Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2011214	11/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc	801 York St, Manitowoc, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the Director of Laboratory Services, the laboratory did not verify the accuracy of an unscored cholesterol result in the first Chemistry event in 2018. Findings include: 1. Review of PT records from event one in 2018 showed the PT program did not score the total cholesterol result for sample CH-02. No evidence of evaluation by the laboratory is present. 2. Interview with the Director of Laboratory Services, Staff A, on November 13, 2018 at 12:45 PM confirmed the laboratory did not verify the accuracy of the unscored result.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the Director of Laboratory Services, the laboratory did not include the initial date of use for two new chemistry procedures and did not include the discontinuance date for the Cell Dyn

	3200 procedures. Findings include: 1. Laboratory procedures include two new chemistry procedures, creatine kinase (CK) and gamma-glutamyl transferase (GGT). The technical consultant, staff B, signed the procedures on May 3, 2017. The procedures do not include the date of initial use. 2. Laboratory procedures also include Cell Dyn 3200 hematology analyzer procedures. The procedures do not include a discontinuation date. 3. Interview with the Director of Laboratory Services, staff A, on November 13, 2018 at 12:45 PM confirmed the laboratory did not maintain dates of initial use and discontinuance with the procedures. Further interview reveals patient CK and GGT testing began on July 10, 2018, and the laboratory discontinued use of the Cell Dyn 3200 analyzer in February 2016.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor comparison of reference ranges shown in the laboratory procedures with those on patient reports, review of product instructions, and interview with the Director of Laboratory Services, reference ranges available on patient reports are not consistent with the approved ranges in the procedure, and the procedure includes an erroneous reference range for male creatinine results. Findings include: 1. Comparison of the reference ranges listed in "Reference Ranges and Reportable Ranges" (policy number 3690) with reference ranges displayed with patient results in the electronic medical record (EMR) for patient 1 show the following discrepancies: AST (Aspartate transaminase); U/L (units per liter) Policy: 15 - 46 U/L EMR: 17 - 59 U/L BUN (Blood Urea Nitrogen); mg/dL (milligrams per deciliter) Policy: Male: 9 - 20 mg/dL Female: 7 - 17 mg/dL EMR: 9 - 20 mg/dL Creatinine; mg/dL Policy: Male 0.8 - 8.5 mg/dL (see Finding 2.) Female 0.7 - 1.2 mg/dL EMR: 0.7 - 1.3 mg/dL Glucose; mg /dL Policy: 74 - 106 mg/dL EMR: 65 - 99 mg/dL Potassium; mmol/L (millimoles per liter) Policy: 3.5 - 5.1 mmol/L EMR: 3.2 - 5.5 mmol/L Total Protein; g/dL (grams per deciliter) Policy: 6.0 - 8.2 g/dL EMR: 6.3 - 8.2 g/dL 2. The manufacturer's product instructions show the expected creatinine reference range for males is 0.66 - 1.25 mg /dL. 3. Interview with the Director of Laboratory Services, staff A, on November 13, 2018 at 12:45 PM confirmed the reference ranges provided in the EMR for evaluation of test results are not consistent with those approved in the laboratory's policy.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures, and interview with the Director of Laboratory Services, the laboratory director did not evaluate reference ranges for two of two new analytes added to the chemistry test menu in July 2018. Findings include: 1. Review of verification records for creatine kinase (CK) and

	gamma-glutamyl transferase (GGT) showed no evidence of evaluation of the reference (normal) ranges for the two analytes. 2. Review of the "Reference Ranges and Reportable Ranges" Policy number 3690, showed no reference ranges identified for CK or GGT. 3. Interview with the Director of Laboratory Services, staff A, on November 13, 2018 at 12:45 PM confirmed the verification records did not include evaluation of the reference ranges for CK and GGT and confirmed the laboratory did not update the policy to include the two new analytes added in July 2018. This is a repeat deficiency previously cited on October 14, 2016.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the Director of Laboratory Services, the laboratory did not develop and follow corrective action plans after receipt of unacceptable chemistry PT results in event one in 2017 and event three in 2018. Findings include: 1. Review of PT records showed the following unacceptable Bilirubin and ALT (alanine transferase) results: 2017 event one, sample CH-02 Bilirubin, direct: lab reported 0.6 mg/dL (milligrams/deciliter) Acceptable range: 0.0 - 0.5 mg/dL 2018 event three, sample CH-11 ALT: lab reported 64 U/L (units per Liter) Acceptable range: 41 - 63 U/L There is no evidence of evaluation or corrective action plans for these unacceptable results. 2. Interview with the Director of Laboratory Services, staff A, on November 13, 2018 at 12:45 PM confirmed the laboratory did not evaluate the unacceptable results and did not develop corrective action plans in response to the unacceptable results.