Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385321	12/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Siouxland Urology Associates	455 Sioux Point Road, Dakota Dunes, 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 12/17/19. The Siouxland Urology Associates laboratory was found not in compliance with the following requirement(s): D3031, D5213, D5401, D5407, D5411, D5429, D5469, D5507, D6079, and D6103.
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 observation, review of the annual test volume form, and interview with laboratory staff A, the laboratory failed to retain: *The results of the daily background checks on the Sysmex PocHi 100-i analyzer for 12 of 12 months (January through December 2019) to ensure critical operating characteristics that affected the stability and calibration of the analyzer met specific criteria defined by the manufacturer. *The results of quality control (QC), calibration, and patient specimen testing on three of three analyzers (Sysmex PocHi 100-i, Nanoentek Frend, and Siemens Immulite) used to test patient specimens to ensure the accurate manual entry of QC and patient specimen test results. Findings include: 1. Observation and demonstration on 12/17/19 at 11:45 a.m. of the Sysmex PocHi 100-i hematology analyzer's electronic files revealed: *Laboratory personnel A was unable to pull up a record of the analyzers background counts. *At the above time various menu functions had been accessed to attempt to pull up the background check data by laboratory personnel A. *There was no way to verify if the background counts had been acceptable. Increased background counts could lead to inaccurate patient specimen test results. *Only the current lot of QC material in use was stored in the Sysmex PocHi 100-i. *Only the most recent calibration was stored in the Sysmex PocHi 100-i. *The oldest retained patient

	specimen result in the Sysmex PocHi 100-i was 2/27/19. *There was no way to verify the accuracy of manual QC and patient test result entry at a later date. 2. Observation of patient prostate specific antigen (PSA) testing on 12/17/19 at 12:30 p.m. revealed: a. Laboratory personnel A manually entered the QC and patient test results into the laboratory information system (LIS) from the Nanoentek Frend analyzers. *PSA specimens were also processed on the Siemens Immulite analyzer. b. Examination of the electronically stored results revealed: *The oldest test result retained in the upper Nanoentek Frend analyzer was dated 7/23/19. *The oldest test result retained in the lower Nanoentek Frend analyzer was dated 9/26/19. *Laboratory personnel A was unable to access stored QC or patient results on the Siemens Immulite analyzer *There was no way to verify the accuracy of manual QC and patient test result entry at a later date. 3. Review of the annual test volume form revealed: *277 hematology patient specimens were reported in 2018. *388 patient specimens were reported from the Siemens Immulite chemistry analyzer in 2018. *3957 patient specimens were reported from the Nanoentek Frend analyzers in 2018. Interview with laboratory personnel A on 12/17/19 at 12:30 p.m. revealed: *The Sysmex PocHi 100-i analyzer had been put into use early in 2018. He was not certain of the exact date. *He thought the background counts were stored electronically. *He stated background counts rarely failed. If there was an error, he repeated the shutdown procedure. That had cleared the error in the past. *He was unaware the daily background checks needed to be documented. *All results were manually entered into the LIS. *No analyzers were interfaced to the LIS. *The computer interface had been discontinued sometime in 2018. He could not remember the exact date. *The cost of the computer interface had been too expensive. *He tried to be as paperless as possible. He did not print background, QC, or patient specimen test reports from any of the analyzers. *The analyzers were not connected to a printer. *He agreed it would be impossible to verify the accuracy of manually entered QC or patient specimen results at a later date.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) events and interview with laboratory personnel A, the laboratory failed to ensure PT results had been reviewed, evaluated, and those activities documented for 6 of 18 PT events reviewed (2018 first, second, and third; 2019 first, second, and third microbiology events). Agar disk diffusion susceptibility testing was used to assist the provider in determining an appropriate antibiotic for the treatment of a patient's bacterial infection. Findings include: 1. Review of the 2018 API Microbiology PT events revealed the following unacceptable or not graded results: a. First event: Agar Disk Diffusion/Ciprofloxacin UR-01 result graded unacceptable, result reported intermediate resistance, acceptable response was susceptible. b. Second event: *Agar Disc Diffusion/Cefepime UR-06 result graded unacceptable, result reported intermediate resistance, acceptable response was resistant. *Agar Disk Diffusion /Piperacillin/Tazobactam, ungraded. *Urine Colony Count UR-10, ungraded. Review of the 2019 API Microbiology PT events revealed: a. First event: *The following Zone Diameter Agar Disk Diffusion/CLSI were ungraded for specimen UR-01: Amoxicillin, Ampicillin, Cefepime, Cefoxitin, Ceftriaxone, Ciprofloxacin,

