

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2178891	<b>(X3) Date Survey Completed</b>  12/04/2025
<b>Name of Provider or Supplier</b>  Express Gene Molecular Diagnostics Laboratory	<b>Street Address, City, State</b>  9000 Sw 152 St Ste 209, Palmetto Bay, 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 through November 20, 2025, to December 4, 2025 at EXPRESS GENE MOLECULAR DIAGNOSTICS LABORATORY. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6000 493.1403 - Moderate Complexity Laboratory Director
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and technical supervisor (TS) interview, the laboratory failed to verify the accuracy of testing method at least twice annually for 1 out of 39 analytes used in Respiratory Panel test (RPP) since 01/10/2025. Findings included: 1-Review of the test menu provided with the form CMS-116 Clinical Laboratory Improvement Amendment (CLIA) Application for Certification signed by the Laboratory Director on 11/20/2025 listed the RPP using a Real-Time Polymerase Chain Reaction (RT-PCR) laboratory developed test (LDT) which detected the following infectious microorganisms : Acinetobacter Baumannii, Adenovirus, Bocavirus, Bordetella bronchioseptica, Bordetella parapertussis, Bordetella pertussis, Chlamydomphila pneumoniae, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Enterobacter cloacae, Enterovirus, Haemophilus influenzae, HMPV-A, HMPV-B, Influenza A, Influenza B, Klebsiella aerogenes, Klebsiella pneumoniae, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Parainfluenza Virus-1, Parainfluenza Virus-2, Parainfluenza Virus-3, Parainfluenza Virus-4, Parechovirus, Pneumocystis jirovecii, Pseudomonas aeruginosa, Rhinovirus-A, Rhinovirus-B, RSV A &amp; B, S aureus MecA, S pyogenes group A, SARS-CoV 2, Staphylococcus aureus, Streptococcus pneumoniae. 2-Review of the Verification of Performance</p>

Specifications of the RPP test with RT-PCR, revealed that the Laboratory Director signed on 01/10/2025. 3-Review of Proficiency testing records for American Proficiency Testing (API), revealed that the Microbiology Panels that the laboratory used in the second event of 2025 did not include the detection of Pneumocystis jirovecii. The laboratory failed to perform the accuracy verification twice a year for this microorganism. 4-The laboratory tested 196 samples with the RPP test that included Pneumocystis jirovecii from 10/30/2025 to 11/06/2025. 5-During an interview on 11/20/2024 at 02:00 PM, the TS confirmed that the laboratory failed to do twice a year verification for the Pneumocystis jirovecii, listed in the RPP test.

**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 record review and staff interview, the laboratory report failed to ensure that accurate specimen information was included on the final report of the Respiratory Panel test (RPP) in 3 out of 3 reports reviewed. Findings Included: 1-Review of three final reports for the RPP and the printed requisitions revealed the following: a)Patient #1 (P#1): final report listed a collection date of 11/04/2025, received date of 11/05/2025 and released date of 11/06/2025. Review of the original printed requisition revealed that the specimen was collected on 10/25/2025. b)P#2: Final report for RPP listed a collection date of 11/04/2025, received date 11/05/2025 and reported 11/06/2025. Review of the original printed requisition revealed a collection date of 10/28/2025. c)P#3: Final report listed a collection date of 11/04/2025, received date of 11/05/2025 and reported date of 11/11/2025. The printed requisition listed a collection date of 10/28/2025. 2- During an interview on 11/20/2025 at 04:30 PM, the Laboratory Director stated that the RPP test final reports used a collection date that was the date the referral laboratory registered in the digital requisition they submitted and confirmed that the reports failed to record the actual date the sample was collected at the primary collection site.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on record review and staff interview, the Laboratory Director failed to have documentation of qualifications to manage and direct the laboratory personnel and the performance of tests categorized as moderate complexity for Hematology and

Chemistry tests in the laboratory from 05/15/2025 to 11/20/2025. (See D6003). Based on record review and staff interview, The Laboratory Director failed to delegate in writing to the Technical Consultant (TC) the duties to review the proficiency testing results for the Hematology and Chemistry specialties. (See D6032).

**D6003**

**LABORATORY DIRECTOR QUALIFICATIONS**

CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (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, 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical 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) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(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 (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, 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 (b)(4)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(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 (b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory

science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate 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 Laboratory Director (LD), the LD did not have a Florida State Laboratory Director license in the specialties of Hematology and Chemistry from 05/25/2025 to 11/20/2025. The findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 11/20/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC). 2- During a laboratory tour on 11/20/2025 at approximately 9:52 AM, the surveyor observed the laboratory had a Mindray BC-5390 Hematology analyzer and the Diazyme DZ-Lite c 270 Chemistry analyzer. 3-Review of Test Menu GEN-03, revealed that the document was implemented and signed by the LD on 05/15/2025 contained the list of Hematology and Chemistry tests. Review of American Proficiency Institute (API) and College of American Pathologist (CAP) records, revealed that the laboratory had enrolled and participated in proficiency testing for the following programs: Hematology : AAB 2025 (participated in 1st and second event of Hematology with 5 Part Differential), CAP 2025 participated in CAP FH17-C for Hematology; Routine Chemistry: API 2025 Chemistry Core 1st event, 2nd event and 3rd event. Review of the 116 CMS form signed by the laboratory director on 11/20/2025 revealed an estimated annual volume of 7000 for Chemistry Routine 310, and annual volume of 10 for Hematology 400. 4- Review of the LD's State of Florida license revealed that he was licensed as a Molecular Pathology Director dated May 15, 2024, with an expiration date August 31, 2026. 5- Interview on 11/20/2025 at approximately 5:25 PM, the LD stated that the laboratory had not started testing in these two specialties and confirmed that did not have LD's State of Florida License for Hematology and Chemistry.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the Laboratory Director (LD) failed to specify in writing the duties and responsibilities for the Technical Consultant (TC). Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 11/20/2025, revealed the following: The Laboratory had a Technical Consultant (TC) for Hematology and Chemistry specialties for moderate complexity testing. 2- Review of employee (TC) job description records with hire date 11/06/2020 did not include moderate complexity responsibilities. 3- Review of College of American Pathologist (CAP) proficiency test result for Hematology FH17-C 2025, revealed that results were reviewed and signed by the TC on 11/04/2025 and not the LD. 4- During phone interview on 11/25/2025 at approximately 10:05 AM, the TC confirmed that the LD did not specify in writing the duties and responsibilities of the TC performed during the year 2025.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the Laboratory Director (LD), failed to ensure that the laboratory verified the accuracy of testing method at least twice annually for 1 out of 39 analytes used in Respiratory Panel test (RPP) since 01/10 /2025. (See 5217)