Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0942841	04/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
L A Good Samaritan Pathology Medical Group Inc	15021 Ventura Blvd, Ste 771, Sherman Oaks, CA	

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 reviews of laboratory written procedures and patients tests requisitions and lab reports; the lack of laboratory documents, and interview with the Laboratory Director (Technical Consultant-1) and testing personnel, the laboratory failed to establish written policy and procedures for urine specimen acceptability and rejection for Drug Screen testing. Findings include: a. The laboratory written procedures failed to specify Stability criteria of acceptability and rejection for urine specimen for Drug Screen testing. b. The Laboratory Director and testing personnel affirmed (3/28/18) the aforementioned lack of written procedures and the laboratory's non-written policy of 4 days stability. c. Laboratory Drug Screen test reports and test requisition documents revealed urines received more than 4 days after date of collection were not rejected, but tested for multiple drugs and reported: Amphetamines Barbiturates Buprenorphine Benzodiazepines Cocaine metabolites Fentanyl Ethyl alcohol Opiates Oxycodone Propoxyphene Cannabinoids Phencyclidine e. The reliability and quality of results reported could not be assured in the absence of written criteria for urine stability. Based on the stated annual estimated test volume (4/13/18), the laboratory reported approximately 69,200 results each year for testing drugs. A few examples are as follows: Collected Received Reported ID

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D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on reviews of laboratory written procedures for Drug Screen testing using an Olympus AU400 analyzer with Thermo Scientific reagents, manufacturer's instructions, and patients test requisitions and lab reports; the lack of laboratory documents, and interview with the Laboratory Director (Technical Consultant-1) and laboratory personnel, the laboratory failed to follow manufactuer's instructions for urine specimen storage and stability. Findings include: a. The laboratory written procedures failed to specify storage time and temperature requirements to maintain the stability of urine specimen for Drug Screen testing. b. The Laboratory Director and testing personnel affirmed (3/28/18) the aforementioned lack of written instructions. c. The "DRI Amphetamines Assay" by Thermo Scientific was observed available for use in the laboratory. A Thermo Scientific technical support representative affirmed (4/13/18) that the product was FDA-approved and that the product information package insert posted on the website stated specific instructions for Specimen Collection and Handling. d. The reliability and quality of results reported could not be assured in the absence of following the manufacturer's instructions for urine specimen handling and storage. Based on the stated annual estimated test volume (4/13/18), the laboratory reported approximately 69,200 results each year for testing drugs. A few examples are as follows: Collected Received Reported ID ---------- 6/29/17 7/06/17 7/11/17 1014549 11/22/17 11/29/17 11/30/17 1016036 1/07/18 1/16/18 1/18/18 1016508 2/19 /18 2/26/18 2/27/18 1016956