albumin level 2 = -5.47 SD; glucose level 1 = 2.59 SD; glucose level 3 = 4.32 SD; total cholesterol level 1 = 3.03; total cholesterol level 3 = 3.32 SD; chloride level 3 = 5.83 SD; sodium level 3 = -8.30 SD; potassium level 3 = -5.04 SD; and CO2 level 3 = -5.46 SD. 3. At the time of the survey, GS #1 confirmed the laboratory did not take corrective action for the above dates when QC fell outside of the established criteria of acceptability. GS #1 also confirmed that the laboratory reported out patient results on the above dates when QC fell outside of the established criteria of acceptability. |