Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0418238	12/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology S C	3253 S Harlem Ave - Ste 1a, Berwyn, IL	

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
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 review of laboratory policies and records and interview, the laboratory failed to verify the accuracy of its Potassium Hydroxide (KOH) and Histopathology procedures. Repeat deficiency. (Repeat Deficiency) Findings include: 1. Review of the laboratory policies and procedures revealed that personnel were instructed as follows: "Quarterly, the tech or Regional Clinic Manager will send three cases containing the original slides, label it with only the surgical case number, and send it out for microscopic examination by a Board Certified Pathologist/Mohs surgeon. NO differential diagnosis will be offered with the specimen..... Upon receipt of the pathology report form the Pathologist /Mohs surgeon, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician." 2. The "KOH QA/QC" states, "A minimum of 3 cases to be reviewed quarterly. Complete an Error Form for any fails. 3. Review laboratory records revealed the following: a. Verification of Histopathology procedures was only performed once in 2018 (on 11/27/18) for the following cases: 18-007; 18-0019; 18-009; 18-0025; 18-0030; and 18-0034. There was no outside diagnosis report available for comparison, as stated in the procedures. b. There was no documentation to show verification procedures for KOH testing was not performed twice in 2018. 4. At 10:00 AM on 12/03/18, the Regional Clinic Manager confirmed the surveyor's findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially

	available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and records and interview, the laboratory failed to perform and document maintenance and function checks as specified. (Repeat Deficiency) Findings include: 1. The laboratory's procedures manual instructed personnel on maintenance of equipment as follows: a. Fume Hood Policy - Replace filter annually or as needed and document on log. b. Microscope-Change bulbs as needed and have regular service contracts performed. Document daily, monthly care. c. Room Temp/Humidity - The room temperature and humidity will be checked at the beginning of each day. Any corrective action will be documented for out of range and addressed immediately. 2. Review of laboratory records revealed that there was no documentation to show maintenance and function checks were performed on the following: Fume Hood (filter last changed 09-18-17); Microscope; and Room Temp/Humidity. 3. At 10:00 AM on 12/03/18, the Regional Clinic Manager confirmed the surveyor's findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 review of Laboratory Personnel Report (CMS FORM 209) and personnel records; the laboratory director failed to ensure that prior to testing patients' specimens, all personnel has the appropriate education and experience, received the appropriate training for the type and complexity of services, and has demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Review of CMS FORM 209 revealed that the laboratory has 5 persons listed as testing personnel. 2. Review of personnel records revealed that there was no documentation to show the highest level of education (degree or diploma) for 1 of 5 testing personnel. Also, there was no documenation to show what tests this individual was trained to perform. 3. At 10:00 AM on 12/03/18, the Regional Clinic Manager confirmed the surveyor's findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (CMS FORM 209) and personnel records, and interview; the laboratory director failed to ensure that policies and procedures are established to ensure that testing personnel are competent and maintained their competency to process specimens and perform test procedures and report test results. Findings include: 1. Review of CMS FORM 209 revealed that the laboratory has 5 persons listed as testing personnel. 2. Review of personnel records revealed that there was no documentation to show that competency assessments were performed for 3 of 5 testing personnel 3. At 10:00 AM on 12/03/18, the Regional Clinic Manager confirmed the surveyor's findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; Laboratory Personnel Report (CMS FORM 209); and personnel records, and interview, the laboratory director failed to specify, in writing, which examinations and procedures each individual is authorized to perform. Findings include: 1. Review of the laboratory's testing menu revealed that the laboratory performs Potassium Hydroxide (KOH) testing and Mohs Micrographic Surgery (Histopathology) procedures. 2. Review of CMS FORM 209 revealed that the laboratory has 5 persons listed as testing personnel. 3. There was no documentation to show that the laboratory director assigned which procedures 4 of 5 testing personnel were responsible for performing. 4. At 10:00 AM on 12/03/18, the Regional Clinic Manager confirmed the surveyor's findings.