Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2082338	01/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lifespring Pain Management Center	275 W 200 N #7, Kaysville, UT	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on new instrument verification records review, lack of documentation, and confirmation by the laboratory director, the director failed to sign and date as approved a step by step procedure for ThermoFisher Indiko instrument operation for qualitative urine drug screen assays performed. The laboratory performed approximately 25,000 urine drug screens per year. Findings include: 1. The laboratory replaced the drug screen immunoassay instrument with one from another manufacturer in June 2018. The laboratory failed to ensure the director approved the new instrument procedure manual. 2. In an interview with the director on 01/30/2019 at approximately 6:30 P.M. the director confirmed the Indiko instrument procedure was not approved, signed, or dated.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on ThermoFisher Indiko analyzer verification studies review, laboratory test report review, and interview with the director, the laboratory failed to evaluate the immunoassay analyzer's limit of detection for 19 of 19 substances reported as positive or negative depending on the laboratory's established cut off concentration assayed by the Indiko instrument. The laboratory performed approximately 100 samples per day (25000 per year). Findings include: 1. The laboratory verification studies for 19 analytes (6AM -heroin, AMP- amphetamines, BAR- barbiturates, BENZ benzodiazepines, BUP -buprenorphine, COC - cocaine, Creat - creatinine, ETOH - ehtyl alcohol, MTD -methadone, OPI -opiates, OXID general oxidant (adulterant) , OXY- oxycodone, PCP- pencyclidine, pH (-[hyrogen ion]), SG -specific gravity, TCA - tricyclic antidepressants, THC -cannabinoids-marajuana, TRAM - tramadol, and XTC - ecstasy synthetic) failed to establish the limit of detection for each of the substances being reported as positive or negative. 2. Laboratory test reports reviewed included the positive result cut off values for: 6AM was 10 ng/mL AMP was 500 ng /mL BAR was 200 ng/mL BENZ was 200 ng/mL BUP was 20 ng/mL COC was 150 ng/mL Creat was 20 ng/mL ETOH was 100 ng/mL MTD was 300 ng/mL OPI was 300 ng/mL OXID was 300 ng.mL OXY was 300ng.mL PCP was 25 ng/mL pH was 9 ng/mL[sic] SG was 1.035 ng/mL[sic], TCA was 50 ng/mL THC was 50 ng/mL TRAM was 200 ng/mL and XTC was 500 ng/mL 3. Manufacturer's specifications for minimum limits of detection were the same values as the laboratory's cut off determination for reporting positive results, (reported as positive greater than or equal to the cut off value). 4. The laboratory verification summary for the 2 Standard deviation (SD) limit of blank was stated as 0 ng/mL for all 19 analytes with detection limits as stated in finding #2. The values used to calculate the limit of blank included 20 samples each of the low and high control values for each analyte tested. The summary included values below the manufacturer's limit of detection for the low control and values above the limits of detection for the high control, although the stated concentration for both of the controls were 0 ng/mL. These values provided 2SD limit of Blank (95% Conf) values of 0 ng/mL for all 19 analytes assayed. A value of zero for a limit of detection indicates the instrument can not detect the presence of a substance in sufficient volume to report a value of greater than 0 and an SD of 0 indicates the laboratory 20 quality control values were all at the same concentration without variation. This was not what the reports indicated. 5. In an interview with staff on 01/30/3019 at approximately 7:00 P.M. the director confirmed the verification summary information was incorrect and that it would be re-evaluated.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient test reports review, lack of documentation, and interview with staff, the laboratory failed to include the address of the laboratory location where urine

	qualitative drug screen testing was performed for 9 of 9 test reports reviewed. The laboratory reported approximately 25,000 tests per year. Findings include: 1. Test reports reviewed were generated by the qualitative assay instrument as the report to the physician ordering the tests and posted to the patient's chart record. (Quantitative assay reports were then requested from a reference laboratory at another location, if the physician requested a more sensitive test.) The reports generated by the qualitative testing laboratory failed to include the location of the laboratory where testing was performed for patients: TB030870, tested on 09/06/2017, SH100160 tested on 10/31 /2017, HR081459 tested on 12/19/2017, Accession number 0100003865 tested on 03 /05/2018, DZ081749 tested on 05/03/2018, MC080678 tested on 07/12/2018, NJ082887 tested on 09/12/2018, MJ051667 tested on 11/13/2018 and ST042174 tested on 01/02/2019. 2. In an interview with the director on 01/30/2019 at approximately 7:00 P.M. the laboratory director stated the test report did not include the address of the laboratory where qualitative testing was performed.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on new instrument verification documentation review, lack of documentation, and confirmation by the director, the laboratory director failed to document verification procedures used to determine 1 of 1 new instruments added to the laboratory inventory could provide accurate and precise results within the testing range the laboratory used to determine patient's qualitative urine drug screens had drugs present or absent or if specimens were adulterated. The laboratory performed approximately 25,000 tests per year on the ThermoFisher Indiko immunoassay instrument in use since June of 2018. Findings include: 1. The new instrument verification studies review failed to include the signature and date of approval by the laboratory director to document the director had reviewed the study results, finding them to be within the manufacturer's specifications for accuracy, precision, and that the instrument was capable of detecting drugs in urine specimens at the cut off values to report the specimen as positive for the presence of 19 assays for drugs and adulterants. (See D5421) 2. In an interview with the laboratory director on 01/30/2019 at approximately 7:15 P.M. the director confirmed the verification studies for the new instrument were not signed and dated as approved prior to testing patient samples. The director also confirmed the laboratory studies for the instrument limit of detection had not been accurately calculated to verify the instrument precision for urine assay at the positive cut off value(s) which are at the lower end of the instrument limit of detection (per the manufacturer's stated sensitivity).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and

	assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on new instrument verification records review, personnel records review, lack of documentation and interview with the director, the technical consultant failed to ensure the laboratory documented testing personnel received training and assured 1 of 1 testing person received in-service training for performing testing on the ThermoFisher Indiko instrument prior to reporting patient test results from June 2018 to January 30, 2019. The laboratory performed approximately 25,000 urine qualitative drug screens per year. Findings include: 1. The laboratory failed to document testing personnel in service training and competency for testing and reporting patient test results following installation of the new instrument in June of 2018. 2. In an interview with the director on 01/30/2019 at approximately 7:00 P.M. the director stated the manufacturer provided training but the laboratory failed to ensure the training and competency were evaluated for the primary testing person by the technical consultant prior to testing patient samples or since 09/03/2017.