Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0642688	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Usc Arcadia Hospital	300 W Huntington Dr, Arcadia, CA	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to ensure that bacteriology quality control organisms were stored at an appropriate temperature for accurate and reliable bacteriology test system operations and patient bacteriology culture results reporting (see D5413), the statistical parameters for unassayed gram stain quality control materials had been established over time by the laboratory through concurrent testing of gram stain quality control materials having previously determined statistical parameters (see D5469), the statistical parameters for assayed chemistry quality control materials being used as unassayed chemistry quality control materials had been established over time by the laboratory through concurrent testing of chemistry quality control materials having previously determined statistical parameters (see D5469), the laboratory had a record system to indicate that all bacteriology media used to culture patient bacteriology specimens had met the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient bacteriology test results (see D5481), the laboratory had documented all bacteriology quality control procedures specifically relating to the identity of bacteriology quality control organisms (see D5481), and the records of patient testing included the lots of stains used to stain patient histopahtology specimens (see D5789).

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 direct observation, microbiology general supervisor interview, and bacteriology policies and procedures and quality control organisms records reviewed on July 8, 2026 at 03:45 pm, the laboratory failed to ensure that bacteriology quality control organisms were stored at an appropriate temperature for accurate and reliable bacteriology test system operation and patient bacteriology culture results reporting. Findings included: a. In bacteriology, it was the practice of the laboratory to use ATCC (American Type Culture Collection) quality control organisms to ensure accurate and reliable bacteriology test system operation and patient bacteriology culture results reporting. For example, according to the laboratory's bacteriology quality control forms or manufacturer's written instructions, to monitor patient bacteriology gram stain testing, the laboratory used ATCC 29213 and ATCC 25922 organisms. To monitor microaerophilic culture environments, the laboratory used ATCC 33291. To monitor patient bacteriology specimen testing on the Biomerieux Vitek 2, the laboratory used ATCC organisms required by the manufacturer. b. According to the laboratory's written protocol titled "Microbiology - Quality Assurance and Quality Improvement," stock cultures of bacteriology quality control organisms are stored at -70 degrees C. c. On July 8, 2026 at 03:45 pm, stock cultures of bacteriology quality control organisms were found stored at -30 degrees C. These findings were confirmed by the microbiology general supervisor. d. According to the microbiology general supervisor, the laboratory performed and reported culture results from approximately 6,200 patient bacteriology specimens monthly.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: 1. Based on microbiology general supervisor interview and bacteriology gram stain quality control record reviewed on July 9, 2026 at 09:15 am, the laboratory failed to

	ensure that the statistical parameters for unassayed gram stain quality control materials had been established over time by the laboratory through concurrent testing of gram stain quality control materials having previously determined statistical parameters. Findings included: a. In bacteriology, it was the practice of the laboratory to use unassayed quality control slides to monitor patient gram stain testing. The unassayed gram stain quality control slides were made by the laboratory using ATCC (American Type Culture Collection) quality control organisms. b. On July 9, 2026 at 09:15 am, according to the microbiology general supervisor, the laboratory maintained no documentation to indicate that the statistical parameters (i.e., gram positive/gram negative) of the unassayed gram stain quality control slides made by the laboratory and used to monitor patient gram stain testing had been established over time through concurrent testing of gram stain quality control materials having previously determine statistical parameters. c. According to the microbiology general supervisor, the laboratory performed and reported culture results from approximately 6,200 patient bacteriology specimens monthly. 2. Based on chemistry general supervisor interview and chemistry quality control record reviewed on July 9, 2026 at 11:00 am, the laboratory failed to ensure that the statistical parameters for assayed chemistry quality control materials being used as unassayed chemistry quality control materials had been established over time by the laboratory through concurrent testing of chemistry quality control materials having previously determined statistical parameters. Findings included: a. In chemistry, it was the practice of the laboratory to use assayed chemistry quality control materials as unassayed chemistry quality control materials to monitor the testing of patient chemistry specimens using one of two Beckman Coulter DxC 600i. b. On July 9, 2026 at 11:15 am, according to the chemistry general supervisor, the criteria used to accept glucose level 1 quality control material (lot number 93021, expiration date November 30, 2026) test results was 74 - 86 mg/dl. As confirmed by the chemistry general supervisor, the laboratory maintained no documentation to show how this glucose level 1 quality control material test results criteria for acceptability had been established over time and when the laboratory initiated its use. In addition, the chemistry general supervisor confirmed that the laboratory handled quality control materials used to monitor the testing of patient chemistry specimens for all analytes on the two Beckman Coulter DxC 600i in the same manner as glucose level 1 quality control material lot number 93021, expiration date November 30, 2026. c. According to laboratory records, the laboratory performs and reports approximately 1,400,000 patient chemistry results annually.
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: 1. Based on microbiology general supervisor interview and bacteriology media quality control and patient testing records reviewed on July 8, 2026 at 03:25 pm, the laboratory failed to have a record system to indicate that all bacteriology media used to culture patient bacteriology specimens had met the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient bacteriology test results. Findings included: a. In bacteriology, it was the practice of the laboratory to use bacteriology culture media purchased from a manufacturer to culture patient bacteriology specimens. As established by the laboratory's IQCP