	Gentamicin, Imipenem, Nitrofurantoin, Piperacillin/Tazobactam, Tetracycline, and Trimethoprim/Sulfamethoxazole. * Urine Identification UR-03, ungraded. b. Second event- *The following Zone Diameter Agar Disk Diffusion/CLSI were ungraded for specimen UR-06: Ampicillin, Cefdinir, Cefoxitin, Gentamicin, Linezolid, Nitrofurantoin, Penicillin, Rifampin, Tetracycline, and Trimethoprim /Sulfamethoxazole. *Agar Disk Diffusion/CLSI/Cefdinir UR-06-ungraded. c. Third event- *The following Zone Diameter Agar Disk Diffusion/CLSI were ungraded for specimen UR-01: Amoxicillin, Ampicillin, Cefoxitin, Ceftriaxone, Ciprofloxacin, Gentamicin, Imipenem, Nitrofurantoin, Piperacillin/Tazobactam, Tetracycline, and Trimethoprim/Sulfamethoxazole. Review of the laboratory's PT reports revealed there had been no investigation on unacceptable or ungraded results for the above listed samples. Interview on 12/17/19 at 10:00 a.m. with laboratory personnel A revealed: *He was not aware the unacceptable results had not been reviewed. *He stated, "The result may have differed by a millimeter or two. Reading disk diffusion susceptibilities is not an exact science." *He was unaware he needed to review ungraded results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation, review of the procedure manual, quality control (QC) logs, and annual test volume form, and interview with laboratory personnel A, the laboratory failed to follow 6 of 14 microbiology procedures (Urine Culture Procedure, Phenol Red Broth with Carbohydrates, Moeller Decarboxylase, H2S [hydrogen sulfide] Kligler Iron Agar slant, Malonate, Antimicrobial Susceptibility Testing Procedure) for the accurate identification and susceptibility testing of urinary tract bacterial isolates from patient culture specimens. Findings include: 1. Observation on 12/17/19 at 11:45 a.m. of laboratory personnel A examining patients' urine cultures revealed: *Urine culture specimens were set up on blood, macconkey, and several Hardy Chrom agar media plates. *The use of a plastic tray with numerous small wells containing various reagents. *The use of Kirby Bauer (KB) disk diffusion for antibiotic susceptibility testing. Review of the procedure manual revealed: a. Urine Culture Procedure last reviewed and signed by the laboratory director on 9/26/19 revealed: *Urine specimens would be plated to blood, macconkey, and CNA (colistin naladixic acid) agar media plates. The procedure did not not specify the use of any other media. Refer to D5407. b. Phenol Red Broth with Carbohydrates procedure last reviewed and signed by the laboratory director on 9/26/19 revealed: *Step 1. Using a heavy inoculum, inoculate tubes of media with growth from an 18 to 24 hr (hour) pure culture using an inoculating loop. *Step 2. Incubate tubes with loosened caps at 33 to 37 degrees centigrade (C) for 18 to 48 hr either in an aerobic or anaerobic atmosphere depending on the organism being evaluated. Incubation up to thirty days might be necessary for a negative result. c. Moeller Decarboxylase procedure last reviewed and signed by the laboratory director on 9/26/19 revealed: *Step 1. Inoculate the broth media by transferring one or two colonies from an 18 to 24 hour culture (BAP [blood agar plate]). One tube with lysine, ornithine, or arginine; one tube without amino acid. *Step 2. Mix to distribute the culture throughout the medium. *Step 3. Overlay the

medium with 1 ml (milliliter) of sterile mineral oil. *Step 4. Incubate the tubes with the caps tightened at 33 to 37 degrees C. *Step 5. Examine for growth and decarboxylase reactions at 24, 48, 72, and 96 hours before reporting as negative. *The medium would become yellow initially, if the dextrose is fermented, and then would gradually turn purple if the decarboxylase reaction occurred and elevated the pH. d. The procedure manual also included an H2S Kligler Iron Agar Slant procedure last reviewed and signed by the laboratory director on 9/26/19. That reagent was not available for use at the time of the survey. e. The procedure manual also included a Malonate procedure last reviewed and signed by the laboratory director on 9/28/19. That reagent was not available for use at the time of the survey. f. Antimicrobial Susceptibility Testing Procedure last reviewed and signed and dated by the laboratory director on 9/29/19 revealed: *Step 1. Using a sterile cotton tipped applicator, touch the top of a well isolated colony from a BAP (blood agar plate) and transfer to a tube containing 