Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2008906	**(X3) Date Survey Completed** 11/06/2018
Name of Provider or Supplier Friendswood Urgent Care	**Street Address, City, State** 1305 W Parkwood Suite 101, Friendswood, TX	
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**
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5024 - 42 C.F.R. 493.1215 Condition: Hematology; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIAcertified and CLIA-exempt laboratories The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: A. Based on review of 2017 and 2018 laboratory records and confirmed in interview, the laboratory failed to retain laboratory records for wet prep testing. Findings were: 1. Review of all the laboratory records from 2017 and 2018 revealed no documentation of the patient test records for wet prep testing. 2. An interview with the laboratory manager on 11/6/18 at 1100 hours in the break room confirmed the above findings. He stated that the physicians rarely performed them, but he was unsure where they kept the results. B. Based on review of 2018 quality control records and confirmed in interview, the laboratory failed to retain CBC (complete blood count) patient instrument records on the Cell Dyn Emerald hematology analyzer. Findings include: 1. Review of all the laboratory records revealed no documentation of the instrument patient records for 7 of 7 patients when the laboratory performed CBC

	(complete blood count) patient testing on the Cell Dyn Emerald hematology analyzer. 2. An interview with the laboratory manager on 11/6/18 at 1100 hours in the break room confirmed the above findings. He stated that the laboratory scanned the reports onto their computer system but they discarded the original printout. He was also unaware that the scanned copies were unreadable.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of Hematology records, patient test results, observations, and interviews, the laboratory failed to meet applicable requirements in the specialty of hematology as evidence by: 1. The laboratory failed to follow manufacturer's instructions for suspected R flags on the Cell Dyn Emerald for the complete blood counts (CBCs) (see D5405). 3. The laboratory failed to monitor over time the accuracy and precision of the Cell Dyn Emerald hematology analyzer (See D5441). 4. The laboratory failed to establish their own control means and acceptable ranges (see D5469). 5. The laboratory failed to have a mechanism in place to review the analytical systems for the Cell Dyn Emerald (See D5793).
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 the laboratory procedures and laboratory records and confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 1 of 2 tests. (wet mount) Findings were: 1. A review of laboratory proficiency testing records from 2016 & 2017 revealed no documentation of the laboratory verifying the accuracy of the following test: wet mount. 2. An interview with the lab manager on 11 /6/18 at 1110 hours in break room confirmed the above findings. He stated that it was hard to perform the accuracy assessment when they rarely performed the test.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on review of the manufacturer's instructions, patient records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to ensure

