

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2036230	(X3) Date Survey Completed 01/29/2026
Name of Provider or Supplier Millennium Physicians Association, PLLC	Street Address, City, State 9303 Pinecroft Dr Ste 320, The Woodlands, TX	
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
D0000	An announced survey of the laboratory was conducted on 01/29/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations and staff interview, the laboratory failed to maintain unidirectional workflow and to have separate areas for specimen or reagent preparation, amplification and product detection for one of one molecular microbiology tests performed by the laboratory, the laboratory developed Urinary Tract Infection (UTI) by Polymerase Chain Reaction (PCR) test panel. Findings included: 1. Surveyor's observations on 01/29/2026 at 1320 hours in the laboratory revealed that all processes for the UTI by PCR testing were performed in a small room dedicated to the molecular microbiology laboratory. Within the room the equipment was arranged on work benches along each wall, in such a way that the testing person had to crisscross the room and/or work areas between tasks not allowing for unidirectional workflow or separation of areas for specimen accessioning, processing, amplification and target detection. 2. In an interview on 01/29/2026 at 1320 hours in the laboratory, the Technical Supervisor (as indicted on submitted Form CMS 209), after discussion of the steps in the workflow, confirmed the findings.</p>

D5427

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(c)

(c) Documentation. The laboratory must document all activities specified in this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, test menu, individualized quality control plan (IQCP), test establishment studies and staff interview, the laboratory failed to document IQCP establishment studies to allow for reduction of each target's positive control testing frequency from each day of patient testing to monthly testing for one of one molecular microbiology tests performed by the laboratory, the laboratory developed Urinary Tract Infection (UTI) by Polymerase Chain Reaction (PCR) TaqMan Custom Array Card test. Findings included: 1. Review of laboratory's policy "Quality Assurance and Procedures" (document: GEN-002, effective:06/01/2025) revealed: "We will also run an amplification control for each target on the panel with the first card run of the month, post background calibration, to verify we can identify each assay." 2. Review of laboratory's provided test menu revealed the laboratory developed UTI by PCR test panel had thirty-five molecular amplification targets reported to provider. 3. Review of laboratory's IQCP for the "UTI qPCR Assay" (approved by laboratory director 6/1/2025) revealed: "QC on UTI TaqMan Array Card NTC (Negative) - each card run B. atropheus (Positive) - each sample Comprehensive Microbiota Control (Positive) - monthly after background calibration" 4. Review of laboratory's establishment studies for the laboratory developed UTI by PCR test TaqMan Custom Array Card test panel revealed the laboratory did not have documentation of performing establishment studies for reduction of each target's Positive Control (Comprehensive Microbiota Control) testing from each day of patient testing to once per month. 5. In an interview on 01/29/2026 at 1415 hours in the laboratory, the facility's Technical Supervisor (as indicted on submitted Form CMS 209) confirmed the findings.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on review of the laboratory's individualized quality control plan (IQCP), quality control (QC) records, patient test volumes and staff interview, the laboratory failed to follow its own IQCP protocols and document the monthly Comprehensive Microbiota Positive Control for the Urinary Tract Infection (UTI) by Polymerase Chain Reaction (PCR) TaqMan Custom Array Card test for five of five months reviewed from August to December 2025. Findings included: 1. Review of

laboratory's IQCP for the "UTI qPCR Assay" (approved by laboratory director 6/1/2025) revealed: "Comprehensive Microbiota Control (Positive) - monthly after background calibration" 2. Review of laboratory's QC records from August to December 2025 revealed there was no documentation of monthly Comprehensive Microbiota Positive Control testing, per IQCP protocols, to verify the laboratory can accurately identify each target. 3. Review of laboratory's patient test volumes revealed the laboratory performed UTI by PCR TaqMan Custom Array Card testing on approximately 89 patient samples from August to December 2025. 4. In an interview on 01/29/2026 at 1415 hours in the laboratory, the facility's Technical Supervisor (as indicted on submitted Form CMS 209) confirmed the findings.

