

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2138479	(X3) Date Survey Completed 01/18/2023
Name of Provider or Supplier Pathology Watch, Pllc	Street Address, City, State 810 Ethel St, Austin, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control (QC) records, the processing laboratory's policy and procedure, pre-survey paperwork, test reports, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain used in dermatopathology interpretations stained predictably for 10 of 10 days of testing over a three-week period reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Document and Process Control, adopted 10/22 /21, under DC.02.01.0 stated, "The scope of services provided by the Laboratory is limited to histopathologic interpretation of previously processed and prepared anatomic pathology specimens. Each slide (digital or glass) received for interpretation by a pathologist will be comprehensively reviewed. All slides pertaining to a case will be reviewed prior to issuing an interpretive report. When slides are deemed inadequate for any reason by the interpreting pathologist, the contract laboratory will be notified, and the staining or test repeated if possible, or otherwise fixed. Professional interpretation of the slides will take place within contract laboratory LIS systems. Pathologists will access the LIS digitally, where they will issue the</p>

interpretive results pertaining to the case, confirming the unique identifiers match in order to ensure specimen integrity. When critical values are reported, the ordering clinician will be notified directly by the pathologist, and such notification will be documented in the patient report. If additional testing is required, it will be ordered by the pathologist utilizing the digital means provided within the contract laboratory LIS, or by utilizing whatever procedure or protocol has been developed by the contract laboratory. Appropriate controls will be performed and evaluated by laboratory Pathologists where appropriate, or by pathologists at the contract laboratory where appropriate." B. Review of QC records showed they were performed by a laboratory in San Antonio, CLIA #45D1064267. Quality control records for the facility surveyed were requested on January 12, 2023, at 1415 hours, but not provided. C. Review of the pre-survey paperwork showed dermatopathology interpretations began 06/14/2021. D. Review of the H&E staining procedure from the processing laboratory titled 242.000 Routine Hematoxylin and Eosin Staining Protocol under Results described the characteristics of the H&E stain: "1. Nuclei- Blue with clear chromatin patterns, 2. Cytoplasm and Connective Tissue- Varying shades of pink with cytoplasmic granules visible, 3. Cartilage and calcium deposits- Dark Blue, 4. Blood- Bright Red". E. The following test reports/cases of the H&E stain with no QC were reviewed: Date Reported Accession # 1. 12/20/22 PSI22-01237 PSI22-01240 2. 12/21/22 PSI22-01255 PSI22-01257 3. 12/29/22 PSI22-01299 PSI22-01300 PSI22-01301 4. 12/31/22 PSI22-01314 5. 01/04/23 PSI22-01313 PSI23-00001 6. 01/05/23 PSI22-01312 PSI23-00003 PSI23-00011 PSI23-00012 PSI23-00013 PSI23-00014 7. 01/06/23 PSI23-00002 8. 01/07/23 PSI23-00031 9. 01/10/23 PSI23-00023 PSI23-00028 PSI23-00029 PSI23-00030 PSI23-00047 PSI23-00048 10. 01/11/23 PSI23-00046 PSI23-00052 F. Interview with the Laboratory Director on January 12, 2023, at 1350 hours acknowledged there was a gap in testing from the last Laboratory Director/testing person and he only began testing in December 2022 at this location under this CLIA number. Further interview with the Laboratory Director on January 12, 2023, at 1415 hours confirmed the QC for the H&E stain was performed by another physician at another CLIA location.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, test reports / quality control (QC) records, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Immunohistochemical (IHC) stains and Special stains for the interpretation of dermatopathology specimens for one of three reports reviewed. Finding follow. A. Review of the laboratory's policy and procedure titled Document and Process Control, adopted 10/22/21, under DC. 02.01.0 stated, "The scope of services provided by the Laboratory is limited to histopathologic interpretation of previously processed and prepared anatomic pathology specimens. Each slide (digital or glass) received for interpretation by a pathologist will be comprehensively reviewed. All slides pertaining to a case will be

reviewed prior to issuing an interpretive report. When slides are deemed inadequate for any reason by the interpreting pathologist, the contract laboratory will be notified, and the staining or test repeated if possible, or otherwise fixed. Professional interpretation of the slides will take place within contract laboratory LIS systems. Pathologists will access the LIS digitally, where they will issue the interpretive results pertaining to the case, confirming the unique identifiers match in order to ensure specimen integrity. When critical values are reported, the ordering clinician will be notified directly by the pathologist, and such notification will be documented in the patient report. If additional testing is required, it will be ordered by the pathologist utilizing the digital means provided within the contract laboratory LIS, or by utilizing whatever procedure or protocol has been developed by the contract laboratory. Appropriate controls will be performed and evaluated by laboratory Pathologists where appropriate, or by pathologists at the contract laboratory where appropriate." B. Review of 1 of 3 test reports/cases from 12/20/22 - 01/11/23 did not include QC for the intended reactivity to ensure predictable staining characteristics for the following IHC and Special stains: Accession # Date Reported IHC/Special Stain 1. PSI22-01313 01/04/2023 GMS Stain The laboratory's practice was to record the controls of the IHC and Special Stains in the test report. C. Interview with the Laboratory Director on January 12, 2023, at 1350 hours acknowledged there was a gap in testing from the last Laboratory Director/testing person and he only began testing in December 2022 at this location under this CLIA number. Further interview with the Laboratory Director on January 12, 2023, at 1530 hours confirmed the performance of the QC for the Special stain was not recorded.