Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0967163	08/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sjc Medical Group - Jose M Rendon, Md	11909 D Mcauley Drive, Savannah, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 14, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. An immediate jeopardy situation was identified due to the laboratory's inability to demonstrate compliance in the speciality of Hematology , specifically the laboratory's inability to employ qualified testing personnel and a qualified technical consultant, lack of oversight by the laboratory director and the laboratory's continued non-compliance demonstrated by repeat deficiencies. A cease testing letter was submitted by the laboratory director at the summation discussion. The following deficiencies were cited:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from the American Proficiency Institute (API) and staff interview, the laboratory failed to retain documentation signed by the testing personnel (TP) and laboratory director (LD) attesting to routine integration of samples into the patient workload. Findings include: 1. Review of 2016, 2017 & 2018 attestation statements for PT from API in the speciality of hematology for complete blood counts (CBC) revealed no documentation of attestation statements for the 3rd event of 2017 and the 1st event of 2018 . 2. Interview with the office manager, testing personnel # 3, (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed attestation statements for the events listed above are not available at the time of the survey.

D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of 2018 PT records from API and staff interview, the laboratory failed to document each step to the testing and reporting of PT samples and failed to retain documentation for a minimum of two years from the date of the PT event. Findings include: 1. Review of 2018 event 1 API PT records revealed instrument printouts, raw data, attestation statement and testing records are not available for review. 2. Interview with the testing personnel # 3 (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed testing records for the 1st event of 2018 are not available for the surveyor.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on observation during a tour of the laboratory and staff interview, the laboratory failed to comply with rules governing storage of non-biohazard material in an area designated for biohazard material. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed injectable vaccines and insulin stored in the refrigerator that had a biohazard sign posted on the outside door. Control material used in laborortory testing which contains blood was also stored in this refrigerator. 2. Interview with the testing personnel # 3 (see CMS 209) on August 14, 2018 at 11 am in the laboratory confirmed injectable vaccines and insulin used to treat patients are stored in the refrigerator designated for biohazard storage.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of records to review, documentation of

	repeat deficiencies and staff interview, the laboratory failed to meet testing requirements in the speciality of Hematology for testing of complete blood counts (CBC) on the Emerald Cell Dyn hematology analyzer. Findings include: Refer to D 5429 & D 5439 Note: These are repeat deficiencies and were also cited at the October 2014 survey. This condition contributed to the Immediate Jeopardy determination.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records, lack of quality assessment activity and staff interview, the laboratory failed to monitor and evaluate the overall quality of the laboratory and failed to correct identified problems. Note: This condition level deficiency contributed to the Immediate Jeopardy determination. Finding include: Refer to D 5211, D 5221 and D 5291
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 PT records from API and staff interview the laboratory failed to document review of PT evaluations for testing performed in the speciality of hematology. NOTE: This is a repeat deficiency. It was cited at both the 2014 and 2016 surveys and contributed to Immediate jeopardy determination.. Findings include: 1. Review of PT records for event 3 of 2017 revealed no API evaluation is available and and no documentation showing the laboratory reviewed results. 2. Review of PT records for event 1 of 2018 revealed no documentation showing the laboratory reviewed results.. 3. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed PT records listed above are not available.
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 review of the laboratory's CMS CASPER 0096D report, lack of PT records from event 3 of 2017 and event 1 of 2018 and staff interview, the laboratory failed to document corrective action for unsatisfactory results. Note: This is a repeat deficiency

	and was cited on the July 26, 2016 survey. This contributed to the Immediate Jeopardy determination. Findings include: 1. Review of the CMS CASPER 0096D report revealed the laboratory received a failing score of 60% for RBC testing on event 3 of 2017 and an unsatisfactory score of 80% on platelet count for event 1 of 2018. 2. Review of the laboratory's PT records for event 3 of 2017 and event 1 of 2018 revealed no documentation of corrective action. 3 Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed documentation of corrective action for unsatisfactory PT is not available.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment(QA) plan, lack of records to review and staff interview, the laboratory failed to follow its QA plan in 2016, 2017 and 2018. This is repeat deficiency from the February 2012 and October 2014 surveys. Findings include: 1. Review of the laboratory's QA plan revealed a written plan with charts and checklist designed to be used to monitor, evaluate and correct problems. 2. Review of QA records revealed the last documentation of activity is August 2016. 3. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 2 pm in the office assigned to the surveyor confirmed no documentation of QA activity is available after August 2016.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation by the surveyor during a tour of the laboratory, review of the laboratory's temperature charts and staff interview, the laboratory failed to take corrective action when the temperature of the refrigerator fell outside the acceptable range. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed two refrigerators in the laboratory. The refrigerator under the counter is used to store control material for the Emerald Cell Dyn. 2. Review of temperature charts revealed results are recorded for two refrigerators. No notation is made showing which chart corresponds with the refrigerator used to store laboratory controls. 3. Review of temperature charts revealed the temperature is outside the acceptable on the following: August 2016 9 of 11 days reviewed. September 2016 11 of 12 days

