Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466251	01/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Banister-Lieblong Clinic	2425 Dave Ward Drive, Suite 401, Conway, AR	

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	This is a CLIA complaint investigation conducted on 1/12/2018. 493.5 Categories of tests by complexity (a) Laboratory tests are categorized as one of the following: (1) Waived tests (2) Tests of moderate complexity, including the subcategory of PPM procedures (3) Tests of high complexity (b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests. (c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in 493.2 (1) Certificate of registration or registration certificate (2) Certificate of waiver (3) Certificate for PPM procedures (4) Certificate of compliance (5) Certificate of accreditation Based on observations and interview it was determined the Laboratory did not possess an active CLIA number at the time of the complaint
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 observations and interview it was determined the Laboratory was performing testing without a CLIA Certificate as evidenced by: D8105 - the laboratory performed waived testing without a CLIA certificate.
D8105	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(e)(f)(g) (e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results. (f)

	Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part. (g) Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part. This STANDARD is not met as evidenced by: Based on observations and interview it was determined the Laboratory was performing testing without a CLIA Certificate. The findings follow: A. A complaint survey was conducted on 1/12/2018. During a tour of the clinic (09:40 on 1/12/2018) the surveyor observed the following test kits in use, without a current CLIA Certificate. Henry Shein One Step + ER Fecal Occult Blood Henry Shein True METRIX Pro Whole Blood Glucose B. In an interview with the Clinic Administrator, (10:02 on 1/12/2018), she confirmed the clinic employees performed the listed laboratory tests.