Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0658924	09/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Platte Health Center Avera	601 East 7th, Platte, SD	

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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 9/13/18. The Platte Health Center Avera laboratory was found not in compliance with the following requirements: D2015, D5471, and D6091.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) events, quality assurance (QA) activities, and interview with laboratory manager, the laboratory failed to ensure the laboratory director signed the attestation statements for nine of sixteen PT events (Immunology /Immunohematology 2017 3rd, 2018 1st and 2nd events, Hematology/Coagulation 2017 3rd, and 2018 1st events, Chemistry Miscellaneous 2018 1st event, Microbiology 2018 1st and 2nd events, and 2018 CG-S4-A) submitted for grading to American Proficiency Institute and College of American Pathologists. Findings include: 1. Review of the records for the PT events identified above revealed the attestation statements had not been signed by the laboratory director attesting the PT specimens had been tested in the same manner as patient specimens. Review of QA

	activities for 2017 and to date in 2018 revealed review of the attestation forms had not been included in PT testing review. Interview on 9/13/18 at 9:10 a.m. with the laboratory manager revealed the laboratory director comes on a quarterly basis. She must have forgotten to give the laboratory director the PT book on her previous visits.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Plan (IQCP) for streamlined quality control (QC) of commercial identification (ID) cards for the Vitek 2, Vitek 2 ID card package inserts, and interview with the laboratory supervisor, the laboratory failed to check each lot number or shipment for two of two lot numbers reviewed of Vitek 2 gram positive and negative ID cards (lot 2420567103 and 21410317103) for their positive and negative reactivity in each biochemical well prior to use for patient testing to ensure accurate identification of microorganisms. Findings include: 1. Review of the bacteriology QC records of Vitek 2 gram negative ID cards (lot 21410317103) revealed: *The cards did not have the positive reactivity checked in the L-pyrrolydonyl-arylamidase, L-arabitol, hydrogen sulfide production, glutamyl arylamidase pNA, beta-alanine arylamidase pNA, urease, D-Tagatose, 5-keto-D-gluconate, alpha-glucosidase, lysine decarboxylase, L-histidine assimilation, coumarate, beta-glucoronidase, l-malate assimilation, ellman, and L-lactate assimilation biochemical wells. *The cards did not have the negative reactivity verified in the beta-n-acetyl-glucosaminidase, gamma-glutamyl-transferase, citrate, l-lactate alkalinization, and, succinate alkalinization biochemical wells. *Gram negative ID card lot 21410317103 was currently in use for patient testing at the time of this survey. 2. Review of the bacteriology QC records of Vitek 2 gram positive ID cards (lot 2420567103) revealed: *The cards did not have the positive reactivity verified in the alpha-glucosidase, Ala-Phe-Pro arylamidase, cyclodextrin, leucine arylamidase, beta-glucoronidase, D-orbital, and phosphatase biochemical wells. *The cards did not have the negative reactivity verified in the beta-glucosidase, D-glucose, D-maltose, lactose, growth in 6.5% sodium chloride, O/129 resistance, pullulan, saccharose /sucrose, D-mannitol, and D-trehalose biochemical wells. *Gram positive ID card lot 2420567103 was currently in use for patient testing. Review of the Vitek 2 ID IQCP policy approved and signed by the laboratory director on 4/28/17 revealed the IQCP did not address the identity and number of QC organisms to be tested. Review of the Vitek 2 GN ID package insert dated October 2016 revealed testing of seven additional organisms (Actintobacter baumanii ATCC BAA-747, Elizabethkingia meningoseptica ATCC 13253, Klebsiella oxytoca ATCC 700324, Ochrobactrum anthropi ATCC BAA-749, Proteus vulgaris ATCC 6380, Pseudomonas aerginosa ATCC 9721, and Pseudomonas aerginosa ATCC BAA-1744) was necessary to check the positive and negative reaction of all biochemical wells. Review of eht Vitek 2 GP ID package insert dated October 2016 revealed testing of seven additional organisms (Streptococcus salivarius ssp. thermophilus ATCC 19258, Kocuria kristinae ATCC

	BAA-752, Listeria monocytogenes ATCC BAA-751, Streptococcus pneumoniae ATCC 49619, Staphylococcus sciuri ATCC 29061, Streptococcus equi ssp. zooepidemicus ATCC 43079, and Enterococcus saccharolyticus ATCC 43076) was necessary to check the positive and negative reactivity of all biochemical wells. Review of the annual testing volume survey form indicated 264 patient microorganism IDs had been performed in 2017. Interview on 9/13/18 at 12:30 p.m. with the laboratory manager revealed she thought the IQCP plan covered QC. She stated they were following streamlined QC. She was not aware the IQCP needed to specifically address the number and identity of the QC organisms tested.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) events, Quality Assurance (QA) policy, QA Dashboard, and interview with the laboratory manager, the laboratory failed to ensure PT results had been reviewed, evaluated, and those activities documented for nine samples with unacceptable results for 6 of 16 (2017 first, second, and third, and 2018 first and second events) PT reports reviewed. Findings include: 1. Review of the 2017 PT events revealed the following unacceptable results or not graded: *Hematology/Coagulation 1st event: urobilinogen sample US-02, not graded. *Microbiology 2017 1st event: culture and sensitivity sample ES-01, not graded. *Hematology 2017 3rd event: monocyte % sample XE-13, graded as unacceptable. *Hematology 2017 3rd event: blood cell identification samples BC-20 and BC-21, ungraded. Review of the 2018 PT events revealed the following unacceptable or not graded results: *Chemistry Core 2018 1st event: pCO2 sample BG-05, graded as unacceptable. *Hematology/Coagulation 2018 1st event: MCH sample XE-02, graded. as unacceptable. *Hematology/Coagulation 2018 1st event: blood cell identification sample BC-01, ungraded. *Microbiology 2018 1st event: gram stain sample GS-01, graded as unacceptable. *Microbiology 2018 1st event: culture and sensitivity sample ES-01, ungraded. Review of the lab's PT flow sheets revealed there had been no investigation on unacceptable or ungraded results. Review of the laboratory's 2018 QA policy revealed: *"Any results that are below below 100% or graded as no consensus or not graded will be investigated and repeated if able." Review of the QA Dashboard revealed: "Proficiency testing passed 100% " was documented for the above listed events. Interview on 9/13/18 at 9:10 a.m. with the laboratory manager revealed: *She had only recently taken on the position of laboratory manager about a year ago. *She "must have just missed these" in her review of PT results.