Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2043149	06/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
West Gray Properties Llc Dba Bellaire Er	5302 Bellaire Blvd, Bellaire, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on proficiency testing records for 2018 and 2019 and staff interview, it was revealed the laboratory failed to have documentation of performing a self-evaluation for 2 of 2 samples that were not graded by American Proficiency Institute. Findings include: 1. Review of the 2018 Chemistry- Miscellaneous- 1st event proficiency testing performance evaluation (signed by the laboratory director on 6/7/18) revealed the laboratory received a grade of 'Not Graded' for Urine drug screen Opiates sample UDS-02. 2. Review of the 2019 Chemistry- Miscellaneous- 1st event proficiency testing performance evaluation (signed by the laboratory director on 5/31/19) revealed the laboratory received a grade of 'Not Graded' for Urine drug screen Opiates sample UDS-01. 3. The American Proficiency Institute proficiency testing performance evaluation form states, "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 4.

	An interview with the laboratory director on 6/17/19 at 11:03 in the nurses station revealed the laboratory failed to have documentation of performing a self evaluation for 'Not Graded' proficiency test results. This confirmed the above findings.
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: Based on review of the manufacturer's instructions, laboratory records, patient records, interview of Sysmex technical support, and confirmed in interview with the lab director, the laboratory failed to follow the manufacturer's instructions for histogram flags for CBC (complete blood count) analysis on the Sysmex XP-300 hematology analyzer. Findings were: 1. Review of the Sysmex XP-300 Instructions for use (Code No. AU553517, Revised 2015) revealed under Histogram Flags "When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following: AG - Probable cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. corrective action: check smear, etc. 2. Review of the laboratory policy Sysmex XP-300 (version 1.02) under Procedure Notes revealed "Any flags that are present on the report that denote possible concerns related to the differential, are remixed and repeated according to the sample handling instructions above. If the flags persist, the sample is sent to a reference lab for confirmatory studies; i.e. Manual smear review and /or manual differential." 3. Random review of the QA records from June 2018 to May 2019 revealed 1 of 10 patients (Patient ID 1192820278) with an AG flag. 4. Review of the the laboratory QA documentation revealed the corrective action as "Plt [platelet] flagged on CBC. Visually checked for clot - not present. sample remixed and reran. Flag still present. No Hem [hemolytic], ICT [icteric], or LIP [lipemia]. sample spun down. Dr. states to cancel PLT" 5. An interview with the laboratory director on 6/17/19 at 1300 hours in the nurses station confirmed that it is laboratory policy to spin down the specimen to verify if the specimen was hemolyzed, icteric, or lipemic. Then the testing person would resuspended the cells and re-analyze the sample for CBC. 6. Observations on 6/17/19 at 1320 hours in the nurses station revealed the laboratory used a Horizon Model 642E centrifuge for specimen centrifugation. Review of the centrifuge calibration records revealed it centrifuges at 2297 rmp for 10 minutes. 7. A message from the Sysmex technical representative via phone on 6/17/19 revealed that Sysmex has not performed studies to determine if analysis after centrifugation were valid. He further indicated that none of the Sysmex procedures state that is a validated procedure. 8. Review of the laboratory documentation available revealed no documentation of establishment studies to determine if CBC analysis after centrifugation provided accurate and reliable results. 9. Review of the patient test records revealed the laboratory reported the CBC analysis after centrifugation for Patient ID 1192820278. Furthermore, no documentation was available of the smear review per the manufacturer's instructions for the AG flag. 10. An interview with the lab director on 6/17/19 at 1330 hours in the nurses station

