Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2115513	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
University Of Maryland Urgent Care	105 Penn Street, Baltimore, MD	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record and patient sample log review and interview with the technical consultant (TC), the laboratory did not handle hematology PT specimens in the same manner as patient samples. Findings: 1. All patient samples which enter the laboratory are recorded on a patient log. 2. During an interview on 2 /20/18 at 11:15 AM, the TC stated that hematology PT samples were not listed individually on the patient log in the same manner as patient specimens.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on maintenance log record review and interview with the technical consultant

	(TC), the laboratory failed to ensure that the lot numbers and expiration dates of hematology reagents were documented to ensure that they are not used when they have exceeded their expiration date. Findings: 1. The laboratory documents the lot number and expiration date of the hematology reagents on the bottom of the "Instrument Maintenance Sheet." The form instructs testing personnel to "Complete information below when replacing pocH-100i reagents." 2. Instrument Maintenance Sheets from November, 2017 to January, 2018 were reviewed. The Instrument Maintenance sheet for December, 2017 showed that the "pocH-pack L Reagent" was put on the instrument on 12/11/17 and expired 1/24/18; and 3. The Instrument Maintenance Sheet for January, 2017 did not show that a new "pocH-pack L Reagent" was recorded or put on the instrument. 4. During a tour of the laboratory at 11:45 AM, it was observed that there was a "pocH-pack L Reagent" in use that was not expired, but not logged on the Instrument Maintenance Sheet. 5. During an interview on 2/20 /18 at 12:30 PM, the TC confirmed that the lot numbers and expiration dates of all hematology reagents used in the laboratory were not documented on the Instrument Maintenance Sheets.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: I. Based on review of the standard operating procedure manual (SOPM), quality assurance (QA) plan, QA records, and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the QA plan was maintained to identify failures and corrective actions taken when failures are identified. Findings: 1. The procedure, "Point of Care Quality Management Program" in the SOPM contains a section, "Overall Monitors" which states that, "Each testing area is required to submit all QC, maintenance, and patient result logs to the point of care office each month. POC staff reviews the data for compliance." 2. During the survey, the TC stated that one of the testing personnel is responsible for performing a "primary review" of the temperature and maintenance logs before they are sent to the TC to review monthly. The TC then reviews all of the logs and then writes a monthly data review which is shared with the LD and clinical consultant. 3. A review of "Monthly Data Review" reports from October, 2017 to December, 2017 showed that the same problems were noted each month, including the use of white-out on the laboratory logs, the absence of primary reviews, and that hematology patient results were not scanned in to the electronic medical record by the hospital information management department. 4. The section, "Thresholds" states, "One hundred percent compliance is expected for point of care testing monitors. Any and all out of compliance findings are sent each month to the nurse manager and medical director responsible for the testing area. Chronic issues require an action plan be submitted to POC Services." No "action plans" were available at the time of the survey. 5. During the survey, the TC stated that they had held laboratory staff meetings quarterly but were going to have them monthly because there was no improvement in the problems identified above. There was no documentation of the laboratory staff meetings available at the time of the survey. 6.

	During an interview on 2/20/18 at 12:30 PM, the TC confirmed that the laboratory's QA plan was not maintained to identify failures in quality as they occur. II. Based on review of the standard operating procedure manual (SOPM), quality assurance (QA) plan, and maintenance logs and interview with the technical consultant (TC), the laboratory director failed to ensure that the QA plan was maintained to identify failures and corrective actions taken when failures are identified. 1. The procedure, "Point of Care Quality Management Program" in the SOPM contains a section, "Analytic Monitors" which states, "Lot numbers, expiration dates, and proper storage of test components are reviewed by POC staff for accuracy and compliance with manufacturer's requirements. This is done by review of the data logs each month and periodic audits of the testing sites." 2. A review of maintenance logs from December, 2017 to January, 2018 showed that documentation of the lot number and expiration date of hematology reagents was missing, and there was no date or initials of the monthly "Point of Care Review" by the TC. See D5417 for details.
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 the competency documentation and interview with the technical consultant (TC), the TC failed to perform and document the competency review on all testing personnel. Findings: 1. The laboratory currently has 5 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." A review of competency assessments for 2016 and 2017 showed that competency assessments on 4 of 5 testing personnel were performed by a laboratory staff member who was not qualified to be TC. 2. During the survey on 02/20/18 at 12:30 PM the TC confirmed that the evaluations for 2016 and 2017 were not performed by the qualified TC (Bachelor of Science with two years experience).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the competency documentation and interview with the technical consultant (TC), the TC failed to perform and document the competency review on all testing personnel. Findings: 1. The laboratory currently has 5 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." A review of competency assessments for 2016 through 2017 showed that 2 of 5 testing personnel did not have their 6 month competency assessment performed after their initial training. 2. During the survey on 02/20/18 at 12:30 PM the TC confirmed that there were no 6 month competency assessments performed on 2 of 5 testing personnel for 2016 and 2017.