

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2066019	<b>(X3) Date Survey Completed</b>  09/10/2025
<b>Name of Provider or Supplier</b>  Express Docs Llc	<b>Street Address, City, State</b>  14530 S Military Trl Ste A1-5, Delray 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 initial survey was conducted at Express Docs LLC on June 11, 2025 to September 10, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5400- 493. 120 Condition: Analytic Systems
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to write open dates and expiration dates on the following reagents: Dade Innovin, Calcium Chloride (CaCL2) solution and Actin FSL used in Prothrombin Time (PT), Partial Thromboplastin Time (APTT) and International Normalized Ratio (INR) testing (See D5415); failed to complete performance specifications for Xpert Xpress Multiplex Vaginal panel (MVP) -US-IVD before running patients (See D5421); and failed to run external positive and negative controls for 4 out of 4 patients reviewed for MVP, Xpert (Chlamydia trachomatis and Neisseria Gonorrhoeae (CT/NG) and Vitamin D (See D5449).</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1)</p>

Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to write open dates and expiration dates on the following reagents: Dade Innovin, Calcium Chloride (CaCL<sub>2</sub>) solution and Actin FSL used in Prothrombin Time (PT), Partial Thromboplastin Time (APTT) and International Normalized Ratio (INR) testing.

Findings Included: 1. On 6/11/2025 at 2:07 PM, Dade Innovin, CaCl<sub>2</sub> solution and Actin FSL were observed unlabeled with open and expiration dates in use on BFT II analyzer for PT, APTT and INR. 2. Review of Dade Innovin package insert read, "Store at 2 to 8 Celsius (C). At this temperature, the unopened reagent can be used until its expiry date (see vial label). Stability after reconstitution: 2 to 8 Celsius (C) 10 days (closed vial) 15 to 25 C 5 days (closed vial) 37 C 24 hours (closed vial)." 3. Review of Dade Actin FS Activated PTT Reagent package inset read, "Dade Actin FS Activated PTT Reagent: Stability 2-15 C: once opened, 7 days." 4. On 6/11/2025 at 4:34 PM, the General Clinical Supervisor confirmed the laboratory failed to write open and expiration dates for Dade Innovin, Calcium chloride (CaCL<sub>2</sub>) solution and actin FSL.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete performance specifications for Xpert Xpress Multiplex Vaginal panel (MVP)-US-IVD before running a patient. Findings included: 1. Review of Cepheid Gene Xpert Validation for MVP signed by the laboratory director on 2/1/2025 revealed verification of Cepheid Xpert Xpress MVP was not filled for accuracy, precision and report range. There were no attached instrument printout documentation for accuracy, precision and report range. 2. Review of patient test results revealed the following: 2a. Patient 1 was tested for MVP on 2/7/2025 at 5:18 PM, for Bacterial Vaginosis, Vulvovaginal Candidiasis, and Trichomoniasis on GeneXpert Dx system. 3. On 6/11/2025 at 4:34 PM, the General Supervisor confirmed the laboratory failed to complete their performance specifications for Xpert Xpress Multiplex Vaginal panel (MVP) -US -IVD. Multiplex Vaginal panel (MVP).

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to run external positive and negative controls for 4 out of 4 patients reviewed for Multiplex Vaginal panel (MVP), Xpert (Chlamydia trachomatis and Neisseria Gonorrhoeae (CT/NG) and Vitamin D, (#1, #2, #3, #4). Findings Included: 1. Review of patient test results revealed the following: 1a. Patient #1 was tested for MVP on 2/7/2025 at 5:18 PM, for Bacterial Vaginosis, Vulvovaginal Candidiasis, and Trichomoniasis on GeneXpert Dx system. 1b. Patient #2 was tested for CT/NG on 2/7/2025 at 5:15 PM, on GeneXpert Dx system. 1c. Patient #3 was tested for CT/NG on 2/10/2025 at 4:34 PM, on GeneXpert Dx system. 1d. Patient #4 was tested for Vitamin D on 5/27/2025 at 2:30 PM, on Fast Pack Vitamin D (Vit). 2. Review of GeneXpert Dx systems control reports revealed the following: 2a. There was no documentation of positive and negative controls for CT/NG on 2/7/2025 and 2/10/2025. 2b. There was no documentation of positive and negative controls for MVP on 2/7/2025. 3. Review of Fast Pack Vit control reports revealed the following: 3a. There was no documentation of positive and negative controls for Vitamin D on 5/27/2025. 4. Review of General QC Policy signed by the laboratory director on 2/1/2025 read, "E.) Qualitative Results Qualitative tests require a positive and negative control with each assay." 5. On 6/11/2025 at 4:34 PM, the General Supervisor confirmed the laboratory failed to run external positive and negative controls for 4 out of 4 patients reviewed.