Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0652581	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pender Community Hospital	100 Hospital Drive, Pender, NE	

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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of Bacteriology records and staff interviews, the laboratory failed to perform control procedures for Gram stain testing (refer to D5503). This problem resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of Immunohematolgy records and interview with general supervisor, the laboratory failed to ensure no outdated reagents were used for patient testing (refer to D5417) and failed to perform quality control on days of patient testing (refer to D5551). The cumulative effect of these problems resulted in the laboratory's inability to ensure accuracy and reliability of patient test results.
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 record review of blood bank quality control logs, record review of blood bank patient logs, and staff interview, the laboratory failed to ensure testing personnel did not use outdated reagents to perform ABO blood typing and antibody detection testing. 1. Review of quality control documentation indicates quality control performed from: I. 3/15/2018 - 3/27/2018 was done with expired A1/B Cells (Lot#84770 Exp. 3/13/2018) II. 3/29/2018 - 5/2/2018 was done with expired A1/B Cells (Lot#84770 Exp. 3/13/2018) and Screen Cells (Lot#VSS982 Exp.3/27/2018) III. 3/27/2019 - 4/9/2019 was done with expired Screen Cells (Lot#VSS072 Exp. 3/26 /2019) IV. 4/10/2019 - 5/1/2019 was done with expired A1/B Cells (Lot#8A927 Exp. 4 /9/2019) and expired Screen Cells (Lot#VSS072 Exp. 3/26/2019) V. 5/9/2019 - 5/20 /2019 was done with expired A1/B Cells (Lot#8A937 Exp. 5/7/2019) VI. 5/22/2019 - 6 /11/2019 was done with expired A1/B Cells (Lot#8A937 Exp. 5/7/2019) and expired Screen Cells (Lot#VSS086 Exp. 5/21/2019). 2. Review of quality control documentation reveals no documentation of quality control for current reagents in use. 3. Review of blood bank patient logs revealed 112 patients were tested using expired reagents. 4. Interview with general supervisor at 1:10 PM on 6/12/2019 confirmed the laboratory was unable to prove outdated reagents were not used for patient testing.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on surveyor record review of gram stain patient testing log, record review of gram stain quality control records, and interview with general supervisor, the laboratory failed to provide documentation staff performed a positive and negative control during the week of June 2nd - June 8th. 1. Review of gram stain patient testing log indicated patient testing was performed on 6/1/2019 and 6/3/2019 through 6/7 /2019. 2. Review of gram stain quality control records indicated the last time quality control was performed on 5/18/2019. 3. Interview with general supervisor at 2:00PM on 6/12/2019, confirmed lack of documentation for gram stain quality control for the week of June 2nd - June 8th.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D

	(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor record review of blood bank patient testing logs, record review of blood bank quality control records, and interview with general supervisor, the laboratory failed to provide documentation staff performed quality control on 6 days of patient testing. 1. Review of blood bank patient testing logs for 2018 indicated 2 patients tested on 3/22/2018, 1 patient tested on 3/28/2018, 2 patients tested on 5/1 /2018, 2 patients tested on 10/19/2018, 1 patient tested on 10/23/2018, and 1 patient tested on 10/26/2018. 2. Review of blood bank quality control records revealed no documentation of quality control performed on 3/22/2018, 3/28/2018, 5/1/2018, 10/19 /2018, 10/23/2018, and 10/26/2018. 3. Interview with general supervisor at 3:00PM on 6/12/2019 confirmed the lack of quality control documentation.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on surveyor review of the CMS 209, competency evaluations for 2017 and 2018, and an interview with general supervisor, the laboratory failed to perform competency evaluations on 1 of 4 high complexity testing personnel for both years. Findings are: 1. The CMS 209 form completed by the laboratory revealed 4 high complexity testing personnel performing patient testing. 2. Review of competency evaluations for 2017 and 2018 revealed 1 high complexity testing personnel had no annual competencies performed for 2017 and 2018. 3. Interview with the general supervisor at 11:00AM on 6/12/2019, confirmed the competency evaluations for 1 high complexity testing personnel had not been performed for 2017 and 2018.