

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1094068	(X3) Date Survey Completed 08/06/2021
Name of Provider or Supplier American Clinical Solutions Llc	Street Address, City, State 721 Cortaro Dr, Sun City Center, FL	
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	<p>An unannounced complaint survey for complaint number 2021008611, was conducted 08/02/21 to 08/06/21 at American Clinical Solutions LLC. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. The following Conditions were not met: D5200 - 493.1230 General Laboratory Systems D5300 - 493.1240 Preanalytic Systems</p>
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to have a system in place to document all reported complaints and failed to have a mechanism for determining investigation of complaints received from patients. (See D5205)</p>
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and Staff interviews the laboratory failed to document and investigate complaints that came from patients from 08/20/20 to 08/03/21. Findings included: On 08/02/21 at 1:22 PM., the Laboratory Supervisor reported that a letter was received from Patient #1 on 04/23/21, and Patient #1 had also called the laboratory (date unknown). The Laboratory Supervisor stated "I can't discuss patient results with the patient. We only discuss this with the doctor, and the doctor never contacted us." The Laboratory Supervisor stated that the letter was placed in a book and no action was taken. Review of the letter from Patient #1 revealed a complaint that stated "...The only drug which should have been detected was hydrocodone, which is the only opiate I regularly use. I can't imagine what may have happened in your lab that was so wrong, unless it was just unintended carelessness ...Believe what you will, but I have never taken, or thought about taking the other drugs which tested positive on what was supposed to be my swab/saliva test. I can't tell you how stressful this has been. I now have to go to a pain management facility for treatment..." On 08/02/21 at 12:45 PM., the Laboratory Supervisor and the Laboratory's Clinical Laboratory Improvement Amendment (CLIA) Specialist were informed of a discrepancy found on Patient #1's requisition, which indicated a source type of oral, but had an accessioning label and test result report indicating "Urine Drug Test". The Laboratory Supervisor stated, "I don't know what could have happened. It's impossible that this wasn't urine." The Laboratory Supervisor and CLIA Specialist reported that they needed to look into this to determine what occurred. Follow-up interview with the Laboratory Supervisor on 08/02/21 at 4:39 PM confirmed that the laboratory never follows up on any concerns that were not from a doctor's office. The Laboratory Supervisor stated that she was just informed that day of Patient #1's letter and had not seen it prior to this. She stated that even if she had seen it sooner, she would not have taken any action on it as they do not speak to or follow-up on any complaints from patients and that it was a strict policy to not speak to patients. The Laboratory Supervisor stated that the Toxicologist was responsible for responding to the complaints received by the laboratory. Interview on 08/02/21 at 4:42 PM with the Toxicologist revealed she did not know anything about the letter from Patient #1. The Toxicologist confirmed that she only received and responded to complaints that were from physicians. On 08/03/21 at 9:13 AM, a log or other documentation of complaints received from patients from 08/20/20 to current was requested from the Laboratory Supervisor. Electronic correspondence (email) and telephonic communication with the Laboratory Supervisor from 08/03/2021 to 08/05/21 revealed no documentation of complaints from patients was provided. The Laboratory Supervisor provided a document from the receptionist protocol via email on 08/03/21 at 12:42 PM. Review of the document titled "Phone System" updated on 01/02/19 revealed a yellow highlighted section on the bottom stating: "***IMPORTANT*** do not give information to patients. ALWAYS re-direct patient calls back to the physician." Record review of the laboratory's undated "Complaints Protocol" policy and procedure revealed "The purpose of this procedure is to outline the process to receive, evaluate and make decisions on complaints and internal corrective actions... Employees receiving complaints are responsible for recording the details of the customer complaint, do what they can to resolve the immediate problem or assure the customer that the complaint will receive immediate attention, inform the customer that the laboratory will contact them by a certain time or date, pass the details of the complaint on to their supervisor and advise them if the nature of the complaint is serious or might lead to legal action. Toxicologist/supervisors analyze the nature of the complaint (contacting the customer for further information if necessary), initiate action to resolve the complaint (keeping records of these actions), contact the customer to determine whether the solution is sufficient, implement long-term solutions to prevent the recurrence of this type of complaint (keeping records of these

solutions), and monitor the effectiveness of the long-term solution (keeping records of follow-up verifications)..." Review of electronic correspondence (email) received 08/03/21 at 2:34 PM from the Laboratory Supervisor revealed that the definition of "customer" as it related to the complaint protocol was "...the Doctors. We work for the Doctors who order testing." Telephone interview on 08/05/2021 at 10:45 AM with the Laboratory Director confirmed that the laboratory does not communicate with patients, only doctors.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on observation, record review, and Staff interviews, the laboratory failed to identify test requisition source discrepancies for 2 (#1,#2) out of 26 (#1-#26) sampled test requisitions (See D5305), failed to have an effective specimen processing procedure to address specimen source concerns (See D5311), and failed to have an effective quality assurance (QA) plan that identified specimen and requisition discrepancies during the preanalytic phase of testing (See D5391).

