Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2312773	06/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Biodx Laboratories Llc	3550 E Post Road #600, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA initial certification survey conducted at your facility on June 12, 2025. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory policies and procedure manuals, a review of the policy entitled "QAQC Standard Program", a review of the validation studies for the Urinary Tract Infection Panel, and an interview with the laboratory supervisor, the laboratory failed to ensure that a written procedure manual for all tests, assays and examinations performed by the laboratory were available to and followed by the laboratory personnel. Findings include: 1. A review of the director approved policy entitled, "QAQC Standard Program" stated, "Written procedure manuals containing procedures for all activities of the laboratory are maintained and readily available and followed by laboratory personnel." 2. There was no director approved general laboratory procedure for validation of the Bio-Speedy Urinary Tract Infection (UTI) Focus and Antibiotic Resistance Markers (ABR) panel for the staff to have step by step instructions for the performance of the validation studies, and to define the performance characteristics and parameters of acceptability for accuracy, precision, Limit of Detection (LoD), and specificity. 3. A review of the validation studies for the

	Bio-Speedy Urinary Tract Infection (UTI) Focus and Antibiotic Resistance Markers (ABR) panel revealed that there were discrepant statements between the overall validation summary and the accuracy study summary regarding the number of specimens used for the study. The overall summary stated that for accuracy, the laboratory used 19 specimens for correlation with another laboratory. The summary of the accuracy study stated that 24 specimens for correlation were used to determine the accuracy of the test. 4. There was no director approved policy and procedure available to the staff for the calibration and maintenance of the pipettes and for maintenance and function checks of the centrifuge for the minimum acceptable speed of 3000 rpm as defined in the manufacturer's instructions for the performance of the UTI + ABR panel. 5. The findings were confirmed during an interview with the laboratory supervisor conducted on June 12, 2025 at approximately 10:15 AM. The laboratory performs approximately 2000 microbiology tests annually.
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 a review of the laboratory procedure manual, and an interview with the laboratory supervisor, the laboratory failed to ensure that the laboratory director approved the step by step procedure available from the manufacturer of the Bio-Speedy Urinary Tract Infection (UTI) Focus and Antibiotic Resistance Markers (ABR) for the performance of the UTI panel. Findings include: 1. There was no documentation of director approval of the procedure entitled "Bio-Speedy UTI Focus + ABR Panel" that was provided by the manufacturer of the strips for testing. There was an abbreviated procedure entitled, "Short SOP for Bio-Speedy Urinary Tract Infections Focus + ABR Panel" that the director had signed as approved on March 26, 2025. The Short SOP did not include specific information for the sample preparation and test performance. 2. The finding was confirmed during an interview with the laboratory supervisor conducted on June 12, 2025 at approximately 10:30 AM. The laboratory performs approximately 2000 microbiology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for the Bio-Speedy UTI Focus + ABR panel, a review of the laboratory freezer temperature log, observation of the heat block, a review of the laboratory temperature logs, a review of the manufacturer's

	procedure for the Bio-Speedy UTI Focus + ABR panel, and an interview with the laboratory supervisor, the laboratory failed to ensure that the acceptable freezer temperature range was consistent with the manufacturer's instructions, and that the temperature of the heat block was monitored and documented to ensure that the temperatures for the 65 degree Celsius and 95 degree Celsius temperatures required for incubation during the sample preparation were acceptable. Findings include: 1. A review of the manufacturer's instructions for the Bio-Speedy UTI Focus + ABR panel revealed that the acceptable temperature range for storage of the components of the kit was between -22 degrees Celsius and -18 degrees Celsius. 2. A review of the laboratory freezer log revealed that the acceptable temperature range established by the laboratory was listed as -18 degrees Celsius and -24 degrees Celsius. 3. It was observed that there was no thermometer placed in the heat block to monitor the temperature of the block to ensure that the temperatures required for incubation of the samples during preparation were acceptable. 4. There was no documentation of the heat block temperatures for acceptability in accordance with the manufacturer's instructions. The manufacturer's procedure for the performance of the Bio-Speedy UTI Focus + ABR panel stated that the samples were to be incubated at 65 degrees Celsius for 5 minutes, followed by a 95 degree Celsius incubation for an additional 5 minutes. The laboratory relied on the digital display on the front of the heat block for the acceptable temperatures for incubation. 5. The laboratory supervisor confirmed the findings during an interview conducted on June 12, 2025 at approximately 11:30 AM. The laboratory performs approximately 2000 microbiology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the operator's manual for the Biorad CFX96 Touch Real-Time PCR System, a review of the laboratory maintenance records, and an interview with the laboratory supervisor, the laboratory failed to ensure that maintenance was performed and documented as required by the manufacturer of the system. Findings include: 1. There was no documentation of periodic maintenance performed on the Biorad CFX96 Touch Real-Time PCR System. 2. A review of the operator's manual for the Biorad CFX96 Touch Real-Time PCR System stated on page 144, "The block of the optical reaction module should be cleaned, along with the C1000 Thermal cycler base, on a regular schedule to remove any debris and spilled liquid with a soft, lint-free cloth that is dampened with water." The instructions continue on page 145 and 146, giving specific instructions on the cleaning of the instrument. 3. The findings were confirmed during an interview with the laboratory supervisor on June 12, 2025 at approximately 11:30 AM. The laboratory performs approximately 2000 microbiology tests annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

