

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0609318	(X3) Date Survey Completed 09/25/2018
Name of Provider or Supplier Sutter Gould Medical Foundation	Street Address, City, State 2545 W Hammer Lane, Stockton, 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
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's patient log book, reports, slides, random patient sampling records, and interview with the office personnel, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems. The findings included: a. Based on review of (patient #1): Patient's specimen slide last name comparing to the patient's Moh's map record, and patient's test report revealed discrepancies. b. Moh's procedure was ordered, analyzed and reported on 10/12/2017. c. For one (1) out of six (6) random patient test results reviewed covering period from 11/3/2016 to 5/17/2018, one (1) patient had Moh's procedure that cannot be assured. d. The office personnel affirmed (9/25/2018, 12N), that the laboratory has not established or written policy and procedure to correct any problems that are identified.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's patient log book, reports, slides, random patient sampling records, and interview with the office personnel, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the analytic systems. The findings included: a. Based on review of (patient #1): Patient's specimen slide last name comparing to the patient's Moh's map record, and patient's test report revealed discrepancies. b. Moh's procedure was ordered, analyzed and reported on 10/12/2017. c. For one (1) out of six (6) random patient test results reviewed covering period from 11/3/2016 to 5/17/2018, one (1) patient had Moh's procedure that cannot be assured. d. The office personnel affirmed (9/25/2018, 12N), that the laboratory has not established or written policy and procedure to correct any problems that are identified.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's patient log book, reports, slides, random patient sampling records, and interview with the office personnel, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings included: a. Based on review of (patient #1): Patient's specimen slide last name comparing to the patient's Moh's map record, and patient's test report revealed discrepancies. b. Moh's procedure was ordered, analyzed and reported on 10/12/2017. c. For one (1) out of six (6) random patient test results reviewed covering period from 11/3/2016 to 5/17/2018, one (1) patient had Moh's procedure that cannot be assured. d. The office personnel affirmed (9/25/2018, 12N), that the laboratory has not established or written policy and procedure to correct any problems that are identified.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's patient log book, reports, slides, random patient sampling records, and interview with the office personnel, it was determined that the laboratory director failed to ensure that quality assessment programs (D5391, D5791 and D5891) are established and maintained to assure the quality of laboratory services provided.