2 ml of Mueller Hinton broth. *Step 2. Allow the broth to incubate at 35 C until it matches the #0.5 McFarland standard. Mix the standard vigorously and compare with the broth culture using the Wickerham card. Add broth as necessary to obtain a turbidity visually comparable to that of the standard. *Step 3. Within 15 minutes of the turbidity adjustment dip a sterile cotton tipped applicator into the bacterial suspension to remove the excess vinculum, and rotate the applicator on the side of the tube above the liquid medium. *Step 4. Streak the entire surface of a Mueller Hinton plate with the applicator a total of three times rotating the plate 60 degrees each time. *Step 5. Allow the inoculated plate to dry for approximately 5 minutes. (No longer than 15 minutes.) *Step 6. Dispense the Antimicrobial disks by placing disk dispenser over the plate. Make sure the dispenser's marks were lined up. Push lightly on the handle. *Step 7. Tap any loose disks down with a wooden applicator stick. Do not move a disk once it had come in contact with the agar surface as the drug diffused almost instantaneously. *Step 8. Invert plates and place in a 35 C incubator within 15 minutes of disk application. Incubate 18 to 24 hours. *Step 9. Zones should have been measured across the diameter of the clearing to the nearest millimeter using the naked eye. Place a ruler on the bottom of the plate and interpret the appropriate organism/antibiotic from the charts below. Enter all results into patient records in the computer. *Quality Control: performed each day of testing. Refer to D5469. Review of the annual test volume form revealed 867 patient urine cultures and 398 patient specimen KB sensitivities had been performed in 2018. Accurate identification of microbial isolates and accurate antibiotic susceptibility testing is necessary for the provider to determine the appropriate treatment for a patient's infection. Interview on 12/17/19 at 12:55 p.m. with laboratory personnel A revealed: *He did use the Hardy Chrom media routinely for setting up urine cultures. The color of growth on the media was used in the identification of the microbial isolates from patient urine cultures. *He thought his communication with the laboratory director was good. *He had not discussed nor obtained the director's approval for the changes in media used to set up urine cultures prior to use for patient specimen testing. *He set up his own identification panels in the small plastic trays. He would add the various reagents to individual wells. He would fill the well to just below the rim with the necessary reagent. He would then add one drop of his diluted bacterial isolate to each well. Oil would be added to the necessary wells. The tray would be incubated overnight. Results would be read the next day. Reactions would be entered into the LIS (laboratory information system). *He confirmed test methods used for identification of bacterial isolates varied depending on what was available and the cost of the reagent. *He confirmed there were no procedures for the use of the Hardy Chrom media or for setting up bacterial identification panels in the plastic trays. *He was "old-school" when it came to microbiology. *He had developed his own "database" of reactions to identify the bacterial isolates based on Koneman's Color

	Atlas and Textbook of Diagnostic Microbiology, 6th edition, copyrighted 2006. *He had not discussed or obtained the director's approval of the microbial identification system he had developed and used to identify patient microbial isolates. *He did not compare his diluted patient bacterial isolates to a 0.5 McFarland standard. He added 1 bacterial colony to a specified amount of liquid. He had been doing that for years, and "could tell just by looking at it if was a 0.5 McFarland." *He had had a 0.5 McFarland standard, but it had expired. He had not purchased a new one. *He confirmed KB sensitivity testing QC had been performed on a weekly basis and not each day of patient testing as required in the Antimicrobial Susceptibility Testing Procedure. *He used to do it daily but had switched back to weekly testing about two years ago. *He was an "old-school" technologist. He followed the CLSI (Clinical & Laboratory Standards Institute) standards. He was aware CLIA (Clinical Laboratory Improvement Amendments) no longer recognized CLSI standards.