

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2082979	<b>(X3) Date Survey Completed</b>  04/18/2018
<b>Name of Provider or Supplier</b>  Derick Dermatology, Llc	<b>Street Address, City, State</b>  1600 N Randall Rd, Ste 400, Elgin, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records, laboratory records, and interview; the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems requirements in 493.1231 through 493.1236. Findings: 1. The laboratory failed to monitor and assess the competency of all personnel involved in the testing process for all tests performed. See D tag 5209. 2. The laboratory failed to yearly verify its histopathology procedures in 2016 and 2017 for all personnel performing histopathology procedures. See D tag 5217. 3. The laboratory failed to document the date and time of all specimens received into the laboratory. See D tag 5787.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; Laboratory Personnel Report</p>

(CMS 209), personnel records and interview; the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency. Findings: 1. There were no procedures that gives instructions for assessing the competency of personnel who are fulfill the responsibilities and duties of the following positions: a. Technical Supervisor b. Clinical Consultant c. General Supervisor e. Moderate complexity personnel performing KOH procedures. 2. Review of the CMS 209 revealed that there were personnel listed as follows: a. Laboratory Director who is also listed as a Clinical Consultant (CC) b. 2 other CCs c. 1 Technical Supervisor who is also listed as a CC and High Complexity Testing Person (HCTP) d. 2 HCTPs (Pathologists) e. 1 GS who is also listed as HCTP f. 2 HCTPs g. 7 Moderate complexity testing persons (6 Physicians Assistants and 1 Mohs Tech) 3. Review of personnel records revealed that there was no documentation to show that competency assessments were performed on the following: a. 1 of 1 Technical Supervisor b. 3 of 3 Clinical Consultants c. 1 General Supervisor 4. During survey date 04/18/18, the General Supervisor confirmed the surveyor's findings.

**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 the laboratory's procedures manual, personnel records and interview; the laboratory failed to verify the accuracy of its Histopathology procedures at least twice annually. Findings: 1. Review of the laboratory procedures revealed that it listed 1 pathologist as the Technical Supervisor of the laboratory. There were no written laboratory procedures that described the laboratory process for verifying its histopathology procedures. 2. Review of personnel records revealed that there was no documentation to show that the laboratory verified its Histopathology procedures, twice in 2016 (At least once between January and June, and once between July and December); and twice in 2017 At least once between January and June, and once between July and December) for 3 of 3 pathologist performing testing. 3. During survey date 04/18/18, the General Supervisor confirmed the surveyor's findings.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview; the laboratory failed to maintain an information or record system that includes the following: \*The date and time of specimen receipt into the laboratory. Findings: 1. Review of 6 patients test records revealed that the date and time of specimen receipt was not documented in the specimen tracking log nor patient test reports for 6 of 6 patients' test records reviewed.

2. During survey date 04/16/16, the General Supervisor confirmed the surveyor's findings.

**D6100**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(10)

The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures manual and personnel records, the laboratory director failed to ensure that the General Supervisor of the laboratory qualifies under 493.1489(b)(4). Findings: 1. Review of personnel records revealed that the Laboratory Manager occupies the position of the General Supervisor; however, there are no documents on file that show that she is qualified to supervise personnel responsible for performing histopathology procedures. See D tag 6143.

**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 personnel records and patients' test records and interview; the laboratory director failed to ensure that all testing personnel had the appropriate education and experience for examining patients' tissue specimens and performing and documenting the gross description of tissue of patients' specimens. Findings: 1. Review of personnel records revealed that the Histology Technicians are the only person's approved to describe the gross description of patients' tissue samples. Personnel competency assessments show that the Mohs Technician is only authorized to embed, cut, and stain patients' tissue specimens. 2. Review of patients' test records show that the Mohs Technician performed and documented the gross description of patients' specimens for 33 of 40 patients test recorded. See D tag 6171 3. During survey date 04/18/18, the General Supervisor confirmed the surveyor' finings.

