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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0987784 | (X3) Date Survey Completed 07/18/2024 |
| Name of Provider or Supplier Keys Pathology Associates Pa | Street Address, City, State 11400 Overseas Highway #223, Marathon, FL | |
| 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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| D0000 | An initial certification survey conducted at KEYS PATHOLOGY ASSOCIATES PA on 07/18/2024 found the laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. |
| D5601 | <p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have and record the negative control reactivity verification for the immunohistochemical (IHC) stain interpretation that the laboratory performed at least from 05/01/2024 to 06/30/2024. Findings included: -Review of the Form CLINICAL LABORATORY IMPROVEMENT AMMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION Form CMS-116 signed by the Laboratory Director on 07/18/2024 revealed the following test menu for IHC: CD (Cluster of Differentiation) 3 leukocyte Antigen, CD5, CD20 Antigen, CD34 Antigen, Actin Antigen, AE1/AE3 (Epithelial) Antigen, MelanA Antigen, Vimentin, S100 (Neural Tissue/Lesion and Melanoma, Cytokeratin 7 Protein, Cytokeratin 20, HMB45 antigen, HMW Keratin Antigen, P63 tumor suppressor protein, Preferentially expressed antigen in Melanoma (PRAME)). - Review of worksheet and slides for IHC stains revealed the following: a) 07/05/2024: the laboratory tested two patients (P#1 and P#2). P#1 they used the following IHC stains: CD3, CD5, CD20, CD30, positive controls for all the IHC stains. P#2 they used the following IHC stains: MelanA, HMB45, S100 and PRAME. Positive controls</p> |

for all stains. They used only one negative slide that included P#1 and P#2, it doesn't say that negative control for which stain. b) 07/17/2024 revealed that the laboratory performed stain CD3 for P#3, they used a positive control no documentation of the negative control. -The laboratory performed IHC on 47 specimens in May and 62 specimens in June. During an interview on 07/18/2024 at 03:30 PM, the laboratory director confirmed that the laboratory failed to have and record negative control reactivity for all IHC stains for the specimens of reference.