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation, review of the procedure manual, review of the annual test volume form, and interview with laboratory personnel A, the laboratory failed to develop procedures and obtain approval from the laboratory director prior to use for five of nine plated agar media (Hardy Chrom Candida, Hardy Chrom HUrBi [urine biplate], MacConkey with Ciprofloxacin, MacConkey with Cefotaxime, and BHI with Vancomycin) used for the isolation and identification of microorganisms. Findings include: 1. Observation on 12/17/19 at 1:40 p.m. of microbiologic media stored in the left side of the double-door laboratory refrigerator revealed the following media was in use: *Hardy Chrom Candida lot # 451239, expiration date 2/18/20. *Hardy Chrom HUrBi lot #451367, expiration date 1/20/20. *MacConkey with Ciprofloxacin lot #450599, expiration date 2/9/20. *MacConkey with Cefotaxime lot #447803 12/29 /19. *BHI (Brain Heart Infusion) with Vancomycin lot #450757, expiration date 1/11 /20. Review of the procedure manual revealed: *The Urine Culture Procedure last signed by the laboratory director on 9/26/19 referred to the use of BAP (blood agar plate), MAC (MacConkey agar), and CNA (colistin and nalidixic acid agar) for setting up urine cultures. *There was no policy or procedure for the use of the Hardy Chrom Candida, Hardy Chrom HUrBi, MacConkey with Ciprofloxacin, MacConkey with Cefotaxime, and BHI with Vancomycin plated agar medias. Review of the annual test volume form revealed the laboratory had performed 867 patient urine cultures during 2018 set up using unapproved procedures. Interview with laboratory personnel A on 12/17/19 at 1:40 p.m. revealed: *He confirmed he used the above media for setting up patient urine cultures. *He had been using the the above media for awhile. *He used the color of the growth on the Hardy Chrom medias to assist in the identification of microbiological isolates in patient urine cultures. *He had not informed the laboratory director or obtained the director's approval prior to the use of the above listed media in patient urine culture examinations. *He was "old school" when it came to microbiology. *He had not written procedures for the above media as he might not be using it next week. It would depend on what was available and the cost. *He thought his communication with the laboratory director was good. *He had not discussed nor obtained the director's approval for the changes in media used to set up urine cultures prior to use for patient specimen testing.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's package insert, review of proficiency testing records, procedure manual review, maintenance records and annual test volume review, and interview with laboratory personnel A, the laboratory failed to: *Follow the manufacturer's instructions of use for optimum performance for three of three hematology controls (Bio-Rad Liquicheck Hematology-16T low, normal, and high controls) used to verify the proper operation and accuracy of test results produced by the Sysmex PocHi 100-i analyzer. *Follow the manufacturer's Instructions For Use on one of one analyzer (Sysmex PocHi 100-i) by failing to use Sysmex calibrators and Controls to ensure proper performance and accurate patient test results. *Follow the manufacturer's Instructions For Use for one of one analyzer (Sysmex PocHi 100-i) by failing to complete the required daily shutdown of the analyzer. Findings include: 1. Observations in the laboratory on 12/17/19 from 9:00 a. m. through 10:30 a.m. revealed three Bio-Rad Hematology 16T controls in a plastic cup sitting on the counter next to the Sysmex PocHi 100-i analyzer. Review of the Bio-Rad Hematology 16T manufacturer's package insert revealed: a. Storage and Stability: *That product would be stable until the expiration date when stored unopened at 2 to 8 degrees centigrade (C). Once opened that product will be stable for 14 days when handled properly and stored tightly capped at 2 to 8 degrees C. b. Procedure: *Step 1. Remove the tubes from the refrigerator and allow to warm to room temperature (15-30 degrees C) for 15 minutes before mixing. *Step 4. After Sampling: Return tubes to refrigerator within 30 minutes of use. Interview on 12/17 /19 at 10:30 a.m. with laboratory personnel A revealed: *He thought the Sysmex PocHi 100-i analyzer had been put into use in early 2018. He was not certain of the exact date. *He routinely left the hematology controls out on the counter until he had a patient specimen to process which might be several hours. 2. Review on 12/18/19 at 10:40 a.m. of the Sysmex PocHi 100-i Instructions For Use reviewed and signed by the laboratory director on 3/28/18, revealed, "The performance of Sysmex instruments cannot be guaranteed if using other control material." Observation on 12/18/19 at 9:00 a.m. revealed Bio-Rad Hematology 16T controls in use. No Sysmex controls were present in the laboratory. Review of the annual test volume form revealed 277 hematology patient specimens had been reported in 2018 without the use of appropriate controls to ensure accuracy of patient test specimen results. Review of American Proficiency Testing Hematology/Coagulation proficiency testing reports revealed: *2018 first testing event: -0% MCV (mean corpuscular volume). -0% leukocyte (white blood cell) count. -80% or above is a considered a passing score. - The documented corrective action was- "Sysmex PocHi 100-i calibrated to Cell Dyn 1800 using Streck calibrator. Calibrated to KX-21, closest analyzer". *2018 third testing event: -60% MCV. *2019 second testing event: -60% MCHC (mean corpuscular hemoglobin concentration). -0% MCV. - The documented corrective action was- "MCV unsuccessful. Hematocrits are running low. This increases MCV. Using Bio-Rad controls, KX-21 range as that is closest. PocHi ranges not available". Interview on 12/17/19 at 10:10 a.m. with laboratory personal A revealed: *He thought the Sysmex PocHi 100-i had been put into use in early 2018. He was not certain of the

