Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0591084	11/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sutter Health Shared Laboratory	2950 Collier Canyon Rd, Livermore, 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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and parasitology test requisitions record review on November 9, 2018, the laboratory failed to have written or electronic requests for patient Giardia and/or Cryptosporidium antigen testing from an authorized person. Findings included: a. It was the practice of the laboratory to perform patient Giardia and Cryptosporidium antigen testing on patient specimens. b. For 8 (accession numbers H1152672, T1117629, H1182379, M117555, W133012, S1168240, T1215411, and W159256) of 8 patient Giardia and/or Cryptosporidium antigen tests performed and reported between January 1, 2018 and June 30, 2018, the laboratory failed to maintain written or electronic requests from an authorized person.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and bacteriology patient specimen processing documents record review on November 9, 2018, the laboratory's

	preanalytic systems assessment failed to include a review of the effectiveness of corrective actions taken when problems were identified with the laboratory's automated bacteriology patient specimen processing system, the Walk Away Specimen Processor (WASP) instruments. The laboratory maintained only partial and incomplete documentation indicating whether patient test results had been affected by the WASP instruments' "Sterility Checks" failures. Findings included: a. It was the practice of the laboratory to use the automated WASP instrument to process patient bacteriology specimens. According to laboratory protocols, the WASP instrument "automatically de-caps, plants, streaks and re-caps all specimen types" and "provides a comprehensive system which encompasses all aspects of automated specimen processing that includes plate planting and streaking, Gram slide preparation and enrichment broth inoculation." b. To ensure that the WASP instruments did not "carryover" sample from one patient specimen to the next, the laboratory performed "Sterility Checks" each shift the WASP instruments were operating. These "Sterility Checks" involved the WASP instruments plating on separate and consecutive plates a "sterile (water)" sample, followed by a "carryover (stool)" sample, followed by a "sterile (water)" sample. c. According to laboratory records, from June 3, 2018 to July 2, 2018, the "Sterility Checks" occasionally failed. That is, bacteria would be found cultured from the second "sterile (water)" sample. The laboratory continued to utilize the WASP instruments during this time period. d. After investigating these failures, on July 3, 2018, the laboratory adopted an updated "Sterility Checks" protocol. Since the adoption of the updated "Sterility Checks" protocol to the date of this investigation, November 9, 2018, the laboratory experienced no "Sterility Checks" failures using the WASP instruments. e. Although the laboratory documented the investigation of the "Sterility Checks" failures, the laboratory maintained only partial and incomplete documentation indicating whether patient test results had been affected by the WASP instruments' "Sterility Checks" failures from June 3, 2018 to July 2, 2018. f. According to laboratory personnel, from June 3, 2018 to July 2, 2018, the laboratory used the WASP instruments to plate and culture approximately 18,000 patient bacteriology specimens.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 laboratory personnel interviews and bacteriology automated gram stainer protocol record review on November 9, 2018, the laboratory failed to have a change in its written MGS-80 procedure approved, signed, and dated by the current laboratory director before use. Findings included: a. It was the practice of the laboratory to use the MGS-80 for patient specimens which "automates the traditional gram stain technique." b. To remediate the occurrence described at D5783, the laboratory required that quality control slides be stained and acceptable when using the MGS-80 following the performance of the "Scrub Procedure." c. The laboratory's MGS-80 written protocol reviewed on November 9, 2018 did not include the laboratory's requirement that quality control slides be stained and acceptable following the performance of the "Scrub Procedure," even though the laboratory required its testing personnel follow the updated protocol as evidenced by this additional requirement being listed on the MGS-80's maintenance logs.

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 laboratory personnel interviews and bacteriology gram stainer documents record review on November 9, 2018, the laboratory failed to ensure that all patient gram stain test results in the unacceptable test run and since the last acceptable test run were evaluated to determine if patient gram stain test results had been adversely affected. Findings included: a. According to laboratory protocols, it was the practice of the laboratory to use the MGS-80 for patient specimens which "automates the traditional gram stain technique." To ensure the MGS-80 operated properly, the laboratory tested gram positive and gram negative quality control slides weekly. b. Laboratory records for the MGS-80 indicated the following: i. On February 2, 2018, quality control slides stained by the MGS-80 were acceptable. ii. On February 5, 2018, the laboratory performed the "Scrub Procedure." When performing the "Scrub Procedure," reagents/stains were removed and re-attached to the MGS-80. iii. On February 8, 2018, quality control slides stained by the MGS-80 were acceptable. iv. On February 13, 2018, quality control slides stained by the MGS-80 were unacceptable. That is, the gram positive quality control slide stained as "gram negative," and the gram negative quality control slide stained as "gram positive." The laboratory stopped performing patient gram stains using the MGS-80. v. On February 14, 2018, a laboratory investigation revealed "that the MGS 80 had two [reagent/stain] lines, the Crystal Violet and Gram's Iodine, incorrectly placed in the wrong supply bottle." After reagent/stain lines were cleaned, quality control slides stained using the MGS-80 were acceptable. c. According to laboratory personnel, it was presumed that the reagents/stains may have been incorrectly re-attached to the MGS-80 on February 5, 2018 when the reagents/stains were removed, even though quality control slides stained by the MGS-80 on February 8, 2018 were "acceptable." d. According to laboratory records, to ensure that all patient gram stain test results obtained in the unacceptable run and since the last acceptable test run were not adversely affected, the laboratory evaluated all patient gram stain test results stained using the MGS-80 from February 8, 2018 to February 14, 2018. This review consisted of all 204 patient gram stain test results reported during this period. e. However, based on laboratory personnel's presumption that the reagents/stains may have been incorrectly re-attached to the MGS-80 on February 5, 2018 when the reagents/stains were removed, the laboratory maintained no documentation to indicate that the laboratory had evaluated patient gram stain test results stained using the MGS-80 from February 2, 2018 to February 7, 2018, when MGS-80 quality control test results were acceptable and prior to the February 5, 2018 "Scrub Procedure," to determine whether patient gram stain test results were adversely affected.