Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2244851	11/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Watch, Llc	18316 Murdock Circle, Unit 106, Port Charlotte, 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
D0000	An announced CLIA recertification survey was conducted at Mark & Kambour, MD, PA on 11/06/2025 - 11/10/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6076 493.1441 Condition: Laboratory Director
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction for 2024-2025. See D6080, D6091, D6093, D6102, and D6103.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to develop a

	policy or provide evidence of the required every 6 month onsite visits from 01/2025-11 /2025. Findings Included: 1. Review of records revealed no approved policy regarding the Laboratory Director being onsite every 6 months and no evidence of visits for 01 /2025 to 11/2025. An unapproved policy regarding the required onsite every 6 month visits was presented for review. 2. The Laboratory Director stated via email interview on 11/10/2025 at 12:11 p.m., he had not been able to visit the laboratory from 01 /2025-11/2025.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to review proficiency testing reports/peer reviews for two of two years (2024-2025). Findings included: 1. The policy presented for proficiency (peer review) was an unapproved policy which stated the (Laboratory) Director would review and approve proficiency testing results. 2. The Laboratory Professional Staff , who read digital patient slides for Histopathology, performed peer reviews as required to meet proficiency requirements. The peer reviews failed to be reviewed or approved by the Laboratory Director of this laboratory for 2024-2025. 3. The Laboratory Director confirmed via email interview on 11/10/2025 at 12:11 p.m. that he had not understood as Laboratory Director he was responsible for documenting his review of peer reviews.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 record review and interview, the Laboratory Director failed to ensure that the quality assessment program was established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occurred for two of two years (2024-2025). Findings included: 1. The Quality Management Policy approved by the Laboratory Director on 4/24/2025, indicated under 4.0 - it was the Laboratory Director who was responsible for the Quality Management Plan to ensure laboratory performance. No documentation was presented of the Laboratory Director of this laboratory reviewing Quality Management reports or identifying and correcting the listed deficient practices found during the recertification survey. a. The Laboratory Director failed to develop a policy or provide evidence of the required every 6 month onsite visits from 01/2025-11/2025. (see D6080). b. The Laboratory Director failed to review proficiency testing reports/peer reviews for two of two years (2024-2025). (See D6091) c. The Laboratory Director failed to ensure that prior to testing Patients' specimens, all Testing Personnel received the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for three (TP-B, C, and D) of three Testing

	Personnel (TP-B, C, and D), for professional Histopathology testing (reading and interpreting patient slides). (See D6102) d. The Laboratory Director failed to ensure that the policy for monitoring Testing Personnel demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for one (TP-F) of three Testing Personnel (TP-A, TP- E, and TP-F) for technical Histopathology testing (grossing of Patient samples) for two of two years (2024-2025). (See D6103)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that prior to testing patients' specimens, all testing personnel received the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for three (TP-B, C, and D) of three Testing Personnel (TP-B, C, and D), for professional Histopathology testing (reading and interpreting patient slides). Findings included: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 11/05 /2025, listed three Testing Personnel (TP-B, C, and D) who performed professional High Complexity Histology testing. 2. The laboratory policy titled GEN-SOP-040 Competency Assessment revised 11/04/2025 signed by the Laboratory Director 11/04 /2025 stated the Laboratory Director was responsible for ensuring competencies were performed semiannually and no later than 12 months during first year of employment, then annually thereafter. There was no policy presented for review regarding training of High Complexity professional histology Testing Personnel. 3. The Quality Manager stated on 11/06/2025 at 12:40 p.m. that TP-B started testing 01/30/2024,TP-C's start date was prior to 7/11/2025, and TP-D's hire date was 05/09/2025. There was no record presented at the time of the survey of training and competency for this laboratory prior to patient testing. 4. The Laboratory Director stated via email interview on 11/10/2025 at 12:11 p.m., he failed to document training and competency at this laboratory for TP-B, TP-C, and TP-D prior to testing patient samples (reading digital Histology slides remotely).
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that

	the policy for monitoring Testing Personnel demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for one (TP-F) of three Testing Personnel (TP-A, TP- E, and TP-F) for technical Histopathology testing (grossing of patient samples) for two of two years (2024-2025). Findings included: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 11/05/2025, listed three Testing Personnel (TP-A, TP- E, and TP-F) who performed technical Histopathology testing (grossing of Patient samples). 2. The laboratory policy titled GEN-SOP-040 Competency Assessment revised 11/04/2025 signed by the Laboratory Director on 11/04/2025 stated the Laboratory Director was responsible for ensuring competencies were performed semiannually and no later than 12 months during first year of employment, then annually thereafter. 3. The Quality Manager stated on 11/06/2025 at 12:55 p.m. that TP-F failed to have documentation of annual competencies for 2024 or 2025.