

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0270354	(X3) Date Survey Completed 02/21/2025
Name of Provider or Supplier Doctors Memorial Hospital Clinical Laboratory	Street Address, City, State 333 N Byron Butler Pkwy, Perry, 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 announced CLIA recertification survey was conducted at Doctors Memorial Hospital Clinical Laboratory on 02/04/2025-02/12/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 493.1421 Condition: Laboratory Testing Personnel
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, the Laboratory Director failed to perform annual competencies on 5 of 5 Technical Consultants (TC) for 2 of 2 years (2023 and 2024) reviewed. Findings include: 1. Interview conducted at 9:30am on 02/04/2025 with TP# M confirmed that TC# A, TC# B, TC# C, TC# D, and TC# E do not have annual competencies completed for years 2023-2024. 2. Record review of personnel competency records revealed no competency records completed for TC# A, TC# B, TC# C, TC# D, and TC# E for years 2023-2024.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the Laboratory</p>

	<p>Director failed to sign the Policies and Procedures for 2 of 2 years reviewed (2023-2025). Findings Included: 1. Review of Policies and Procedures revealed that the Laboratory Director did not sign them as reviewed. 2. Interview on 02/05/2025 at 11:00 am the Laboratory Manager confirmed that the Laboratory Director did not sign the Policies and Procedures.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the Laboratory failed to label Complete Blood Count (CBC) controls (QC) with the date open and expiration on the High, Normal, and Low levels of QC. Findings Included: 1. Observations on 02/04/2025 at 10:00 AM during the tour, revealed High, Normal, and Low levels of QC without open date and expiration date. 2. Review of package insert for the High, Normal, and Low levels of QC revealed that once punctured (opened) the QC is good for 15 days. 3. Interview on 02/05/2025 at 1:00 PM the Laboratory Manager confirmed that there was no legible open and expiration date on the High, Normal, and Low levels of QC.</p>
<p>D5545</p>	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to ensure Coagulation quality control (QC) is ran every 8 hours for 2 out of 2 months (June 2023 and August 2024) reviewed. Findings Included: 1. Review of Coagulation QC revealed that the Laboratory had 2 Coagulation instruments and that the policy was to alternatively run the Coagulation machines every other day. 2. Review of QC for June 2023 and August 2024 revealed that the QC and Patient samples were not ran on the assigned (by day) Coagulation instrument. 3. Interview on 02/05/2025 at 5:00 pm the Laboratory Manager confirmed that the QC was not ran every 8 hours on the Coagulation instruments.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, the Technical Consultant failed to</p>

	<p>complete six-month competencies on 5 out of 5 new hire Testing Persons. Findings include: 1. Interview with TP# M conducted at 11:15 am on 02/04/2025 confirmed the Laboratory does not perform six-month competencies on new hire employees. 2. Record review of personnel competency records revealed no six-month competency records on TP# D, TP# L, TP# N, TP# O, TP# P. a. TP# D (date of hire: 03/23/2023) showed no competency record for 09/2023. b. TP# L (date of hire: 05/10/2022) showed no competency record for 11/2022. c. TP# N (date of hire: 10/07/2022) showed no competency record for 04/2023. d. TP# O (date of hire: 10/25/2022) showed no competency for record for 04/2023. e. TP# P (date of hire: 12/01/2023) showed no competency record for 06/2024.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview, the Technical Consultant failed to complete annual competencies for 5 out of 5 Testing Persons (TP) for 2 out of 2 years (2023-2024) reviewed. Findings include: 1. Record review of Testing Personnel competencies revealed no annual competencies for 5 out of 5, TP# J, TP# H, TP# I, TP# L, TP# N, TP# O, TP# P, blood gas Testing Personnel signed by a qualified technical consultant for two (of two) years 2023-2024. 2. Interview with TP# H at 1:23 pm 02/05/2025 confirmed that all annual competencies must be signed by the qualified Technical Consultant for blood gas personnel.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records and interview, the Laboratory failed to have 5 out of 16 Testing Persons (TP) documentation of education (See D6065).</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical</p>

Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview, the Laboratory failed to have documentation of education for 3 out of 16 Testing Persons (TP) reviewed. Findings Include: 1. Review of testing personnel education records revealed TP# L, TP# O, TP# P did not have documentation of education. 2. E-mail interview on 02/10/2025 at 10:29 am the Blood Gas Manager confirmed that the 3 Testing Personnel did not have documentation of their education.