

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2093854	(X3) Date Survey Completed 07/09/2019
Name of Provider or Supplier Sutter Gould Medical Foundation - Turlock Urgent	Street Address, City, State 3100 W Christoffersen Pkwy, Turlock, 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
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory patient complete blood counts (CBC) test report record review and laboratory personnel interviews on July 9, 2019, the laboratory failed to retain or was not able to retrieve a copy of patient CBC preliminary test reports for at least two (2) years after the date of reporting. The findings included: a. It was the practice of the laboratory to test and report patient CBC specimens using the Sysmex POCH-100i CBC analyzer. Although the CBC instrument patient test results ran at the sister facility and electronically transmitted to the laboratory's information system, the laboratory personnel provided the CBC analyzer results performed onsite, of the patient CBC test result, to the physicians as a preliminary test report. b. For 11 (patient medical record numbers 52659302, 55066805, 58337137, 58368925, 53421360, 58368925, 53421360, 53718264, 58542993, 58508473, and 62800675) of 11 randomly selected patient CBC reports from January 11, 2019 to July2, 2019, the laboratory failed to retain or did retrieve copies of patient CBC instrument print outs used as preliminary reports. c. The laboratory personnel confirmed by interview on July 9, 2019 at 10:17 a.m. that the laboratory did not retain copies of patient CBC instrument printouts given as preliminary results. d. According to the laboratory records, the laboratory report performing and reporting approximately 1,936 patient CBC tests annually.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

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 procedure manual review, record review and laboratory personnel interview on July 9, 2019, the laboratory failed to have procedures and changes in procedure approved and signed by the current laboratory director before use. The findings included: a. The laboratory utilizes an electronic on-line procedure manual system. b. For the following electronic procedures, the laboratory maintained no documentation of current laboratory director's approval. 1. Sysmex POCH-100i CBC analyzer calibration procedure; and, 2. Quality Assessment procedures. c. According to laboratory records the laboratory performed and reported approximately 1,936 CBC tests annually.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on laboratory personnel training record review and laboratory personnel interviews on July 9, 2019, the laboratory director (moderate complexity testing), failed to ensure that prior to testing patients' specimens, all personnel received the appropriate training for the type of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. The findings included: a. On the day of the survey (July 9, 2019), the laboratory maintained no documentation to indicate that all laboratory personnel were appropriately trained, including documentation that all testing personnel had reviewed written protocols (per laboratory's own policies), for the Sysmex POCH-100i CBC analyzer. b. The laboratory personnel confirmed that as of May 2019, new LVN testing personnel were allowed to perform patient CBC testing and report test results using the Sysmex POCH-100i analyzer. Laboratory personnel confirmed by interview on July 9, 2019 at approximately 10:25 a.m. the laboratory did not have documentation of training for new LVN testing personnel on the Sysmex POCH-100i c. In addition the laboratory maintained no documentation that the current laboratory director had ensured all testing personnel performed all testing operations reliably to provide an report accurate patient testing results as testing competency documents provided for review during the survey were not approved by the laboratory director. d. According to the laboratory records the laboratory reports performing and reporting approximately 1,936 CBC tests annually.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on laboratory personnel competency record review and laboratory personnel interviews on July 9, 2019, the technical consultant failed to ensure that laboratory personnel were evaluated for competency pursuant to the laboratory's established competency policies and procedures. The findings included: a. Pursuant to the laboratory's competency policies and procedures, one of the criteria used to evaluate testing personnel competency was to determine whether testing personnel reviewed the laboratory's written procedure manual. b. According to laboratory testing personnel competency records, all testing personnel did not review the laboratory's written protocol for the Sysmex POCH-100i CBC analyzer prior to performing and reporting patient CBC test results. c. The laboratory testing personnel and site Chief executive confirmed by interview on July 9, 2019 that the laboratory new staff had not read the policy's and procedures prior to performing and reporting patient CBC results. d. According to the laboratory records, the laboratory performed and reported approximately 1,936 patient CBC tests annually.