	system flags were verified prior to reporting patient results from the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the manufacturer's instructions for the Cell-Dyn Emerald hematology analyzer (9140847E-June 2010) under "Section 3: Principles of Operations" subsection "Instrument Alarms, Operational alerts, and Measured Data Flags" revealed the following result flags and corrective actions to perform: Flag S (with an L3) Corrective Action: "Corrective Action: "Check the specimen of clots or agglutination. Follow your laboratory's review criteria or review a stained smear verify the WBC count. Redraw and retest the specimen as required." 2. Review of the laboratory policies available revealed no documentation of a laboratory policy for the above flags. 3. Random review of patient records from October 2017 to April 2018 revealed 2 of 7 patients with L3 flags with no documentation of the laboratory review. Refer to patient alias list. 4. An interview with the laboratory manager on 11/6/18 at 1030 hours in the break room confirmed the above findings. B. Based on review of the manufacturer's instructions, quality control records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to establish the acceptable range for the Cell-Dyn Emerald quality control. Findings were: 1. Review of the package insert for the Cell-Dyn Emerald quality control (Ref 09H69-01, 09H69-02, 350006-3, October 2012) revealed "the mean range does not represent standard deviations" 2. Review of the package insert for the Cell-Dyn Emerald quality control revealed the follow manufacturer's assay values and mean ranges. Lot L7324, exp 3/9/18 Analyte Assay Value Mean range WBC (10^9/L) 2.1 0.4 LYM (10^9/L) 1.1 0.6 LYM % 51.3 10 MID (10^9/L) 0.2 0.2 MID % 6 6 GRA (10^9/L) 0.9 0.8 GRA (%) 43.5 10 RBC (10^12/L) 2.22 0.2 HGB (g/dL) 5.4 0.5 HCT (%) 17.3 2 MCV (fL) 78 4 MCH (pg) 24.3 2.5 MCHC (g /dL) 31.2 3 PLT (10^9/L) 68 25 Lot N7324, exp 3/9/18 Analyte Assay Value Mean range WBC (10^9/L) 8.3 1 LYM (10^9/L) 2.1 1.2 LYM % 25.6 9 MID (10^9/L) 0.4 0.3 MID % 5 5 GRA (10^9/L) 5.8 2 GRA (%) 70.4 9 RBC (10^12/L) 4.15 0.25 HGB (g/dL) 11.2 0.7 HCT (%) 34.9 3.5 MCV (fL) 84 5 MCH (pg) 27 2.5 MCHC (g/dL) 32.1 3 PLT (10^9/L) 207 35 Lot H7324, exp 3/9/18 Analyte Assay Value Mean range WBC (10^9/L) 17.8 2.5 LYM (10^9/L) 2.3 2 LYM % 12.7 6 MID (10^9/L) 1.2 1.2 MID % 5 5 GRA (10^9/L) 15 3.5 GRA (%) 84.1 8 RBC (10^12/L) 5.09 0.3 HGB (g /dL) 14.8 1 HCT (%) 45.3 3.5 MCV (fL) 89 5 MCH (pg) 29.1 2.5 MCHC (g/dL) 32.7 3 PLT (10^9/L) 436 85 3. Review of the laboratory quality control records revealed no documentation the laboratory established its own acceptable ranges. 4. An interview with the laboratory manager on 11/6/18 at 1115 hours in the break room confirmed the above findings. He stated the laboratory used the manufacturer's published ranges. He was unaware the laboratory should establish their own.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of quality control records from February to April 2018, and confirmed in interview, the laboratory failed to have a quality control plan that would monitor quality control over time for CBC (complete blood count) testing on the Cell Dyn Emerald hematology analyzer. The findings were: 1. Review of the February to April 2018 quality control data revealed no documentation the laboratory monitored quality control data over time. The laboratory failed to review the Levy Jennings or statistical calculations (mean, standard deviations, and coefficient of variation), which present an overall evaluation of quality control performance, and is a tool used to evaluate the accuracy and precision of controls over time. 2. An interview with the laboratory manager on 11/6/18 at 1110 hours in the break room confirmed the above findings.
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 a review of the laboratory policy, Cell Dyn Emerald hematology quality control reports for 2018, and confirmed in interview, the laboratory failed to document corrective actions when quality controls failed to meet the laboratory's established criteria for acceptability. Findings were: 1. Random review of the Cell Dyn Emerald hematology quality control (QC) from 01/2018 to 03/2018 revealed 12 of 40 days when there were quality control failures. 1/2/18 1/8/18 1/15/18 2/3/18 2/6 /18 2/15/18 2/18/18 2/20/18 2/24/18 3/11/18 3/23/18 3/27/18 2. Review of the corresponding laboratory records revealed no documentation of the corrective action for the above quality control failures. 3. Random review of the patient final reports from 01/2018 to 03/2018 revealed the laboratory performed patient testing on the above dates with no documentation of corrective actions. Refer to patient alias list. 4. An interview with the laboratory manager on 11/6/18 at 1005 hours in the break room confirmed the above findings.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel records for 2016 and 2017, and verified by interview, the Technical Consultant, who is also the lab director, failed to perform the 2016 and 2017 annual competency evaluations for testing personnel (TP) for moderately complex testing in hematology. Findings were: 1. A review of the 2016 -

	2017 facility's personnel files revealed 7 of 7 testing personnel (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7) had documentation of an annual 2016 and 2017 competency assessment performed by the general supervisor who does not qualify as a technical consultant. The general supervisor has an associate's degree. 3. An interview with the laboratory manager on 11/6/18 at 1135 hours in the break room confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of training for 4 of 5 testing personnel for moderately complex testing for CBC (complete blood count) on the Cell Dyn Emerald hematology analyzer. Findings were: 1. A review of personnel records available revealed no documentation of training for 4 of 5 testing personnel for moderately complex testing for CBC (complete blood count) on the Cell Dyn Emerald hematology analyzer. 2. An interview with the technical consultant on 11/6/18 at 1010 hours confirmed the above findings.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to meet the requirements in 493.1773. Refer to D8103
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a

	reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview, it was revealed the laboratory was not an active laboratory ready to perform non-waived hematology, parasitology, bacteriology, and mycology testing. No instrument, supplies, or test records were available for review on the date of survey 11/6/18. Findings were: 1. Review of the CMS116 revealed the laboratory performed 50 wet preps and 1950 hematology tests annually. The certificate of compliance was effective from 09/11/16 to 09/10/18. 2. A tour of the facility on 11/6/18 at 0910 hours revealed no CBC instrument available for use. 3. A tour of the laboratory on 11/6/18 at 0905 hours revealed no reagents and quality control to perform CBC testing on the Cell-Dyn Emerald hematology analyzer. 4. A tour of the laboratory on 11/6/18 at 0910 hours revealed no test records available for review for wet prep testing nor CBC instrument printouts from the Cell-Dyn Emerald hematology analyzer. Refer to D3031A, B 5. Review of the laboratory records available revealed no documentation of the training records for 4 of 5 testing personnel who performed non-waived testing from 09/11/16 to 09/10/18. Refer to D6066 6. An interview with the laboratory manager on 11/6/18 at 1150 hours in the break room confirmed the above findings. He stated that the laboratory were having "instrument problems" and were unable to resolve and correct the instrument. A phone interview on 12/12/18 at 1000 hours with the laboratory manager stated the laboratory ceased CBC and wet prep patient testing in July 2018. A request for documentation was made 12/12/18, but no documentation was provided as of 01/11/19.