Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383043	05/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
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 American Proficiency Institute (API) proficiency testing (PT) attestation statements for 2016-2018 and confirmed by laboratory personnel, identifier #2 (refer to Laboratory Personnel Report) at approximately 10:30 am on 05/22/2018, the laboratory failed to maintain a copy of the attestation statement signed by the laboratory director and testing personnel for three out of six PT testing events. The findings include: 1. The laboratory director did not sign the attestation statements for the following testing events: *2017-Event 3: Hematology; and *2018-Event 1: Hematology. 2. The laboratory failed to have the attestation statement for 2016-Event 3: Hematology. THIS IS A REPEAT DEFICIENCY.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I

	of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency records and reports, the laboratory fails to successfully participate in a proficiency testing program for the analyte, platelets, for two consecutive testing events: 2017 event 3 and 2018 event 1; and the analyte, automated white blood cell differential, for two out of three consecutive testing events: 2017 event 2 and 2018 event 1 (refer to D2130).
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing reports and records, the laboratory failed to achieve satisfactory performance for the analyte, platelets, for two consecutive testing events and for the analyte, automated white blood cell differential, for two out of three testing events for unsuccessful participation. The findings include: 1. The laboratory received unsatisfactory performance scores of 60 percent (%) for 2017 testing event 3 and 2018 testing event 1 for platelets. 2. The laboratory received unsatisfactory performance scores of 50% for 2017 testing event 2 and 2018 testing event 1 for automated white blood cell differential.
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 records for 2016-2018 and confirmed by the laboratory personnel, identifier #2 (refer to the Laboratory Personnel Report) at 11:45 am on 05/22/2018, the laboratory failed to verify the accuracy of the urine microscopy twice annually for three out of four time periods from June 2016 through May 2018. The findings include: 1. The laboratory records revealed that the laboratory verified

	the accuracy of the urine microscopy on 06/09/2016. The laboratory failed to have verification records for 2017 and 2018. 2. The laboratory personnel confirmed that the laboratory failed to verify the accuracy of the urine microscopy in 2017 and 2018. THIS IS A REPEAT DEFICIENCY.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the QBC Star hematology analyzer quality control (QC) logs and patient records and confirmed by the laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 11:20 am on 05/22/2018, the laboratory failed to take and document correct action when the hematology QC failed to meet the laboratory's established criteria for 4 out of 4 days of testing in January 2018 (1/25, 1/29, 1/30 and 1/31) and failed to evaluate the complete blood count (CBC) test results for 14 out of 14 patients. The findings include: 1. The laboratory documented the QBC hematology control ranges used on 01/25/2018 - 01/31/2018 as follows: *Hematocrit (HCT): Level 1 [23.7-28.5] *Hemoglobin (HGB): Level 1 [7.8-9.4] *Platelets (PLT): Level 2 [110-145] *White Blood Cell (WBC): Level 2 [10.1-17.0] *Granulocytes (absolute count) (GRAN): Level 2 [4.6-7.8] *Lymphocytes (absolute count) (LYMPH): Level 2 [5.5-10.1] The laboratory failed to retain the package inserts to verify the lot number, expiration and acceptable control ranges (refer D-5787). 2. Records for 01/25/2018 revealed the following unacceptable QC results: HGB Level 1-22.7; HCT Level 1 - 7.4; and PLT Level 2-188. The laboratory failed to take corrective action and reported CBC results for three patients. 3. Records for 01/29/2018 revealed the following unacceptable QC results: PLT Level 2-226; WBC Level 2-24.1; GRAN Level 2-10.4; and LYMPH Level 2-13.7. The laboratory failed to take corrective action and reported CBC results for five patients. 4. Records for 01/30/2018 revealed the following unacceptable QC results: PLT Level 2-275; WBC Level 2-20.9; GRAN Level 2-9.2; and LYMPH Level 2-11.7. The laboratory failed to take corrective action and reported CBC results for two patients. 5. Records for 01/31/2018 revealed the following unacceptable QC results: PLT Level 2-289; WBC Level 2-23.7; GRAN Level 2-9.5; and LYMPH Level 2-14.2. The laboratory failed to take corrective action and reported CBC results for four patients.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

	This STANDARD is not met as evidenced by: Based on review of the testing records for the QBC Star hematology test system and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at 11:40 am on 05/22/2018, the laboratory failed to maintain the manufacturer's package inserts for control solutions used between 01/25/2018 and 03 /08/2018. The findings include: 1. At the time of the survey, the laboratory could not verify the acceptable control ranges for the QBC Star from 01/25/2018 through 03/08 /2018 due to the lack of the manufacturer's package inserts. 2. The laboratory personnel #2 confirmed that the laboratory failed to retained the package inserts during this time frame.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that 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) reports for 2016-2018 and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 10:45 on 05/22/2018, the laboratory director failed to ensure the review of PT reports by the appropriate staff for five out of six testing events: 2016 event-3, 2017 events-1-3 and 2018 event-1. Findings include: 1. Review of PT reports listed above revealed that the laboratory director did not document their review with a signature and date. 2. Laboratory personnel identifier #2 confirmed that the laboratory director did not document their review by signing and dating the PT reports. THIS IS A REPEAT DEFICIENCY.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 11:55 am on 05 /22/2018, the laboratory director failed to ensure that prior to testing patient

	specimens all testing personnel performing moderate complexity testing received the appropriate training for one out of two new testing personnel (identifier #3). The findings include: 1. According to the laboratory personnel identifier #2, the laboratory hired a temporary testing personnel (identifier #3) to work during a leave of absence from 01/25/2018 through 03/08/2018. The new testing personnel performed complete blood cell counts (CBC) testing during this time. 2. At the time of the survey, the laboratory did not have training records and competency assessments for testing personnel (identifier #3). The laboratory personnel identifier #2 confirmed the lack of documentation.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #2 (Laboratory Personnel Report) at approximately 11:00 am on 05/22/2018, the laboratory fails to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform moderate complexity as specified in standard D6065, 493.1423(b).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #3 at approximately 111:00 am on 5/22/2018, the laboratory fails to have documentation to qualify one out of two testing personnel (identifier #1, refer to the Laboratory Personnel Report, Form CMS-209) who perform moderate complexity testing.