Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652272	09/09/2021
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of procedures and interview with the Chief Executive Officer (CEO), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated correct problems. Findings: 1. Review of procedures showed a lack of quality assessment (QA) policies or procedures for an ongoing mechanism to monitor, assess, and, when indicated correct problems. 2. Interview with the CEO on September 9, 2021 at 12:00 PM confirmed the laboratory failed to establish written QA policies or procedures.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure "Laboratory Quality Control Testing

	and Corrective Action Protocol", chemistry procedures, Vitros XT 7600 chemistry quality control (QC), and blood bank procedures and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to provide a procedure for acceptability of quality control (QC) results (Refer to D5403); the laboratory failed to perform two control materials of different concentrations each day of patient testing (Refer to D5447); the laboratory failed to establish criteria for acceptability of control materials providing quantitative results (Refer to D5469); the laboratory failed to provide an accurate procedure for checking patient history in blood bank (Refer to D5551).
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 review of chemistry procedures and interview with the laboratory director (LD), technical supervisor (TS) #2, and chief executive officer (CEO), the laboratory failed to provide a procedure for acceptability of quality control (QC) results. Findings: 1. Review of the procedure"Laboratory Quality Control Testing and Corrective Action Protocol" showed no criteria for acceptability of QC results. 2. Interview with the LD, TS #2 and CEO on September 8, 2021 at 12:15 PM confirmed the laboratory failed to provide a procedure for the acceptability of QC results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of July 1, 2021 to date September 8, 2021 chemistry quality control

	(QC) and interview with the laboratory director (LD), technical supervisor (TS) #2, and chief executive officer (CEO), the laboratory failed to include two control materials of different concentrations each day of patient testing. Findings: 1. Review of Vitros XT 7600 free thyroxine QC showed two acceptable levels of QC were not performed on 7/5, 7/9, 7/12, 7/14, 7/16, 7/17, 7/19 and 7/22. The laboratory could not provide how many patients were reported. 2. Review of Vitros XT 7600 ammonia QC showed two acceptable levels of QC were not performed from July 1, 2021 through September 8, 2021. The laboratory could not provide how many patients were reported. 3. Review of Vitros XT 7600 alkaline phosphatase QC showed two acceptable levels of QC were not performed on 7/30, 8/1, 8/2, 8/4, 8/3, 8/14, 8/15, 8 /17, 8/26, 9/3, 9/5 and 9/6. The laboratory could not provide how many patients were reported. 4. Interview with the LD, TS #2 and CEO on September 8, 2021 at 12:15 PM confirmed the laboratory failed to include two control materials each day of patient testing for free thyroxine, ammonia and alkaline phosphatase.
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 "Laboratory Quality Control Testing and Corrective Action Protocol" procedure, Vitros XT 7600 chemistry quality control (QC) and interview with the laboratory director (LD), technical supervisor (TS) #2, and chief executive officer (CEO), the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the "Laboratory Quality Control Testing and Corrective Action Protocol" procedure, and Vitros XT 7600 chemistry QC showed the laboratory did not establish and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC results reported on the XT 7600 chemistry analyzer for the analytes: acetaminophen, albumin, alcohol, ammonia, amylase, vitamin B12, unconjugated bilirubin, creatine kinase, chloride, covid IGG and total antibody, c-reactive protein test, carbamazepine, digoxin, high-density lipoprotein, low-density lipoprotein, total iron-binding capacity, iron, ferritin, carbon dioxide, folate, free thyroxine, gamma-glutamyl transferase, glucose, hemoglobin A1C, potassium, lactate, lithium, lipase, magnesium, phosphate, prostrate-specific antigen, salicylate, total bilirubin, alkaline phosphatase, triglycerides, sodium, cholesterol, troponin, thyroid stimulating hormone, vitamin D, creatinine, uric acid, valproic acid and vancomycin. The laboratory could not provide how many patients were reported. 2. Interview with the LD, TS #2 and CEO on September 8, 2021 at 12:15 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.

