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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D0964857 | (X3) Date Survey Completed 08/22/2018 |
| Name of Provider or Supplier Dermatology Partners Of The North Shore | Street Address, City, State 400 Skokie Blvd, Suite #475, Northbrook, 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 |
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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 the surveyor's review of the laboratory's records, manuals, and an interview with the laboratory director (LD); the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Bacteriology and Histopathology testing, affecting 12 out of 12 testing personnel (TP). Findings: Fungal Cultures 1. The Laboratory Personnel Report (CMS 209) lists 9 licensed physicians (TP listed on lines 1-9), performing fungal testing using Acuderm Dermatophyte Test Medium (ACU-DTM) in the laboratory. 2. The laboratory's current competency policy and step-by-step procedure for TP performing ACU-DTM testing does not include the following personnel assessment requirements: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b). Monitoring the recording and reporting of test results; c). If applicable, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d). Direct observation of performance of instrument maintenance and function checks (i.e. microscope maintenance); and f). The frequency for evaluating and documenting the performance TP responsible for testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 3. The DTM fungal log reveals that 9 out of 9 physicians were performing DTM testing on patients during the years of 2016-2018. Potassium Hydroxide (KOH) and Scabies 4. The CMS 209 lists 9 licensed physicians (TP listed on lines 1-9) performing KOH and Scabies testing in the laboratory. 5. The laboratory's manual does not include an established</p> |

competency policy and step-by-step procedure for assessing TP performing KOH testing that includes the personnel assessment requirements specified in subpart M to assess employees. 6. The KOH log reveals that 8 out of 9 physicians were performing KOH preps on patients during the years of 2016-2018. Histopathology 7. The CMS 209 lists 9 licensed and board certified dermatologists (TP listed on lines 1-9) and 3 licensed and board certified pathologists (TP listed on lines 10-12) performing Histopathology slide interpretations (or reading slides) in the laboratory. 8. The laboratory's manual does not define the method that will be used to assess and evaluate the continued competency of its 12 TP interpreting Histopathology slides. The Histology logs reveal that 11 out of 12 physicians were reading patients' slides during the years of 2016-2018. 9. On a Recertification survey conducted on August 22, 2018 at 2:45 PM, the LD confirmed the above 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 the surveyor's review of the laboratory's records and an interview with the laboratory director (LD) and staff; the laboratory failed to verify the accuracy of tests performed in the specialty of Microbiology and Histopathology at least twice annually. Findings: 1. The manual and test records reveal that the laboratory performs the following tests and procedures: Potassium Hydroxide (KOH) preparations (Preps), Acuderm Dermatophyte Test Medium (ACU-DTM), Scabies, Histopathology slide interpretation, and Mohs surgery tissue processing. 2. The laboratory's manual does not define the method and procedure the laboratory will use to verify the accuracy of each test listed in findings #1. 3. The laboratory was performing the tests listed in findings #1 during the years of 2016 through 2018. 4. On a Recertification survey conducted on August 22, 2018 at 2:45 PM, the LD and staff confirmed the above findings.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's manual, records, and an interview with the laboratory director (LD) and staff, the laboratory failed to perform control procedures using the number and frequency specified by the manufacturer when they meet or exceed the requirements in paragraph (d)(3) of this section for tests in the subspecialty of Bacteriological testing, affecting 448 patients. Findings: 1. Review of

