Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2292448	03/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
First Bio Lab Of Illinois Llc	415 W Golf Rd, Arlington Heights, IL	

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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the general supervisor (GS), the laboratory failed to ensure corrective action was taken for 28 of 28 unacceptable PT performances (see D5211) and failed to ensure accuracy of 249 of 249 PT sample results not evaluated by the PT provider (see D5213) for three of three PT events reviewed in the subspecialties of bacteriology and mycology in 2024.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the general supervisor (GS), the laboratory failed to ensure corrective action was taken for

	28 of 28 unacceptable PT performances for three of three PT events reviewed in the subspecialties of bacteriology and mycology in 2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy "Proficiency Testing Policy", which stated, a) Under "2. Procedure ... c. For External Proficiency Testing Program:", "ix. Follow up: Upon receipt of evaluation from the PT provider, the supervisor will initiate appropriate action as outlined below: ... "2. Survey performance that demonstrates a score less than 100% will require further investigation and corrective action. 3. Any analyte that fails the proficiency evaluation against grade criteria mut be re-evaluated to identify the reason for the failure and corrective action." b) Under "2. Procedure ... e. Evaluation of Proficiency Testing Reports:", "ii. Corrective Action "1. Corrective action is required whenever an unacceptable response is obtained." 2. Review of API PT summary records for events 1 through 3 of 2024 revealed the following unacceptable PT results: PT Event: Analyte: Sample: 2024 Event 1 Enterobacter cloacae UTI-03 2024 Event 1 Enterobacter cloacae UTI-04 2024 Event 1 Enterococcus faecalis UTI-01 2024 Event 1 Enterococcus faecalis UTI-02 2024 Event 1 Enterococcus faecalis UTI-05 2024 Event 1 Resistance gene: dfrA UTI-04 2024 Event 1 Resistance gene: dfrA UTI-05 2024 Event 1 Resistance gene: NDM UTI-01 2024 Event 1 Resistance gene: SHV UTI-04 2024 Event 1 Resistance gene: SHV UTI-05 2024 Event 1 Resistance gene: VIM UTI-05 2024 Event 2 Resistance gene: dfrA UTI-08 2024 Event 3 Citrobacter freundii UTI-12 2024 Event 3 Enterobacter cloacae UTI-11 2024 Event 3 Enterococcus faecalis UTI-11 2024 Event 3 Enterococcus faecalis UTI-15 2024 Event 3 Klebsiella oxytoca UTI-12 2024 Event 3 Staph* saprophyticus UTI-11 *Staph. = Staphylococcus 2024 Event 3 Candida albicans UTI-15 2024 Event 3 Candida glabrata UTI-13 2024 Event 3 Candida lusitaniae UTI-12 2024 Event 3 Candida tropicalis UTI-12 2024 Event 3 Resistance gene: dfrA UTI-12 2024 Event 3 Resistance gene: sul1 UTI-12 2024 Event 3 Resistance gene: vanA UTI-11 2024 Event 3 Resistance gene: VIM UTI-12 3. Review of API PT records revealed the document titled "Proficiency Testing Performance Evaluation", in which the laboratory director signed and commented, under "Corrective action taken (if indicated):", "No action needed". 4. Interview with the GS on 03/11/2025, at 11:22 am, confirmed the laboratory failed to ensure corrective action was taken for 28 of 28 unacceptable PT performances for three of three PT events reviewed in the subspecialties of bacteriology and mycology in 2024.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the general supervisor (GS), the laboratory failed to ensure accuracy of 249 of 249 PT sample results not evaluated by the PT provider for three of three PT events reviewed in the subspecialties of bacteriology and mycology in 2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy "Proficiency Testing Policy", which stated, a) Under "2. Procedure ... c. For External Proficiency Testing Program:", "ix. Follow up: Upon receipt of evaluation from the PT provider, the supervisor will initiate appropriate action as outlined below: ... "4. Any analyte that is

