

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2311677	(X3) Date Survey Completed 02/03/2025
Name of Provider or Supplier Medical Colleagues Of Texas - Dr William Currie	Street Address, City, State 21700 Kingsland Blvd # 201, Katy, 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	The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition(s) not met was/were: D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel;
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 a review of the laboratory's policy manual, the laboratory's records, and staff interview, the laboratory failed to have documentation of the laboratory director signing and approving 12 of 12 policies used by laboratory personnel for testing from September 2024 to January 2025. Findings include: 1. A review of the laboratory's policy manual revealed the current laboratory director failed to sign and approve the following 12 policies: - Specimen Collection and Labeling - Formalin Fixation - Gross Examination and Dissection - Histology Laboratory Record Retention Policy - Grossing Station Clean-Up Protocol - Personnel Qualifications and Training - Quality Control and Assurance - Laboratory Policy on Specimen Handling and Processing - Missing and Rejected Specimens - Safety and Personal Protective Equipment (PPE) - Tissue Sampling and Submission for Processing - Safety Data Sheets (SDS) 2. A review of the laboratory's records revealed the current laboratory director was employed by the laboratory in September 2024. 3. In an interview on 2/3/25 at 10:00 a. m. in the laboratory, after review of the records, the operations manager confirmed the above findings.</p>
D5805	TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a random review of patient's test reports from November 2024 and January 2025 and staff interview, the laboratory failed to include the name and address of the testing facility on two of two patient's test reports reviewed. Findings include: 1. A random review of patient's test reports from November 2024 and January 2025 revealed the laboratory failed to include the name and address of the testing facility on the following 2 patient's test reports: Accession #: HS24-2290 Reported: 11/17/24 Accession #: WC24-60009 Reported: 1/1/25 2. In an interview on 2/3/25 at 11:25 p. m. in the laboratory, after review of the records, the operations manager confirmed the above findings.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's records, the laboratory's personnel records, and staff interview, the laboratory director failed to provide overall management of the laboratory for one of one high complexity test- grossing of patient's tissue specimens from September 2024 to January 2025. Findings include: 1. The laboratory director failed to ensure three of three testing personnel had documentation of education and training prior to grossing patient's tissue specimens. (Refer to D6102)

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory director failed to ensure three of three testing personnel had documentation of education and training prior to grossing patient's tissue specimens from September 2024 to January 2025. Findings include: 1.

A review of the laboratory's submitted CMS 209 form and the laboratory's personnel records revealed the laboratory identified 3 testing personnel performing grossing on patient's tissue specimens. - Testing person #1 started grossing in October 2024 - Testing person #2 started grossing in December 2024 - Testing person #3 started grossing in September 2024 2. Further review of the laboratory's personnel records revealed the laboratory failed to have documentation of education and training prior to grossing patient's tissue specimens for all three testing personnel. 3. In an interview on 2/3/25 at 11:55 a.m. in the laboratory, after review of the records, the operations manager confirmed the above findings.

D6143

GENERAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g).

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's CMS 209 form, personnel records, a random review of patient reports from October to December 2024, and staff interview, the laboratory failed to have documentation of the technical supervisor reviewing the gross examination of patient's tissue specimens within 24 hours for 19 of 19 patient's

reports reviewed. Findings include: 1. A review of the laboratory's CMS 209 form revealed the laboratory listed 3 testing personnel performing high complexity testing-grossing on patient's tissue specimens. 2. A review of the laboratory's personnel records for all 3 testing personnel found no documentation of records to qualify them as a technical supervisor for high complexity testing in the specialty of histopathology. Therefore, grossing must be reviewed by the technical supervisor within 24 hours. 3. A random review of the laboratory's patient reports from October to December 2024 revealed the following 19 patient's specimens were grossed and the laboratory failed to have documentation of the technical supervisor reviewing the grossing within 24 hours: Patient Accession number: WC-24-00603 Grossed by TP#3 on 10/21/24 Patient Accession number: WC-24-00604 Grossed by TP#3 on 10/21/24 Patient Accession number: WC-24-00612 Grossed by TP#1 on 10/23/24 Patient Accession number: WC-24-00613 Grossed by TP#1 on 10/23/24 Patient Accession number: WC-24-00614 Grossed by TP#1 on 10/23/24 Patient Accession number: WC-24-00615 Grossed by TP#1 on 10/23/24 Patient Accession number: WC-24-00621 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00622 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00623 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00624 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00629 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00630 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00631 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00632 Grossed by TP#1 on 10/29/24 Patient Accession number: WC-24-00628 Grossed by TP#1 on 11/5/24 Patient Accession number: WC-24-00643 Grossed by TP#1 on 11/7/24 Patient Accession number: WC-24-00644 Grossed by TP#1 on 11/7/24 Patient Accession number: WC-24-60009 Grossed by TP#2 on 12/23/24 Patient Accession number: WC-24-60010 Grossed by TP#2 on 12/23/24 4. In an interview on 2/3/25 at 10:45 a.m. in the laboratory, after review of the records, the operations manager 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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of education to qualify three of three testing personnel to perform high complexity testing- grossing of patient's tissue specimens from September 2024 to January 2025. (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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or

(b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to ensure three of three testing personnel met the requirements to perform high complexity testing- grossing of patient's tissue specimens from September 2024 to January 2025. Findings include:

1. A review of the laboratory's submitted CMS-209 form listed 3 testing personnel performing high complexity testing- grossing of patient's tissue specimens.
2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for all three testing personnel that met the qualifications of a high complexity testing person.
3. In an interview on 2/3/25 at 11:00 a.m. in the laboratory, after review of the records, the operations manager confirmed the above findings.