Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0395696	08/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Aspirus Tomahawk Hospital	401 W Mohawk Dr Ste 100, Tomahawk, WI	

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
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 surveyor review of laboratory procedures and interview with the interim laboratory manager the laboratory's procedures for tests performed on the Architect analyzer do not include the criteria used to decide whether quality control (QC) results are acceptable and do not identify the corrective actions to take when control results do not meet the laboratory's criteria for acceptability. Findings include: 1. The "Laboratory Overall Quality Control Program" Procedure section stated each department has its own QC policy that includes interpretation of QC results and troubleshooting techniques. The "Quality Control - Architect ci4100" procedure,

	section f. "Reviewing Quality Control Data" stated, "The technologist assigned to chemistry is responsible for performing all QC as required, evaluating results, troubleshooting if necessary, and notifying the chemistry supervisor / lead tech of any problems. In the event of a Q.C. failure, the technologist should follow procedures for corrective action for out-of-range controls and not report patient results until results are within acceptable range." The procedure did not outline the corrective actions required and did not specify what constituted a QC failure. The "Troponin I - Architect ci4100" procedure stated, "To perform quality control, refer to Quality Control-Architect ci4100 procedure." 2. Interview with the interim laboratory manager (staff B) on August 1, 2022 at 3:30 PM confirmed the current chemistry procedures did not include directions for evaluating quality control results for testing performed on the Architect analyzer and did not define the corrective actions testing personnel should take when control results are not acceptable.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of a phlebotomy tray in the laboratory and interview with the interim laboratory manager, labels on four of the four SPS (sodium polyanethol sulfonate) evacuated tubes on the phlebotomy tray showed all four tubes were past the expiration date on the label and were available for use in blood collection. Findings include: 1. Observation of a phlebotomy tray on the counter in the laboratory on August 2, 2022 at 9:00 AM revealed four SPS tubes available for use on the tray. The labels on the four tubes showed all were from lot number 1195670 with an expiration date of 2022 0731 (July 31, 2022). 2. Interview with the interim laboratory manager (staff B) on August 2, 2022 at 9:00 AM confirmed the four tubes were expired and were available for use in blood collection.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory records and interview with the interim laboratory manager, the laboratory did not document corrective actions when the controls were not in range for troponin tests performed on the Architect analyzer in June and July 2022. Findings include: 1. Review of Levey Jennings Reports from

	June 15 through 30, 2022 and July 3 through August 2, 2022 showed the Architect analyzer flagged the control results as above or below two standard deviations from the mean forty-eight times. The reports showed staff used two lot numbers of reagent interchangeably from June 15 through June 30, 2022. Nine of the flagged results occurred with troponin reagent lot 88618UN21, thirty-nine flagged results occurred with troponin reagent lot 35628UN22. Lot 88618UN21 was used on June 15, 16, 17, 18, 20, 21, 22, 28, 29, 30, July 3 through 13. Lot 35628UN22- was used on June 19, 20, 23, 24, 25, 26, 27, 28, and July 13 through August 2. 2. Review of the "Cal Curve Summary Report" for Troponin lot #35628UN22 showed the laboratory calibrated the lot on June 19, twice on June 20, and again on July 14 and 17, 2022. 3. Review of the "ATH Laboratory Chemistry Quality Control Logs" for June and July 2022 showed the log included a section for documentation of corrective actions. The two logs included no documentation of corrective actions taken for troponin testing. 4. Interview with the interim laboratory manager (staff B) on August 2, 2022 at 10:45 AM confirmed testing personnel did not document corrective actions taken for troponin testing when controls were not acceptable and when staff performed calibrations. Item 2: Based on surveyor interview with testing personnel and the interim laboratory supervisor and review of laboratory records, the laboratory did not document corrective actions taken when testing personnel reused disposable sample cups for the Sysmex CA-1500 coagulation analyzer in April 2022. Findings include: 1. Interview with testing personnel (staff C) on August 1, 2022 at 4:45 PM revealed staff were directed to wash and reuse disposable sample cups for testing controls on the Sysmex CA-1500 coagulation analyzer when new sample cups were not available due to supply disruptions. 2. Interview with testing personnel (staff D) on August 2, 2022 at 12:45 PM confirmed personnel reused disposable sample cups for testing quality control material on the Sysmex CA-1500 coagulation analyzer when new cups were not available. 3. Review of the laboratory's "Communication Log" for April 28, 2022 showed re-use of the sample cups was communicated for performing maintenance on the coagulation analyzer. No documentation allowing re-use of disposable cups for control testing was found. 4. Interview with the interim laboratory supervisor (staff A) on August 1, 2022 at 5:00 PM confirmed testing personnel re-used sample cups intermittently in March and April 2022 for cleaning solution for performing instrument maintenance and confirmed corrective actions were not documented.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the interim laboratory manager, testing personnel did not adhere to the quality control (QC) policies and did not document all quality control activities and calibrations performed for troponin reagent lot number 35628UN22. Findings include: 1. Review of the "Lot to Lot Patient Comparison" worksheet for troponin lot 35628UN22 from June 20, 2022 at 6:37 PM showed the quality control results after calibration for level 2 were not within the acceptable range. The form showed the acceptable range was 8529.9 - 9841.9 and the control results were 10293.0 and 10432.5. The form included a question, "Is QC within acceptable limits?" Personnel marked the answer to this

