Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0720425	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Medical Group Via Christi Pa E Central	8020 E Central Suite 200, Wichita, KS	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) for 2017, 2018, 2019 and interview with testing personnel #1 on February 22, 2019 at 1:45 PM confirmed the laboratory failed to verify accuracy twice annually of microscopic urines for 2017, 2018 and to date 2019.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of centrifuge and microscope maintenance and interview with testing personnel #1 on February 22, 2019 at 1:45 PM confirmed the laboratory failed to define a function check protocol that ensures the microscope and centrifuge are performing accurately in 2017, 2018 and to date 2019.

D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of procedure manuals, patient test reports and interview with testing personnel #1 the laboratory director failed approve reference ranges for hematology and microscopic urinalysis. Findings: 1. Review of Sysmex XP300 procedure manual and patient test report shows the laboratory director failed to approve reference ranges on patient test reports. 2. Review of microscopic urinalysis procedure manual and patient test report shows no approved reference ranges documented in procedure or on patient test report. 3. Interview with the laboratory director on February 22, 2019 at 1: 45 PM confirmed the laboratory directory failed to approve reference ranges for hematology and microscopic urinalysis.
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 review of competencies and interview with testing personnel #1 on February 22, 2019 at 1:45 PM confirmed the technical consultant failed to evaluate and document competency for testing personnel #2 for 2017, 2018 and to date 2019.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of competencies and interview with testing personnel #1 on February 22, 2019 at 1:45 PM confirmed the technical consultant failed to include direct observation of routine patient test performance, including patient preparation on competencies.