Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2064623	09/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Stopwatch Urgent Care	3029 Allison Bonnett Memorial Drive, Hueytown, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the temperature logs, the manufacturer's storage requirements for the Hematology quality control (QC) vials, and an interview with Diagnostic Manager, the surveyor determined the laboratory failed to ensure QC was stored at 2-8 degrees Celcius (C) as per manufacturer's requirements on eleven out of seventeen days in September 2020. The findings include: 1. Storage requirements on the vials of QC for the Abbott Cell Dyn Emerald Hematology analyzer specified a temperature range of 2-8 degrees C (or 35.6-46.4 degrees F [Fahrenheit]). 2. A review of the September 2020 temperature logs on 9/17/2020 revealed refrigerator temperatures were greater than 46 degrees F eleven out of seventeen days. 3. During the exit interview on 9/17/2020 at 3:30 PM, the surveyor reviewed and confirmed the the high QC storage temperatures with the Diagnostic Manager; the surveyor explained improper QC storage could be one contributing factor to the numerous QC problems the laboratory has had with the Cell Dyn Emerald (refer to D5793). .
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on reviews of proficiency testing records, quality control documentation, and service reports, and an interview with the Diagnostic Manager, the surveyor determined the facility has failed to determine the cause of underlying problems evidenced by continual QC outages with the Abbott Cell Dyn Emerald Hematology analyzer in use since 11/20/2019. The findings include: 1. A review of Hematology records revealed the Abbott Cell Dyn Emerald Hematology analyzer was approved for patient testing on 11/19/2019, and testing personnel began using the analyzer for patient CBC's (Complete Blood Counts) on 11/20/2019. The new instrument was in use for a week, then testing personnel documented problems with the low QC on 11 /29 and 11/30/19. Service was called on 11/30, however the technician could not come until 12/6/19. (From 12/1-12/5/19, the analyzer was not used.) 2. Despite the 12 /6/2019 service on the analyzer, testing personnel documented QC outages on six days from 12/13-12/28/19, including two levels out on 12/22 when one patient CBC was run. (Corrective action included review of the CBC by the physician.) 3. The laboratory called for additional service on 1/12/2020, however the surveyor noted 15 days when testing personnel had problems obtaining QC within acceptable limits 1/13 thru 3/5/2020, including two levels out on 1/17 when patient CBC's were run. (Corrective action documented: "Patients still ran; pulled one patient, MD reviewed chart and signed".) 4. Service was called again and returned to the lab on 3/6/2020, however there were five days when testing personnel had problems obtaining QC within acceptable limits 3/16 thru 3/26/2020. Thereafter, there were no patient CBC's from 3/27 thru 7/31/2020 (except for 6/3/2020) due to the CoVID-19 pandemic. During that period the analyzer was serviced on 5/29/2020. QC records document the Testing Personnel ran some QC in June and July, however the low level was out of acceptable ranges on 6/7-6/13, 6/15-6/20, and 7/16/20. Low and normal QC were out on 7/31/20, however the lab was still collecting only CoVID-19 specimens, no patient CBC's. Also of note was the failure of the 7/29/2020 proficiency testing with a score of 0% for platelets, despite in-range QC on that date. 5. Regular CBC testing resumed in August 2020, with documentation of difficulty obtaining QC within acceptable limits on eleven days from 8/1 thru 8/17/2020, when Abbott performed additional service on the instrument. After the service, QC failed on again on 8/20, 8/21 and 8 /22. There was no testing 8/23-31/20 because the laboratory ran out of cleaner for the Emerald. 6. Review of the daily individual QC printouts for September 1-17, 2020, revealed testing personnel had difficulties (requiring repeat running of the QC one to three times) on 9/9, 9/12, and 9/15/2020. 7. During the exit interview with the Diagnostic Manager on 9/17/2020, the surveyor reviewed and confirmed the numerous days when the testing personnel had difficulty obtaining QC within acceptable limits. The surveyor expressed concern with the reliability of the Emerald and explained continual QC outages requiring repeat runs or other corrective action indicated a problem with the analyzer that five service calls have been unable to correct; problems have resumed each time shortly after service. A review of the facility calendar revealed the laboratory had been open and the instrument was operational for approximately 157 days from 11/20/2019 thru 9/17/2020; on 63 of those days, the testing personnel documented problems with the QC requiring addition actions; this was approximately 40% of the time. On 7/29/2020 when the QC was

	within acceptable ranges, the laboratory failed platelets (0%) on the Event #2 proficiency testing survey; this indicated the Emerald results could be unreliable even on days when QC was acceptable. The surveyor explained the laboratory must ensure Abbott has thoroughly investigated these problems, and implemented repairs for a long-term resolution of the issues. In addition the laboratory should should review other parameters affecting the QC itself such as storage temperature (refer to D5413) and handling of the QC to ensure these issues are not contributing to the QC problems. SURVEYOR ID#32558 Licensure and Certification Surveyor