Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2273288	08/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Walk-In Md Clinic, Llc Dba Walk-In Md Urgent Care	81 Memorial Pkwy, Randolph, MA	

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	A CLIA validation survey was conducted for Walk-in MD Clinic, MD Urgent Care on August 13, 2026 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) 2025 and 2026 records, and interview with the technical supervisor (TS) conducted on 08/13/2026, the laboratory failed to have all staff testing PT samples sign the attestation statements for PT for American Proficiency Institute (API) 2026 Microbiology PT events 1 and 2. Findings include: 1. Record review of the laboratory's 2026 API PT attestations revealed that only testing personnel (TP2) signed the attestations statements for 2026 API Microbiology events 1and 2. 2. Record review of the 2026 API PT testing records revealed that TP1 tested 5 PT samples in 2026 API Microbiology events 1and 2 but failed to sign the attestation statements for these events. 3. Interview with the TS on 08 /13/2026 at 11:30 AM confirmed the findings above.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--

	This STANDARD is not met as evidenced by: Based on record review of 2025 and 2026 proficiency testing (PT) records and interview with the technical supervisor (TS) conducted on 08/13/2026, the laboratory failed to ensure that the laboratory was enrolled in an approved PT program for all regulated analytes under the microbiology specialty. Findings include: 1. Record review on 08/13/2026 of PT 2026 American Proficiency Institute (API) testing documentation and patient testing records revealed the laboratory failed to enroll in an HHS approved PT program for all regulated analytes under the microbiology specialty for the 1st event of 2026. The review further revealed that the laboratory conducted a PT Self-Evaluation for the API Microbiology 2026 1st event on March 20, 2026. The API Performance summary shows the laboratory received 100% for all graded analytes. 2. Record review of patient test results for 2025 and 2026 revealed that the laboratory started patient testing and reporting test results for all regulated analytes under the specialty of microbiology in October 2025. 3. Interview with the TS on 08 /13/2026 at 11:45 AM confirmed the findings above.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on record review conducted on 08/13/2026 of the laboratory's standard operating procedures (SOP), patient test reports for the Urinary Tract Infection (UTI) and Respiratory Pathogen Plus (RPP) panels, and interview with the technical supervisor (TS) on 08/13/2026, the laboratory director failed to ensure the patient test reports included the laboratory report disclaimer in the approved UTI and RPP SOPs. Findings include: 1. Record review of Urinary Tract Infection (UTI) and the Respiratory Pathogen Plus Panel (RPP) final reports issued between 06/01/2026 - 8/13 /2026 in patient charts revealed the following report disclaimer for both panels: "These results should be interpreted in the context of other clinical findings to aid in diagnosis and treatment decisions. Test results may be affected by improper specimen collection, improper specimen storage, technical error, contamination, or specimen mix-up. Testing performed by real-time PCR with a limit of detection of 10'4 CFU /ml. Presence of an antibiotic resistance gene does not definitively confer resistance, and absence of an antibiotic resistance gene does not guarantee sensitivity, as testing may not detect all possible resistance factors. Tests were developed and performance characteristics determined by Walk In MD Clinic. They have not been cleared or approved by the FDA. The laboratory is regulated under CUBA as qualified to perform high-complexity testing. This test is used for clinical purposes and should not be regarded as investigational or for research. All testing was performed at Walk In MD Clinic, CLIA No.22D2273288." 2. Record review of the Urinary Tract Infection (UTI) SOP approved by the LD on 05/19/2026 revealed the following disclaimer for reports found on page 7 of the SOP: "This Urinary Tract Infection (UTI) Panel is a real-time Polymerase Chain Reaction (RT-PCR) test that has not been FDA-cleared or approved. This laboratory-developed test is a TaqMan assay intended to detect nucleic acid from clinically relevant pathogens in specimens from individuals suspected of infection by their healthcare provider(s). Walkln MD Urgent Care is regulated under CLIA and is qualified to perform high-complexity molecular testing. In accordance with State, Federal, and local public health agencies, Walkln MD Urgent Care will

	report test results to the appropriate health agencies." "A "Detected" result indicates the presence of nucleic acid from a pathogen or antibiotic resistance marker; clinical correlation with patient history and other diagnostic information is necessary to make a clinical diagnosis. The Limit of Detection (LoD) for pathogens covered in this panel has been experimentally determined to be approximately - 1 00 copies/uL. Pathogens at lower concentrations may not be reliably detected with this LDT. A "Not Detected" result does not preclude or rule out the presence of a pathogen and should not be the sole basis for patient management decisions. A "Detected" or "Not Detected" result does not rule out co-infections with other pathogens. Additionally, RT-qPCR tests do not differentiate between patients with acute infection or asymptomatic carriers. The information contained in this report is intended to be interpreted concurrently with clinical symptoms by a licensed healthcare professional. This report is not intended to take the place of professional medical advice." 3. Record review of the Respiratory Pathogen Plus Panel (RPP) SOP approved by the LD on 04/22//2026 revealed the following Disclaimer for Laboratory Reports found on page 7 of the SOP: "This Respiratory Pathogen Panel (RPP) is a real-time Polymerase Chain Reaction (RT-PCR) test that has not been FDA-cleared or approved. This laboratory-developed test is a TaqMan assay intended to detect nucleic acid from clinically relevant pathogens in specimens from individuals suspected of infection by their healthcare provider(s). Walkln MD Urgent Care is regulated under CLIA and is qualified to perform high-complexity molecular testing. In accordance with State, Federal, and local public health agencies, Walkln MD Urgent Care will report test results to the appropriate health agencies. "A "Detected" result indicates the presence of nucleic acid from a pathogen or antibiotic resistance marker; clinical correlation with patient history and other diagnostic information is necessary to make a clinical diagnosis. The Limit of Detection (LoD) for pathogens covered in this panel has been experimentally determined to be approximately - 1 00 copies/uL. Pathogens at lower concentrations may not be reliably detected with this LDT. A "Not Detected" result does not preclude or rule out the presence of a pathogen and should not be the sole basis for patient management decisions. A "Detected" or "Not Detected" result does not rule out co-infections with other pathogens. Additionally, RT-qPCR tests do not differentiate between patients with acute infection or asymptomatic carriers. The information contained in this report is intended to be interpreted concurrently with clinical symptoms by a licensed healthcare professional. This report is not intended to take the place of professional medical advice." 4. The TS confirmed on 08/13/2026 at 12:20 PM these discrepancies existed between the UTI and RPP test reports and the SOPs. 5. The laboratory performs 468,000 tests in the specialty of Microbiology annually.