	(Individualized Quality Control Plan), the laboratory relied on the manufacturer's documentation to established that all lots/batches of bacteriology media used to culture patient bacteriology specimens had met the laboratory's and manufacturer's test system criteria for acceptability before reporting patient bacteriology test results. b. On July 8, 2026 at 03:25 pm, the microbiology general supervisor confirmed that, although each lot/batch of bacteriology culture media had met the laboratory's and the manufacturer's test system criteria for acceptability, laboratory records did not indicate which lot/batch of bacteriology culture media was used to isolate and differentiate bacteria isolated from patient bacteriology specimens. That is, because the laboratory's record system did not indicate which lot/batch of bacteriology culture media was used to isolate and differentiate bacteria isolated from any given patient bacteriology specimen, the laboratory's documentation could not show that bacteriology culture media used had met the laboratory's and manufacturer's test system criteria for acceptability. c. According to the microbiology general supervisor, the laboratory performed and reported culture results from approximately 6,200 patient bacteriology specimens monthly. 2. Based on microbiology general supervisor interview and bacteriology quality control organisms records reviewed on July 9, 2026 at 09:45 am, the laboratory failed to ensure that it had documented all bacteriology quality control procedures related to the identity of bacteriology quality control organisms used by the laboratory. Findings included: a. In bacteriology, it was the practice of the laboratory to use ATCC (American Type Culture Collection) quality control organisms to ensure accurate and reliable bacteriology test system operation and patient bacteriology culture results reporting. For example, according to the laboratory's bacteriology quality control forms or manufacturer's written instructions, to monitor patient bacteriology gram stain testing, the laboratory used ATCC 29213 and ATCC 25922 organisms. To monitor microaerophilic culture environments, the laboratory used ATCC 33291. To monitor patient bacteriology specimen testing on the Biomerieux Vitek 2, the laboratory used ATCC organisms required by the manufacturer. b. Although stock cultures of bacteriology quality control organisms were labeled with handwritten ATCC numbers, the laboratory maintained no documentation to establish the source and validity of the ATCC organisms, whether the ATCC organisms were being used beyond their expiration dates, and whether the ATCC organisms were being cultured and subcultured according to the laboratory's written protocol titled "Microbiology - Quality Assurance and Quality Improvement." c. On July 9, 2026 at 09:45 am, these findings were confirmed by the microbiology general supervisor. d. According to the microbiology general supervisor, the laboratory performed and reported culture results from approximately 6,200 patient bacteriology specimens monthly.
D5789	TEST RECORDS CFR(s): 493.1283(b) (b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on laboratory director interview and histopathology H&E (hematoxylin and eosin) stains record reviewed on July 9, 2026 at 12:40 pm, the laboratory failed to ensure that the records of patient testing included the lots of stains used to stain patient histopathology specimens. Findings included: a. In histopathology, when performing frozen sections, it was the practice of the laboratory to H&E stains to stain patient histopathology specimens. b. As confirmed by the laboratory director on July

	9, 2026 at 12:40 pm, the laboratory maintained no documentation to indicate the lots and expiration dates of the H&E stains used to stain patient histopathology specimens. c. According to the laboratory director, the laboratory performed and reported approximately 5 patient frozen sections weekly.
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 the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing, Laboratory Director was not met. The laboratory director, high complexity testing, failed to ensure that laboratory personnel were performing test methods as required for accurate and reliable patient bacteriology test results (see D6087), and bacteriology and chemistry quality control programs were maintained to assure the quality of laboratory bacteriology and chemistry services provided (see D6093).
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on direct observation, microbiology general supervisor interview, and bacteriology policies and procedures and quality control organisms records reviewed on July 8, 2026 at 03:45 pm, the laboratory director, high complexity testing, failed to ensure that laboratory personnel were performing test methods as required for accurate and reliable patient bacteriology test results. Findings included: The laboratory failed to ensure that bacteriology quality control organisms were stored at an appropriate temperature as established by the laboratory written protocol titled "Microbiology - Quality Assurance and Quality Improvement." See D5413.
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 chemistry and microbiology general supervisor interviews, and bacteriology and chemistry quality control records reviewed on July 9, 2026, the laboratory director, high complexity testing, failed to ensure that bacteriology and chemistry quality control programs were maintained to assure the quality of laboratory bacteriology and chemistry services provided. Findings included: a. The laboratory

	failed to meet the Condition: Analytic Systems. See D5400. b. The laboratory failed to ensue that the statistical parameters for unassayed gram stain quality control materials had been established over time by the laboratory through concurrent testing of gram stain quality control materials having previously determined statistical parameters. See D5469. c. The laboratory failed to ensue that the statistical parameters for assayed chemistry quality control materials being used as unassayed chemistry quality control materials had been established over time by the laboratory through concurrent testing of chemistry quality control materials having previously determined statistical parameters. See D5469. d. The laboratory failed to have a record system to indicate that all bacteriology media used to culture patient bacteriology specimens had met the laboratory's criteria for acceptability before reporting patient bacteriology test results. See D5481. e. The laboratory failed to ensure that it had documented all bacteriology quality control procedures related to the identity of bacteriology quality control organisms used by the laboratory. See D5481.