D5305

TEST REQUEST
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:
Based on observation, record review, and Staff interview the laboratory failed to clarify a test requisition specimen source discrepancy (Patient #1) and failed to ensure the test requisition solicited the specimen source (Patient #2) for 2 out of 26 Patients sampled (#1-#26) from 08/20/20 to 08/02/21. Findings Included: Observation of the processing of samples on 08/02/21 at 11:15 a.m. with Laboratory Assistant A and Laboratory Assistant B revealed they placed all specimens and requisitions to the side for follow-up if the requisition was incomplete or had any inaccuracies. Laboratory

Assistant A reported that these discrepancies were followed up on by the receptionist who would call the ordering physician's office. A review of Patient #1's test requisition, stamped as received by the laboratory on 03/25/21, revealed the specimen type was marked oral, however, the laboratory's accessioning label placed on the requisition indicated that a urine specimen was received. A review of the 3/25/21 lab report revealed a urine toxicology was completed which resulted in the patient testing positive for Oxycodone, Noroxycodone, Oxymorphone, Alprazolam, and Alpha-Hydroxyalprazolam for which she was not prescribed. Additionally, Patient #1 tested negative for Hydrocodone and Gabapentin, for which she was prescribed. Interview with the Laboratory Supervisor on 08/02/21 at 1:22 p.m. revealed Patient #1's physician sent in three samples that day, one oral and two urine. The requisition, raw data, and test result was requested for the patient with the oral sample (Patient #2). On 08/02/21 at approximately 1:30 p.m., the Laboratory Supervisor returned with Patient #2's information. As the Laboratory Supervisor reviewed Patient #1 and Patient #2's results, she reported that it looked like Patient #2 tested positive for the medications Patient #1 was taking and vice-versa. Review of Patient #2's test requisition, stamped as received by the laboratory on 03/25/21, showed the specimen type (source) was not marked. The laboratory's accessioning label placed on the requisition indicated that an oral specimen was received. A review of the 3/25/21 lab report revealed an oral toxicology was completed which resulted in the patient testing positive for Hydrocodone, for which she was not prescribed. Additionally, Patient #2 tested negative for Oxycodone and Alprazolam, for which she was prescribed. On 08/02/21 at 4:00 p.m., the Receptionist was interviewed and shown the source type discrepancies for Patient #1 and Patient #2 and asked if these requisitions would be pulled for her to call the physician. She stated "possibly" for Patient #1, but not necessarily. She indicated that Patient #2's requisition which did not have a source indicated would not be pulled for physician follow up. Phone interview on 08/05/21 at 10:47 AM with the Laboratory Director revealed that Patient #1 and Patient #2 should not have been processed based on the concerns with the specimen types. Review of the policy and procedure, titled "Processing", updated 02/27/19 revealed under Data Verification: "5. Check that requisition form is properly completed. 5a. If it can still be tested, stamp requisition with received date, signature, no face sheet, poc [point of care] if the requisition doesn't have the poc box checked... or the cup doesn't have the testing strips stamp the requisition with the no poc stamp. 5b. If the sample cannot be tested, follow Held Sample SOP [Standard Operating Procedure]." Review of the policy and procedure, titled "Held Samples", updated 02/27/19 revealed the following steps for Held Samples: "Held samples will be labeled with a Held Number. Held samples will be labeled with a Held Number. The requisition and the specimen will each be labeled with a Held Number make sure they match. A Held Sample form with corresponding held number will be completed for each specimen. Held sample form, requisition, and demographics (in that order) will be scanned and saved with daily samples. The sales rep will be notified. The office will be contacted for required information. Once received: Log it on the Call Log. Update the requisition properly. If the information has not been received within 2 weeks from the date received: The specimen will be discarded. Notify the sales rep and office. Once testable, process the specimen following normal protocol."