the laboratory's Individual Quality Control Plan (IQCP) revealed the following: a). In the proficiency policy under 'Reagent/Test Medium' section, the method is not specified for verifying the accuracy of the Acuderm Dermatophyte Test Medium (ACU-DTM) performed in the laboratory for at least twice annually; b). The 'IQCP Summary' section states the following concerning controls: "Part #1. 'Users are able to perform patient testing whether or not controls have been performed.'"; and "Part #2. '.... Users are able to read patient samples whether or not control testing falls within range.'" 2. The manufacturer's instructions requires with each new lot or every 2 weeks, that the ACU-DTM media be tested with 4 specified organisms which must yield, at the specified time, expected results as defined in the instructions. 3. The LD records on the CLIA certification application (CMS 116), that the laboratory has tested 449 patients during the years of 2016 through 2018. 4. On a Recertification survey conducted on August 22, 2018 at 2:45 PM, the LD and staff confirmed the above findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's records, manuals, and an interview with the laboratory director (LD) and staff, the technical consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year, affecting 9 out of 9 testing personnel (TP). Findings: 1. The Laboratory Personnel Report (CMS 209) lists 9 licensed physicians (TP listed on line 1-9) who perform Potassium Hydroxide (KOH) preparations (Preps) and Acuderm Dermatophyte Test Medium (ACU-DTM) testing in the laboratory. 2. The competency documents, manual, and test log books revealed the following: a). The laboratory's competency procedure does not meet CLIA personnel assessment requirements. See D5209. b). A slide identification test was given to 5 out of 9 TP in 2017. c). A new competency assessment procedure was presented for the 9 TP dated 08/14/2018, however it does not indicate which test or test procedure used to evaluate the TP, as well as not providing the supporting documents the TC reviewed, which proved the TPs' competence. d). No other documented evidence was submitted as proof the 9 TP were assessed during the years of 2016 thru 2018. e). The manual includes the written authorization by the LD for the 9 TP to perform the KOH and ACU-DTM testing. f). The initials of 8 out of 9 TP are recorded in the patients' test logs for patient tested during the years of 2016 through 2018. 3. On a Recertification survey conducted on August 22, 2018 at 2:45 PM, the LD and staff confirmed the above findings.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's records, manuals, and an interview with the laboratory director (LD) and staff, the technical supervisor (TS) failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually, after the first year, affecting 12 out of 12 testing personnel (TP). Findings: 1. The Laboratory Personnel Report (CMS 209) lists 9 licensed and board certified dermatologists (DTP listed on line 1-9) and 3 licensed and board certified pathologists (TP2 listed on lines 10-12) performing Histopathology slide interpretations (or reading slides) in the laboratory. 2. The competency documents, manual, and test log books revealed the following: a). The manual does not include a written method to assess the competency of its 9 DTP & 3 TP2. b). A slide identification test was given to 5 out of 9 DTP in 2017 which includes 4 types of skin carcinomas. c). A new competency assessment procedure was presented for the 9 DTP dated 08/14/2018, however it does not indicate which test or test procedure that it used to assess the DTP, as well as not providing the supporting documents the TS reviewed, which proved the DTPs' competence. d). No other documented evidence was submitted as proof the 9 DTP were assessed during the years of 2016 thru 2018. e). The manual includes the written authorization by the LD for the 9 DTP to perform the Dermatopathology (or Histopathology) testing. f). The initials of 11 out of 12 TP are recorded in the patients' test logs for patient tested during the years of 2016 through 2018. 3. On a Recertification survey conducted on August 22, 2018 at 2:45 PM, the LD and staff confirmed the above findings.

D6168

TESTING PERSONNEL
 CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
 Based on the surveyor's review of the laboratory's records, manuals, and an interview with the laboratory director (LD) and staff, the laboratory failed to employ individuals who meet the qualification requirements of 493.1489. Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing highly complex testing in the specialty of Histopathology. See D6171.

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 on the surveyor's review of employee files, and an interview with the laboratory director (LD) and staff, the laboratory failed to ensure laboratory employees meet the qualification requirements for performing highly complex testing in the specialty of Histopathology. Findings: 1. The Laboratory Personnel Report (CMS-209), list 1 employee (TP-AT5 on line 13) performing tissue grossing and processing in the laboratory. 2. The employee files revealed that TP-AT5 has a high school diploma which does not meet the education requirement as defined 493.1489 (b) (1) - (7) for highly complex testing. 3. On a Recertification survey conducted on August 22, 2018 at 3:15PM, the LD and staff confirmed the above findings.