Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0694743	01/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
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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
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 proficiency testing records review and interview with staff, the laboratory failed to retain work sheets for bacteriology testing for 2 of 10 American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing events reviewed and attestation statements for 1 of 10 events reviewed. Findings include: 1. Proficiency test records failed to include test work sheets for the second and third CAP events of 2018 and the second CAP event of 2019; and failed to retain the attestation statement signed by the testing person and the director for the second and third API events of 2019. 2. In an interview with staff on 01/10/2020 at approximately 1:45 P.M. staff confirmed they did not have the work sheets and signed attestation statements.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Individualized Quality Control Plan (IQCP) review, quality control records review, patient test records review, lack of documentation, and interview with staff, the laboratory failed to check each lot number of Quidel Quick Vue + rapid Streptococcus (Strep) Group A tests prior to testing patient samples for 2 years of testing reviewed (January 2018 to January 2020). The laboratory tested approximately one specimen per day. Findings include: 1. The laboratory IQCP was to perform 2 levels of liquid quality control with each new lot number or shipment of nonwaived Strep tests' and/or every 30 days. 2. Laboratory quality control records failed to include the lot number of rapid Strep kit used when recording positive and negative monthly quality control performance. 3. Patient test records review document rapid Group A Strep lot numbers 703621 was in use on 03/02/2018 for patient #10406, lot number 703983 was in use on 11/21/2018 for patient 801327831, lot number 74204 was in use on 01/09/2019 for patient 18702, lot number 704458 was in use on 04/15 /2019 for patient 297989, and lot number 704655 on 10/09/2019 for patient 15079. 4. In an interview conducted on 01/10/2020 at approximately 1:30 P.M. staff stated the lot number of Quidel Quick Vue + Strep were recorded on the log where daily internal control was documented but the dates the laboratory performed external positive and negative controls did not include the kit lot number the laboratory used to perform monthly controls. It could not be determined the patients tested and reported in finding #3 had two levels of quality control performed prior to testing patient samples.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on media and antibiotic quality control records review and interview with staff, the laboratory failed to record the lot number of each lot number or shipment for 6 of 6 antibiotic disks used for susceptibility testing received when opened for positive and negative reactivity from January 2018 to January 2020. The laboratory performed approximately 1 to 2 susceptibility tests per month. Findings include: 1. Quality control records review failed to include lot number and expiration dates Amoxicillin, Ampicillin, Cefozoline, Ceftriaxone, Nitrofurantoin and Trimethoprim Sufamethoxizole were first opened and performing positive and negative quality control. 2. In an interview conducted on 01/10/2020 at approximately 1:40 P.M. staff confirmed they did not record antibiotic disk lot numbers and expiration dates.

D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on cystine lactose electrolyte deficient, (CLED), media manufacturer's instructions review, direct observation, and interview with staff, the laboratory failed to follow the manufacturer's specification for using the media for urine culture and susceptibility testing for 2 years of Urine culture tests performed (2018 and 2019). The laboratory performed approxmately 3 to 4 urine cultures per month. Findings include: 1. CLED media manufacturer's instructions state: "...immerse loop up to loop-shaft junction, aseptically transfer the specimen onto the CLED media. Disperse by touching the loop gently to the agar surface and streak down the center with out re-dipping the loop. ZigZag back and fourth over entire plate. Place media side up in 34 to 37 degree incubator for 18 to 24 hours." Multiply the colonies counted by the dilution factor of the loop for the number of colony forming units per ml. 2. Direct observation of urine culture on 01/10/2020 at approximately 10:00 A.M. the testing person dipped the 10 ml side of the loop 3 times into the specimen streaking the plate by thirds for isolation. 3. In an interview with the laboratory director on 10/10/2020 at approximately 1:30 P.M. the director and testing staff personnel confirmed they repeatedly dipped the calibrated loop. The director confirmed they did not perform colony counts or have a stated growth quantification to determine if a culture susceptibility is indicated.
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 patient test records review and interview with staff testing personnel performing antibiotic susceptibility testing 1 of 3 personnel (test person B) did not qualify as a high complexity testing person. (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 patient test records review and interview with staff, one of three testing personnel performing antibiotic susceptibility testing did not qualify as a high complexity testing person for antimicrobial susceptibility testing from 05/09/2018 to 08/04/2019 . Findings include: 1. Patient test records for susceptibility test performed on 05/09/2018 was reported by testing person B. 2. In an interview with testing person B on 01/10/2020 at approximately 1:30 P.M. staff confirmed she did not have an associate's degree or higher in a biological, chemical, physical, or health science to

	qualify to perform high complexity susceptibility testing.