Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2304868	06/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Fpca Molecular Labs Llc	610 Solarex St Suite B, Frederick, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM), review of validation summaries, and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory's SOPM included procedures that didn't match laboratory practice, didn't align with the validation studies used to establish performance specifications, and were outdated. Findings: 1. During the original recertification survey, the laboratory was performing three molecular assays from the manufacturer ATILA: 1) urinary tract infection plus (UTI+), 2) UTI antibiotic resistance markers

(ABR), and 3) a mini respiratory pathogen panel (mini RPP). At the time of the onsite revisit survey, the laboratory was performing four molecular assays from the manufacturer MarinaBioLab: 1) UTI panel that included antibiotic resistance genes, 2) Women's Health panel, 3) mini respiratory panel, and 4) Streptococcus A (Strep A) panel. 2. The SOPM at the time of the onsite revisit survey included the manufacturers' instructions for use (IFU) and the laboratory's "Technical and Operational SOPs." 3. The laboratory was using the MarinaBioLab IFUs as the testing procedure for each of the assays. Some instructions in the IFUs weren't consistent with laboratory practice or the validation procedures used to establish performance specifications. For example: a. The IFUs discussed how to interpret quality control and patient results using Bacillus atrophaeus as an external control. The laboratory didn't use Bacillus atrophaeus as an external control. b. The IFU for the UTI panel stated that a "result is considered positive if the Cq [quantification cycle) value is [less than or equal to] 38, or as determined by your laboratory's protocols." The validation studies determined a Cq cutoff value of 34 for Enterococcus species which was not specified in any procedure. c. The Women's Health and Strep A validation summaries included an initial "Reverse Transcription" cycling step of 52 degrees Celsius for 5 minutes in the amplification profile that wasn't included in the IFUs. d. The threshold settings listed in the IFUs didn't match what was stated in the validation summaries. For example, all the IFUs stated the threshold settings should be set to 500 relative fluorescence units (RFU), but the validation summary for the Women's Health panel stated the threshold settings should be set at 400 RFU for the fluorescent dye FAM, 300 RFU for HEX, 400 RFU for ROX, and 200 RFU for Cy5. 4. The "Technical and Operational SOPs" were not updated to reflect the current testing that was performed in the laboratory at the time of the revisit survey. Some examples include: a. "SOP 2.1: Specimen Collection, Handling & Transport" i. The "Purpose" section of the SOP stated, "ensures the integrity of specimens for the UTI+, ABR, and mini RPP panels." The SOP did not address specimen requirements for the Women's Health or Strep A panels. ii. The chart titled "Specimen Types and Requirements" stated the collection device to be used for the mini RPP assay was "Dry flocked swab (no media)." The MarinaBioLab mini respiratory panel was validated for use with a mini-tip HydraFlock Swab submitted in liquid Amies collection media. iii. The chart titled "Acceptance & Rejection Criteria" stated to reject specimens if "Received at room temp [greater than] 2 hours post- collection." The validation summaries for all assays stated that specimens were stable up to 24 hours at room temperature. b. "SOP 2.2: Specimen Receipt & Accessioning" i. The SOP stated that specimen transport temperature was tracked using a "courier temperature log" that was reviewed daily. The log was not in use at the time of the onsite revisit survey. ii. The SOP stated to "Create Platemap LIS [laboratory information system] based on the method being used and the specimens being tested on ordered panels." There were no instructions in any of the approved procedures for how to create the plate map in the LIS. c. "SOP 2.3: Test method Selection & Validation" i. The "Method Validation (Prior to Use)" section stated to "Use ATILA IFUs and internal SOPs as primary guides." The laboratory was no longer using ATILA molecular assays and performed new validations using MarinaBioLab molecular assays. d. "SOP 2.4: Reagent and Instrument Quality Control" i. The "Documentation" section listed logs that were no longer in use at the time of the onsite revisit survey. For example, the "Inventory Log," "Ancillary Instrument Maintenance Log," and "General Lab Maintenance Log." e. "SOP 2.5: Molecular Testing Workflow" i. The "Purpose" section stated, "To outline standardized, step-by-step molecular testing procedures for UTI+, ABR, and mini RPP panels using ATLIA protocols." The laboratory was no longer using ATILA molecular assays. ii. The test instructions stated in this SOP did not match the procedures for performing the MarinaBioLab molecular assays. f. "SOP 2.6: Result

	Review & Release" i. The "Purpose" section stated, "To define the procedure for reviewing, verifying, and releasing molecular test results for UTI+, ABR, and mini RPP panels." The SOP didn't include the Women's Health or Strep A assays. g. "SOP 2.7: Reporting and Communication" i. The "Client Result Reporting" section stated to "Notify the provider immediately by phone for: Unexpected detection of high-risk resistance markers (as necessary/requested)," "Positive result in a pediatric or immunocompromised patient," "and when "Result inconsistent with patient history (flagged by director)." There were no procedures that defined what a high-risk marker was, how to identify an immunocompromised patient, or how to determine if a result was inconsistent with patient history. ii. The "Troubleshooting and FAQs" section stated that an amended report was delivered "via same channel, clearly marked as 'Amended'." There were no instructions for when or how to amend a final test report. h. "SOP 2.11: Proficiency Testing & External QA" i. The "Enrollment" section stated to "Enroll annually with an approved PT provider for each analyte and assay in the current test menu (UTI+, ABR, Mini RPP)." The SOP didn't include the gene targets included in the Women's Health and Strep A assays. 5. None of the SOPS or IFUs included instructions for how create and enter the plate map into the instrument, how to upload patient results into the LIS to create final test reports, how to name and save data files, how to complete the "Molecular Assay Worksheet," or how to document corrective actions if QC were to fail. 6. None of the SOPs or IFUs included instructions for the operation and maintenance of the Systaaq Diagnostic Automated Nucleic Acid Purification Instrument. 7. During the exit interview on 05/08/2026 at 12:45 PM, the TS and LD confirmed that the SOPM included procedures that didn't match laboratory practice, didn't align with the validation studies used to establish performance specifications, and were outdated.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical supervisor (TS) and laboratory director (LD), the LD failed to approve, sign, and date the manufacturers' instructions for use (IFUs) that were used as testing procedures at the time of the onsite revisit survey. Findings: 1. At the time of the onsite revisit survey on 05/08/2026, the laboratory was using the manufacturers' IFUs as testing procedures. 2. The following IFUs were not approved, signed, and dated by the LD: a. "BIGFISH MagaPure DNA/RNA Extraction/Purification Kit" b. "Pre-Plated Urinary Tract Infection Plus Panel PCR Kit" c. "Pre-Plated Vaginal Women Health Panel PCR Kit" d. "PrePlated (PP) Respiratory Mini Panel PCR Kit" 3. During the exit interview on 05/08/2026 at 12:45 PM, the TS and LD confirmed that the manufacturer's IFUs that were in use as testing procedures were not approved, signed, and dated by the LD.