	reviewed January 2017 7 of 20 days reviewed February 2017 12 of 21 days reviewed June 2017 4 of 13 days recorded between June 1 & June 15. There is no recording between June 16 and 30. August 2017 2 of 11 days reviewed 4. Review of temperature charts and laboratory records revealed no documentation of corrective action for any of the out of range temperatures. 5. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed no documentation of corrective action is available for out of range temperatures and there is no way to determine which charts correspond with the refrigerator used to store control material.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by the surveyor during a tour of the laboratory and staff interview, the laboratory failed to ensure blood collection supplies are not used past their expiration date. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed 12 of 12 blue top blood collection tubes containing Sodium Citrate which are used to collect samples for coagulation testing expired on 12/31/17. 2. Interview with testing personnel # 2 & 3 (see CMS 209) on August 14, 2018 at 11 am in the laboratory confirmed the tubes are expired and no other Sodium Citrate tubes are available. Testing personnel # 2 (see CMS 209) revealed these tubes were missed when they were disposing of expired laboratory supplies the previous day.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of maintenance requirements for the Emerald Cell Dyn, lack of records to review and staff interview, the laboratory failed to document the required maintenance in 2016, 2017 and 2018. Note: This is a repeat deficiency and was cited at the October 2014 survey. Findings include: 1. Review of maintenance requirements for the Emerald Cell Dyn revealed monthly bleaching and semi-annual piston lubrication is required. 2. Review of maintenance records revealed no documentation of maintenance after August 2016. 3. Interview with the testing personnel # 3 (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed maintenance records for the Emerald Cell Dyn after August 2016 are not available.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records for the Emerald Cell Dyn used to perform complete blood counts (CBC) and staff interview, the laboratory failed to document calibration at least every 6 months as required. Note: This is a repeat deficiency and was cited at the October 2014 survey. Findings include: 1. Review of calibration verification records for the Emerald Cell Dyn revealed no documentation of calibration or calibration verification between 12/30/16 and 2/12/18. 2. Interview with the testing personnel # 3 (see CMS 209) on August 14, 2018 at 2 pm in the office assigned to the surveyor confirmed calibration records for the Emerald Cell Dyn between 12/30/16 and 2/12/18 which spans more than 13 months are not available for the surveyor. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of records to review, lack of documentation of qualifications for testing personnel and the technical consultant, lack of documentation of activity by the technical consultant , continued repeat deficiencies, and staff interview, the laboratory failed to provide management and direction for the laboratory. Note: This condition level deficiency contributed to the Immediate Jeopardy determination. Findings include: Refer to D 6004, D 6018, D 6019, D 6029
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of CMS 209, review of laboratory records and staff interview, the laboratory director failed to ensure the duties of the technical consultant were performed. Findings include: Note: This is a repeat deficiency from the October 2014 survey and contributed to the Immediate Jeopardy determination. 1. Review of laboratory personnel records revealed no documentation of initial or semi-annual competency assessment is available for testing personnel # 1 & 2 (see CMS 209) and no documentation of annual competency assessment for 2016, 2017 and 2018 is available for testing personnel # 3. 2. Review of laboratory records also revealed no documenetaion of review of records or visits to the laboratory by the technical consultant. 2. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 2 pm in the office assigned to the surveyor confirmed no documentation of competency assessment is available and the technical consultant has not visited the laboratory in 2016, 2017 or 2018..
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 review of proficiency testing (PT) records, lack of records to review and staff interview, the laboratory director failed to ensure PT records were reviewed. Findings include: Note; This is a repeat deficiency from the October 2014 survey and contributed to the Immediate Jeopardy determination. Refer to D 5211
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of records to review and staff interview, the laboratory director failed to ensure corrective action was taken for unacceptable and unsatisfactory PT performance. Finding include: Note: This contributed to the Immediate Jeopardy determination. Refer to D 5221
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of quality assessment (QA) records to review, and staff interview, the laboratory director failed to ensure the QA program was maintained in 2017 and 2018. Note: This is a repeat deficiency from the October 2014 survey. Findings Include: Refer to D 5291
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of records to review and staff interview, the laboratory director failed to ensure testing personnel had the the appropriate education, experience and training and failed to ensure they demonstrated competency to perform moderate complexity testing in the speciality of hematology prior to testing and reporting patient specimens. Note: This is a repeat deficiency from the October 2014 survey and contributed to the Immediate Jeopardy determination. Refer to : D 6065 D 6066
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the CMS 209 form, review of laboratory records, lack of records to review and staff interview, the laboratory failed to have documentation showing the technical consultant meets the qualification requirements and failed to have documentation showing the technical consultant provides technical oversight of the laboratory. Note: This condition level deficiency contributed to the Immediate Jeopardy determination. Refer to D 6035, D 6036, and D 6046 Findings include: 1. Review of laboratory records revealed no documentation of education or training for the person listed on the CMS 209 as the technical consultant. 2. Review of laboratory records revealed no documentation of review of records or documentation of visits to the laboratory by the technical consultant. 3. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 2 pm in the office assigned to the surveyor confirmed no documentation of technical consultant activity in the laboratory is available and the technical consultant has not visited the laboratory in 2016, 2017 or 2018..
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

