

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0686510	(X3) Date Survey Completed 04/20/2022
Name of Provider or Supplier Forefront Dermatology, S C	Street Address, City, State 706 W Huron St, Ann Arbor, MI	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with the Office Manager (OM), the laboratory failed to ensure reagents were labeled with the identity, preparation, and expiration dates for 2 (colored reagent and a clear reagent) of 2 staining reservoirs observed. Findings include: 1. During a tour of the laboratory on 4/20/2022 at 9:01 am, the surveyor observed 2 glass reservoirs (a colored and clear reagent) of 2 in a pull out draw in a cabinet unlabeled. 2. An interview on 4/20/2022 at 9:01 am, the OM confirmed the 2 glass reservoirs in the pull out draw in the cabinet were not labeled with the identity, preparation, and expiration dates. ***Repeat Deficiency from 1/07/2016 survey***</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory</p>

failed to ensure Testing Personnel (TP) performing the duties of a Technical Consultant (TC), met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035. ***Repeat Deficiency from 9/21/2020 survey***

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager (OM), the laboratory failed to ensure personnel performing the Technical Consultant (TC) duty of performing testing personnel (TP) competency assessments was qualified or on the CMS 209 for 2 (2020 to 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's personnel competency records on 4/20/2022 at 10:56 am revealed testing personnel other than the TC had performed competency assessments for testing personnel as follows: a. TP1 - competency performed on 10/14/2020 and 7/26/2021 b. TP2 - competency performed on 4/11/2022 (no testing in 2020 and 2021) c. TP3 - competency performed on 10/12/2020 and 6/30/2021 d. TP4 - competency performed on 10/26/2020 and 12/21/2021 2. An interview on 4/20/2022 at 12:45 pm,

the OM confirmed the TP performing the competency assessments are no longer employed and would not have meet the qualification requirements to perform TC responsibilities. ***Repeat Deficiency from 9/21/2020 survey***