not evaluated by the PT provider (due to lack of consensus, limited participants, a zero score for non-participation, or late return of results) will require further investigation and documentation. b) Under "2. Procedure ... e. Evaluation of Proficiency Testing Reports:", "ii. Corrective Action .... 2. Investigation and evaluation is required whenever a test result is un-graded due to non-consensus." 2. Review of API PT comparative evaluation summaries for the following PT events of 2024 revealed the following un-graded PT samples: PT Event: Analyte: Sample: 2024 Event 1 Resistance gene: AmpC UTI-02 2024 Event 1 Resistance gene: AmpC UTI-03 2024 Event 1 Resistance gene: AmpC UTI-04 2024 Event 1 Resistance gene: CTX-M (1) UTI-02 2024 Event 1 Resistance gene: CTX-M (1) UTI-03 2024 Event 1 Resistance gene: CTX-M (2) UTI-02 2024 Event 1 Resistance gene: CTX-M (2) UTI-03 2024 Event 1 Resistance gene: dfrA UTI-02 2024 Event 1 Resistance gene: dfrA UTI-03 2024 Event 1 Resistance gene: ErmA UTI-02 2024 Event 1 Resistance gene: ErmA UTI-04 2024 Event 1 Resistance gene: ErmA UTI-05 2024 Event 1 Resistance gene: ErmB UTI-02 2024 Event 1 Resistance gene: ErmB UTI-03 2024 Event 1 Resistance gene: femA UTI-01 2024 Event 1 Resistance gene: femA UTI-02 2024 Event 1 Resistance gene: femA UTI-03 2024 Event 1 Resistance gene: femA UTI-04 2024 Event 1 Resistance gene: femA UTI-05 2024 Event 1 Resistance gene: IMP-7 UTI-01 2024 Event 1 Resistance gene: IMP-7 UTI-02 2024 Event 1 Resistance gene: IMP-7 UTI-03 2024 Event 1 Resistance gene: IMP-7 UTI-04 2024 Event 1 Resistance gene: IMP-7 UTI-05 2024 Event 1 Resistance gene: KPC UTI-02 2024 Event 1 Resistance gene: KPC UTI-03 2024 Event 1 Resistance gene: mecA UTI-01 2024 Event 1 Resistance gene: mecA UTI-02 2024 Event 1 Resistance gene: mecA UTI-03 2024 Event 1 Resistance gene: mecA UTI-04 2024 Event 1 Resistance gene: mecA UTI-05 2024 Event 1 Resistance gene: mefA UTI-02 2024 Event 1 Resistance gene: mefA UTI-03 2024 Event 1 Resistance gene: mefA UTI-05 2024 Event 1 Resistance gene: NDM UTI-02 2024 Event 1 Resistance gene: NDM UTI-03 2024 Event 1 Resistance gene: OXA-48 UTI-02 2024 Event 1 Resistance gene: OXA-48 UTI-03 2024 Event 1 Resistance gene: qnrA UTI-02 2024 Event 1 Resistance gene: qnrA UTI-03 2024 Event 1 Resistance gene: qnrB UTI-02 2024 Event 1 Resistance gene: qnrB UTI-03 2024 Event 1 Resistance gene: SHV UTI-02 2024 Event 1 Resistance gene: SHV UTI-03 2024 Event 1 Resistance gene: sul1 UTI-02 2024 Event 1 Resistance gene: sul1 UTI-03 2024 Event 1 Resistance gene: sul2 UTI-02 2024 Event 1 Resistance gene: sul2 UTI-03 2024 Event 1 Resistance gene: TEM UTI-02 2024 Event 1 Resistance gene: TEM UTI-03 2024 Event 1 Resistance gene: Tet B UTI-01 2024 Event 1 Resistance gene: Tet B UTI-02 2024 Event 1 Resistance gene: Tet B UTI-03 2024 Event 1 Resistance gene: Tet B UTI-05 2024 Event 1 Resistance gene: Tet M UTI-02 2024 Event 1 Resistance gene: Tet M UTI-03 2024 Event 1 Resistance gene: vanA/B UTI-01 2024 Event 1 Resistance gene: vanA/B UTI-02 2024 Event 1 Resistance gene: vanA/B UTI-03 2024 Event 1 Resistance gene: vanA/B UTI-04 2024 Event 1 Resistance gene: vanA/B UTI-05 2024 Event 1 Resistance gene: vanB UTI-01 2024 Event 1 Resistance gene: vanB UTI-02 2024 Event 1 Resistance gene: vanB UTI-03 2024 Event 1 Resistance gene: vanB UTI-04 2024 Event 1 Resistance gene: vanB UTI-05 2024 Event 1 Resistance gene: VIM UTI-02 2024 Event 1 Resistance gene: VIM UTI-03 2024 Event 2 Resistance gene: AmpC UTI-06 2024 Event 2 Resistance gene: AmpC UTI-07 2024 Event 2 Resistance gene: AmpC UTI-09 2024 Event 2 Resistance gene: AmpC UTI-10 2024 Event 2 Resistance gene: CTX-M (1) UTI-06 2024 Event 2 Resistance gene: CTX-M (1) UTI-07 2024 Event 2 Resistance gene: CTX-M (1) UTI-09 2024 Event 2 Resistance gene: CTX-M (1) UTI-10 2024 Event 2 Resistance gene: CTX-M (2) UTI-06 2024 Event 2 Resistance gene: CTX-M (2) UTI-07 2024 Event 2 Resistance gene: CTX-M (2) UTI-09 2024 Event 2 Resistance gene: CTX-M (2) UTI-10 2024 Event 2 Resistance gene: dfrA UTI-06 2024 Event 2 Resistance gene: dfrA UTI-07 2024 Event 2 Resistance gene: dfrA UTI-09 2024

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D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of laboratory records, personnel records, and interview with the laboratory representative; the laboratory's delegated general supervisor (GS) failed to meet the qualification requirements of 493.1459 for high complexity testing in the subspecialties of bacteriology and mycology (see D6143).
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g). This STANDARD is not met as evidenced by: Based on review of laboratory records, personnel records, and interview with the laboratory representative; one of one of the laboratory's delegated general supervisor (GS) failed to meet the qualification requirements of 493.1459 for the subspecialties of bacteriology and mycology. Findings include: 1. Review of laboratory records revealed the GS delegation form for the individual identified to serve as the GS for high complexity testing, signed by the laboratory director, and dated 10/18/2023. 2. Review of personnel records for the GS revealed they failed to qualify as a GS for high complexity testing. 3. Interview with the laboratory representative on 03/11

	/2025, at 09:31 am, confirmed the laboratory's delegated GS failed to meet the qualification requirements of 493.1459 for high complexity testing in the subspecialties of bacteriology and mycology.