Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0175980	01/11/2024
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to provide 6 of 6 attestation statements for chemistry PT events performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 01/11/2024 at 09:00 am, the laboratory failed provide 6 of 6 API PT attestation statements for the following chemistry testing events in 2022 and 2023: - 2022 Chemistry core - 1st, 2nd, and 3rd event - 2023 Chemistry core - 1st, 2nd, and 3rd event 2. The LD confirmed the finding above on 01/11/2024 at 01:30 pm.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on a lack of documentation and interview with the laboratory director (LD), the laboratory failed to retain quality control (QC) documents and patient reports for hematology and virology testing performed in 2022 and 2023. Findings include: 1. On the day of the survey, 01/11/2024 at 11:30 am, the laboratory failed to provide patient reports and QC documentation for the following tests performed in the laboratory in 2022 and 2023. - Prothrombin time international normalized ratio- Coag-Sense Professional Prothrombin Time Test (PT/INR). - Influenza A & B- McKesson Consult Influenza A & B Test. - Covid 19-waived- Quidel Quickvue Covid 19. 2. The laboratory performed 2355 waived testing in 2023 (CMS 116). 3. The LD confirmed the findings above on 01/11/2024 at 01:30 pm.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of analytes that were not evaluated or scored for 4 of 18 Urinalysis, hematology, and microbiology PT events in 2022 and 2023. Findings include: 1. On the day of survey, 10/24/2023 at 12:15 PM, review of the laboratory's CAP PT records revealed that the laboratory did not verify the accuracy for the following events that were not graded due to educational challenge in 2022, and 2023: FH2 A 2022 Blood Cell ID- BCP 06, BCP 07, BCP 08, BCP 09, BCP 10 CM A 2023 Clinical Microscopy- CM01, CM 02, CM 03 RMC A 2023 Routine Microbiology combination - UC 01 RMC B 2023 Routine Microbiology Combination UC 06 2. The LD confirmed the findings above on 01/11/2024 at 04:00 PM.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to document the evaluation and verification activities for 1 of 3 PT testing event in hematology in 2022. Findings include: 1. On the day of survey, 01/11/2024 at 09: 45 am, a review of laboratory's CAP PT records revealed that the laboratory did not document the review and corrective action taken for the following 1 of 3 PT event in 2022 that received an unacceptable score: - FH 2 C 2022 Hematology Auto Differentials- Granulocyte Absolute 2. The LD confirmed the findings above on 01/11 /2024 at 01:30 pm.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of quality control (QC) documents, review of laboratory's procedure and interview with the laboratory director (LD), the laboratory failed to perform and document control procedure using the number and frequency established by the laboratory each day of patient testing for microscopic urinalysis examinations performed in 2022 and 2023. Findings Include: 1. According to laboratory's microscopic urinalysis procedure, visual QC should be performed with each patient testing. 2. On the day of the survey, 01/11/2024 at 12:30 pm, the laboratory could not provide documentation of microscopic urinalysis QC for patient testing performed in 2022 and 2023. 3. The laboratory performed 40062 chemistry and urinalysis testing in 2023. 4. LD confirmed the findings above on 01/11/2024 at 01:30 pm.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records for microbiology media and interview with the laboratory director (LD), the laboratory failed to check and document each batch or shipment of microbiology media for physical characteristics from 02/15/2022 to 01/11/2024. Findings Include: 1. On the day of survey 01/11/2024 at 09:30 am, review of microbiology quality control records revealed, the laboratory did not document the visual checks for each batch or shipment for the following microbiology media from 02/15/2022 to the date of the survey. A. 10 of 10 Shipments of Levine Eosin methylene blue Agar. B. 12 of 12 Shipments of Tryptic Soy Agar. 2. The LD confirmed the findings above on 01/11/2024 around 01:30 pm.
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 review of the laboratory's quality control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to provide documentation of corrective actions taken for QC results that failed to meet the laboratory's established acceptable criteria for hematology testing in 2023 and 2024. Findings Included: 1. On the day of survey, 01/11/2024 at 11:00 am, review of the laboratory's QC records revealed that the QC results for hematology testing performed on the Horiba analyzer failed to meet the laboratory's established acceptable criteria for the following analyte: - White Blood Cell, Red Blood Cell, Platelets - 12/29/2023 - White Blood Cell- 01/09 /2024 2. The laboratory could not provide documentation of the corrective actions taken for QC performed on the Horiba that did not meet the laboratory's established acceptable criteria on 01/09/2024 and 12/29/2023. 3. The LD confirmed the findings above on 01/11/2024 at 01:30 pm.