	question "Yes". The form also included a notation "Lot shift will monitor". 2. Review of the "Cal Curve Summary Report" for troponin lot 35628UN22 showed the laboratory recalibrated the assay at 10:59 PM on June 20, 2022. 3. Review of the "ATH Laboratory Chemistry Quality Control Log" for June 2022 that included a section to document corrective actions taken showed no evidence of evaluation of the out-of-range quality control results or corrective actions taken to explain the additional calibration performed at 10:59 PM on June 20, 2022. 4. Interview with the interim laboratory manager (staff B) on August 2, 2022 at 9:30 AM confirmed the laboratory had not documented any corrective actions taken and that the "Lot to Lot Patient Comparison" form showed personnel determined the QC was acceptable when the results were not in the acceptable range. Item 2: Based on surveyor review of laboratory records and interview with the interim laboratory manager, testing personnel did not correctly identify the lot number of the control material (Bio-Rad Liquichek Cardiac Markers Plus Control LT) evaluated on the Architect analyzer in June and July 2022. Findings include: 1. Review of troponin Levey Jennings reports from June 15 - 30, 2022 and July 3 - August 2, 2022 showed testing personnel used two lot numbers for control level one, 67640 and 67670, on the following days: Lot 67640: June 16, 17, 18, 19, 20, 23, 24, 25, 30 Lot 67670: June 15, 20, 21, 22, 26, 27, 28, 29 Staff identified all level two controls tested as lot 67640. 2. Interview with the interim laboratory manager (staff B) on August 2, 2022 at 9:45 AM revealed the laboratory had changed control lot numbers in May to lot 67670 and confirmed testing personnel were not consistently entering the correct lot number for the controls in the Architect analyzer.
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 surveyor review of laboratory records and procedures and interview with laboratory staff, the director did not provide overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The director did not ensure the quality control procedures were maintained. See D6093. 2. The director did not ensure the quality assessment program was maintained. See D6094 3. The director did not ensure patient results were not reported when the system was not functioning properly. See D6097.
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 surveyor review of laboratory procedures and interview with the interim laboratory manager, the laboratory director did not ensure laboratory staff maintained the quality control (QC) procedures and program. Findings include: 1. Review of

	Quality Control procedures for the Architect analyzer showed the procedures did not define how testing personnel were to evaluate quality control results or the steps to take to troubleshoot problems. See D5403. 2. Interview with the interim laboratory manager (staff B) on August 2, 2022 at 9:00 AM revealed an earlier procedure, "Quality Control Procedures Using Bio-Rad Unity QC Program Siemens Dimension", was used to build rules in the Architect analyzer and the Bio-Rad Unity program. Staff B confirmed the laboratory staff were responsible for recognizing and responding to flagged results from the analyzer. 3. Review of the "Quality Control Procedures Using Bio-Rad Unity QC Program Siemens Dimension" procedure showed testing personnel needed to take corrective action when one level of QC was greater than three standard deviations (SD) from the mean (1-3s) and when the last two control runs were outside of two SD but within three SD (2-2s) from the mean. 4. Review of "Levey-Jennings Reports" for the troponin assay on the Architect analyzer from July 3 through August 2, 2022 showed the following flagged results with no documented corrective action. July 7, Level 1: 1-2s July 8, Level 1: 1-2s July 13, Level 1: 1-3s at 1:12 AM 1-2s at 1:39, 2:29, and 6:11 AM Level 2: 1-3s at 3:06, 3:59, 4:35, and 6:12 AM July 14, Level 1: 1-3s July 15, Level 1: 1-2s Level 2: 1-2s July 16, Level 1: 1-3s at 3:01 AM 1-2s at 3:22 AM Level 2: 1-3s at 3:03 AM 1-3s at 03:24 AM July 17, Level 1: 1-2s Level 2: 1-3s July 18 Level 2: 1-2s July 19, Level 2: 1-3s at 1:00 and 1:50 AM July 28, Level 1: 1-3s July 31, Level 1: 1-2s August 1, Level 1: 1-2s 5. Further interview with staff B on August 2, 2022 at 9:00 AM confirmed the quality control program was not maintained and confirmed the current procedures did not define the steps staff should take to evaluate quality control results or resolve problems.
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 surveyor review of laboratory procedures and quality control (QC) records and interview with the interim laboratory supervisor, the laboratory director did not ensure laboratory staff maintained quality assessment programs in January, February, and March 2022. Findings include: 1. Review of the "Laboratory Overall Quality Control Program" procedure showed the procedure included the following statement "All quality control data will be reviewed monthly by the department key operator or designated testing personnel and laboratory manager." The procedure also stated, "Each month various chemistry, blood gas, coagulation and hematology quality control results are sent to the control manufacturer for data reduction statistics comparing our in-house results to other labs performing the same or similar methodology." 2. Review of three QC Summary Reports from the Architect analyzer for January 1 through February 1, February 1 through March 1, and March 1 through April 1, 2022 showed the interim laboratory supervisor signed all three reports on May 10, 2022. The reports all showed a printed date of May 6, 2022. Further review of the reports showed significant differences in the expected and actual mean values for the cardiac QC results. The March 1 through April 1, 2022 report showed the following results for B-type natriuretic peptide (BNP) and Troponin: Test / QC Level / Actual Mean / Expected Mean / expected SD BNP / 1 / 92.18 / 117.3 / 6.15 BNP / 2 / 512.68 / 677.6 / 30.5 Troponin / 1 / 65.62 / 146.3 / 6.35 Troponin / 2 / 8580.0 / 8202.9