	This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for the Bio-Speedy UTI Focus + ABR panel, a review of the laboratory freezer temperature log and an interview with the laboratory supervisor, the laboratory failed to ensure that corrective action was taken when the freezer temperature exceeded the acceptable storage temperatures established by the manufacturer of the UTI Panel. Findings include: 1. There was no documentation of corrective action for the freezer temperatures below the acceptable ranges established by the manufacturer on 76 of 98 days between the dates of January 2, 2025 and June 11, 2025. 2. A review of the manufacturer's instructions for the Bio-Speedy UTI Focus + ABR panel revealed that the acceptable temperature range for storage of the components of the kit was between -22 degrees Celsius and -18 degrees Celsius. 3. The finding was confirmed during an interview with the laboratory supervisor conducted on June 12, 2025 at approximately 11:30 AM. The laboratory performs approximately 2000 microbiology tests annually.
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 a review of the director approved Quality Assurance policy and of the director approved Quality Improvement policy, the lack of documentation of quality assessment activities, and an interview with the laboratory supervisor, the director failed to ensure that quality assessment activities were performed and documented to detect errors and correct them. Findings include: 1. There was no documentation of quality assessment activities for the lab to detect and correct errors when they occurred. 2. The director approved policy entitled "QAQC Standard Program", in the section entitled "Test Methods and Equipment", stated, "All equipment in the laboratory are maintained according to the manufacturer's recommendations." 3. The director approved policy entitled "QAQC Standard Program", in the section entitled "Test Methods and Equipment", stated that the acceptable range for the freezer was -20 to -2 degrees Celsius. That temperature range is discrepant with both the range the laboratory established on the temperature log (-24 degrees Celsius and -18 degrees Celsius), and the acceptable storage temperature range established by the manufacturer of the UTI + ABR panel (-22 degrees Celsius and -18 degrees Celsius). 4. The director approved policy entitled "QAQC Standard Program", in the section entitled "Test Methods and Equipment", stated, "Temperatures for all temperature dependent equipment are monitored and recorded." There was no documentation of monitoring and recording of the heat block temperatures. 5. The director approved policy entitled, "Quality Improvement Policy" stated, "The laboratory director... oversees the successful implementation of the Quality Improvement program to identify and correct problems as they occur. Problems identified by the plan are documentation along with the correction action taken by the laboratory personnel and the director/designee." 6. The director approved policy entitled, "Quality Improvement Policy" in the section entitled, "Situations that prompt a QA review", stated "Routine, scheduled review of an element." The policy did not specify the frequency at which the routine scheduled review was to occur. 7. The findings were

	confirmed during an interview with the laboratory supervisor on June 12, 2025 at approximately 11:45 AM. The laboratory performs approximately 2000 microbiology tests annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on a review of the laboratory policies and procedure manuals, a review of the policy entitled "QAQC Standard Program", a review of the validation studies for the Urinary Tract Infection Panel, and an interview with the laboratory supervisor, the laboratory failed to ensure that a written procedure manual for all tests, assays and examinations performed by the laboratory were available to and followed by the laboratory personnel. Findings include: 1. A review of the director approved policy entitled, "QAQC Standard Program" stated, "Written procedure manuals containing procedures for all activities of the laboratory are maintained and readily available and followed by laboratory personnel." 2. There was no director approved general laboratory procedure for validation of the Bio-Speedy Urinary Tract Infection (UTI) Focus and Antibiotic Resistance Markers (ABR) panel for the staff to have step by step instructions for the performance of the validation studies, and to define the performance characteristics and parameters of acceptability for accuracy, precision, Limit of Detection (LoD), and specificity. 3. There was no director approved policy and procedure available to the staff for the calibration and maintenance of the pipettes and for maintenance and function checks of the centrifuge for the minimum acceptable speed of 3000 rpm as defined in the manufacturer's instructions for the performance of the UTI PCR panel. 4. The findings were confirmed during an interview with the laboratory supervisor conducted on June 12, 2025 at approximately 10:15 AM. The laboratory performs approximately 2000 microbiology tests annually.