

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1056555	(X3) Date Survey Completed 02/04/2026
Name of Provider or Supplier Watson Clinic Llp	Street Address, City, State 924 A Cypress Village Blvd, Ruskin, 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 Watson Clinic LLP on 02/04/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, one testing person (TP) TP #E failed to attest they performed the proficiency testing in the same manner as patient testing for one (2nd test event 2024) of four test events reviewed for 2024 and 2025 for the subspecialty of Mycology. Findings included: 1. The laboratory participated in proficiency testing (PT) with Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing in 2024 and 2025. There were two test events (POC1 and POC2) each year. The 2024 POC2 PT documentation was reviewed. Testing Person #E participated in this event. The WSLH PT Attestation/Signature Section stated "I/we attest that the results for this event were obtained by analysis of proficiency testing samples with the same frequency and, as closely as possible, in the same routine manner as performed on patient specimens. Furthermore, these results were not obtained through discussion or collaboration with any other laboratory." There was a line for the TP analyzing the specimens to sign & date. It was unsigned. 2. Interview with the Laboratory Director on 02/04/2026 via electronic communication confirmed TP #E failed to attest they performed the PT as described above.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p>

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the lab failed to follow its policy to complete and document an initial competency on one of one new employees (testing person [TP] #E) selected for review, for testing performed for the subspecialties of Mycology and Parasitology. Findings included; 1. The laboratories Competency Assessment Policy, approved by the Laboratory Director on 12/19/2022, was reviewed. The policy directed initial training (competency) would be completed for new testing personnel. 2. Interview with the Clinical Services Coordinator and Director of Laboratory Services on 02/04/2026 at 12:55 p.m. revealed testing person #E was hired on 03/18/2024. 3. Review of TP #E training and competency failed to reveal documented initial training/competency. 4. Interview with the Laboratory Director on 02/04/2026 via electronic communication confirmed the above.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to verify the accuracy of an analyte not evaluated by the proficiency testing program used by the laboratory, Wisconsin State Laboratory of Hygiene (WSLH), for one of one test event (POC2) from 2024 for the subspecialty of Mycology. Findings included: 1. The test event POC2 documents from WSLH from 2024 were reviewed. The lab scored a 100%. Sample PM-3 was flagged by WSLH for non-consensus & the need to perform a self-assessment. No self-assessment documents were completed by the laboratory. 2. The Laboratory Director confirmed the above via electronic interview on 02/04/2026.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure one (#1) of three patients (#1, #2, #3) final reports selected for review contained the test results. The missing result was for the subspecialty of Parasitology. Findings included: 1. The final test reports for patients #1, #2 and #3 were reviewed. Patient #1's final test report did not contain the results. 2. Interview with the Clinical Services Coordinator on 02/04/2026 at 2:30 p.m. confirmed the above.