	exact date. *He was unable to obtain Sysmex calibrators and controls due the purchase of the analyzer from an "unauthorized vendor." *He used the Bio-Rad hematology calibrator and QC materials since patient testing had begun on the analyzer. *He used the Sysmex KX-21 QC values as ranges, as that analyzer was the "closest" to the Sysmex PocHi 100-i. 3. Observation on 12/17/19 at 11:45 am revealed: *Laboratory personnel A attempting to locate stored background counts on the Sysmex PocHi 100-i analyzer. *He performed a shutdown procedure that was required for daily maintenance of the analyzer in an attempt to access a background count. *At the end of the shutdown cycle, the analyzer displayed a message to power down the analyzer to complete the shutdown cycle. *He powered down the analyzer after questioned whether he completed the daily shutdown cycle by powering down the analyzer. Interview at the above time with laboratory personnel A revealed: *He did perform the shut down procedure daily. *He did not complete the cycle by powering down the analyzer on a daily basis. *He would proceed immediately to start-up procedures. *He only powered down the analyzer on Fridays.
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 the centrifuge manual, review of maintenance records, and interview with laboratory personnel A, the laboratory failed to ensure one of one centrifuge (McKesson Variable Speed Centrifuge) currently in use had been calibrated every six months as required by the manufacturer to ensure its optimum performance when used with patient testing methods. Findings include: 1. Review of the McKesson Variable Speed Centrifuge manufacturer's manual revealed it should have been calibrated (RPMs verified) every six months. Review of the available maintenance records revealed the manufacturer's required maintenance as noted above had not been documented. Interview on 12/17/19 at 2:05 p.m. with laboratory personnel A revealed: *The centrifuge was used daily for centrifuging whole blood patient specimens to separate the plasma/serum from the patient's cells. The plasma/serum would be used for patient testing. *He was aware the centrifuge needed to be calibrated periodically. Mercy was used to do the RPM checks, but they did not use them any longer. *He was not certain when the centrifuge had last been calibrated.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials

	having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, review of quality control (QC) records, manufacturer's manual review, and manufacturer's package insert, and interview with laboratory personnel A, the laboratory failed to establish acceptable ranges for three of three levels (Bio-Rad Hematology 16T low, normal, and high) of hematology quality control (QC) materials prior to testing patient specimens to verify the Sysmex PocHi 100-i analyzer was producing accurate patient specimen test results. Findings include: 1. Observation on 12/17/19 at 9:00 a.m. revealed three vials of Bio-Rad Hematology 16T controls on the counter next to the Sysmex PocHi 100-i analyzer. Review of the Bio-Rad Hematology 16T control package insert revealed: *Complete blood count (CBC) analyte QC ranges for the Abbott Cell-Dyn 1800 and the Sysmex KX-21 analyzers only. *Under Assignment of Values, the package insert stated "Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides." Review of the Sysmex PocHi 100-i Instructions for Use manual revealed, "The performance of Sysmex instruments cannot be guaranteed if using other control material." Review of American Proficiency Testing Hematology/Coagulation proficiency testing reports revealed: *2018 first testing event: -0% MCV (mean corpuscular volume). -0% leukocyte (white blood cell) count. -80% or above was considered a passing score. -The documented corrective action was: "Sysmex PocHi 100-i calibrated to Cell Dyn 1800 using Streck calibrator. Calibrated to KX-21, closest analyzer." *2018 third testing event: -60% MCV. *2019 second testing event: -60% MCHC (mean corpuscular hemoglobin concentration). -0% MCV. -The documented corrective action was: "MCV unsuccessful. Hematocrits are running low. This increases MCV. Using Bio-Rad controls, KX-21 range as that is closest. PocHi ranges not available". Interview with laboratory personnel A on 12/17 /19 at 10:10 a.m. revealed: *The Sysmex PocHi 