Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2133898	(X3) Date Survey Completed 04/16/2018
Name of Provider or Supplier Fmccp Tosa Health Center	**Street Address, City, State** 1155 N Mayfair Road, Wauwatosa, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of reagents and interview with the general supervisor, the hematology cell differential stain and immersion oil secondary containers were not labeled with the identity of the solution, the storage requirements, or the preparation and expiration dates. Findings include: 1. During the laboratory tour on April 16, 2018 at 1:30 PM, the surveyor observed three containers by the sink labeled "1", "2", and "3". The surveyor also observed a small, unlabeled dropper bottle by the microscope containing liquid. 2. Interview with the general supervisor on April 16, 2018 at 1:30 PM revealed that the three containers by the sink contained hematology differential stain, and the dropper bottle by the microscope contained immersion oil. The general supervisor confirmed the containers were not labeled with the required information stated above.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

	This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for serum pregnancy testing and interview with the general supervisor, the laboratory developed the control procedures outlined in the IQCP without evaluating data from this laboratory. Findings include: 1. Review of the IQCP for serum pregnancy did not show data collected at this laboratory was used to determine the frequency of external quality control testing and the other control procedures described in the IQCP. 2. Interview with the general supervisor on April 16, 2018 at 11:00 AM confirmed the laboratory did not have data from this laboratory to support the frequency of external control testing or other control procedures defined in the IQCP for serum pregnancy testing.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: A. Based on surveyor review of procedures and interview with the general supervisor, the technical consultant (who is also the laboratory director) did not ensure quality control requirements were specified in the hematology procedures for the DxH 800 analyzer. Findings include: 1. Review of hematology procedures show the number and frequency of external controls required at this laboratory is not specified. 2. Interview with the general supervisor on April 16, 2018 at 12:00 PM confirmed the hematology procedures do not specify the number and frequency of external control testing required at this laboratory for the DxH 800 analyzer. B. Based on surveyor review of quality control (QC) records, observation of controls, and interview with the general supervisor, the technical consultant (who is also the laboratory director) did not ensure the quality control program was established and maintained for serum pregnancy testing. Findings include: 1. Review of control records in the laboratory information system (LIS) show QC testing was performed on serum pregnancy test kit lot #703671 on April 11, 2018. 2. Observation of the pregnancy test kit in the laboratory on April 16, 2018 at 1:45 PM showed the lot number in use is #703576. The box includes a hand written note stating QC was performed on April 11, 2018. 3. Interview with the general supervisor on April 16, 2018 at 1:45 PM confirmed the QC record in the LIS for the serum pregnancy test does not show the correct lot number for the testing performed on April 11, 2018. 4. The Individualized Quality Control Plan (IQCP) for serum pregnancy testing did not use data from this laboratory to determine the frequency of control testing. See D5425. C. Based on surveyor review of quality control (QC) records, observation of controls, and interview with the general supervisor and testing personnel, the technical consultant (who is also the laboratory director) did not ensure quality control programs were established and maintained for the Piccolo analyzer. Findings include: 1. Review of chemistry control records in the LIS for the Piccolo analyzer show the current lot is #1703007. 2. Observation of the BRT (Bioresource Technology) controls in the laboratory freezer on April 16, 2018 at 12:45 PM show a partly used open box, lot #1705005, labeled "Ready to Use". Interview with testing personnel (Staff A) on April 16, 2018 at 12:45 PM confirmed the controls in this box (lot #1705005) are in current use. 3.

	Comparisons of the level two assayed ranges in the LIS with the ranges from the BRT package insert for lot #1705005 and #1703007 show the ranges for 16 of 19 analytes do not match the range for either lot number. Examples of the acceptable ranges from the LIS and BRT package inserts are shown below for the level 2 control for three random analytes; ALB (albumin), GGT (Gamma Glutamyl Transferase) and PHOS (Phosphorus). Analyte / LIS range / Lot 1705005 / Lot 1703007 ALB / 3.4-5.5 / 3.3-5.2 / 3.3-5.3 GGT / 138-216 / 142-222 / 143-224 PHOS / 4.1-5.9 / 4.6-6.7 / 4.6-6.6 4. Interview with the general supervisor at 1:15 PM on April 16, 2018 confirmed the acceptable ranges for the level one and two controls in the LIS did not match the assayed control ranges provided from the manufacturer for the Piccolo analyzer. Further interview confirmed the LIS ranges and lot numbers were not updated when a new lot number of controls was put into use.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on surveyor review of calibration and quality control (QC) data for the Beckman Coulter DxH 800 hematology analyzer and interview with the general supervisor, the technical consultant did not ensure the hemoglobin calibration factor was changed when recommended to resolve technical problems. Findings include: 1. Review of data from the routine calibration of the Beckman Coulter DxH 800 analyzer on January 27, 2018 shows the hemoglobin (hgb) calibration failed and a new calibration (cal) factor was recommended. The reference value of the calibrator was 12.2, the mean value obtained by the laboratory was 12.05. The calibration documentation includes a handwritten comment "Did not accept new cal factor for hgb. QC is not running low / no need to increase cal factor." 2. Review of the January inter-lab QC reports from Beckman Coulter dated February 18, 2018 revealed this laboratory's hemoglobin results showed a negative bias; all three control levels were below the mean when compared to peers and the low level control was nearly two standard deviations below the mean. 3. Interview with the general supervisor on April 16, 2018 at 11:45 AM confirmed the calibration factor should have been adjusted for hemoglobin and that the technical consultant did not ensure remedial actions were taken when indicated.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 surveyor review of competency evaluation records and interview with the general supervisor, the technical consultant (who is also the laboratory director) has not evaluated competency of testing personnel. Findings include: 1. Review of competency evaluation records shows no evidence of review or evaluation of

	competency by the technical consultant. 2. Interview with the general supervisor on April 16, 2018 at 9:45 AM confirmed the technical consultant has not evaluated competency of testing personnel.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory policies and procedures and interview with the general supervisor, the laboratory director has not specified, in writing, the responsibilities and duties of the general supervisor. Findings include: 1. Review of laboratory policies and procedures showed no documentation of the assigned responsibilities of the general supervisor. 2. Interview with the general supervisor on April 16, 2018 at 10:15 AM confirms the laboratory director has not specified the responsibilities and duties of the general supervisor.