Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648060	11/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Myrtue Medical Center Laboratory	1213 Garfield Avenue, Harlan, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/13/2020, the laboratory failed to retain copies of the Abbott Cell-Dyn Ruby instrument QC assay sheets for three out of three lot numbers of hematology QC (L0055, N0055, and H0055). The findings include: 1. During the survey, hematology QC records were reviewed from April 2020. 2. QC records indicated that the following lot numbers of QC were in use during April 2020: L0055, N0055, and H0055. 3. At the time of the survey, personnel identifier #1 confirmed that the manufacturer's assay sheets were not available for hematology QC lot numbers L0055, N0055, and H0055.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of hematology quality control records, patient testing records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel

	Report) at approximately 1:00 pm on 11/13/2020, the laboratory failed to meet hematology requirements for: performing two control materials of different concentrations as specified in the standard D5447;ensuring quality control results are acceptable prior to reporting patient test results as specified in the standard D5481; and taking corrective action when the quality control results failed to meet the laboratory's established criteria for acceptability as specified in the standard D5783.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 11/13/2020, the laboratory failed to verify the accuracy of the analyte, transferrin, at least twice annually for five out of five time periods from 01/01/2018- 11/13/2020. The findings include: 1. During review of proficiency testing records, personnel identifier #1 stated that the laboratory performs the analyte, transferrin, but had forgotten to add it to the Laboratory Test List & Annual Volume form. 2. Personnel identifier #1 confirmed that the laboratory did not enroll in PT for the analyte, transferrin, in 2018, 2019, or 2020. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have additional records indicating the verification of accuracy for the analyte, transferrin, in 2018, 2019, or 2020.
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 quality control (QC) records, patient testing records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/13/2020, the laboratory failed to performed two levels of hematology QC materials each day of patient testing for three out of 30 days of patient testing in April 2020. The findings include: 1. The laboratory uses two Abbott Cell-Dyn Ruby hematology instruments labeled Ruby One (serial number 70918BG) and Ruby Two (serial number 70949BG). 2. Review of QC records from the Ruby One instrument revealed that the laboratory only performed one level of QC (Low) on 04/25/2020. 3. Review of QC records from the Ruby Two instrument revealed that the laboratory did not perform any QC on 04/13/2020 or 04/14/2020. 4. Personnel identifier #1 confirmed that patient testing had been performed on the Ruby One instrument on 04/25/2020 and on the Ruby Two instrument on 04/13/2020 and 04 /14/2020. 5. At the time of the survey, no hematology quality control records could be found for the above dates.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Cell-Dyn Ruby hematology quality control (QC) records, patient testing records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/13/2020, the laboratory failed to ensure that results of complete blood count (CBC) control materials were acceptable before reporting patient test results for six out of 30 days of patient testing in April 2020. The findings include: 1. The laboratory uses two Abbott Cell-Dyn Ruby hematology instruments labeled Ruby One (serial number 70918BG) and Ruby Two (serial number 70949BG). 2. Review of QC records from the Ruby One instrument revealed that the laboratory did not have at least two levels of acceptable QC prior to reporting patient test results on the following dates: 04/10/2020, 04/23 /2020, 04/25/2020, and 04/26/2020. 3. Review of QC records from the Ruby Two instrument revealed that the laboratory did not have at least two levels of acceptable QC prior to reporting patient test results on the following dates: 04/13/2020 and 04/14 /2020. 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have additional QC records for the dates listed above.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) 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 antimicrobial susceptibility testing (AST) quality control (QC) records, the laboratory's AST Individualized Quality Control Plan (IQCP), the laboratory's "Stock Organism Quality Control" policy, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11: 30 am on 11/13/2020, the laboratory failed to perform one out of three QC organisms for gram negative AST QC for one out of four weeks in April 2020 . The findings include: 1. The laboratory had a written IQCP stating that AST QC would be performed weekly. 2. The laboratory's "Stock Organism Quality Control" policy stated that the following organisms were to be set up weekly for gram negative panels: Escherichia coli ATCC 25922, Pseudomonas aeruginosis ATCC 27853, and Klebsiella pneumoniae ATCC 70063. 3. The laboratory performed gram negative AST QC testing on 04/07/2020, 04/14/2020, 04/21/2020, and 04/28/2020. 4. On 04/07 /2020, the laboratory had gram negative AST QC records for the organisms, Escherichia coli ATCC 25922 and Klebsiella pneumoniae ATCC 70063, but not

	Pseudomonas aeruginosis ATCC 27853. 5. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have gram negative AST QC records for the organism, Pseudomonas aeruginosis ATCC 27853, for 04/07/2020.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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. This STANDARD is not met as evidenced by: Based on review of Cell-Dyn Ruby hematology quality control (QC) records, patient testing records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/13/2020, the laboratory failed to take and document corrective action when results of complete blood count (CBC) control materials fell outside the laboratory's established criteria for acceptability for four out of 30 days of patient testing in April 2020. The findings include: 1. Personnel identifier #1 indicated that printed QC records from the Cell-Dyn Ruby instruments show an underlined result for any QC parameters considered to be out of control. 2. Review of QC records from the Ruby One instrument (serial number 70918BG) indicated that the laboratory had out of control results without corrective action on the following dates: *04/10/2020: Level Low- white blood cell count (WBC) *04/23/2020: Level Low- red blood cell count (RBC) *04/23/2020: Level High- mean corpuscular hemoglobin concentration (MCHC) *04/25/2020: Level Low- WBC, mean corpuscular volume (MCV), and platelet count (PLT) *04/26 /2020: Level Low- WBC, MCV, and PLT 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have documented corrective action for the out of control QC results listed above.
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 and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:10 am on 11/13/2020, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing high complexity testing received the appropriate training for two out of two new testing personnel (laboratory personnel identifiers #7 and #8) hired in 2018-2019. The findings include: 1. The laboratory hired personnel identifier #7 in December 2018. 2. The laboratory hired personnel

	identifier #8 in December 2019. 3. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifiers #7 and #8.