Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2325449	03/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
First Priority Lab	26797 Hanna Rd, Building 4, Suite 6, Conroe, 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 03/16/2026. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D2000 - 42 C. F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director;
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory's submitted Form CMS-116 and test menu, test records, proficiency testing records and staff interview, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for two of two microbiology subspecialties tested by the laboratory, bacteriology and mycology. Findings included: 1. Review of laboratory's submitted Form CMS-116 and corresponding test menu revealed the laboratory performed testing in microbiology - subspecialties in bacteriology and mycology - with laboratory developed tests using polymerase chain reaction (PCR) to identify microorganisms and determine antimicrobial resistance. 2. Review of laboratory's test records revealed the laboratory started testing patient samples on 10/31/2025 and tested approximately 1500 patient samples from 10/31

	/2025 through 03/16/2026. 3. The surveyor attempted to review laboratory's proficiency testing records and found there were no such records available for review. Surveyor asked for proficiency testing enrollment documentation, and none was provided. 4. In an interview on 03/16/2026 at 1015 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS-209) stated that the laboratory has not yet enrolled in a PT program, confirming the findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted "Laboratory Personnel Report (CLIA)" Form CMS-209, personnel records, policies/procedures and staff interview, the laboratory failed to ensure competency assessment was documented for one of one of the laboratory's technical/general supervisors. Findings included: 1. Review of laboratory's submitted Form CMS-209 revealed the laboratory employed one technical supervisor who also held the position of general supervisor. 2. Review of laboratory's personnel records revealed the technical supervisor/general supervisor (as indicated on submitted Form CMS-209) did not have documentation of competency assessment for these positions. 3. Review of laboratory's policies/procedures revealed the laboratory did not have written protocols in place addressing the specific requirements for competency assessments of technical supervisor or general supervisor. 4. In an interview on 03/16/2026 at 0950 hours in the laboratory, the facility's technical supervisor confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of laboratory's test menu, manufacturer's instructions, test establishment studies, policies/procedures, laboratory's quality control records, patient test records and staff interview, the laboratory failed to ensure positive control results are acceptable prior to reporting patient results for one of five reviewed instances where positive control results were unacceptable for the "NOVA UTI (urinary tract infection)/Wound w (with) ABX (antimicrobial resistance) Pathogens Panel" targets. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory used the NOVA UTI RT (real time) PCR (polymerase chain reaction) Panel for detection of urinary tract infection pathogens and determination of antimicrobial resistance. 2. Review of the manufacturer's instructions for the "NOVA UTI /Wound w ABX Pathogens Panel" (document: UTI Check IFU 11.6.23, Reference NP9603) revealed: "Interpretation of Quality Control Note: The below conditions must be met at the same time, otherwise this experiment is invalid and needs to be repeated. Assessment of sample test results should be performed after the

positive and negative controls have been determined to be valid. If controls are not valid the patient results cannot be interpreted" 3. Review of laboratory's test establishment studies for the NOVA UTI RT PCR Panel (effective: 10/27/2025) revealed: "Quality Control External Control (Positive Control): Serves as an amplification control intended for the detection of all 18 targets in the UTI panel. The positive control results should show an exponential curve in the designated dye channel for each UTI targets being profiled." 4. Review of laboratory's policy "UTI Pathogen Panel" (document: MOL.1002 Effective Date: 10/15/2025) revealed: "Positive and Negative Test Controls should be added to every experiment plate." 5. Review of random laboratory's quality control records revealed positive control (PTC) results were unacceptable for the following NOVA UTI RT PCR Panel's targets: On 12/18/2025 run 1: PTC Target: Result: Pass/fail: van A UNDETERMINED Failed van B UNDETERMINED Failed blaKPC UNDETERMINED Failed Note: Van A and van B are resistance genes for vancomycin in Enterococci, blaKPC is a gene determining resistance to carbapenems, cephalosporins, penicillins and monobactam drugs in Enterobacteriaceae. 6. Review of random patient original test data and final reports for 12/18/2025 run 1 revealed the laboratory issued following patient reports without an acceptable positive control for van A, van B and blaKPC targets, thus without being able to verify no false negative reports were issued: Accession: 2512100002 Organism detected: K. oxytoca Semi quantitative interpretation: Severe infection Resistance target result: blaKPC - UNDETERMINED Reported resistance result: blaKPC: NEG (Negative) Accession: 2512100005 Organism detected: Enterococcus spp Semi quantitative interpretation: Severe infection Resistance target result: van A - UNDETERMINED van B - UNDETERMINED Reported resistance result: Van-A: NEG Van-B: NEG Accession: 2512100008 Organism detected: C. koseri, E. coli, Enterococcus spp. Semi quantitative interpretation: Moderate infection Resistance target result: blaKPC - UNDETERMINED van A - UNDETERMINED van B - UNDETERMINED Reported resistance result: Van-A: NEG Van-B: NEG blaKPC: NEG Accession: 2512100019 Organism detected: E. coli Semi quantitative interpretation: Severe infection Resistance target