

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2007017	(X3) Date Survey Completed 09/17/2024
Name of Provider or Supplier Dr Manjit S Randhawa, Do, Pa	Street Address, City, State 1980 E Mulberry Street, Angleton, TX	
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 announced validation survey was performed on September 17, 2024. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the manufacturer's manual, the laboratory's maintenance logs in 2023, CMS 116 application, and confirmed in an interview, the laboratory failed to document 7 of 8 Quarterly maintenance for 2 of 2 Siemens Viva E Chemistry Analyzers. The findings were: 1. The surveyor's direct observation at 11:00 am on 09/17/2024 during the laboratory tour revealed the laboratory used 2 Siemens Viva E Chemistry analyzers. SN: 10-2468 SN: 16-2331 2. Review of the manufacturer's manual titled Operator's Manual Viva E Distributed by SIEMENS (Article No: 6002-380-410 V05) under chapter 6.1.1 User Maintenance (VITAL SCIENTIFIC B.V.) revealed the following, "Quarterly --Replace mixer belts. If not done by the service technician during preventive maintenance; --Replace water filter. --Replace drying block on wash arm. 3. Review of the laboratory's maintenance logs in 2023 for 2 Siemens Viva E revealed the laboratory failed to document 7 of 8 quarterly maintenance. SN: 10-2468 Quarter 1 Quarter 2 Quarter 3 Quarter 4 SN: 16-2331 Quarter 1 Quarter 3 Quarter 4 4. Review of the laboratory's CMS 116 application, signed by the Laboratory Director on 09/17/2024, revealed the</p>

laboratory's Chemistry annual volume was 10000. 5. An interview at 1:30 pm on 09/17 /2024 in the break room, the laboratory director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

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 the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have documentation of qualification for 1 of 2 TP performing high complexity testing. (Refer to 6171)

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 the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have documentation of qualification for 1 of 2 TP performing high complexity testing. The findings were: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 09/17 /2024, revealed the laboratory identified 2 TP who performed high complexity testing. 2. Review of the laboratory's TP educational credential records revealed the laboratory failed to have documentation of qualification for 1 of 2 TP performing high complexity testing. TP#2 Hired Date: 11/04/2020 3. An interview on 09/17/2024 at 10:30 am in the break room, the Laboratory Director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel