

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2032824	(X3) Date Survey Completed 09/30/2019
Name of Provider or Supplier Forefront Dermatology, Sc	Street Address, City, State 1300 S Green Bay Rd, Ste 100, Racine, WI	
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
D5028	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of patient logs, test reports, and procedures, observation of patient slides and interview with the regional clinic manager, the laboratory did not follow written policies and procedures and did not document or correct identified problems. Findings include: 1. Laboratory personnel did not follow procedures to ensure specimen identification. See D5203. 2. Laboratory personnel did not document and correct identified problems. See D5791.</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures, the "Mohs Patient Log", and test reports, observation of specimen slides and interview with the regional clinic manager, laboratory personnel did not follow their procedure for specimen identification for five of eleven specimens processed on September 17, 2019. Findings include: 1. Review of the laboratory procedure," MOHS Specimen Handling Procedure and</p>

Mapping Procedure", effective January 1, 2017, showed step 1: "The tissue is brought to the laboratory by the Mohs surgeon". Step 2 showed, "The specimen is given an accession number and logged in the Mohs logbook". 2. Review of the "Mohs Patient Log" showed eleven entries from September 17, 2019 on two pages. The first set of six accession numbers, specimens one through six, accession numbers 19-0612 through 19-0617, were entered in the log after September 12, 2019. Further review of the log showed a second set of accession numbers, specimens seven through eleven, accession numbers 19-0646 through 19-0650, entered after September 25, 2019. 3. Observation of specimen slides on September 30, 2019 at 1:50 PM showed personnel assigned each of the accession numbers 19-0618 through 19-0622 to two different specimens. Personnel used accession number 19-0618 for specimens seven and twelve. Personnel used accession number 19-0619 for specimens eight and thirteen. Personnel used accession number 19-0620 for specimens nine and fourteen. Personnel used accession number 19-0621 for specimens ten and fifteen. Personnel used accession number 19-0622 for specimens eleven and sixteen. 3. Review of patient test reports for specimens seven and twelve showed both reports used 19-0618 as the identifying accession number. 4. Interview with the regional clinic manager, staff A, on September 30, 2019 at 1:55 PM, confirmed staff did not follow the procedure for specimen identification and confirmed five individual accession numbers were assigned to two patients each.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:
Based on surveyor review of the "Mohs Patient Log", observation of specimen slides, and interview with the regional clinic manager, laboratory personnel recognized that the patient log was not complete on eleven of eleven patients and accession numbers were not consistent between the patient log and slides on five of eleven patients on September 17, 2019, and had not corrected or documented the identified problem. Findings include: 1. Review of the "Mohs Patient Log" showed no documentation of the number of stages or the number of slides for specimens one through eleven processed on September 17, 2019. Further review of the log showed the laboratory documented the eleven entries from September 17, 2019 on two pages; personnel entered specimens one through six after September 12, 2019 and entered specimens seven through eleven after September 25, 2019 and before September 26, 2019 using accession numbers 19-0646 through 19-0650. 2. Observation of patient slides on September 30, 2019 at 1:50 PM, showed personnel labeled slides for specimens seven through eleven with accession numbers 19-0618 through 19-0622. The accession numbers on the slides do not match the numbers assigned to the specimens in the "Mohs Patient Log". 3. Interview with the regional clinic manager, staff A, on September 30, 2019 at 1:55 PM, confirmed personnel were aware of the incomplete patient log and accession number discrepancies between the "Mohs Patient Log" and the labeled slides for specimens seven through eleven from September 17, 2019, and had not corrected or documented the identified problem.