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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2089195 | (X3) Date Survey Completed 09/24/2020 |
| Name of Provider or Supplier Premier Dermatology | Street Address, City, State 1525 Hickory St, Abilene, TX | |
| 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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| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, observation, and interview, the laboratory failed to ensure the microscope maintenance was performed annually for one of one year reviewed. Findings follow. Review of the laboratory's Policy and Procedure approved on 1/27/15 for the Microscope stated, "have regular service contracts performed." Observation of the sticker on the microscope showed service was performed on 10/08/18 and next service was due on 10/2019. Interview with the Laboratory Director at 11:35 in the laboratory stated he would send the 2019 service record. As of 9/30/2020 no documentation has been received.</p> |
| 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 observation, testing logs, and interview, the laboratory failed to ensure reagents were not used past their expiration date for 6 of 9 bottles. Findings follow. At 9:15, 5 unopen bottles, and 1 open bottle of Tissue-Plus O.C.T. Compound were</p> |

found in the cabinet with an expiration date of 5/2020. Review of the Mohls testing records showed 45 patients were processed from 6/01/2020 - 9/24/2020. There were no logs for the H&E (Hematoxylin and Eosin) cases, so they were not counted. Interview with the Histotech at 9:15 verified the bottles were expired. She stated she was not aware the expiration dates were on the bottom of the bottle.