Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2138257	03/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Revere Health Salem Dermatology	555 West Sr-164 Winter Hallway, Salem, UT	

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
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on laboratory sample processing record review, test report review, and interview with staff, the laboratory failed to refer 8 of 8 pathology samples reviewed to a CLIA certified laboratory for gross analysis testing. The laboratory began testing in 08/2017 and had send out approximately 200 biopsy samples for processing. Finding include: 1. Laboratory records reviewed for biopsy samples 18, 51, and 110 in 2017 and samples 51 A&B and 80 A,B,&C in 2018 included documentation biopsy samples were sent to an outside histology laboratory for processing and staining. Processed slides were returned to the laboratory with a gross description of the tissue sample received. 2. Test report review for the 8 samples reviewed included the processing laboratory's results under the gross description as part of the pathology report. 3. The histology laboratory is not a CLIA certified laboratory. 4. Staff stated during an interview on 03/07/2018 at approximately 11:00 a.m. they were not aware their processing laboratory was not CLIA certified to perform gross analysis testing.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on test report review and interview with staff, the test report for 6 of 6 patient results reviewed failed to include the correct name and address of the laboratory location where testing was performed. The laboratory reported approximately 300 tests from 08//2017-03/2018. Finding include: 1. The test report for pathology cases: 18, 51, and 110 of 2017; 51 and 80 of 2018; and KOH testing for patient 370272 tested on 11/12/2017 identified the testing location as; Revere Health 1055 N. 800 W. Provo, UT 84604. 2. Staff confirmed on 03/07/2018 at approximately 11:00 a.m. the referenced testing had been performed on-site at; Revere Health Salem Dermatology 555 West SR-164 Winter Hallway Salem, UT 84653.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 lack of documentation and interview with staff , the laboratory director failed to ensure a quality assessment program was established to assure quality laboratory services were provided and identify failures in quality as they occur. The laboratory began testing in 09/2017 and had performed approximately 300 tests. Finding include: 1. The laboratory lacked documentation of a quality plan describing what they monitor and how to document they evaluated the preanalytic, analytical, and postanalytic phases of testing. 2. Staff stated on 03/07/2018 at approximately 11: 00 a.m., the laboratory did not have a written plan to monitor: specimen collection, labeling, storage, transportation, and processing; analytical accuracy; and test report accuracy and completion to ensure procedures were being followed and to correct errors when identified.