Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2023923	01/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
F C Lab Lemont	807 State St, Lemont, IL	

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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to meet the requirements specified in 493.1230 through 493.1256. Findings Include: 1. The laboratory failed to perform quality control procedures as outlined in the Individual Quality Control procedure for Kirby-Bauer susceptibility testing for 21 of 26 patient test reports reviewed. See D5445.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory director (LD); the laboratory failed to establish policies and procedures to assess employee competency. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of personnel listed on the CMS-209 which include the technical supervisors, general supervisors,

	clinical consultants and testing personnel. 2. On survey date 01-11-2018 at 2:15 pm the LD confirmed the laboratory had failed to establish a competency assessment policy for all personnel listed on the CMS-209.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform control procedures using the number and frequency specified by the laboratory's individual quality control plan (IQCP) for antimicrobial susceptibility testing for 21 of 26 patient test reports reviewed. Findings include: 1. Review of the IQCP for Kirby-Bauer (KB) antimicrobial susceptibility testing stated the following, "Testing of appropriate QC strains on each panel type weekly." 2. Review of the laboratory policy and procedure manual under section 12, "Quality Control Procedures for Microbiology" additionally stated the following: "Sensitivity Disc: Proper reaction and zone sizes. Procedure: Use no. 2 procedures of part A above once a week. Read all zones sizes on quality control materials, dated, logged and initialed." 3. Review of patient tests results found that for 1 of 5 dates reviewed the KB sensitivity disk weekly quality control (QC) zones sizes were not performed. Patient Identification Test Date C6 11-28-2017 4. Review of the "Mueller Hinton Plates and Sensitivity Disk Quality Control" log found the November 2017 log was an exact photocopy of the December 2017 quality control log. 5. Further review of "Mueller Hinton Plates and Sensitivity Disk Quality Control" logs for KB susceptibility testing found that in addition to the November 2017 log the October 2017 log was an exact copy of the December 2017 log. 6. Review of patient testing logs identified an additional 20 patients who had results reported for KB susceptibility testing during the months of October and November of 2017 when no QC was performed/documented for KB susceptibility testing. Patient Identification Test Date C7 11-28-2017 C8 11-28-2017 C9 11-14-2017 C10 11-13-2017 C11 11-09-2017 C12 10-31-2017 C13 10-23-2017 C14 10-23-2017 C15 10-20-2017 C16 10-19-2017 C17 10-19-2017 C18 10-19-2017 C19 10-18-2017 C21 10-11-2017 C22 10-06-2017 C23 10-06-2017 C24 10-05-2017 C25 10-03-2017 C27 10-27-2017 C28 10-04-2017 7. On survey date 01-11-2018, at 2:15 pm, the LD confirmed that the quality control logs for October and November of 2017 were photocopies of the December 2017 "Mueller Hinton Plates and Sensitivity Disk Quality Control" log and no weekly quality controls were documented for KB susceptibility testing during that time frame.
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 review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have 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. Findings Include: 1. The laboratory failed to ensure 2 of 2 testing personnel were qualified for high complexity testing. See D6171.
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 review of laboratory records and interview with the laboratory director (LD); the laboratory failed to ensure 2 of 2 testing personnel were qualified for high complexity testing. Findings Include: 1. Review of educational documentation for 2 of 2 testing personnel identified on the CMS-209 failed to have foreign equivelency documentation for foreign degrees. 2. On survey date 01-11-2018, at 2:15 pm, the above findings were confirmed by the LD.