Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652272	06/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Harrison County Community Hospital	2600 Miller Street, Bethany, 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
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 2019, 2020 and to date June 15, 2021. Findings: 1. Review of hematology records showed the laboratory failed to document the quality of staining materials each day of use for manual differentials. 2. Interview with GS #1 on June 15, 2021 at 10:15 AM confirmed the laboratory failed to document the quality of the manual differential stain each day of use.
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 and interview with the general supervisor (GS) #1, the laboratory failed to provide a procedure for checking patient history and manually washing cells. Findings: 1. Review of blood bank procedures showed no procedure for checking patient history prior to performing blood bank procedures. Interview with GS #1 stated "blood bank cards and Community Blood Center American Red Cross book is checked for blood bank patient history". 2. Review of blood bank procedures showed no procedure for manually washing cells. The blood bank cell washer has been out of service since summer 2020 and the laboratory has been manually washing cells. 3. Interview with the GS #1 on June 15, 2021 at 1:00 PM confirmed the laboratory failed to provide a blood bank procedure for checking patient history and washing cells manually.
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 "ABG Lab Reference Ranges" procedure, blood gas patient report, and interview with the general supervisor (GS) #1 , the laboratory failed to ensure the blood gas procedure reference ranges matched the reference ranges on the blood gas patient report. Findings: 1. Review of the "ABG Lab Reference Ranges" procedure showed the reference ranges as: pCO2: 35 - 48 mmHg pO2: 83 - 108 mmHg tHb: 11.7 - 17.4 g/dL O2Hb: 95.0 - 98.0 % COHb: 0.5 - 1.5 % MetHb: 0 - 1.5 % BE: -2.0 - 3.0 mmol/L 2. Review of the blood gas patient report showed the reference ranges as: pCO2: 35 - 45 mmHg pO2: 80 - 100 mmHg tHb: 12.0 - 15.0 g/dL O2Hb: 94.0 - 100.0 % COHb: 0.0 - 2.0 % MetHb: 0.0 - 2.0 % BE: -2.0 - 2.0 mmol/L 3. Interview with the GS #1 on June 15, 2021 at 11:30 AM confirmed the laboratory failed to ensure the blood gas procedure reference ranges matched the reference ranges on the blood gas patient report.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records, interviews with the general supervisor (GS) #1, and director of nursing, the laboratory failed to provide academic qualifications required to perform moderate complexity testing for seventeen of twenty-eight testing personnel. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS

	CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of academic credentials and interviews with the general supervisor (GS) #1 and director of nursing, the laboratory failed to provide academic credentials to qualify seventeen of twenty-eight testing personnel. Findings: 1. The laboratory could not provide documentation (academic credentials) to show testing person #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, #27, #28, #29, #30, #31, #32, and #33, were qualified to perform moderate complexity testing. 2. Interview with the GS #1 and director of nursing on June 15, 2021 at 11:00 AM confirmed the documents needed to qualify testing personnel #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, #27, #28, #29, #30, #31, #32, and #33 were not available for review.
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 Vitros XT 7600, Celldyn Ruby, Gem 5000 Premier verification procedures and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Findings: 1. Review of Vitros XT 7600 chemistry analyzer showed no reportable range of test results for the test system and no reference intervals (normal values) for the analytes: acetaminophen, albumin, alcohol, alkaline phosphatase, alanine aminotransferase, amonia, amylase, aspartate aminotransferase, vitamin B12, calcium, cholesterol, creatine kinase, creatine kinase MB, chloride, carbamazepine, creatinine, c-reactive protein, digoxin, high density lipoprotein, low density lipoprotein, carbon dioxide, transferrin and iron binding capacity, iron, ferritin, folate, free thyroxine, gamma glutamyl transferase, glucose, potassium, lithium, lipase, magnesium, sodium, phosphate, phenytoin, prostate specific antigen, salicylate, human gonadotropin, total bilirubin, total protein, triglycerides, thyroid stimulating hormone, vitamin D, blood urea nitrogen, uric acid, valproic acid and vancomycin. 2. Review of the Celldyn Ruby hematology analyzer showed no reference intervals (normal values) for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet. 3. Review of the Gem 5000 Premier blood gas analyzer verification procedure showed

	no reportable range for the analytes: carboxyhemoglobin, methemoglobin and oxygenated hemoglobin. Review of reference intervals (normal values) showed no reference intervals for the analytes: pH, carbon dioxide, oxygen, hemoglobin, carboxyhemoglobin, methemoglobin and oxygenated hemoglobin. 4. Interview with the GS on June 15, 2021 at 1:30 PM confirmed the LD failed to ensure that verification procedures used were adequate to determine reportable range and reference intervals (normal values) are appropriate for the laboratory's patient population..
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of initial training documentation, and interview with the general supervisor (GS) #1, the laboratory director failed to ensure seventeen of thirty-three testing personnel (TP) received appropriate training prior to testing patient specimens in the point of care testing laboratory located in the emergency department. Findings: 1. Review of personnel records showed the laboratory could not provide documentation for initial training prior to testing patient specimens for TP #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, #27, #28, #29, #30, #31, #32, and #33 in the point of care testing laboratory located in the emergency department. 2. Interview with the GS #2 on June 15, 2021 at 11:00 AM confirmed the laboratory director failed to ensure all testing personnel received appropriate training prior to testing patient specimens.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the general supervisor (GS) #1, the technical supervisor (TS) failed to evaluate and document the performance of eighteen of thirty-three testing personnel (TP) at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of 2019/2020/2021 performance evaluations showed the TS failed to perform semi-annual competency evaluations for TP #3 in the laboratory and TP #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, #27, #28, #29, #30, #31, #32, and #33 in the point of care testing laboratory located in the emergency department. 2. Interview with GS #1 on June 15, 2021 at 11: 00 AM confirmed, the TS failed to evaluate and document the performance of eighteen of thirty-three TP at least semiannually during the first year the individual tests patient specimens.

D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of 2019/2020/2021 personnel competency assessments and interview with the general supervisor (GS) #1, the technical supervisor failed to document annual competency assessments for twenty-two of thirty-three testing personnel (TP) in 2019, 2020 and to date June 15, 2021. Findings: 1. Review of 2019/2020/2021 personnel competency evaluations showed the TS failed to document annual competency assessments for TP #1, #2, #3, #4, and #5 in the laboratory. 2. Review of 2019/2020/2021 personnel competency assessments showed the TS failed to document annual competency assessments for TP #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, #27, #28, #29, #30, #31, #32, and #33 in the point of care testing laboratory located in the emergency department. 3. Interview with the GS #1 on June 15, 2021 at 11:00 AM confirmed the technical supervisor failed to document annual competency assessments for twenty-two of thirty-three TP in 2019, 2020 and to date June 15, 2021.