

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2204829	(X3) Date Survey Completed 12/08/2022
Name of Provider or Supplier Pathology Watch, Inc	Street Address, City, State 497 West 4800 South, Suite 201, Murray, UT	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review instrument documentation, laboratory temperature and humidity logs, and interview with compliance manager, the laboratory failed to record laboratory humidity and temperature. The laboratory performs 10,000 histology tests annually. Findings Include: 1. The Panoramic 250 Users Guide states that room temperature for operation must be between 10C to 35C and humidity must be less than 75%. 2. Record review revealed that laboratory temperature and humidity was not recorded 89 of 244 days between 04-01-2022 and 11-30-2022. 3. Interview with compliance manager at approximately 4:30 PM on 12-8-2022 confirmed that laboratory temperature and humidity was not recorded 89 of 244 days between 04-01-2022 and 11-30-2022.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer</p>

must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with staff, the laboratory failed to establish test performance specifications for two of two 3D Histech P250 digital scanners and one of one 3D Histech P1000 digital scanner working in conjunction with Mihm artificial intelligence examination and diagnostic interpretation of digitized histopathology slides before reporting patient test results. The laboratory performed 10,000 histology tests annually. Findings include: 1. Laboratory record review failed to produce documentation that the laboratory developed test performance specifications for two of two 3D Histech P250 digital scanners and one of one 3D Histech P1000 digital scanner working in conjunction with Mihm artificial intelligence examination and diagnostic interpretation of digitized histopathology slides. 2. In an interview with the laboratory compliance manager on 12-08-2022 at approximately 2:45 PM, confirmed the laboratory failed to establish performance specifications before reporting patient test results.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the laboratory did not perform and document maintenance activities on the EpreDia Gemini AS Automated Stainer. The laboratory performs 10,000 histology test annually. Findings include: 1. Record review of "Gemini AutoStainer Preventative Maintenance Record" revealed that daily maintenance was not performed on four of seven days in December 2022. 2. Interview with laboratory personnel at 1:20 PM on 12-8-2022 confirmed the automated stainer was run daily and that daily maintenance was not performed or documented every day the instrument was in use.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The

laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on record review, lack of corrective action documentation, and interview with the compliance manager, the laboratory failed to take corrective actions for 77 of 244 days for humidity and 4 of 244 days for temperature when the readings failed to meet the laboratory's established criteria for acceptability. The laboratory performed 10,000 histology tests annually. Findings include: 1. The laboratory room temperature and humidity log states, "Acceptable Temperature Range: 20 - 25 Celsius" and "Acceptable Humidity Range: 30% - 60%" 2. Record review of temperature and humidity logs showed laboratory room temperature was outside the acceptable range on 4 of 244 days in 2022. Record review showed that laboratory humidity was outside the acceptable range on 77 of 244 days in 2022. 3. Record review failed to include documentation of corrective actions taken for days when laboratory temperature or humidity failed to meet the laboratory's established criteria for acceptability. 4. In an interview conducted on 12-8-2022 the laboratory compliance manager confirmed the laboratory failed to document corrective actions taken when laboratory temperature or humidity failed to meet the laboratory's established criteria for acceptability.