	This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, lack of records to review and staff interview, the laboratory failed to have documentation showing the technical consultant (TC) meets the education and training experience required. Note: Lack of a Qualified TC was cited under D 6034 at the July 26, 2016 survey. This deficiency contributed to the Immediate Jeopardy determination. Findings include: 1. Review of laboratory records revealed no documentation of education or training for the person listed on the CMS 209 as the technical consultant. 2. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 2 pm in the office assigned to the surveyor confirmed no documentation of education or experience for the technical consultant is available.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and staff interview, the technical consultant failed to provide technical oversight of the laboratory. Note: This contributed to the Immediate Jeopardy determination. Findings include: 1. Review of laboratory records revealed no documentation of review of records or documentation of visits to the laboratory by the technical consultant. 2. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 2 pm in the office assigned to the surveyor confirmed no documentation of technical consultant activity in the laboratory is available and the technical consultant has not visited the laboratory in 2016, 2017 or 2018..
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 review the CMS 209 form, review of laboratory records, lack of records to review and staff interview, the technical consultant failed to perform competency assessment of testing personnel as required. Note; This is a repeat deficiency from the October 2014 survey and contributed to the Immediate Jeopardy determination. 1. Review of laboratory personnel records revealed no documentation of initial or semi-annual competency assessment is available for testing personnel # 1 & 2 (see CMS 209) and no documentation of annual competency assessment for 2016, 2017 and 2018 is available for testing personnel # 3. 2. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 2 pm in the office assigned to the surveyor confirmed no documentation of competency assessment for 2016, 2017 and 2018 is available for testing personnel.. .
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

	The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on lack of records to review and staff interview, the laboratory failed to have personnel who meet the qualifications to perform moderate complexity testing on the Emerald Cell Dyn. Note: This deficiency contributed to the Immediate Jeopardy determination. Finding include: Refer to D6065 & D6066
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on lack of records to review and staff interview, the laboratory failed to have documentation that two of three testing personnel listed on the CMS 209 who perform testing on patient samples have at least a high school diploma or equivalent. Findings include: 1. Review of personnel documents and lack of documents to review revealed no documentation of education for 2 of 3 testing personnel (TP) listed on the CMS 209. 2. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed education records are not available for TP #1 & 2 (see CMS 209). TP # 3 revealed both TP 1 & 2 have been employed less than 1 year and education and training records for TP employed in 2017 are also not available.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on lack of records to review and staff interview, the laboratory failed to have documentation that two of three testing personnel listed on the CMS 209 who perform testing on patient samples received training prior to testing patient samples. Findings include: 1. Review of personnel documents and lack of documents to review revealed no documentation of training for 2 of 3 testing personnel (TP) listed on the CMS 209.

	2. Interview with testing personnel # 3 (see CMS 209) on August 14, 2018 at 1 pm in the office assigned to the surveyor confirmed training records are not available for TP #1 & 2 (see CMS 209). TP # 3 revealed both TP # 1 and 2 have been employed less than 1 year and training records for TP employed in 2017 are also not available.