Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0046649	12/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson County Memorial Hospital Lab	408 Delaware St, Winchester, KS	

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
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 the failure to have procedures with required information, patient testing performed prior to the establishment of performance verification, and failure to include rejected quality control (QC) values in the analytical quality assessment (QA) process, the laboratory failed to have procedures that included verified reference ranges, control procedures that include identity of the control, instructions for entering results in the patient record, and instruction for when test system is not available (refer to D5405); failed to have an approved verification study on the NanoEnTek FREND study for Prostatic Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH) and Thyroxine, Free (FT4) prior to reporting patient results (refer to D5421), and failed to include unacceptable QC values in the QA review for the ABX Diagnostics Pentra 60 hematology analyzer, the ITC Hemochron Jr. Microcoagulation analyzer, the Horiba Pentra C400 chemistry analyzer, the Biosite Triage Meter Plus and the NanoEnTek FREND endocrinology analyzer (refer to D5793).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this

	section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based upon a review of the laboratory procedures and interview with laboratory manager (LM), the laboratory failed to define by written procedure: patient reference ranges (normal ranges) as determined by the laboratory for PSA, TSH, FT4 and prothrombin time (PT); type and identity of the QC material for all non-waived assays in routine chemistry, endocrinology, and hematology; system for entering results in the patient record for all non-waived assays in routine chemistry, endocrinology, and hematology; and course of action when the testing system becomes inoperable for all non-waived assays in routine chemistry, endocrinology, and hematology. Findings: 1. Procedures were requested for review. The laboratory provided printed documents from the manufacturer for the ABX Diagnostics Pentra 60 hematology analyzer, Biosite Triage Meter Plus, Horiba Pentra C400 Clinical Chemistry Analyzer, ITC Hemacron Jr. Microcoagulation analyzer, and NanoEnTek FREND System. Procedures written by the laboratory were also provided for review. The following information was not included in the documents provided: a. Patient reference ranges as determined by the laboratory for PSA, TSH, FT4 and PT. b. Type and identity of the QC materials for use for all non-waived assays in routine chemistry, endocrinology, and hematology. c. The laboratory's system for entering results in the patient's record for all non-waived assays in routine chemistry, endocrinology, and hematology. d. Course of action for when the test system becomes inoperable for all non-waived assays in routine chemistry, endocrinology, and hematology. 2. Interview with the LM on 12/12/23 at 11:05 a.m. confirmed, the laboratory failed to define by written procedure: patient reference ranges (normal ranges) as determined by the laboratory for PSA, TSH, FT4 and prothrombin time (PT); type and identity of the QC material for all non-waived assays in routine chemistry, endocrinology, and hematology; system for entering results in the patient record all non-waived assays in routine chemistry, endocrinology, and hematology; and course of action when the testing system becomes inoperable for all non-waived assays in routine chemistry, endocrinology, and hematology. This laboratory reports approximately 14000 non-waived patient results annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of performance verification documentation for the NanoEnTek FREND System, non-waived test lists, and interview with the LM, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population and failed to have an approved verification study prior to performing patient testing for PSA, TSH and FT4. Findings: 1. Review of the

	verification documentation of the NanoEnTek FREND System endocrinology analyzer, S/N F10U200404-007, for the analytes: PSA, TSH and FT4 revealed no verification of normal values for the laboratory's patient population. Patient testing began on 9/20/21. 2. No documentation of approval by the laboratory director or technical consultant for this verification study was provided at survey. 3. Review of the KS-CLIA-PS02 non-waived test lists showed the test volume from 9/20/21 to date of survey to be approximately 432 patient test results. 4. Interview with LM on 12/12 /23 at 1:30 p.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population and failed to have an approved verification study prior to performing patient testing for PSA, TSH and FT4.
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 the review of the QA documentation and interview with the LM, the laboratory failed to document quality control (QC) failures for the ABX Diagnostics Pentra 60 hematology analyzer, Biosite Triage Meter Plus, Horiba Pentra C400 Clinical Chemistry Analyzer, ITC Hemacron Jr. Microcoagulation analyzer, and NanoEnTek FREND System. Findings: 1. Review of QA documents for the ABX Diagnostics Pentra 60 hematology analyzer, Biosite Triage Meter Plus, Horiba Pentra C400 Clinical Chemistry Analyzer, ITC Hemacron Jr. Microcoagulation analyzer, and NanoEnTek FREND System revealed all QC data points on the Levy Jennings graphs were acceptable. The surveyor asked the LM if the report contained all QC values. The LM stated that only acceptable QC values were recorded on the QA Levy Jennings reports. All unacceptable values were excluded. 2. Failure to include unacceptable QC values in the QA documentation impairs the assessment of corrective actions, procedures and the need for additional staff training. 3. Interview with the LM on 12/12/23 at 1:45 p.m. confirmed, the laboratory failed to document quality control (QC) failures in the QA review for the ABX Diagnostics Pentra 60 hematology analyzer, Biosite Triage Meter Plus, Horiba Pentra C400 Clinical Chemistry Analyzer, ITC Hemacron Jr. Microcoagulation analyzer, and NanoEnTek FREND System.