D5455

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(v)(g)

(d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's test menu, random patient test reports, quality control (QC) records, patient test volumes and staff interview, the laboratory failed to document each target's positive control reactivity each day of patient testing for the Urinary Tract Infection (UTI) by Polymerase Chain Reaction (PCR) TaqMan Custom Array Card test panel for five of five months the test was performed from August through December 2025. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory performed TaqMan Custom Array Card testing for the following thirty-five targets: a. Molecular Urinary Tract Infection (UTI) Pathogen Panel: *Pseudomonas aeruginosa* *Streptococcus pyogenes* *Citrobacter koseri* *Acinetobacter baumannii* *Citrobacter freundii* / *braakii* *Enterococcus faecium*, *faecalis* *Escherichia coli* *Gardnerella vaginalis* *Klebsiella aerogenes* *Klebsiella pneumoniae* *Klebsiella oxytoca* *Proteus mirabilis*, *vulgaris* *Staphylococcus aureus* *Staphylococcus saprophyticus* *Streptococcus agalactia* (group B) *Serratia marcescens* *Staphylococcus* (coagulase negative: *epidermidis*, *haemolyticus*, *lugdunensis*, *saprophyticus*) *Candida albicans*, *glabrata*, *parapsilosis*, *tropicalis* *Neisseria gonorrhoeae* *Chlamydia trachomatis* *Trichomonas vaginalis* *Ureaplasma urealyticum* *Mycoplasma genitalium* *Aerococcus urinae* / *sanguinicola* *Corynebacterium urealyticum* *Enterobacter cloacae* *Morganella morganii* *Mycoplasma hominis* b. Molecular UTI Resistance Gene Panel: *tetB*, *tetM* ACT, MIR, FOX, ACC Groups (Beta Lactams) Class A Beta-lactamase; *blaKPC* Class A Beta-lactamase; CTX-M Group Class B Metallo- Beta-lactamase; *blaNDM* Class D oxacillinase OXA-48 MRSA *Mec-A* gene PER-1 / VEB-1 / GES-1 Groups (ESBL) *qnrA1*, *A2* VanA, VanB (Vancomycin) IMP, NDM, VIM Groups (Carbapenem) Class D oxacillinase OXA-51 *dfr* (A1, A5); *sul* (1, 2) probes (Sulfamethoxazole and trimethoprim) *ermB*, C, *mefA* *qnrB*, *qnrS* *blaTEM* OqxA/B 2. Review of a sample of a patient test report (accession 260200503) revealed the laboratory reported the results as "Detected" or "Not Detected" for each of the above thirty-five targets. 3. Review of laboratory's random QuantStudio 7 Flex instrument QC records from August to December 2025 revealed the laboratory documented a positive extraction control (*Bacillus atrophaeus*) with each sample and a negative NTC

	<p>(no template control - reagent) with each TaqMan card run, but there was no documentation of a positive control for each target each day of patient testing. 4. Review of laboratory's patient test volumes revealed the laboratory performed UTI by PCR TaqMan Custom Array Card testing on approximately 89 patient samples from August to December 2025. 5. In an interview on 01/29/2026 at 1415 hours in laboratory, the facility's Technical Supervisor (as indicted on submitted Form CMS 209) confirmed the findings.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) records, quality control records and staff interview, the laboratory's QA failed to identify and correct issues with quality control for one of one molecular microbiology tests performed by the laboratory, the Urinary Tract Infection (UTI) by Polymerase Chain Reaction (PCR) TaqMan Custom Array Card test. Refer to D5445 and D5455.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's random patient test reports and staff interview, the laboratory failed to ensure the correct CLIA number was associated with the name and address of the laboratory on patient's final report for four of four test reports reviewed from October 2025 and January 2026. Findings included: 1. Review of random patient test reports from October 2025 and January 2026 revealed the laboratory had the wrong CLIA number (22D2093470) documented on the laboratory's final patients' reports. The reviewed reports were: Urinary Tract PCR Panel sample number 252830038, reported on 10/13/2025 Urinary Tract PCR Panel sample number 260200503, reported on 01/22/2026 Urinalysis sample number B260270214, reported on 01/27/2026 Urinalysis sample number B260270306, reported on 01/27/2026 2. In an interview on 01/29/2026 at 0955 hours in the breakroom, the facility's Technical Supervisor (as indicted on submitted Form CMS 209), after review of the reports, confirmed the findings.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test establishment studies, individualized quality control plan (IQCP), quality control (QC)/quality assurance (QA) records and staff interview, the Laboratory Director failed to ensure laboratory's QC and QA were established and maintained for one of one molecular microbiology tests performed by the laboratory, the Urinary Tract Infection (UTI) by Polymerase Chain Reaction (PCR) TaqMan Custom Array Card test. Refer to D5427, D5445, D5455 and D5791.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test establishment studies, individualized quality control plan (IQCP), quality control (QC) records and staff interview, the Technical Supervisor failed to ensure laboratory's QC was established and maintained for one of one molecular microbiology tests performed by the laboratory, the Urinary Tract Infection (UTI) by Polymerase Chain Reaction (PCR) TaqMan Custom Array Card test. Refer to D5427, D5445 and D5455.