Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D1011448	10/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Asl Accu-Screen Labs Inc	2801 E Bristol St Ste C, Elkhart, IN	

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
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, interview, and document review, the laboratory failed to ensure three of four control materials for two of nineteen analytes (Buprenorphine and Tramadol) in use had not exceeded the expiration date. Findings include: 1. On 10-18-18 at 3:00 PM, the following expired control materials were observed in the refrigerator, available for use: a. An opened 10 milliliter (mL) bottle of "Oral Fluid Low Positive Control," Lot number "E29649," expiration date "Nov 2017". b. An opened 10 milliliter (mL) bottle of "Oral Fluid Cut Off Calibrator," Lot number "E29650," expiration date "Nov 2017". c. An opened 10 milliliter (mL) bottle of "Oral Fluid High Positive Control," Lot number "E29651," expiration date "Nov 2017". 2. In interview on 10-18-18 at 3:20 PM, SP-1 acknowledged the above control materials were expired and indicated the control materials were opened and used to perform quality control on 10/15/18. SP-1 indicated the "Oral Fluid Cut Off Calibrator," was used as a mid-level control. SP-1 further indicated 46 patients were tested with the above controls on 10/15/18. 3. Document review indicated the following: a. Quality control was performed on 10/15/18 for Buprenorphine and Tramadol, using the above expired controls. b. Patients P-9 through P-16 were tested for Buprenorphine and Tramadol on 10/15/18.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are

	established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to establish and maintain a quality assessment program for 2017. Findings include: 1. Review of quality assessment documents, indicated quality assessment documentation for 2017 was not available. 2. In interview on 10-18-18 at 4:07 PM, SP-1 and SP-2 indicated quality assessment documentation for 2017 was unavailable for review. SP-1 and SP-2 further indicated there was no quality assessment policy.