Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0889196	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Central Clinical Labs Inc	6858 W Archer Ave, Chicago, 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
D2025	BACTERIOLOGY CFR(s): 493.823(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review, the federal data base, and an interview with the technical supervisor (TS) and owner, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program and received unsatisfactory performance scores of '0' for the testing event in the specialty of Microbiology. Findings: 1. The CASPER Individual Laboratory Profile (Report 155), the American Proficiency Institute (API) proficiency testing (PT) reports for the years of 2019 and 2020, and manual were reviewed. 2. The federal Report 155 showed the laboratory received a score of '0' in the specialty of Bacteriology for event #3 of 2020. 3. The laboratory's API-PT reports revealed the laboratory zero (0*) for Event #3 of 2020 was due to late submission. 4. The laboratory failed to include in its PT policies and procedures the requirement to submit PT results to the PT program before the deadline. 5. On a Recertification survey conducted on 12/16/2020 at 12:00 PM, the TS and owner confirmed the above findings.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by:

	Based on record review, the federal data base, and an interview with the technical supervisor (TS) and owner, the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event in the subspecialty of Routine Chemistry. Findings: 1. The CASPER Individual Laboratory Profile (Report 155) and the American Proficiency Institute (API) proficiency testing (PT) reports for the years of 2019 and 2020 and manual were reviewed. 2. The federal Report 155 showed the laboratory received unsatisfactory performances for the following analytes in Event #3 of 2020: *Albumin received a score of zero '0'. *Total Bilirubin received a score of 40%. *Total Protein received a score of 60%. 3. The laboratory's PT reports confirmed the above PT scores. 4. The laboratory failed to include in its PT policies step-by-step procedures to investigate PT failures. 5. On a Recertification survey conducted on 12/16/2020 at 12:00 PM, the TS and owner confirmed the above findings.
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 record review and an interview with the technical supervisor (TS) and owner; the laboratory failed to establish and follow written procedures that meet the requirement to assess employees performing testing in the specialty of Immunology, Hematology and Chemistry, affecting 10 out of 10 testing personnel (TP). Findings include: 1. The procedures manual and personnel records were reviewed. 2. The laboratory's competency procedure failed to include the following requirements: *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and *The assessment of problem solving skills. The competency policy also failed to include "Procedure Review". 3. The personnel records revealed TP1, TP2, TP3, TP4, TP5, TP7, TP10, TP11, TP12, and TP13 training and evaluations were assessed with the above procedure that failed to meet competency requirements. 4. The laboratory failed to follow the written competency policy which required the assessment of test performance and problem solving skills to be included in the procedure to train and/or evaluate 10 out of 10 TP. 5. The competency policy failed to include 'procedure review' as a component of training and maintaining competency. 6. On a continuation Recertification survey conducted on 12/16/2020 at 3:00 PM, the TS and owner confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and an interview with the technical supervisor (TS), the laboratory's procedures manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14) for all tests, assays, and examinations performed by the laboratory in the specialty of Microbiology, prior to testing patients. Findings: 1. The laboratory procedures manual was reviewed. 2. The laboratory performs Real-Time Polymerase Chain Reaction (RT-PCR) procedures to test for the following viral and microbial pathogens: COVID-19 Acinetobacter Baumannii Aerococckus Urinae Candida Albicans Candida Glabrata Candida Parasilosis Citrobacter Freundii Corynebacterium Urealyticum Enterobacter Aerogenes Enterobacter Cloacae Enterococcus Faecalis Enterococcus Faecium Escherichia Coli Klebsiella Oxytoca Klebsiella Pneumonieae Morganella Morganii Proteus Mirabilis Proteus Vulgaris Providencia Stuartii Pseudomonas Aeruginosa Serratia Marcesens Staphylococcus Aureus Staphylococcus Epidermidis Staphlococcus Lugdunensis Staphlococcus Saprophyticus Streptococcus Agalactiae 3. The RT-PCR procedures manual failed to include the following required written policies and procedures: * Requirements from the processing laboratories for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral. *Step-by-step performance of the procedure, including test calculations and interpretation of results. *Procedures for the preparation of solutions, calibrators, controls, reagents, and other materials used in testing. *Calibration and calibration verification procedures, if applicable. *The Control procedures. *Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. *Limitations in the test methodology, including interfering substances. *Reference intervals (normal values). *Imminently life-threatening test results, or panic or alert values. *The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values; and *Description of the course of action to take if a test system becomes inoperable. 4. On a continuation Recertification survey conducted on 12/16 /2020 at 3:00 PM, the TS and owner confirmed the above findings.
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, the Laboratory Personnel Report (CMS 209), and an interview with the technical supervisor (TS), the laboratory failed to employ

	individuals who meet the qualification requirements of 493.1489 to perform the functions of highly complex testing in the specialty of Microbiology, affecting 1 testing personnel (TP14) out of 2 TP. Findings: 1. The laboratory failed to ensure new laboratory staff meet the education criteria specified in 493.1489(b) (1-3) for Real-Time Polymerase Chain Reaction (RT-PCR) procedures. 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 record review, the Laboratory Personnel Report (CMS-209), and an interview with the technical supervisor (TS), the laboratory failed to ensure laboratory employees meet the qualification requirements for performing highly complex testing in the specialty of Microbiology for 1 testing personnel (TP14) out of 2 TP. Findings: 1. The CMS 209 and employee files were reviewed. 2. The CMS 209 list 2 TP (TP1 and TP14) performing Real-Time Polymerase Chain Reaction (RT-PCR) procedures in the laboratory. 3. Review of the employee records revealed TP14 failed to have their foreign education credentials evaluated for United States (US) equivalency. 4. The laboratory failed to ensure TP14 met the education requirement for performing RT-PCR testing, prior to testing patients. 5. On a continuation Recertification survey conducted on 12/16/2020 at 3:00 PM, the TS and owner confirmed the above findings.