Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0914318	07/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sheboygan Physicians Group, Sc	1621 N Taylor Dr, Sheboygan, 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
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of quality control procedures, observation of the Stago Start coagulation test system, and interview with the technical consultant, each testing person performing Prothrombin Time tests did not test two levels of control materials before testing patient samples. Findings include: 1. Review of the "Types of Controls Summary" procedure shows coagulation controls, normal and abnormal, are to be run each day of patient Prothrombin Time testing and prior to using freshly made Neoplastine for patient testing. 2. Observation of the coagulation system in the laboratory on July 29, 2019 at 12:00 PM showed the laboratory uses a manual method, the Stago Start analyzer, for Prothrombin Time testing. 3. Interview with the technical consultant on July 29, 2019 at 12:15 PM confirmed the Stago Start coagulation analyzer is a manual testing method for Prothrombin Time testing. Further interview revealed the laboratory does not batch prothrombin time testing and confirmed each testing person did not test control materials before testing patient samples.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and

	specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory chest freezer, review of temperature monitoring records, and interview with the technical consultant, the laboratory did not document corrective actions taken when the freezer was not operating within the parameters required by the manufacturer for proper storage of Bio-Rad chemistry control materials in June 2019. Findings include: 1. Observation of the chest freezer on July 29, 2019 at 12:15 PM revealed Bio-Rad chemistry controls were stored in the freezer. The manufacturer's acceptable storage temperature range identified on the package was -20 to -70 C (degrees Celsius). 2. Review of the logs used to document the chest freezer temperature in June 2019 showed the laboratory's acceptable temperature range is less than or equal to -20 C. Of the eighteen days the laboratory recorded temperatures in June 2019, the temperature was above -20 C on seven days. The laboratory did not document corrective actions taken for any of the seven days when they recorded unacceptable temperatures. 3. Interview with the technical consultant on July 29, 2019 at 12:30 PM confirmed the laboratory did not take corrective actions when the temperatures in the chest freezer did not meet the manufacturer's requirements for proper storage of Bio-Rad chemistry controls.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's quality assessment procedures and records, and interview with the technical consultant, laboratory personnel have not followed their written procedures for weekly review of quality control data for shifts and trends. Findings include: 1. Review of the "Sheboygan Physicians Group Laboratory Quality Control Plan" showed the plan required weekly review of control charts, graphs, and statistical indices "to detect such changes or shifts or trends that may be indicators of test system problems that need to be addressed." 2. Review of "Weekly QC Check for Shifts / Trends" forms for December 2018 through April 2019 showed the laboratory did not document weekly review of quality control 14 of 22 weeks. 3. Interview with the technical consultant on July 29, 2019 at 2:00 PM confirmed the laboratory had not documented weekly review of quality control as required by their procedures.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by:

	Based on surveyor review of laboratory procedures, observation of the laboratory freezer, review of temperature records, and interview with the technical consultant, testing personnel have not ensured samples tested on the Tosoh AIA 900 analyzer are stored at acceptable temperature ranges. Findings include: 1. Review of the laboratory procedure for PSA (Prostate Specific Antigen) tests performed on the Tosoh AIA 900 analyzer showed the procedure states, "If the analysis cannot be done within 24 hours, the sample should be stored frozen at -20 C (degrees Celsius) or below...". The procedure further states, "Repeated freeze thaw cycles should be avoided." 2. Observation of the laboratory freezer on July 29, 2019 at 12:30 PM revealed patient samples are stored in a freezer with an automatic defrost function. 3. Review of temperature records from June 2019 shows the acceptable freezer temperature identified on the form is less than or equal to -15 C. Of the nineteen temperatures recorded by testing personnel, seven were higher than -20 C. 4. Interview with the technical consultant on July 29, 2019 at 12:30 PM confirmed testing personnel stored PSA samples in a freezer that does not maintain the storage temperatures required by laboratory procedures and confirmed the automatic defrost function of the freezer could result in repeated freeze thaw cycles of the samples.