

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2264084	<b>(X3) Date Survey Completed</b>  03/06/2026
<b>Name of Provider or Supplier</b>  Frontage Laboratories, Inc	<b>Street Address, City, State</b>  394 Sw 12th Ave (Building 6), Deerfield Beach, FL	
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>D0000</b>	An announced CLIA validation survey was conducted at FRONTAGE LABORATORIES, INC on March 04, 2026 to March 06, 2026 . The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6076 493.1441 Condition: Laboratory Director D6168 493.1487 Condition: Testing Personnel
<b>D5209</b>	<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 record review and staff interview, the laboratory failed to follow procedure for yearly competency evaluations for the Clinical Consultant (CC), Technical Supervisor (TS) and General Supervisor (GS) positions in the specialty of Chemistry in 2025. Findings included: 1-Review of personnel record's competency evaluations for CC, GS, and TS roles revealed that there were no roles. The roles for CC, GS, and TS were requested and not provided. 2- Review of the laboratory policy titled Training and Competency Assessment, # GNMS-0006, effective date 06/06/2023, section 5.6.21 stated "the CLIA Laboratory Director will annually assess the competency of supervisory / management employees who have been delegated responsibilities by the CLIA Laboratory Director." 3- During interview on 03/04/2025 at 11:15 AM, the LD confirmed that the competency of the GS was not performed in 2025. 4- Email from Laboratory Manager on 03/06/2025 at 12:09 PM, confirmed that the LD had not performed competency evaluations for CC, GS and TS roles in 2025.</p>
<b>D6076</b>	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 observation, record review, and staff interview, the Laboratory Director failed to provide the overall management and direction for the laboratory for two out of two years 2024 and 2025, failed to employ sufficient number of laboratory personnel to provide appropriate consultation and properly supervise and accurately perform testing based on the job responsibility (See D6101), failed to 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 (See D6102), failed to monitor individuals who conduct testing and failed to ensure competency was performed for personnel performing high complexity testing (See D6103).

**D6101**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(11)

(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director failed to employ sufficient number of laboratory personnel, provide appropriate consultation, and to properly supervise testing personnel to ensure that they accurately perform testing based on the job responsibility in the specialty of Chemistry from 06/20/2022 to 03/06/2026. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 01/23/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC) and Technical Supervisor (TS). 2-Review of personnel record's competency evaluations for CC, General Supervisor (GS) and TS roles were not included. The roles were requested and not provided. 3- During an interview on 03/04/2026 at 11:15 AM, LD confirmed that the GS, who was also Testing Personnel A, had LD delegated responsibilities (signed by the LD on 10/18/2018).

**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 record review and staff interview, the Laboratory Director (LD) failed to ensure that prior to testing patients' specimens, that 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 for one of two testing personnel for years 2022-2026. Finding included: 1. According to Florida Administrative Code (FAC) Rule 64B3 -5.003, Laboratory Testing Personnel who work in an Independent Laboratory must be licensed in the specialty that the testing is being performed. 2. Review of the Florida Department of Health website revealed that Testing Personnel B did not have a Florida State License. Testing Personnel B obtained a Master of Science degree in Biology in 05/14/2022. 3. On 03/06/2026 at 8:53 AM email from the Laboratory Manager confirmed that Testing Personnel B started working for the laboratory on 06/20/2022, and that all training records for demonstrated performance for dry testing laboratory were done 3/2/2026 in preparation for the survey.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to ensure that policies and procedures established for monitoring individuals to assure that they are competent and maintain their competency to perform high complexity testing in the specialty of Chemistry from January 2025 to March 6, 2026. Findings Included: 1. Review of FORM CMS 209 signed by the Laboratory Director on 01/23/2026, revealed the following: LD was also Clinical Consultant (CC) and Technical Supervisor (TS). The laboratory had a General Supervisor, who was also Testing Person A, with delegation signed by the LD on 10/18/2018 to perform competency assessments. 2-Review of personnel record's annual competency for TP-A signed on 08/22/2025, and TP-B signed on 03/02/2026, revealed that Patient testing was not observed and not initialed by the LD/TS. The annual competency evaluations were observed and initialed by the Laboratory Manager, who did not have a CLIA role. 3-Review of the laboratory policy titled Training and Competency Assessment, #GNMS-0006, effective date 06/06/2023, section 5.6.21 stated "the CLIA Laboratory Director will annually assess the competency of supervisory / management employees who have been delegated responsibilities by the CLIA Laboratory Director." Also section 5.6.6 stated " ...The performance of employees is evaluated and documented at least semi-annually during the first year, thereafter, evaluations must be performed at least annually ...". 4- During an interview on 03/04/2026 at 11:15 AM, LD confirmed that he did not perform the competency assessments for TP-A and TP-B. 5-Email from Laboratory Manager on 03/06/2025 at 12:09 PM, confirmed that the LD had not performed competency evaluations for CC, GS/TS and TP roles in 2025. Also that TP-B competency assessments were documented 03/02/2026 in preparation for the survey.

