

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D0365085	<b>(X3) Date Survey Completed</b> 12/19/2024
<b>Name of Provider or Supplier</b> Northland Family Planning - South	<b>Street Address, City, State</b> 24450 Evergreen Rd Suite 220, Southfield, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have a laboratory director qualified to direct high complexity testing. Refer to D6078.</p>
<b>D6078</b>	<p><b>LABORATORY DIRECTOR QUALIFICATIONS</b> CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical</p>

laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

This STANDARD is not met as evidenced by:  
 . Based on record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have a laboratory director qualified to direct high complexity testing for two (December 2022 to December 2024) of two years reviewed. Findings include: 1. A review of the laboratory's test menu revealed the laboratory was performing "Rh (D) Type" testing using "Eldon Card", a high complexity test. 2. A review of the laboratory director's qualification records revealed only a State of Michigan Osteopathic Physician's license. 3. An interview on 12/19/24 at 3:54 pm with the Chief Operating Officer and Owner confirmed the laboratory director was not qualified to direct high complexity testing.

**D6108**

**LABORATORY TECHNICAL SUPERVISOR**  
 CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:  
 . Based on record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have a technical supervisor qualified to supervise high complexity testing. Refer to D6111.

**D6111**

**TECHNICAL SUPERVISOR QUALIFICATIONS**  
 CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a

doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology. (c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must-

- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
- (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or
- (c)(2)(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; and
- (c)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or
- (c)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (c)(3)(i)(B) Meet the requirements in 493.1443(b)(3)(i)(B); and
- (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or
- (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or
- (c)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (c)(4)(i)(B)(1) Meet bachelor's degree equivalency; and
- (c)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or
- (c)(4)(i)(C)(1) Meet bachelor's degree equivalency; and
- (c)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and
- (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or
- (c)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (c)(5)(i)(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either-

  - (c)(5)(i)(B)(1) 48 semester hours of medical laboratory technology courses; or
  - (c)(5)(i)(B)(2) 48 semester hours of science courses that include-

    - (c)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;
    - (c)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and
    - (c)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or technology in any combination; and
    - (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty.

(d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology - If the requirements of paragraph (b) of this section are not met

and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must-

- (d)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
- (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or
- (d)(2)(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; and
- (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or
- (d)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (d)(3)(i)(B) Meet the education requirement at 493.1443(b)(3)(i)(B); and
- (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or
- (d)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (d)(4)(i)(B) Meet the education requirement at paragraphs (c)(4)(i)(B) or (C) of this section; and
- (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or
- (d)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (d)(5)(i)(B) Meet the education requirement at paragraph (c)(5)(i)(B) of this section; and
- (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

(e) Cytology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-

- (e)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
- (e)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or
- (e)(2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(f) Histopathology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-

- (f)(1) Meet one of the following requirements:
  - (f)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
  - (f)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or
  - (f)(1)(ii) An individual qualified under paragraph (b) or (f)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.
- (f)(2) For tests in dermatopathology, meet one of the following requirements:
  - (f)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
  - (f)(2)(i)(B) Meet one of the following requirements:
    - (f)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or
    - (f)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or

(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology; or (f) (2)(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (f)(3) For tests in ophthalmic pathology, meet one of the following requirements: (f)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(3)(i)(B) Must meet one of the following requirements: (f)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f) (3)(i)(B)(2) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (f)(3)(ii) An individual qualified under paragraph (b) or (f) (3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (g) Oral Pathology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (g)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g) (1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (g)(2) Be certified in oral pathology by the American Board of Oral Pathology; or (g)(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g) (1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (h) Histocompatibility - If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either- (h)(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; and (h)(1)(ii) Have training or experience that meets one of the following requirements: (h)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(1)(ii) (B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (h)(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (h)(2)(ii) Have training or experience that meets one of the following requirements: (h)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must- (i)(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; and (i)(1)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (i)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)

(B); and (i)(2)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have a technical supervisor qualified to supervise high complexity testing for two (December 2022 to December 2024) of two years reviewed. Findings include: 1. A review of the laboratory's test menu revealed the laboratory was performing "Rh (D) Type" testing using "Eldon Card", a high complexity test. 2. A review of Form CMS-209 revealed a lack of personnel designated as a technical supervisor. A review of the technical consultant's qualification records revealed only a State of Michigan Osteopathic Physician's license. 3. An interview on 12/19/24 at 3:54 pm with the Chief Operating Officer and Owner confirmed the technical consultant was not qualified to supervise high complexity testing.

**D6141**

**GENERAL SUPERVISOR**

CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have a general supervisor qualified to supervise high complexity testing. Refer to D6143.

**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 record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have a general supervisor qualified to supervise high complexity testing for two (December 2022 to December 2024) of two years reviewed. Findings include: 1. A review of the laboratory's test menu revealed the laboratory was performing "Rh (D) Type" testing using "Eldon Card", a high complexity test. 2. A review of Form CMS-209 revealed a lack of personnel designated as a general supervisor. A review of the technical consultant's qualification records revealed only a State of Michigan Osteopathic Physician's license. 3. An interview on 12/19/24 at 3:54 pm with the Chief Operating Officer and Owner confirmed the technical consultant was not qualified to supervise high complexity testing.

**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 record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have laboratory testing personnel qualified 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 (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 record review and interview with the Chief Operating Officer and Owner, the laboratory failed to have laboratory testing personnel qualified to perform high complexity testing for two (December 2022 to December 2024) of two years reviewed. Findings include: 1. A review of the laboratory's test menu revealed the laboratory was performing "Rh (D) Type" testing using "Eldon Card", a high complexity test. 2. A review of the testing personnel qualifications revealed a lack of documentation showing they met requirements to perform high complexity testing: a. Testing Personnel #1 had a high school diploma. b. Testing Personnel #2 had a high school transcript. c. Testing Personnel #3 had a high school diploma. 3. An interview on 12/19/24 at 3:54 pm with the Chief Operating Officer and Owner confirmed the testing personnel listed above were not qualified to perform high complexity testing.