Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2019342	05/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Stopwatch Urgent Care	2415 Moore'S Mill Road, Suite 230, Auburn, AL	

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
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 a review of the installation documentation, quality control (QC) and calibration records for the Abbott Cell Dyn Emerald, a review of patient results logs, and an interview with the Clinical Manager, the surveyor determined the laboratory failed to ensure the manufacturer's analytical specifications were verified after moving the Hematology instrument from another clinic 80 miles away to the current location on 6/26/2017. Record reviews revealed testing personnel utilized the analyzer for twenty days despite daily problems with QC outages which were not alleviated until a calibration was performed on 7/18/2017. The findings include: 1. During the entrance tour on 5/16/2019 at 9:30 AM, the surveyor asked if the laboratory had any new analyzers or assays; the Clinical Manager stated the Abbott Cell Dyn Emerald Hematology analyzer was new for this location. The instrument had been moved from the Eufaula Clinic in June 2017. 2. A review of the "Installation" binder for Abbott Cell Dyn Emerald revealed testing personnel ran seven patient CBC's (Complete Blood Counts) on the machine in Eufaula, then moved the analyzer 80 miles to Auburn, and reran the same seven patient CBC's on 6/26/2017. The previous Testing Personnel (TP #1 on the 2017 CMS-209 form; the code indicated she had high school diploma educational qualifications) referred to the verification as a "Correlation Calibration", with a note "No drastic changes noted", and signed her name; the Clinic

	physician also signed the sheet. The surveyor noted the only approval by the Laboratory Director was his signature on the first page of the Cell Dyn Operators Manual. 3. A review of Hematology records revealed QC problems with the Red Blood Cell (RBC) parameters (RBC, Hemoglobin, Hematocrit, and RBC indices) began the next day (6/27/2017), and continued until the instrument was calibrated on the afternoon of 7/18/2017. 4. A review of the 6/27/17 CBC QC revealed testing personnel repeated the Normal and High levels seven times each, however they were unable to obtain QC results within the acceptable limits. Fourteen patient CBC's were performed on 6/27/2017; three had the initials of the physician to indicate review of the results. There was no documentation the physician was informed two out of three levels of QC were unacceptable. 5. Testing personnel continued to perform patient testing despite daily QC problems with the RBC parameters which required multiple repeats to obtain results within acceptable QC ranges. (Refer to D5481.) A review of the patient results logs printed from the instrument revealed 212 patient CBC's were performed between 6/27 - 7/18/2017. 6. The surveyor reviewed these records with the Clinical Manager on 5/16/2019 at approximately 3:00 PM; the Manager stated the Cell Dyn was installed before she began working for the clinic, and further stated she had no idea why the previous testing personnel or the Laboratory Director had not ensured the instrument performance was fully validated. Thus the above noted findings were confirmed. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the installation documentation, quality control (QC) and calibration records for the Abbott Cell Dyn Emerald, a review of patient results logs, and an interview with the Clinical Manager, the surveyor determined the laboratory failed to ensure Red Blood Cell (RBC) parameters (RBC, Hemoglobin, Hematocrit, and RBC indices) were stable after moving the Hematology instrument from another clinic 80 miles away to the current location on 6/26/2017. Hematology record reviews revealed testing personnel utilized the analyzer for twenty days despite daily problems with QC outages which were eventually alleviated when a calibration was performed on 7/18/2017. The findings include: 1. During the entrance tour on 5/16/2019 at 9:30 AM, the surveyor asked if the laboratory had any new analyzers or assays; the Clinical Manager stated the Abbott Cell Dyn Emerald Hematology analyzer was new for this location. The instrument had been moved from the Eufaula Clinic on the 26th of June, 2017. 2. A review of Hematology records revealed QC problems with the Red Blood Cell (RBC) parameters (RBC, Hemoglobin, Hematocrit, and RBC indices) began the next day on 6/27/17 when testing personnel repeated the Normal and High QC levels seven times each, however they were unable to obtain QC results within the acceptable limits. Fourteen patient CBC's were performed on 6/27/2017; three had the initials of the physician to indicate review of the results. There was no documentation the physician was informed two out of three levels of QC were unacceptable. 3. Testing personnel continued to perform patient testing despite daily QC problems with the RBC parameters; most days the Normal (N) and High (H) QC required repeat testing two to three times to obtain results within acceptable ranges. The surveyor noted on 6/30/2017 the N and H QC were repeated ten times; the N QC was within

	acceptable limits on the tenth try, however the H QC was still unacceptable. The High QC was also outside of acceptable limits on 7/1, 7/3, 7/6, 7/10, and 7/12/17 despite repeat testing. The Normal QC was also outside of acceptable limits on 6/28, 7/9 and 7 /15/17 despite repeat testing. 4. QC problems with the RBC parameters continued and were not resolved until the Cell Dyn Emerald was calibrated on 7/18/2017. A review of the patient results logs printed from the instrument revealed 212 patient CBC's were performed between 6/27 - 7/18/2017. 5. During an interview with the Clinic Manager on 5/16/2019 at approximately 3:00 PM, the surveyor explained the continual QC problems after the installation of the Cell Dyn were indicative of a problem and should have been investigated after the first day when QC was outside acceptable limits. The Manager then reviewed the patient log with the surveyor, and confirmed the testing personnel had continued to run patient CBC's until a calibration was performed on 7/18/2017. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance documentation and interviews with the Clinical Manager, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance (QA) documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems in the following areas: A.) May 2017 QA documented "Cell Dyn moved from eufaula to auburn 6/26/17", however the laboratory had failed to implement QA procedures to ensure the manufacturer's analytical specifications were verified after the move, or to ensure the Laboratory Director reviewed and documented his approval of the validation procedures. (Refer to D5421 and D6013.) B.) June 2017 QA documented the Normal and High Hematology QC were "out", with the notation "Verify and pull patients for MD review". The surveyor noted QC was outside acceptable ranges on 6 /27/2017, with 14 patient CBC's (Complete Blood Counts) performed. Three of the 14 CBC's were initialed by the provider (indicating review). However there was no indication the other CBC's were reviewed, or whether the physician was informed two out of three levels of QC were unacceptable. (Refer to D5481.) C.) July 2017 QA documented the Cell Dyn analyzer had service and a calibration on 7/18/2017, however there was no documentation of the continual daily QC problems from the date of the move on 6/27/2017 till the date of calibration on 7/18/2017, or an assessment of whether the patient results were reliable The surveyor further noted there were no corrective action protocols for the testing personnel to follow when QC was out of acceptable ranges. The Clinical Manager was only able to provide QC procedures found in the Cell Dyn Operators Manual, which did not specify the number of times testing personnel should repeat QC, and other actions to take when QC results were outside acceptable ranges. (Refer to D5481.) 2. During the exit summation on 5/16/2019 at 4:00 PM, these concerns were reviewed and discussed with the Clinical Manager. .

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the installation documentation, quality control (QC) and calibration records for the Abbott Cell Dyn Emerald, a review of patient results logs, and an interview with the Clinical Manager, the surveyor determined the Laboratory Director failed to ensure the instrument performance was fully validated, and the manufacturer's analytical specifications were verified after moving the Hematology instrument from another clinic 80 miles away to the current location on 6/26/2017. Record reviews revealed testing personnel utilized the analyzer for twenty days despite daily problems with QC outages which were eventually alleviated when service and a calibration were performed on 7/18/2017. The findings include: 1. Refer to D5421. SURVEYOR ID# 32558 Licensure and Certification Surveyor