Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1021651	02/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology Sc	1157 First Colonial Road - Suite 300, Virginia Beach, VA	

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
D0000	An announced CLIA recertification survey was conducted at Tidewater Skin Care and Pathology, PC on February 28, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory Quality Assessment (QA) manual, competency assessment records, and an interview, the laboratory failed to follow its policy for competency assessment of five (5) of five (5) testing personnel (TP) in 2016 and 2017. Findings include: 1. Review of the CMS 209: Laboratory Personnel revealed five (5) clincial consultants that are also testing personnel. 2. Review of the QA manual revealed the following statement: "The competency of Testing Personnel and all staff members will be evaluated and documented every six (6) months by the Laboratory Director or an appropriate, designated staff member (e.g. Technical Consultant or Technical Supervisor) to ensure that all laboratory staff maintain their competency in testing and laboratory management functions." 3. Review of competency assessment records for Potassium Hydroxide (KOH) microscopic examinations revealed the following KOH competnecy assessments: Testing Personnel A: assessed 12/13/17, no second competency assessment in 2017, Testing Personnel B: assessed 6/10/16, no second competency assessment in 2016, Testing

	Personnel C: assessed 6/21/16 , no second competency assessment in 2016, Testing Personnel D: assessed 6/18/16 , no second competency assessment in 2016, Testing Personnel E: assessed 6/18/16 , no second competency assessment in 2016. 4. An interview with the office CLIA coordinator at approximately 4:00 PM confirmed that the laboratory failed to assess competency every 6 months per their policy for four (4) of five (5) TP in 2016 and one (1) of five (5) TP in 2017.
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 a tour of the laboratory, review of the procedure manual, maintenance logs, and an interview, the laboratory failed to establish a maintenance protocol for the calibration of one (1) thermometer used in the laboratory in calendar years 2016 and 2017. Findings include: 1. During a tour of the laboratory, the inspectors noted an Acurite non-certified thermometer utilized to monitor room temperature in the histology laboratory. 2. Review of the laboratory's procedure manual revealed no policy for the periodic calibration of laboratory thermometers. 3. Review of maintenance logs revealed no documentation of thermometer calibrations in 2016 and 2017. The inspectors requested documentation for thermometer calibrations. No documentation was available for review. 4. An interview with the office CLIA coordinator at approximately 4:00 PM confirmed that the laboratory failed to establish a maintenance policy to ensure calibration of non-certified thermometers in the laboratory.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interview, the laboratory director failed to ensure maintenance of personnel education documentation for one (1) of six (6) testing personnel (TP). See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interview, the laboratory director failed to ensure maintenance of personnel education documentation for one (1) of six (6) testing personnel (TP). Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed six (6) testing personnel. 2. Review of the laboratory personnel files revealed no documentation of education or training for Testing Personnel F. (See Personnel Code Sheet.) The inspector requested to review the documentation. It was not available for review. 3. An interview with the office CLIA coordinator at approximately 4:00 PM confirmed that the laboratory director failed to maintain documentation of personnel qualifications for the one (1) testing personnel listed above.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interview, the technical supervisor failed to ensure maintenance of competency assessment documentation for one (1) of six (6) testing personnel (TP) in 2016 and 2017. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed six (6) testing personnel. 2. Review of the laboratory personnel files revealed no documentation of competency assessment in calendar years 2016 and 2017 for Testing Personnel F. (See Personnel Code Sheet.) The inspector requested to review the competency documentation. No documentation was available for review. 3. An interview with the office CLIA coordinator at approximately 4:00 PM confirmed that the technical supervisor failed to maintain documentation of competency assessment for the one (1) testing personnel listed above in 2016 and 2017.