	/ 328.0 The other two monthly reports showed comparable results. The reports showed no evidence the supervisor noted the differences in expected and actual mean values and showed no indication of review other than staff A's signature and date. 3. Review of Unity Monthly evaluation reports from February and March 2022 for Cardiac Markers Plus LT showed the reports were signed by staff A on May 10, 2022. The reports included the following statement, " Unable to submit data due to computer transition from Ascension to Aspirus. Unity interface and access temporarily lost. Package ranges followed." 4. Interview with the interim laboratory supervisor (staff A) on August 1, 2022 at 3:15 PM confirmed the supervisor did not complete the quality assurance review of the QC reports monthly and revealed they had not recognized the differences in actual and expected means on the Architect reports at the time of review. Staff A also confirmed they had not completed quality assurance review of the Unity peer comparison reports for February and March 2022.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on surveyor review of patient results, quality control records, and corrective action logs and interview with the interim laboratory manager, the laboratory director did not ensure that testing personnel took corrective actions before releasing four of four patient Troponin results when the analyzer flagged the control results as unacceptable. Findings include: 1. Review of four patient troponin test results from the Architect analyzer showed the analyzer flagged the control results as unacceptable on July 13 for patient one and two and on July 16, 2022 for two test results for patient three. 2. Review of patient results in the electronic medical record showed testing personnel released the troponin test results for patients 1, 2, and 3. Patient 1: tested with lot 35628UN22 reported in the EMR July 13, 2022 at 1:43 PM Patient 2: tested with lot 35628UN22 reported in the EMR on July 13, 2022 at 2:33 PM Patient 3: tested with lot 35628UN22 reported in the EMR on July 16, 2022 at 4:24 and 7:39 PM 3. Review of quality control records from the Architect analyzer on July 13, 2022 showed testing personnel evaluated both levels of control multiple times using two different reagent lots. The error flag 1-2s showed results were between two and three standard deviations from the expected mean, 1-3s showed results were more than three standard deviations from the expected mean. Level 1 acceptable range 142.9 - 168.3 lot number / time (AM) / result / error flag 88618UN21 / 01:12 / 177.0 / 1-3s 88618UN21 / 01:39 / 173.3 / 1-2s 88618UN21 / 02:29 / 171.2 / 1-2s 88618UN21 / 02: 30 / result excluded 35628UN22 / 06:11 / 173.3 / 1-2s Level 2 acceptable range 8529.9 - 9841.9 88618UN21 / 01:13 / 94307.7 / none 35628UN22 / 03:06 / 10327.5 / 1-3s 35628UN22 / 03:59 / 10476.3 / 1-3s 35628UN22 / 04:35 / 10719.3 / 1-3s 35628UN22 / 06:12 / 10374.6 / 1-3s Review of quality control records from the Architect analyzer on July 16, 2022 showed both levels of control were evaluated twice. Level 1 acceptable range 142.9 - 168.3 lot number / time (AM) / result / error flag 35628UN22 / 03:01 / 175.1 / 1-3s 35628UN22 / 03:22 / 172.3 / 1-2s Level 2 acceptable range 8529.9 - 9841.9 35628UN22 / 03:03 / 10280.4 / 1-3s 35628UN22 / 03:24 / 10224.4 / 1-3s 4. Review of the "Cal Curve Summary Report" for troponin lot 35628UN22 showed testing personnel calibrated the troponin assay on July 14, 2022 at 1:43 AM and again on July 17, 2022 at 1:52 AM. 5. Review of the "ATH Laboratory Chemistry Quality Control Log" for July 2022 showed the log includes an

	area to document corrective actions taken. Testing personnel documented no calibrations or corrective actions for the troponin assay on the log. 6. Interview with the interim laboratory manager (staff A) on August 2, 2022 at 10:15 AM confirmed testing personnel reported patient troponin test results on July 13 and 16, 2022 when the control results were not acceptable and corrective actions had not been taken to ensure the test system was functioning properly.