Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2131514	02/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Calyx Recovery, Inc	681 Hioaks Road Suite C, Richmond, VA	

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
D0000	An announced CLIA initial survey was conducted at Calyx Recovery, INC on February 5, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, PT Corrective Action Forms, policy manual, and an interview, the laboratory failed to document evaluation and review of results on one (1) of one (1) event reviewed. Findings include: 1. Review of the laboratory's 2017 American Proficiency Institute (API) proficiency documentation revealed that the laboratory is enrolled as customer 73405 for chemistry toxicology testing. The review of PT records also revealed no remedial action for the following unsatisfactory toxicology panel analyte: 2017 API Event 2 - 67% Methadone 2. Review of the laboratory's available PT corrective action forms revealed no corrective or remedial action documentation for the PT analyte and event listed above. 3. Review of the laboratory's Calyx Recovery Services Procedure Manual revealed a Laboratory Proficiency Testing Policy that stated "PT serves as an external check to verify the accuracy of test results. Unsuccessful performance may be an indication of problems with instrumentation, personnel training or quality control procedures. If any result is outside the range of acceptable values, the problem must be identified and corrected. Documentation on the Proficiency Corrective Action Form must include testing personnel and lab director signatures". 4. In an interview with the laboratory director and primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed document review of and remedial actions for the proficiency testing event listed above.

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 a review of the laboratory's policy manual, four (4) randomly selected patient urine drug screen (UDS)reports, and interviews, the laboratory failed to include the unit of measure for test results and the address and name of of the testing facility where the patient results were performed. Findings include: 1. Review of the laboratory's Calyx Recovery Services Procedure Manual revealed a Test Report and Records Policy that stated: "The test report contains the name and address of the laboratory where the test was performed.", "The test report contains the test result and the appropriate unit of measure." 2. The inspectors requested to review of four (4) randomly selected urine drug screen (UDS) reports. The primary testing personnel stated, "We use two formats to report our results based on requests from the ordering providers". The inspectors requested to review the UDS reports of both formats in use to report patient results. The review of the patient reports revealed: Test reports from the laboratory's LimitLIS electronic medical record: did not include the unit of measure for test results, Test reports from the laboratory's Indiko Plus chemistry analyzer: did not include the name and address of the performing testing facility. 3. In an interview with the laboratory director and the primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed to indicate the unit of measure for test results and or the name and address of the testing facility on patient UDS reports from September 2017 to the date of the survey, 2/5/18.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, a review of the laboratory's procedure manual, Quality Assurance (QA) documents, and interviews, the laboratory failed to maintain a mechanism to ensure the accuracy of manually transcribed patient urine drug screen (UDS) quantitative results from September 2017 to the date of the survey on February 5, 2018. Findings include: 1. During a tour of the laboratory and a conversation with the primary testing personnel at approximately 2:30 PM on 2/5/18, revealed that patient UDS results are manually transcribed from the Indiko Plus chemistry analyzer print out into the laboratory's LimitLIS electronic medical record (EMR) by the testing personnel. 2. Review of the laboratory's procedure manual revealed a QA Plan that includes a policy to monitor and correct problems in the laboratory and that the

	monthly QA checks are to be reviewed with the lab director. 3. Review of all available QA documentation revealed no evidence of accuracy checks or review of manually transcribed patient UDS results from September 2017 to the date of the survey. The inspectors requested to review the documentation. No chart review or periodic quality audits were available. 4. In an interview with the laboratory director and primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed to maintain an ongoing mechanism to ensure the accuracy of manually transcribed patient UDS results from September 2017 up to the date of the survey.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) results and an interview, the laboratory director failed to document review of the laboratory's performance in chemistry toxicology proficiency testing in one (1) of one (1) events reviewed. Findings include: 1. Review of the laboratory's 2017 American Proficiency Institute (API) proficiency documentation revealed that the laboratory is enrolled as customer 73405 for chemistry toxicology testing and no documentation of PT result review by the lab director for the following event: 2017 Event 2. 2. In an interview with the laboratory director and primary testing personnel at approximately 4:30 PM, it was confirmed that the lab director failed to document review and evaluation of the laboratory's chemistry toxicology PT performance on the event listed above.