**D6121**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have the Technical Supervisor (TS) or a designee, document the direct observation of patient testing during competency evaluation for two out of two Testing Personnel (TP-A, TP-B) for year 2025, and one of two Testing Personnel (TP-B) in 2026. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 01/23/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC) and Technical Supervisor (TS). The laboratory had a General Supervisor, who was also Testing Person A, with delegation signed by the LD on 10/18/2018 to perform competency assessments. The laboratory also had Testing Personnel B (see D6170). 2- Review of personnel record's annual competency for TP-A signed on 08/22/2025, and TP-B signed on 03/02/2026, revealed that Patient testing was not observed and not initialed by the LD/TS. The annual competency evaluations were observed and initialed by the Laboratory Manager, who did not have a CLIA role. 3-During an interview on 03/04/2026 at 11:15 AM, LD confirmed that he did not perform the competency assessments for TP-A and TP-B. 4- On 03/06/2026 at 8:53 AM email from the Laboratory Manager stated that the initial, six months and annual competency evaluations were documented for Testing Personnel B on 03/02/2026 in preparation for the survey.

**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 personnel record review and staff interview, the laboratory failed to have one (TP-B) of two (A, B) Testing Personnel meet the state licensure as required by the State of Florida personnel requirements from 06/20/2022 to 03/06/2026. See D6170

**D6170**

TESTING PERSONNEL QUALIFICATIONS  
CFR(s): 493.1489(a)

Each individual performing high complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

This STANDARD is not met as evidenced by:

Based on personnel record review and staff interview, one of two Testing Personnel failed to have a state license as required by the State of Florida from 06/20/2022 to 03/06/2026. Findings included: 1. According to Florida Administrative Code (FAC) Rule 64B3 -5.003, Laboratory Testing Personnel who work in an Independent Laboratory must be licensed in the specialty that the testing is being performed. 2. Review of the Florida Department of Health website revealed that Testing Personnel

B did not have a Florida State License. Testing Personnel B obtained a Master of Science degree in Biology in 05/14/2022. 3. Review of the Job Description Sheet listed Testing Personnel B's job title as Computational Biologist in the Bioanalytical Department on 06/20/2022. 4. Review of the College of American Pathologist (CAP) Proficiency Testing records revealed attestations were signed by Testing Personnel B (dry laboratory testing in Bioanalytical) on the following events: ICSP-A 2024 - signed 03/14/2024, ICSP-A 2025 - signed 03/18/2025, ICSP-A 2026. Also, the Quality Assurance checklist revealed CAP rerun samples signed on 06/10/2024 and 08/26/2025. 5. On 03/04/2026 at 2:15 PM, during interview with Laboratory Director and Testing Personnel B confirmed that Testing Personnel B did not have a Florida State License. Laboratory Director also stated that no patient testing has been reported after validation was completed 10/17/2023. 6. On 03/06/2026 at 8:53 AM email from the Laboratory Manager confirmed that Testing Personnel B started working for the laboratory on 06/20/2022.