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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 22D0959317 | (X3) Date Survey Completed 11/22/2019 |
| Name of Provider or Supplier Adult & Pediatric Dermatology, Pc | Street Address, City, State 133 Littleton Road, Suite 205, Westford, MA | |
| 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 | A CLIA recertification survey was conducted for the Adult & Pediatric Dermatology, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. . |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and record review, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date as evidenced by the following: a) During a tour of the laboratory on 11/22/19 at 10:20 AM, the surveyor observed the following expired item in the laboratory area where Physician Performed Microscopy Procedures (PPMP) are performed: * One (1) bottle of Potassium Hydroxide (KOH), lot number 1828308, expiration date 10/10/19. b) There were no other in-date reagents available in the laboratory. Based on this evidence the accuracy and reliability of microscopic examinations, utilizing this reagent, could not be assured. One patient sample for KOH was tested on 10/22/19. c) The laboratory performs approximately 50 KOH preparations annually.</p> |