result: blaKPC - UNDETERMINED Reported resistance result: blaKPC: NEG Accession: 2512100023 Organism detected: E. coli Semi quantitative interpretation: Moderate infection Resistance target result: blaKPC - UNDETERMINED Reported resistance result: blaKPC: NEG Accession: 2512100025 Organism detected: E. coli Semi quantitative interpretation: Moderate infection Resistance target result: blaKPC - UNDETERMINED Reported resistance result: blaKPC: NEG Accession: 2512100036 Organism detected: Enterococcus spp Semi quantitative interpretation: Severe infection Resistance target result: van A - UNDETERMINED van B - UNDETERMINED Reported resistance result: Van-A: NEG Van-B: NEG Accession: 2512100039 Organism detected: Enterococcus spp Semi quantitative interpretation: Severe infection Resistance target result: van A - UNDETERMINED van B - UNDETERMINED Reported resistance result: Van-A: NEG Van-B: NEG And, Organism detected: E. coli Semi quantitative interpretation: Moderate infection Resistance target result: blaKPC - UNDETERMINED Reported resistance result: blaKPC: NEG 7. In an interview on 03/16/2026 at 1150 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS-209) confirmed the findings. B. Based on review of laboratory's test menu, manufacturer's instructions, test establishment studies, policies/procedures, laboratory's quality control records, patient test records and staff interview, the laboratory failed to ensure positive control results are acceptable prior to reporting patient results for four of four reviewed instances where positive control results were unacceptable for the "NOVA Fungal Pathogens Panel" targets. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory used the NOVA Fungal Pathogens Panel for detection of fungal nail infection pathogens. 2. Review of the manufacturer's

	instructions for the "NOVA Fungal Pathogens Panel" (document and/or reference number unavailable) revealed: "Interpretation of Quality Control Note: The below conditions must be met at the same time, otherwise this experiment is invalid and needs to be repeated. o Assessment of sample test results should be performed after the positive and negative controls have been determined to be valid. If controls are not valid the patient results cannot be interpreted" 3. Review of laboratory's test establishment studies for the NOVA Fungal Pathogens Panel (effective: 10/27/2025) revealed: "5. QUALITY CONTROL (QC) MATERIAL 5.1. External Control (Positive Control): Serves as an amplification control intended for the detection of all 17 targets in the Nail fungus panel. The positive control results should show an exponential curve in the designated dye channel for each Nail fungus target being profiled." 4. Review of laboratory's policy "Fungal Pathogen Panel" (document: MOL. 1001 Effective Date: 10/15/2025) revealed: "NOTE: Positive and negative control must be added to all experiments." 5. Review of random laboratory's quality control records for Fungal Pathogen Panel's PCR targets revealed positive control (PTC) results were unacceptable as follows: On 11/25/2025: PTCTarget: Result: Pass/fail: Malassezia UNDETERMINED Failed On 12/03/2025: PTC Target: Result: Pass/fail: Malassezia UNDETERMINED Failed On 12/12/2025: PTC Target: Result: Pass/fail: Malassezia UNDETERMINED Failed On 12/19/2025: PTC Target: Result: Pass/fail: Malassezia UNDETERMINED Failed 6. Review of random patient reports from 11/25 /2025 and 12/03/2025 revealed the laboratory issued following patient reports without acceptable positive control for Malassezia, thus without being able to verify no false negative reports were issued: Accession: 2511200029 Tested: 11/25/2025 Malassezia Target result: Undetermined Reported Result for Malassezia: NEG (Negative) Accession: 2511200089 Tested: 12/03/2025 Malassezia Target result: Undetermined Reported Result for Malassezia: NEG Accession: 2511200105 Tested: 12/03/2025 Malassezia Target result: Undetermined Reported Result for Malassezia: NEG Accession: 2511200107 Tested: 12/03/2025 Malassezia Target result: Undetermined Reported Result for Malassezia: NEG 7. In an interview on 03/16/2026 at 1230 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS-209) confirmed the findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's test menu, manufacturer's instructions, laboratory's quality control records, corrective action records, policies/procedures and staff interview, the laboratory failed to document corrective action for seven of seven failed positive control targets in laboratory developed molecular microbiology testing by PCR (polymerase chain reaction) methods, from November and December 2025. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory used the NOVA Fungal Pathogens Panel for detection of fungal nail infection pathogens, and the NOVA UTI (urinary tract infection)/Wound w (with) ABX (antimicrobial resistance) Pathogens Panel for detection of urinary tract

	infection pathogens and determination of antimicrobial resistance. 2. Review of the manufacturer's instructions for the "NOVA Fungal Pathogens Panel" (document and /or reference number unavailable), and the "NOVA UTI /Wound w ABX Pathogens Panel" (document: UTI Check IFU 11.6.23, Reference NP9603) revealed: "Interpretation of Quality Control Note: The below conditions must be met at the same time, otherwise this experiment is invalid and needs to be repeated. oAssessment of sample test results should be performed after the positive and negative controls have been determined to be valid. If controls are not valid the patient results cannot be interpreted" 3. Review of random laboratory's quality control records for Fungal Pathogen Panel's PCR targets revealed positive control (PTC) results were unacceptable as follows: On 11/14/2025: PTC Target: Result: Pass/fail: Malassezia UNDETERMINED Failed On 12/03/2025: PTC Target: Result: Pass/fail: Malassezia UNDETERMINED Failed On 12/12/2025: PTC Target: Result: Pass/fail: Malassezia UNDETERMINED Failed On 12/19/2025: PTC Target: Result: Pass/fail: Malassezia UNDETERMINED Failed 4. Review of random laboratory's quality control records revealed positive control (PTC) results were unacceptable for the following NOVA UTI RT PCR Panel's antimicrobial resistance targets: On 12/18/2025 run 1: PTC Target: Result: Pass/fail: van A UNDETERMINED Failed van B UNDETERMINED Failed blaKPC UNDETERMINED Failed Note: Van A and van B are resistance genes for vancomycin in Enterococci, blaKPC is a gene determining resistance to carbapenems, cephalosporins, penicillins and monobactam drugs in Enterobacteriaceae. 