100-i analyzer had been put into use sometime in early 2018. He was not certain of the exact date. *He was unable to obtain Sysmex calibrators and controls due the purchase of the analyzer from an "unauthorized vendor." *He had used the Bio-Rad hematology calibrator and QC materials since putting the analyzer into use. *He had used the Sysmex KX-21 QC values as ranges as that analyzer was the "closest" to the Sysmex PocHi 100-i. *He did not run the new lot concurrently with the old lot to verify the QC ranges prior to putting the QC material into use. *He was aware of the issues with PT. He had considered reporting his hematology results under a generic hematology analyzer rather than under the Sysmex PocHi 100-i due to the unacceptable PT results.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as

	specified in this section. This STANDARD is not met as evidenced by: Based on review of the Kirby-Bauer (KB) antibiotic sensitivity quality control (QC) and the annual test volume form, and interview with laboratory personnel A, the laboratory failed to perform QC each day of patient testing for 12 of 12 months (January 2019 through December 2019). Findings include: 1. Review of the KB QC revealed no documentation of QC results each day of use on patient specimens. KB QC was performed only on a weekly basis. Review of the test volume form revealed 398 KB sensitivity tests had been performed on patient specimens in 2018 without adequate QC to ensure the accuracy of patient test results. Interview with laboratory personnel A on 12/17/19 at 1:40 p.m. revealed: *He confirmed KB sensitivity testing QC had been performed on a weekly basis and not each day of patient testing. *He used to do it daily, but had switched back to weekly about two years ago. *He was aware the laboratory needed to have an Individual Quality Control Plan if QC was not run each day of patient testing. *He was an "old-school" technologist. *He followed the CLSI (Clinical & Laboratory Standards Institute) standards. *He was aware CLIA (Clinical Laboratory Improvement Amendments) no longer recognized CLSI standards.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, review of laboratory records, and interview with laboratory personnel A, the laboratory director had failed to be responsible for ensuring compliance with applicable regulations by having laboratory procedures and programs established and followed. Findings include: 1. The laboratory personnel failed to retain background counts, calibrations, quality control, and patient specimen test results. Refer to D3031. 2. Failed to review and evaluate unacceptable and ungraded proficiency testing results. Refer to D5221. 3. Failed to follow the facility's microbiological procedures for the accurate identification and susceptibility testing of microbial isolates from patient specimen urine cultures. Refer to D5401. 4. Failed to develop policies and procedures and obtain approval prior to the use of new plated agar medias before using to test patient specimen urine cultures. Refer to 5407. 5. Failed to follow manufacturer's instructions for the proper storage and use of hematology controls and to complete the required daily maintenance prior to testing patient specimens. Refer to D5411. 6. Failed to follow manufacturer's instructions for the use of appropriate calibration and quality control materials. Refer to 5411. 7. Failed to ensure the manufacturer's required maintenance had been

	performed. Refer to D5429. 8. Failed to verify and develop appropriate quality control ranges for new quality control materials prior to use. Refer to D5469. 9. Failed to ensure quality control testing was performed each day of patient testing to ensure the accuracy of patient test specimens results. Refer to D5507. 10. Failed to ensure competency evaluations had been performed on a yearly basis for laboratory staff processing patient specimens. Refer to D6103.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on observation and interview with laboratory personnel A, the laboratory director failed to ensure four of four sampled staff (B, C, D, and E) had received competency evaluations on an annual basis for the test methods they had been performing under the laboratory's certificate. Findings include: 1. On 12/17/19 at 9:45 a.m. a request was made for the competency evaluations for the laboratory staff listed above. The request was repeated again later that day. No competency records for 2018 or to date in 2019 for the four staff members identified above were provided by the time of the survey exit. Interview on 12/18/19 at 2:30 p.m. with laboratory personnel A revealed: *Staff members B, C, D, and E had performed patient specimen testing. *No competency evaluations had been performed during 2018 or to date in 2019 for staff B, C, D, and E. *He was aware they needed competency evaluations. *He had "just forgotten" to ensure they had been performed.