Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0611720	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Redwood Empire Dermatology, Inc	**Street Address, City, State** 6574 Oakmont Dr, Ste B, Santa Rosa, 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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on record review of a random patient sampling from January 1, 2018 through August 29, 2019, and interview with the laboratory director on September 04, 2019, the laboratory failed to retain records of test requisitions for at least 2 years. The findings included: a. A random sampling of six (6) patients from1/11/2018 through 8 /29/2019 histopathology testing records revealed that the laboratory failed to retain requisitions for histopathology patients for (4) of (6) patients reviewed. Date Patient ID Requisition 01/11/2018 W18-040 Present 06/05/2018 W18-521 Present 08/22 /2018 W18-812 Not Retained 04/16/2019 W19-255 Not Retained 07/23/2019 W19-649 Not Retained 08/29/2019 W19-791 Not Retained b. The laboratory director confirmed by interview on September 04, 2019 at approximately 10:00 a.m. that the laboratory failed to retain the patient histopathology testing requisitions as required by federal regulations for two years, and state law for three years. c. The laboratory reports performing 2000 histopathology patients annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on record review of the laboratory's dermatopathology and tissue histopathology testing records and interview with the laboratory director on September 04, 2019, the laboratory failed to establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1), "to at least twice annually verify the accuracy of any test or procedure it performs that is not included in subpart I". The findings included: a. The laboratory performs histopathology and Moh's dermatopathology patient testing. For the survey review period January 1, 2018 through August 29,2019 the laboratory failed to verify the accuracy of its tissue histopathology and dermatopathology Moh's testing performed. b. The laboratory reports on the CMS-209 to have six (6) dermatopathology surgeons, of which (5) perform Moh slide evaluations for determining clearing of cancerous cells and tissue histopathology slide reviews. c. For (6) of (6) testing personnel the laboratory did not have documentation of verification of accuracy for its tissue histopathology or dermatopathology Moh's testing. d. The laboratory Peer Review Policy states, "Surgical Pathology: ...at least 5 cases per Redwood Empire Dermatology physician (at least 25 per half year) will be reviewed for correlation with diagnosis". The laboratory did not have documentation of 50 patient cases reviewed for 2018 or 25 cases for 2019. e. The laboratory Peer Review Policy states, "Mohs: ...at lease (3) cases per Redwood Empire Dermatology physician (total of at least 15 per half year) will be reviewed for correlation with diagnosis". The laboratory had no documentation of (for physicians who had performed Mohs surgurys), (30) cases reviewed for the years 2018 or 2019. f. The laboratory director confirmed by interview on September 04, 2019 at approximately 10:30 a.m. that failure to perform and document twice annual verification for dermatopathology patient testing. g. The laboratory reports performing approximately 2000 dermatopathology patient tests annually.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the histopathology patient log and interview with the laboratory director and staff on September 04,2019, the laboratory failed to document all control procedures performed, as specified in this section. The findings included: a. The laboratory sends dermatopathology tissue samples to an outside laboratory to prepare and stain histopathology tissue slides. b. A random sampling of (6) patient histopathology records revealed that the laboratory had not documented the quality of the stains for (6) of (6) patients reviewed from 01/11/2018 through 08/29/2019. c. The laboratory did not have documentation regarding the acceptability of the staining quality from the contracted service, or a control slide for the dates of preparation, for (6) out of (6) patients reviewed, the list included: Date Patient ID 01/11/2018 W18-040 06/05/2018 W18-521 08/22/2018 W18-812 04/16/2019 W19-255 07/23/2019 W19-649 08/29/2019 W19-791 d. The laboratory director confirmed by interview on

	September 04, 2019 that the laboratory did not have documentation of slide reactions as specified in 42 C.F.R. 493.1256(e)(3). e. The laboratory reports performing annually 2000 histopathology patient slide reviews annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of a random sampling of patient dermatopathology and tisse pathology records, and interview with the laboratory staff and the laboratory director on September 04, 2019, the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings included: a. The laboratory director failed to ensure that all test requisitions are retained as required by federal and state regulations. See D3027 b. The laboratory director failed to ensure that a quality control process was in place to ensure that stain reactivity for special stains and differential stains are performed and documented. See D5601 c. The laboratory director failed to ensure that verifcation of accuracy is performed and documented for those tests not included in subpart I of 42 C.F.R. 493 laboratory testing. See D5217