Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1094068	09/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
American Clinical Solutions Llc	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
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Manager the Technical Supervisor failed to ensure employee competency evaluations were being performed and failed to identify unqualified Testing personnel (See D6120).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for 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; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the Technical Supervisor failed to perform competency evaluations on 7 (#A,#B,#D,#E,#F,#Gand #H) out of 9 Testing personnel and performed competencies on 3 (#J-#L) out of 3 Testing personnel that were not qualified to perform high complexity testing. Findings Included: Review of the CMS 209 revealed 2 Technical Supervisors listed (Testing Person #B) and the Laboratory Director. Testing Person #B was also listed as the only

	General Supervisor. Competency Evaluations were not found for 2017 for Testing Personnel #A, #B, #D, #E, #F, #G, and #H. No competency evaluations were found in 2018 for Testing Person #H. Competency evaluations for the unqualified Testing Personnel #J, #K, and #L were done on 09/21/18 and signed off by Testing Person #H. During an interview on 09/25/18 at 3:45 PM the Laboratory Manager confirmed that there were no other competency evaluations on the aforementioned staff.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to have licensed personnel performing high complexity testing (See D6170) and failed to have qualified testing personnel (See D6171).
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to ensure 3 (#K, #L, and #M) out of 13 Testing Personnel had a State of Florida Clinical Laboratory Personnel license. Findings Included: Rule 64B3-2.003(19), Florida Administrative Code requires Testing Personnel who work in an Independent Laboratory be licensed by the Board. Review of the CMS 209 revealed Testing Personnel #K, #L, and #M did not have a State of Florida Clinical Laboratory Personnel license. During an interview on 09/25/18 at 3:45 PM the Laboratory Manager confirmed that Testing Personnel #K. #L, and #M did not have a State of Florida Clinical Laboratory Personnel license.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of

biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Laboratory Manager the laboratory failed to have 2 (#K and #M) out of 13 Testing personnel to be qualified to perform high complexity testing. Findings Included: Review of employee competencies conducted on 09/21/18 for Testing Personnel #K and #M revealed that they were deemed competent and signed off to prepare stock solutions , prepare mobile phase solutions, perform daily, weekly, and monthly maintenance of the instruments, diluting specimens, doing pH, making standards, and making controls. Testing Person #K has a GED and Testing Person #M does not have a GED or a High School diploma. During an interview on 10/01/18 via email at 10:08 AM the Laboratory Manager confirmed the education of #K and #M. During an interview on 09/25/18 at 3:45 PM the Laboratory Manager revealed that Testing Person #K and #M were

	originally hired for specimen processing and they were not aware that the pH testing strips were high complexity and that making the stock, controls, standards, and maintenance were part of the analytic systems process. Rule 64B3-2.003(19), Florida Administrative Code states "Manual Pretesting procedures means collecting and labeling specimens; initially separating specimens by centrifugation prior to testing; receiving specimens and requisitions, processing, sorting, accessioning, prior to testing and delivering specimens to the appropriate testing sites; specimen processing for storage and shipping to a reference laboratory; routine hematology and microbiology slide preparation from a primary sample; loading automated stainers; loading specimens onto automated sampling or processing systems; cytopreparatory staining, measuring and alioquoting specimens; and direct primary inoculation of microbiology cultures; Placement of specimens onto an automated instrument or system is considered a manual pretesting duty, provided it does not include any activity that initiates the analytic process." Testing Personnel #K and #M are not qualified to be high complexiy Testing Personnel.