Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0676414	02/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Quad Med Clinic-Sussex	W227 N6103 Sussex Rd, Sussex, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interviews with the Laboratory Director and Laboratory Manager (Staff A), the procedure for the Sysmex XN-330 analyzer did not include current step-by-step instructions for handling complete blood cell count (CBC) samples that required a slide evaluation or manual differential, and the procedure did not include the reference intervals (normal values) for three of five cell types reported as part of the automated differential. Findings include: 1. Review of the procedure for operation of the Sysmex XN-330 analyzer showed the procedure included instructions to perform a slide evaluation or manual

	differential when the analyzer determined automated differential interpretation was "positive". Further review showed the listed normal values for automated differentials included results for neutrophils, lymphocytes and a mixed cell population. The procedure showed the Sysmex XN-330 analyzer reported an automated differential that included neutrophils, lymphocytes, monocytes, eosinophils, and basophils. The procedure did not include normal values for monocytes, eosinophils, or basophils. 2. Interview with the Laboratory Director on February 14, 2024, at 10:00 AM revealed the laboratory had discontinued performance of manual differentials and hematology slide evaluations; further interview at 12:00 PM confirmed the procedure did not provide step-by step instructions for testing personnel to follow when the analyzer flagged results as positive. Interview with Staff A on February 14, 2024, at 12:30 PM confirmed the Sysmex XN-330 procedure did not include the current normal values for the differential portion of the automated CBC.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with the Laboratory Manager (staff A), two of two hematology procedures reviewed for initiation and discontinuation dates did not show dates specific for this laboratory. Findings include: 1. Review of procedures in the PolicyTech electronic storage system for the Sysmex XN-330 hematology analyzer showed an initial effective date of April 1, 2019. Review of the procedure for manual differentials showed an effective date of September 1, 2011, and last reviewed date of April 26, 2023. The procedure showed no indication it was not in use at this location. 2. Interview with Staff A on February 14, 2024, at 10:00 AM confirmed this laboratory discontinued performing manual differential testing. Further interview at 12:30 PM confirmed personnel started patient testing on the Sysmex XN-330 analyzer in July 2022 and confirmed the procedures did not include dates of initial use or discontinuation specific for this laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of verification studies and procedures and interview with the Laboratory Director, the laboratory did not evaluate the upper limit of the reportable range for the Excyte Mini Erythrocyte Sedimentation Rate (ESR) analyzer in April 2023. The laboratory did not evaluate results over 66 mm/hr (millimeters /hour) with a reportable range of 1-140 mm/hr. Findings include: 1. Review of the

	laboratory's verification studies for the Excyte Mini ESR analyzer showed the laboratory evaluated samples with results from 4 to 66 mm/hr. 2. Review of the laboratory's procedure for the Excyte ESR analyzer showed the laboratory used a reportable range of 1 - 140 mm/hr. 3. Interview with the Laboratory Director on February 14, 2024, at 3:30 PM confirmed the laboratory did not evaluate the performance of the Excyte Mini ESR analyzer for samples with results above 66 mm /hr.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control and patient records and procedures and interview with the Laboratory Director, the laboratory did not develop an alternate quality control procedure that provided equivalent quality testing for the Solana Streptococcus test. The laboratory did not perform control procedures including a positive and negative sample each day of patient testing during fourteen of fifteen days of patient testing in April 2023 and limited testing of control material to monthly or with a new lot or shipment in eleven of eleven months from March 2023 through February 14, 2024. Findings include: 1. Review of quality control and patient records from April 2023 showed the laboratory performed Solana Streptococcus testing on fifteen days. Date in 2023 / number of patient results / controls tested: April 4 / 4 / 0 April 5 / 6 / 0 April 6 / 4 / 0 April 10 / 6 / 0 April 11 / 4 / 0 April 12 / 6 / 0 April 13 / 6 / 0 April 17 / 4 / 4 April 18 / 8 / 0 April 20 / 6 / 0 April 21 / 6 / 0 April 24 / 4 / 0 April 25 / 4 / 0 April 27 / 6 / 0 April 28 / 4 / 0 2. Review of Individualized Quality Control Plans (IQCP) showed no evidence the laboratory had developed an IQCP as an approved procedure for providing equivalent quality testing for the Solana test system. 3. Interview with the Laboratory Director on February 14, 2024, at 1:30 PM confirmed the laboratory did not test positive and negative quality control material each day of patient testing and had not developed an IQCP for the Solana Streptococcus test. Further interview confirmed the laboratory only performed quality control testing with new lots or shipments of reagents and at least monthly since March 2023.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality records and interview with the Laboratory Manager (staff A), the laboratory's system to ensure accurate and reliable transmittal of data did not include the evaluation of manually entered test results for two of two years. Findings include: 1. Review of laboratory quality assurance records from 2022 and 2023 showed no evaluation of transmission of manually entered test results. 2. Interview with staff A on February 14, 2024, at 3:00 PM confirmed the laboratory's evaluation of accurate and reliable transmission of data entry did not include manually entered test results during the last two years.