5. Review of laboratory's corrective action records revealed there were no corrective actions documented for the above failed positive control targets. 6. Review of laboratory's policies/procedures revealed: a. For "Fungal Pathogen Panel" (document: MOL.1001 Effective Date: 10/15/2025)" "NOTE: Positive and negative control must be added to all experiments." b. For "UTI Pathogen Panel" (document: MOL.1002 Effective Date: 10/15/2025): "Positive and Negative Test Controls should be added to every experiment plate." There were no protocols in place for corrective action on individual positive control target failures to ensure no false negative reports were issued for patient samples included in the experiment/plate. 7. In an interview on 03/16/2026 at 1230 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS-209) confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's quality control records, corrective action records, policies/procedures and staff interview, the laboratory failed to ensure laboratory's quality assurance protocols identified and corrected issues in quality control for two of two testing platforms, the laboratory developed NOVA UTI (urinary tract infection) and Fungal Pathogens panels. Refer to D5481A and B, and D5783.
D6076	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 review of laboratory's submitted Form CMS-116 and test menu, proficiency testing records, test records, personnel records, quality control records and staff interview, the laboratory director failed to provide overall management and direction for two of two testing platforms, the laboratory developed NOVA UTI (urinary tract infection) and the NOVA Fungal Pathogens panels. Findings included: 1. The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program. Refer to D6088. 2. The laboratory director failed to ensure the laboratory's quality control and quality assurance was maintained. Refer to D6093. 3. The laboratory director failed to ensure the laboratory followed its own policies and documented training for one of one testing person employed by the facility. Refer to D6102. 4. The laboratory director failed to ensure protocols were established and maintained for documentation of competency assessment for one of one technical/general supervisors employed by the facility. Refer to D6103.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of laboratory's submitted Form CMS-116 and test menu, test records, proficiency testing records and staff interview, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for two of two of its testing microbiology subspecialties, bacteriology and mycology. Refer to D2000.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (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 laboratory's quality control records, test records and staff interview, the laboratory director failed to ensure the laboratory's quality control (QC) was maintained, and quality assurance identified and corrected problems in QC for two of two of its testing platforms, the laboratory developed NOVA UTI (urinary tract infection) and the NOVA Fungal Pathogens panels. Refer to D5481A and B, and D5791.
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 review of laboratory's submitted "Laboratory Personnel Report (CLIA)" - Form CMS-209, policies/procedures, personnel records, test records and staff interview, the laboratory director failed to ensure the laboratory followed its own policies and documented training for one of one testing person employed by the facility. Findings included: 1. Review of laboratory's submitted Form CMS-209 revealed the laboratory employed one testing person. 2. Review of laboratory's policy "Training Personnel" (document FPL-042, version 1.0, effective 10/1/2025) revealed: "General Supervisor: ...4. Ensures training is accomplished 5. Submits documentation for completed training for entry into training folder." And, "Technical Supervisor: ...3. Reviews training received and ensures training files are complete. 4. Submits documentation for training completed." 3. Review of laboratory's personnel records revealed the facility's testing person did not have documentation of completed training available for review. 4. Review of patient test records revealed the laboratory performed testing on approximately 1500 patient samples from 10/31/2025 through 03 /16/2026. 5. In an interview on 03/16/2026 at 1000 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS-209) confirmed the findings.
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 review of laboratory's submitted "Laboratory Personnel Report (CLIA)" - Form CMS-209, personnel records, policies/procedures and staff interview, the laboratory director failed to ensure protocols were established and maintained for documentation of competency assessment for one of one technical/general supervisors employed by the facility. Refer to D5209.
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 laboratory's quality control records, test records and staff interview, the laboratory's technical supervisor failed to ensure the laboratory's quality control (QC) was maintained for two of two of its testing platforms, the laboratory developed NOVA UTI (urinary tract infection) and the NOVA Fungal Pathogens panels. Refer to D5481A and B.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records, test records and staff interview, the laboratory's technical supervisor failed to ensure corrective actions were documented for failed controls for two of two of its testing platforms, the laboratory developed NOVA UTI (urinary tract infection) and the NOVA Fungal Pathogens panels. Refer to D5783.