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 Vitros XT 7600, Celldyn Ruby, Gem 5000 Premier verification procedures, the laboratory's procedures, lack of quality control procedures, review of July, August, and to date September 8, 2021 Vitros XT 7600 chemistry analyzer quality control (QC), review of patient test reports generated on September 8, 2021, reference intervals (normal values) established during the Vitros XT 7600 validation, and interviews, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method (Refer to D6086); the LD failed to ensure that the quality control programs are established, and maintained to identify failures in quality as they occur (Refer to D6093); the LD failed to ensure quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur (Refer to D6094); the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the analytes free thyroxine (FT4), ammonia and alkaline phosphatase (Refer to D6095); the LD failed to ensure pertinent normal values as determined by the laboratory were available for interpretation (Refer to D6098).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of quality control procedures and interview with the laboratory director (LD), technical supervisor (TS) #2, and chief executive officer (CEO), the LD failed to ensure that the quality control programs are established and maintained to identify failures in quality as they occur. Findings: 1. Review of the procedure "Laboratory Quality Control Testing and Corrective Action Protocol" showed no criteria for acceptability of QC results. 2. Interview with the LD, TS #2 and CEO on September 8, 2021 at 12:15 PM confirmed the LD failed to ensure the quality control programs are established and maintained to identify failures in quality as they occur.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with the Chief Executive Officer (CEO), the laboratory director (LD) failed to ensure quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur. Findings: 1. No quality assessment programs were available for review. 2. Interview with the CEO on September 8, 2021 at 12:00 PM confirmed the LD failed to ensure quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on lack of quality control procedures, review of July, August, and to date September 8, 2021 Vitros XT 7600 chemistry analyzer quality control (QC) and interview with the laboratory director (LD), the technical supervisor (TS) #2 and the chief executive officer (CEO), the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the analytes free thyroxine (FT4), ammonia and alkaline phosphatase. Findings: 1. Review of the procedure"Laboratory Quality Control Testing and Corrective Action Protocol" showed no criteria for acceptability of QC results. 2. Review of Bio-Rad liquichek level 1 lot #85281 free thyroxine (FT4) showed manufacturer's acceptable range as 1.17-1.76 ng/dl. Based on manufacturer's ranges FT4 was out 7/5, 7/9, 7/12, 7/14, 7 /16, 7/17, 7/19 and 7/22. 3. Interview with testing personnel (TP) #4 stated QC was accepted in Vitros. The QC range in the Vitros analyzer for FT4 was 1.335-2.019. The QC printout from the Vitros analyzer showed FT4 QC was not within acceptable limits on 7/25, 7/27, 7/28, 7/30, 8/1 through 8/30. The laboratory could not provide documentation how ranges were established and which ranges were accurate. 4. Review of Bio-Rad Liquichek level 2 lot #54332 ammonia showed manufacturer's acceptable range as 102-159 ug/dl. The QC range in the Vitros analyzer showed ammonia QC range as 67.2-100.8. QC was not within acceptable limits per manufacturer from July 1, 2021 through September 8, 2021. 5. Review of Bio-Rad Liquicheck level 3 lot #54333 ammonia showed manufacturer's acceptable range as 337-436 ug/dl. The QC range in the Vitros analyzer showed ammonia QC range as 192.8-289.2. QC was not withiin acceptable limits per manufacturer from July 1, 2021 through September 8, 2021. 6. Review of alkaline phosphatase QC showed Bio-Rad liquichek unassayed level 1 control was not within acceptable limits on 7/30, 8/1, 8/2, 8/4, 8/3, 8/14, 8/15, 8/17, 8/26, 9/3, 9/5 and 9/6. Review of Bio-Rad liquichek level 3 control showed QC was not within acceptable limits on 8/17. 7. Interview with the LD, TS #2 and CEO on September 8, 2021 at 12:15 PM confirmed the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the analytes free thyroxine (FT4), ammonia and alkaline phosphatase.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on review of patient test reports generated on September 8, 2021, reference intervals (normal values) established during the Vitros XT 7600 validation and interview with the Chief Executive Officer (CEO), the laboratory director failed to ensure pertinent normal values as determined by the laboratory were available for interpretation. Findings: 1. The differences between normal values included on patient test reports and those established during the Vitros XT 7600 validation are as follows: Normal values included on patient test reports: Hemoglobin A1C 4.7 - 6.4 Albumin 3.5 - 5.0 Ammonia 9 - 30 Amylase 30 - 130 Thyroid-stimulating hormone 0.47 - 4.68 Prostate-specific antigen 0.00 - 6.22 Magnesium 1.6 - 2.3 Lipase 23 - 300 Creatine kinase-MB 0.0 - 2.4 Creatine kinase 55 - 170 Potassium 3.4 - 5.1 Sodium 137 - 145 Alkaline phosphatase 38 - 126 Total bilirubin 0.2 - 1.3 Chloride 98 - 107 Creatinine 0.5 - 1.0 Normal values established during the Vitros XT 7600 validation : Hemoglobin A1C 5.4 -7.0 Albumin 4.0 - 5.2 Ammonia 15.6 - 75.4 Amylase 48.6 - 102.5 Thyroid-stimulating hormone 0.97 - 5.1 Prostate-specific antigen 0.14 - 4.1 Magnesium 1.7 - 2.2 Lipase 38.6 - 239.6 Creatine kinase-MB 0.54 - 1.9 Creatine kinase 49.4 - 236.1 Potassium 4.0 - 5.8 Sodium 137.7 - 144.6 Alkaline phosphatase 31.6 - 338.1 Total bilirubin 0.34 - 0.91 Chloride 102.9 - 116.4 Creatinine 0.67 - 1.22 Amylase 39.5 - 101.40 2. Interview with the CEO on September 8, 2021 at 12:00 PM confirmed that the laboratory director failed to ensure pertinent normal values as determined by the laboratory were available for interpretation.