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 record review and Staff interview the laboratory failed to establish and follow a procedure for specimen processing which addressed the handling of test requisitions with incomplete specimen type and discrepancies in specimen type received for 2 (#1 and #2) out of 26 sampled Patients (#1-#26) from 08/20/20 to 08/02/21. Findings included: Record review of Patient #1's test requisition, stamped as received by the laboratory on 03/25/21, revealed the requisition specimen type was marked for oral specimen, but the laboratory had placed the laboratory's urine accession label on the requisition. Record review of Patient #2's test requisition, stamped as received by the laboratory on 03/25/21, revealed the requisition did not have a specimen type marked. Patient #2's requisition had an oral accession label placed on the requisition. Review of the policy and procedure, titled Processing, updated 2/27/19 revealed under Data Verification: "5. Check that requisition form is properly completed. 5a. If it can still be tested, stamp requisition with received date, signature, no face sheet, poc [point of care] if the requisition doesn't have the poc box checked (see picture below) or the cup doesn't have the testing strips stamp the requisition with the no poc stamp. 5b. If the sample cannot be tested, follow Held Sample SOP [Standard Operating Procedure]. Sample Unpacking 9. Any sample that cannot be tested will be stamped with the following: a. Empty/QNS [quantity not sufficient] b. Rejected i. The sample may come in where we have to reject due to the specimen not being a match to the requisition or the specimen may not have any identifiers stating that it belongs to that specific requisition." Review of the policy and procedure, titled "Held Samples", updated 02/27/19 revealed the following steps for Held Samples: "Held samples will be labeled with a Held Number. The requisition and the specimen will each be labeled with a Held Number make sure they match. A Held Sample form with corresponding held number will be completed for each specimen. Held sample form, requisition, and demographics (in that order) will be scanned and saved with daily samples. The sales rep will be notified. The office will be contacted for required information. Once received: Log it on the Call Log. Update the requisition properly. If the information has not been received within 2 weeks from the date received: The specimen will be discarded. Notify the sales rep and office. Once testable, process the specimen following normal protocol." On 08/02/21 at 4:00 PM, the Receptionist was interviewed and verified that she was responsible for contacting the physician's office for concerns related to test requisitions. She was shown the source type discrepancies for Patient #1 and Patient #2 and asked if these requisitions would be pulled by the Laboratory Assistants for her to follow-up with the physician. She stated "possibly" for Patient #1, but not necessarily. She indicated that Patient #2's requisition which did not have a source indicated would not be pulled for physician follow up. Interview on 08/02/21 at 5:02 PM with the Laboratory Supervisor and the Laboratory's Clinical Laboratory Improvement Amendment (CLIA) Specialist confirmed, that the complete policy and procedure for Processing was provided. Electronic correspondence with the Laboratory Supervisor on 08/04/21 at 10:04 a.m. confirmed that we had received the complete policy and procedure for Held Samples. Review of these policies and procedures revealed no indication that the laboratory would hold a sample due to a discrepancy in source. Interview on 08/05/21 at 10:47 AM, the Laboratory Director stated Patient #1 and Patient #2 should not have been tested due to the specimen type concerns on the requisition. The Laboratory Director was unable to comment about the "Processing" procedure without reading

the procedure. The Laboratory Director did not have access to the policy and procedure at the time of interview.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to have an effective quality assurance (QA) plan that identified issues during the pre-analytic phase of testing from 08/20/2020 to 08/02/2021. The number of specimens tested from 08/20/20 to 07/30/21 was 4,265 (oral specimens) and 20,037 (urine specimens) for a total of 24,302. Findings Included: Record review of the "Quality Assessment Plan" policy (last signed as reviewed by the Laboratory Director on 02/11/15) revealed a section titled: "Pre-Analytic Phase... Because pre-analytic activities are the input to testing, problems in this phase have a significant effect on our output - test results. Most laboratory problems and errors occur in this phase, so we will pay special attention to pre-analytic activities. Test Ordering - ...Test requests must contain essential information that identifies the ordering provider with contact information, the testing laboratory, complete patient identification with sex and age or date of birth, the test to perform, source of the specimen, the date and time of specimen collection, and any additional information necessary to ensure accurate and timely testing and reporting of results..." Review of the "Quality Assurance Review Form" for the Pre-Analytic Phase with the element under review of "Test Tracking (Requisitions)" revealed the Laboratory Manager signed the form as the reviewer on 07/10/21 and the Laboratory Director signed in concurrence on 07/29/21. The evaluation of results on the QA form revealed 10 requisitions were reviewed with 100% compliance for a time period of January 2021 to June 2021. Review of the 5 listed "Measured Parameters" on the form revealed no parameter was present for verification of source of the specimen. Phone interview on 08/05/21 at 10:53 AM, the Laboratory Director stated that the written QA procedure covered everything, but could not comment on the QA form without seeing the form.