Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2176946	03/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Tryon Medical Partners Central Labortaory	3420 Saint Vardell Lane, Suite B, Charlotte, NC	

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 2019, 2020, 2021, and 2022 hematology records, the absence of records, and interview with TP #4 3/23/22, the laboratory failed to retain daily background counts for the Sysmex XN-2000 hematology analyzers from 3/9/20 to 1 /26/21, a period of approximately 10 months. Findings: Review of hematology records revealed the Sysmex XN-2000 hematology analyzers were installed 11/15/19, and patient testing began 3/9/20. Review of hematology records revealed there were no background counts prior to 1/27/21 available for review. During interview at approximately 2:55 p.m., TP #4 stated that since 1/27/21, backgrounds have been backed up to a USB drive. She confirmed that there were no daily background counts available for the 10 month period 3/9/20 to 1/26/21.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020 and 2021 temperature and humidity logs, absence of documentation, and review of temperature corrective action 3/23/22, the laboratory failed to monitor and document room humidity daily for 40 of 42 days in September and October 2021. Findings: The laboratory's "Temperature and Humidity Monitoring" policy and procedure states, "D. Humidity monitoring. 1. Humidity monitoring is required in laboratory areas where the manufacturer has indicated excessively high or low humidity may impact specimen or reagent storage or instrument performance...3. Maintain a humidity log for each hygrometer. The log includes the date, area being monitored and acceptable humidity range for the location in which the hygrometer is placed. 4. Record humidity readings on the humidity log in percent(%)....7. The supervisor or designee inspects humidity and corrective action logs monthly for appropriate documentation..." Review of the 2020 and 2021 temperature and humidity logs revealed a humidity range of 30-80% for "Unit: Juliet" which was located in the coagulation area. The logs revealed no humidity readings documented for 21 of 21 days in September 2021 and 19 of 21 days in October 2021. Review of temperature corrective action logs and in-service meeting notes revealed the laboratory did not notice until 10/27/21 that the humidity column was missing from the logs and humidity monitoring was not performed for all of September 2021 through October 26, 2021.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, review of 2020 and 2021 maintenance logs, and interview with TP (testing personnel) #4 on 3/23/22, the laboratory failed to follow manufacturer's instructions for periodic maintenance on the Hematek stainer used to stain slides for manual differentials. Findings: Manufacturer's instructions for the Hematek stainer state in chapter 7 "Performing maintenance 7.1 Periodic maintenance ... After three Hematek Stain Paks have been used Replace pump tubing After ten Hematek Stain Paks have been used Replace underplaten tubing ..." The laboratory's "Hematek Slide Stainer Operation" procedure states "... Maintenance: ... Every 4th Pack or as needed: Replace the pump tubing. Every 10th Pack or as needed: Replace the bottom under platen tubing. ..." Review of 2020 and 2021 "Hematek Stain Pack and Tubing Change Log" records revealed the laboratory's 2020 logs listed the following: "Pump tubing changed w/ every 3rd pack of stain". The laboratory's 2021 log listed "Pump tubing changed w/ every 4th pack of stain". During interview at approximately 5:10 p.m., TP #4 confirmed that the laboratory's procedure and maintenance log did not match the manufacturer's instructions.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education

	appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and review of personnel records 3/23/22, the TS(Technical Supervisor) failed to evaluate the competency of 1 of 5 TP(testing personnel #3) in 2021. Findings: The laboratory's "Training and competency Assessment Policy" revealed, "New Employee Competency Assessment- The initial evaluation after training, to assess competency of a new employee. The initial competency is followed by a six-month competency assessment and an annual assessment thereafter..." 1. The TS failed to evaluate the competency of 1 of 5 TP (TP#3) in 2021 for the initial competency for the Roche Cobas 8000 and the semiannual competency for the Siemens XN 2000, Sysmex CS 2500, Siemens Clinitek Novus, Iris IQ200, ESR Stat 6, manual differentials and urinalysis. Review of personnel records revealed TP #3 had an initial competency completed for Hematology, coagulation, and urinalysis following training in September 2020, but the semiannual competency was not completed when due in 2021, and was not performed until January 2022, a period of approximately 16 months later. TP#3 was trained on the Roche Cobas 8000 in December 2020, but an initial competency was not performed as required by the laboratory's policy until January 2022, a period of approximately 13 months later.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 hematology and corrective action records and the absence of records 3/23/22, the general supervisor failed to ensure that reactivity of the manual differential stain was documented for 5 of 12 months (March, April, May, June, July) during 2020. Review of 2020, 2021, and 2022 hematology records revealed the laboratory used a "SLIDE STAINING QUALITY CONTROL LOG" to document the reactivity of the stain used for manual differentials. There were no records of slide staining quality control for March 2020, April 2020, May 2020, June 2020, and July 2020 available for review during the survey. Review of 2020 corrective action records revealed the following documentation completed by the "Quality Manager" and dated 7/26/21: "Problem Noted: A retrospective review noted that there was no Slide Staining QC Log in place for the above months. Going forward, this log will be utilized each and every month. It is the expectation that the Supervisor ensure complete documentation with a timely review." The corrective action form also included the following questions: "Was patient affected and what did you do ensure patient safety was not at risk? Was issue resolved? What will you do to prevent reoccurrence?" There were no responses documented on the form.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)

	Each individual performing high 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 review of the laboratory's policies and procedures, review of 2020 and 2021 Coagulation QC(quality control) records, absence of documentation, and interview with the TS(technical supervisor) 3/23/22, the testing personnel failed to follow the laboratory's QC policies to print and review the QC summaries for all coagulation testing performed for 16 of 21 months reviewed in 2020 and 2021. Findings: Review of the laboratory's "Quality Control Review" procedure revealed for Coagulation," Each month, Laboratory technicians/technologists will print QC data from Trellis, print the raw data from Siemens CS2500 analyzer, and gather maintenance logs and any corrective actions that need to be reviewed and signed....To Print QC from Siemens CS2500 Analyzer:...To get INR, go to more at top of page >print report >select date range >print graph >print..." Review of the 2020 and 2021 Coagulation QC records revealed there was no QC summaries on file for INR(International normalized ratio) from March 2020 when testing began to July 2021, a period of approximately 16 months. During interview at approximately 4 p.m, the TS confirmed the QC summaries for INR were not printed prior to August 2021.