Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2044669	10/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Florence Family Medicine, Pllc	3091 Hwy 49 South, Suite B, Florence, MS	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Plan and observation of urine drug screen specimens in the laboratory on 10-25-18 at 10:00 a.m., the laboratory failed to follow its written specimen labeling policy for fourteen urine drug screen specimens observed on 10-25-18. Findings include: Review of the laboratory's Quality Assurance Plan revealed the "Specimen Labeling" policy states, "The samples should be labeled with the patient's full name, identification number (either chart number, account number, or social security number), date of collection, and the collector's initials." Observation of urine drug screen specimens in the laboratory on 10-25-18 at 10:00 a.m. revealed all fourteen of the fourteen specimens observed were labeled with patient name, date of birth, and date of collection. The specimens were not labeled with an identification number, such as a chart number, account number, or social security number, in order to positively identify the specimens.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation of the Siemens Syva Emit Calibrator/Control Levels 0 through 3, in use by the laboratory on 10-25-18 at 10:15 a.m., and review of the manufacturer's instructions for the calibrators/controls, the laboratory used four levels of urine drug screen calibrators/controls on the Siemens Viva Pro E System past the open expiration dates, from 6-12-18 through 10-25-18 when patient urine drug screen testing was performed. Findings include: Manufacturer's instructions for Siemens Syva Emit Calibrator/Control state, "Once opened the Emit Calibrators/Controls are stable for 5 weeks when recapped and stored at 2 - 8 degrees Celsius when not in use." Observation of the open dates of the Siemens Syva Emit Calibrator/Control Levels 0 through 3, in use by the laboratory on 10-25-18 at 10:15 a.m., revealed that the calibrators/controls were used past their open stability dates for the following weeks when patient urine drug screen testing was performed: Level 0 (negative control for all seven drug assays)--open date 8-14-18--used 5 weeks past open stability date of 9-18-18. Level 1 (calibrator for opiate assay)--open date 5-16-18--used 18 weeks past open stability date of 6-20-18. Level 2 (calibrator for amphetamine assay)--open date 5-19-18--used 16 weeks past open stability date of 7-3-18. Level 3 (calibrator for barbiturate, benzodiazepine, methadone, cocaine, and cannabinoid assays)--open date 5-8-18--used 19 weeks past open stability date of 6-12-18.