	confirmed the above results. She was unaware a sample resuspended after centrifugation was not acceptable practice for the Sysmex XP-300 hematology analyzer.
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: A. Based on review of the manufacturer's instructions for Alere Triage D-Dimer Test, review of the manufacturer's instructions for the Alere Triage Cardiac Panel, review of the laboratory's room temperature records from May 2018 to June 2019, review of patient test records, and staff interview, it was revealed the laboratory failed to ensure its defined acceptable temperature range was acceptable for the test kits. The findings were: 1. A review of the manufacturer's instructions for the Alere Triage D-Dimer Test (2017) under the section titled "Storage and Handling Requirements" revealed: "Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20 -24C or 68 -75F)." 2. A review of the manufacturer's instructions for the Alere Triage Cardiac Panel (2014) under the section titled "Storage and Handling Requirements" revealed: "Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20 -24C or 68 -75F)." 3. A review of the laboratory's room temperature records from May 2018 to June 2019 revealed the laboratory's defined acceptable room temperature range was 20 - 26C. Further review revealed the following days were the documented room temperature was outside the manufacturer's define required range: Date Temperature 05/23/18 24.1 05/24/18 24.1 07/23/18 24.1 07/24/18 24.4 08/06/18 24.2 08/08/18 24.3 08/09/18 24.9 08/10/18 24.1 09/27/18 24.3 10/20/18 24.6 10/31/18 24.1 02/03/19 24.7 04/20/19 24.3 04/23/19 24.4 04/24/19 24.1 04/26/19 25.5 04/27/19 25.8 04/28/19 24.6 04/29/19 24.8 05/01/19 25.2 05/16/19 24.3 4. A review of patient test records from May 2018 to June 2019 identified the following patient samples which were tested on days when the documented room temperature was outside the manufacturer's required range: Date Sample ID 05/23/18 19588 05/23/18 19589 05/23/18 19589 05/24/18 19594 07/23/18 20060 07/24/18 20068 07/24/18 20074 08/06/18 11190 09/27/18 11502 09/27/18 11502 10/31/18 11726 02/03/19 13359 04/23/19 11252 04/23/19 14029 04/24/19 11252 04/24/19 11252 04/27/19 13583 04/27/19 14065 04/27/19 14069 05/01/19 1578 5. An interview with the laboratory director on 06/17/2019 at 1300 hours in the nurse's station - after her review of the records - confirmed the findings. 41687 B. Based on the review of manufacturer's instructions, storage conditions for the laboratory supplies and staff interview, it was revealed the laboratory failed to have documentation of temperature monitoring in the area where laboratory supplies were stored. Findings include: 1. Based on the manufacturer's instructions for BD Vacutainer Blood Collection Tubes, the tubes were to be stored within a temperature range of 4C to 25C. 2. During a tour of the laboratory, the surveyor found BD Vacutainer Blood Collection Tubes in the nurses station with no means of temperature monitoring. The following tubes and quantities were found: A.

	BD Vacutainer K2 EDTA (K2E) Blood Collection Tubes -- 354 tubes B. BD Vacutainer Lithium Heparin (LH) Blood Collection Tubes -- 416 tubes C. BD Vacutainer Serum Blood Collection Tubes -- 99 tubes D. BD Vacutainer Sodium Fluoride/Potassium Oxalate (FX) Blood Collection Tubes -- 89 tubes E. BD Vacutainer SST Blood Collection Tubes -- 80 tubes 3. An interview with the laboratory director on 6/17/19 at 12:15 in the nurses station revealed that the laboratory was not monitoring the temperature in the nurses station where the laboratory supplies were stored. This confirmed the above findings.
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 the laboratory's test menu, review of the laboratory's quality control records from 2017, 2018 and 2019, and staff interview it was revealed the laboratory failed to have documentation of monitoring quality control over time for CKMB, Troponin, and D-Dimer testing. The finding were: 1. A review of the laboratory's test menu revealed the laboratory performed the following tests on the Alere Triage analyzer: CKMB Troponin D-Dimer 2. A review of the laboratory's quality control records from 2017, 2018, and 2019 (as of the day of the survey) revealed the laboratory failed to have documentation of monitoring quality control values overt time to detect shifts and trends. 3. The laboratory was asked to provide documentation of having a mechanism in place to monitor the quality control values. No documentation was provided. 4. An interview with the laboratory director on 06/17 /2019 at 1015 hours in the nurse's station revealed the laboratory did not monitor the control values over time to detect shifts and trends. This confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the the laboratory's room temperature records from January 2018 to May 22, 2018, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions for temperatures documented outside the defined acceptable range. The findings were: 1. A review of the laboratory's room temperature records from January 2018 to May 22, 2018 revealed the laboratory had a

	defined acceptable temperature range of 20 - 24C. Further review of the laboratory's records revealed the following days were the documented room temperature was outside the acceptable range and corrective actions were not performed: Date ` Temperature 04/19/18 24.2 04/28/18 24.7 05/04/18 24.1 05/05/18 24.4 05/06/18 24.4 05/08/18 24.3 05/11/18 24.1 05/12/18 24.3 05/13/18 24.2 05/14/18 24.1 05/18/18 24.3 05/21/18 24.1 2. The laboratory was asked to provide documentation of performing corrective actions for the identified temperatures. No documentation was provided. 3. An interview with the laboratory director on 06/17/2019 at 1300 hours in the nurse's station revealed corrective actions had not been performed. This confirmed the findings.
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 review of quality assessment reports and interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5411, D5413-A, B, D5441, D5785
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology. Refer to D5411
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 API proficiency testing records and confirmed in interview, the laboratory director failed to ensure that all proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. Refer to D5213
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and confirmed in interview, the laboratory failed to ensure the laboratory established and maintained a quality control program. Refer to D5441