Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2043149	08/30/2021
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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2020, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director signing 2 of 2 attestation statements in 2020. Findings include: 1. A review of the laboratory's API records from 2020 revealed the laboratory failed to have documentation of the laboratory director signing the following 2 attestation statements: - 2020 Hematology/Coagulation 1st Event - 2020 Hematology /Coagulation 3rd Event 2. Further review of the attestation statements from the above listed testing events revealed the attestation statements were signed by testing person

	#1 (as indicated on the CMS 209 form). 3. A review of the laboratory's records revealed the laboratory failed to have documentation of the laboratory director delegating the responsibility of signing proficiency testing attestation statements to testing person #1. 4. An interview with the laboratory director on 8/30/21 at 9:50 a.m. in the nurse's station, after review of the records, confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's policies, a review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director performing a competency assessment for 1 of 1 clinical consultant. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 8/30/21) identified one clinical consultant employed by the laboratory. 2. A review of the laboratory's policy titled 'Laboratory Staff Responsibilities' revealed the following: "The Laboratory Director is responsible for the overall operation and administration of the laboratory and must ensure the competency of all laboratory personnel." Note: Further review of the 'Laboratory Staff Responsibilities' policy revealed the frequency of the competency assessments for the clinical consultant was not defined. 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the laboratory director performing a competency assessment for the clinical consultant. 4. An interview with the laboratory director on 8/30/21 at 10:30 a.m. in the nurse's station, after review of the records, confirmed the above findings.