**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 policies and procedures manual; Laboratory Personnel Report (CMS 209), personnel records and interview; the laboratory director failed to specify in writing the responsibilities and duties of each consultant, each supervisor and each person engaged in the performance of testing that identifies which examinations and procedures each individual is authorized to perform; and 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. Findings: 1. Review of the laboratory's procedures manual revealed that the laboratory performed Potassium Hydroxide (KOH) Wet Mounts; Histopathology (including grossing and special stains); Mohs procedures. There was no documentation to show who was responsible for performing the duties of the following: a. KOH testing b. Clinical Consultant c. High Complexity Testing Personnel e. Moderate Complexity Testing Personnel 2. Review of the CMS 209 revealed that there were 2 additional pathologists that were not assigned in writing what procedures they are authorized to perform. The person listed as the General Supervisor had to tell the surveyor that the two pathologists read Mohs cases and occasionally they diagnose biopsy specimens. 3. There were no personnel records that gave a description of which procedures the two pathologists performed. 4. During survey date 04/18/18, the General Supervisor confirmed the surveyor's findings.

**D6141**

**GENERAL SUPERVISOR**  
 CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:  
 Based on review of Laboratory Personnel Report (CMS 209) and personnel records; the laboratory failed to have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision (GS) in accordance with 493.1463 of this subpart. Findings: 1. Review of the CMS 209 revealed that there was only one person listed as the GS in the laboratory. 2. Review of personnel records revealed that the individual listed as the GS lacked documentation to show she had the necessary general supervisor experience to provided general supervision in accordance with 493.1463 of this subpart. See. D tag 6143.

**D6143**

**GENERAL SUPERVISOR QUALIFICATIONS**  
 CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(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 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; and (c)(1)(ii) Have at least 1 year of

laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. 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). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures manual; Laboratory Personnel Report (CMS 209), personnel records and interview; there was no documentation to show that the person functioning as the General Supervisor (GS) qualifies for this position in this laboratory. Findings: 1. Review of the laboratory procedures manual revealed that there was a document titled, "Laboratory Organization Chart," (revised 03/05 /2018), which lists persons assigned to the following positions: a. Laboratory Director (MD) b. Technical Supervisor (MD) c. Lab Manager (HT) d. Clinical Staff (RN) e. Clinical Provider (MDs/PAs/APNs) f. Testing Personnel (Histotechs/Lab Assistants) Further review of the procedures manual revealed that there were procedures that described the duties and responsibilities for the following personnel: a. Lab Director b. Technical Supervisor c. Clinical Consultant /Pathologists d. General Supervisor

/Lab Manager e. Histology Technician / Technologist f. Laboratory Assistant 2. Review of the CMS 209 revealed that the person listed as the GS was listed on the "Laboratory Organizational Chart" as Lab Manager. 3. Review of personnel records revealed that the person listed as the GS lacked documentation to show she served as GS of high complexity testing prior to September 1, 1992. 4. During survey date 04/18/18, the person listed as the GS told the surveyor that she was verified as GS by another surveyor when their other laboratory was surveyed. On 04/19/19 the surveyor reviewed records from the other facilities under that share the same name and director. The records show that this person was not listed on any CMS 209s prior to the current survey of 04/18/18. On 04/19/18 the person listed as the GS on the CMS 209 confirmed the surveyor's findings.

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent

stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based review of the laboratory's procedures manual, personnel records, patients' test records and interview; the laboratory fail to have qualified testing personnel to perform the gross examination of patient's tissue specimens. 1. Review of patients' testing grossing logs revealed that on 12/30/2016 a Mohs Technician unqualified to perform high complexity testing was the person who performed the gross description of 15 of 20 patients' specimens; and on 01/05/2018 documentation shows that the same Mohs unqualified Technician also performed the gross description of 16 of 20 patients' specimens. 2. During survey date, the general supervisor confirmed the surveyor's findings.