Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0647002	07/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Department Of Public Health- Springfield	825 N Rutledge St, Springfield, IL	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to report a lead result of 26.3 ug/dl to the IDPH Childhood Lead Program within 48 hours of confirming the test result as required by Illinois State law. The findings include: 1. For all children under 16 years of age all leads results greater than 10 ug/dl must be reported to the State Childhood Lead Program within 48 hours of confirmation of the test lead level. 2. Staff confirmed on July 17, 2018 around 2:00 PM that there was no evidence to demonstrate that this reporting requirement had been met.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow its policy for reporting blood lead levels 35 ug/dl or higher. The findings include: 1. The blood lead level on patient 9971101 was 45 ug/dl. There was no evidence presented to the

	inspector that demonstrated this result had been called to IDPH Childhood Lead Program per the policy. 2. On July 17, 2018 around 2:00 PM, staff verified that this result (45 ug/dl) was not on the call tracking log to the Lead program.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform and establish its own Individualize Quality Control Plan (IQCP) for Legionella testing prior to reporting patient test results. The findings include: 1. The Legionella IQCP in use was performed by Alere (the manufacturer). The IQCP must be performed in house by the laboratory's own testing personnel. 2. Around 1:00 PM on July 17, 2018 staff confirmed the IQCP in use was performed by the manufacturer's representative.