Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0175980	02/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Medi-Help Pc Laboratory	1691 Washington Rd, Mount Lebanon, PA	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 American Proficiency Institute (API) and College of American Pathologist (CAP) proficiency testing (PT) records and interview with the Laboraotry Director (LD), the Laboratory Director (LD) and Testing Personnel (TP) failed to sign the API and CAP PT attestation statement documents in 2020 and 2021. Findings include: 1. On the day of survey, 02/15/2022 at 12:00 a.m., review of API and CAP PT records revealed, the following attestation statement documents were not signed: API Core Chemistry: - 2020: Event #1, Event#2 and Event #3. - 2021: Event #1, Event#2, and Event#3. CAP: - 2020 Hematology: Event #A and Event#C. - 2020 Clinical Microscopic: Event#A. - 2021 Microbiology: Event#A 3. The LD confirmed the findings above on 02/15/2022 at 04:00 p.m.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on lack of Quality Control documentation and interview with the Laboratory Director (LD), the laboratory failed to document a positive and negative reactivity for Bacitracin (A) Discs each lot/shipment of disks use in 2020 and 2021. Findings include: 1. On the day of survey 02/15/2022 at 1:40 p.m, the laboratory could not provide the records for the porsitive and negative of the Bacitracin (A) Discs from 02 /15/2020 to 02/15/2022. 2. The LD confirmed the finding above on 02/15/2022 at 04: 00 p.m.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on lack of Quality Control documentation and interview with the Laboratory Director (LD), the laboratory failed to document a positive and negative reactivity of the gram stain quality controls (QC) each week of use in 2020 and 2021. Findings include: 1. On the day of survey 02/15/2022 at 12:00 p.m, the laboratory could not provide QC record for gram stain from 02/15/2020 to 02/15/2022. 2. The LD confirmed the finding above on 02/15/2022 at 04:00 p.m.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation during the laboratory, quality control (QC) record review, and interview with the Testing Personnel (TP)#2, the laboratory failed to ensure proper standardization of the inoculum for Antimicrobial Susceptibility QC each day of patient testing from 02/15/2020 to 02/15/2022 Findings Include: 1. Observation on 02 /15/2022, at 03:04 p.m., showed the laboratory did not have proper 0.5 McFarland standardization of the inoculum for Antimicrobial Susceptibility test Quality Control (QC). 2 Record review revealed that that the laboratory performed QC on a weekly basis. 3. On 02/15/2022 TP #2 stated the laboratory takes the colonies and emulsify them in saline, they don't have a standard to compare and just inoculate the plate with the solution.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the Micros 60 hematology analyzer validation records and interview with the Laboratory Director (LD), the Laboratory Director failed to approve the performance specifications of precision and accuracy for hematology analytes performed on the Micros 60 used from 12/16/2021 to 02/15/2022. Finding Include: 1. On the day of survey, 02/15/2022 at 11:30 a.m. record review revealed that the LD did not approve and review the validation for the Micros 60 Analyzer performed on 12/16/2021. 2. The LD confirmed the finding above on 02/15/2022 at 04:00 p.m.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) and College of American Pathologists(CAP) proficiency testing (PT) records and interview with the Laboratory Director (LD), the laboratory director failed to identify problems that required a corrective action for API and CAP PT results for Chemistry and Microbiology in 2020 and 2021. Findings Include: 1. On the day of survey, 02/15/2022, review of API and CAP PT records revealed the following events were not assessed and no corrective actions was documented: - API 2020 Chemistry-Core Event 3: 60% Total Calcium, 20% Chloride . - API 2021 Chemistry-Core Event 3: 20% LDL Cholesterol. - CAP 2020 Routine Microbiology Combination Event B: 90% Agar Diffusion Testing. 2. The LD confirmed the findings above on 02/15/2022 at 04:00 p.m.