

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2007279	(X3) Date Survey Completed 01/19/2023
Name of Provider or Supplier Medical Center Clinic Urology	Street Address, City, State 8333 N Davis Hwy 7th Fl, Pensacola, 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
D0000	An initial certification survey was conducted on January 12, 2023 and continued to January 19, 2023 to collect additional documentation. Medical Center Clinic Urology, clinical laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
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 personnel records, the CMS-209 Personnel Report (CLIA), and interview with staff, the laboratory failed to employ one of one testing personnel who meets the qualification requirements to perform high complexity testing. Refer to 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 CMS-209 Personnel Report (CLIA), and interview with Testing Personnel (TP) (#A), the laboratory failed to ensure one of one TP were qualified to perform high complexity testing. The testing performed was *Escherichia Coli*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, *Citrobacter freundii*, *Citrobacter koseri*, *Streptococcus pyogenes*, MRSA, *Candida albicans*, *Candida glabrata*, *Prevotella bivia*, *Streptococcus agalactiae* (GBS), *Citrobacter braakii*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Enterococcus faecium*, *Klebsiella*

oxytoca, *Morganella morganii*, *Proteus mirabilis*, *Bacteroides fragilis*, *Ureaplasma urealyticum*, *Candida parapsilosis*, *Candida dubliniensis*, *Mycoplasma genitalium*, *Pseudomonas aeruginosa*, *Serratia marcescens*, VRE (vanA, and vanB), mecA (Oxicillin resistance), Class A B-lactamase; blaKPC, Class A B-lactamase; CTX GROUP 1, Class B metallo- B-lactamase; blaNDM, Sulfonamides resistance (sul), Fluoroquinones resistance (qnr), Trimethoprim resistance (dfrA), *Candida krusei*, *Candida tropicalis*, and *Mycoplasma hominis*. Findings include: Review of the CMS-209 Personnel Report (CLIA) on January 13, 2023 at 2:00 pm, signed and dated by the laboratory director on January 9, 2023, listed one employee for high complexity testing. Review of personnel records on January 13, 2023 at 2:05 pm, revealed TP #A had a Histology Technician Certificate and college transcripts listed 3 credits for Introduction to Biology and 3 credits for Introduction to Chemistry, which does not meet the requirements for high complexity testing. Interview on January 13, 2023 at 2:30 pm revealed, TP #A stated "The company representative told me I was qualified to perform high complexity testing." TP #A confirmed she did not hold the required education for high complexity testing.