

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2138479	(X3) Date Survey Completed 05/01/2019
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 entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for H&E slides in 2018. The findings were: 1. A review of the laboratory's records revealed the laboratory performed an estimated 8,000 H&E stains in 2018. 2. The laboratory was asked to provide documentation of performing twice annual accuracy assessments for the H&E stains in 2018. No documentation was provided. 3. An interview with the laboratory director on 05/01/2019 at 915 hours in the living room revealed assessments had not been performed in 2018. This confirmed the findings.</p>

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 records, and staff interview it was revealed the laboratory failed to have documentation of staining quality for H&E stains performed in 2018 and 2019. The findings were: 1. A review of the laboratory's records revealed the laboratory read an estimated 8,000 H&E stained slides annually in 2018. 2. The laboratory was asked to provide documentation of assessing the staining quality of the sides for each day of patient testing in 2018 and 2019 (as of the day of the survey). No documentation was provided. 3. An interview with the laboratory director on 05/01/2019 at 0949 hours in the living room revealed the laboratory did not have the required documentation. This confirmed the findings.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure a quality assessment program was developed for the laboratory. The findings were: 1. A review of the laboratory's records revealed the laboratory did not have a written quality assessment program. In addition, the laboratory did not have quality assessment records to review. 2. The laboratory was asked to provide documentation of a quality assessment program. No documentation was provided. 3. An interview with the laboratory director on 05/01/2019 at 0949 in the living room revealed a quality assessment program had not been established. This confirmed the findings.