Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2329722	03/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Franklin Biolabs Inc	411 Swedeland Rd, Bldg 27, King Of Prussia, PA	

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
D5305	TEST REQUEST CFR(s): 493.1241(c) (c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of test requisitions and interview with the Laboratory Director (LD), the laboratory failed to include the name and address or other suitable identifiers of the authorized person requesting the test for AAV Neutralizing Antibody Assay testing performed for 3 of 3 months from 12/2025 to day of the survey. Findings Included: 1. On the day of survey 03/17/2026, 09:45 am, review of patient test requisitions revealed that the test requisition did not include the name and address or other suitable identifiers of the authorized person requesting the test for AAV Neutralizing Antibody Assay testing performed for 3 of 3 months from 12/2025 to 03 /2026. 2. The LD confirmed the above finding on 03/17/2026 at 09:50 am.
D5805	TEST REPORT CFR(s): 493.1291(c)

	(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. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Laboratory Director (LD), the laboratory failed to include the address of the location where Neutralization to AAV8 in HEK293 cells assay was performed on 2 of 2 patient test reports reviewed from 01/14/2026 to the date of the survey. Findings include: 1. On the day of survey, 03/17/2026 at 9:45 am, review of 2 of 2 patient test reports revealed the laboratory failed to ensure the addition of the address of the laboratory where Neutralization to AAV8 in HEK293 cells assay was performed from 01/14/2026 to 03/17/2026. 2. The laboratory performed 180 Neutralization to AAV8 in HEK293 cells assay tests in 2026 (CMS 116, estimated annual volume, dated 03/17/2026). 3. The LD confirmed the above findings on 03/17/2026 at 09:50 am.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA laboratory personnel report (CMS 209), personnel credentials, and interview with the Technical Supervisor (TS), the laboratory failed to ensure that 1 of 1 testing personnel (TP) that performed adeno-associated virus (AAV) assay testing (high complexity) from 12/1/2025 to 3/17/2026 met the minimum educational requirements of 493.1489. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 (b)(2)(i) 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; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that

	include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to ensure that 1 of 1 testing personnel (TP) that performed adeno-associated virus (AAV) assay testing (high complexity) from 12/1/2025 to 3/17/2026 met the minimum educational requirements of 493.1489. Findings Include: 1. On the day of the survey, 03/17/2026 at 9:30 am, review of personnel qualification records revealed 1 of 1 TP (CMS 209, personnel #2 dated 2/2/2026) that performed AAV assay testing from 12/01/2025 to 03/17/2026 not met the minimum educational qualifications to perform high complexity testing (493.1489). - TP#1 received a high school diploma from the School District of Philadelphia on 06/24/1994. 2. The laboratory performed 180 AAV assays in 2025 (CMS 116, estimated annual volume, dated 3/17/2026.) 3. The TS confirmed the findings above on 03/17/2026 at 09:30 am.