Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D2257969	**(X3) Date Survey Completed** 05/09/2023
Name of Provider or Supplier United Clinical Lab, Llc	**Street Address, City, State** 4859 Dover Center Rd, Suite 12, North Olmsted, OH	
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 record review and interviews with the Laboratory Owner (LO), the sole Testing Personnel (TP) and the Laboratory Assistant (LA), the Laboratory Director (LD) and TP failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for the only American Proficiency Institute (API) testing event performed since laboratory testing was implemented on 02/01/2023. This deficient practice had the potential to affect 13,000 patient tests performed in this laboratory in the subspecialty of Virology since the implementation of testing on 02/01/2023 through 05/09/2023. Findings Include: 1. Review of the laboratory's "Proficiency Testing Program" policy and procedure, unapproved by the LD and provided for the inspection, found the following statement: "PT program general information... 10. Attestation statement is signed by the laboratory director or qualified designee and all individuals involved in the testing process." 2. Review of the laboratory's 2023 Microbiology first testing event documentation did not find the LD or TP's signature attesting to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods. 3. The LO, TP and LA confirmed that the LD and TP did not attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods. The interviews occurred on 05/09/2023 at 11:20 AM.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Owner (LO), the sole Testing Personnel (TP) and the Laboratory Assistant (LA), the laboratory failed to review and evaluate their reported results from the only American Proficiency Institute (API) testing event, as specified in subpart H of this part, since laboratory testing was implemented on 02/01/2023. This deficient practice had the potential to affect 13,000 patient tests performed in this laboratory in the subspecialty of Virology since the implementation of testing on 02/01/2023 through 05/09/2023. Findings Include: 1. Review of the laboratory's "Proficiency Testing Program" policy and procedure, unapproved by the LD and provided for the inspection, found the following statement: "Evaluation... r. Evaluation report is reviewed by the Lab supervisor, Lab directory [sic] or designee. The results are evaluated as good, acceptable, unacceptable, or not graded. Good and acceptable indicate satisfactory performance. s. Acceptable results should be signed and dated by the laboratory director or designee." 2. Review of the laboratory's 2023 Microbiology first testing event documentation did not find any signature, date and documented evidence of review/evaluation of the scored API results submitted. 3. The LO, TP and LA confirmed that the laboratory did not document their review/evaluation of the first API testing event in 2023 via signature and date. The interviews occurred on 05/09 /2023 at 11:20 AM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 interviews with the Laboratory Owner (LO), the sole Testing Personnel (TP) and the Laboratory Assistant (LA), the Laboratory Director failed to ensure, prior to testing patients' specimens, that the sole TP had appropriate and documented evidence that they had been trained and could perform all testing operations reliably to provide and report accurate results for the high complexity COVID, Influenza A (FluA), Influenza B (FluB) and respiratory syncytial virus (RSV) testing procedures performed. This deficient practice had the potential to affect 13,000 patient tests performed in this laboratory in the subspecialty of Virology since the implementation of testing on 02/01/2023 through 05/09/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director (LD) on 05/11/2023, revealed one individual listed as a TP to perform high complexity PCR COVID, FluA, FluB and RSV testing procedures which were implemented on 02 /01/2023. 2. Review of the laboratory's "Competency and Training" policy and procedure, provided on the date of the inspection revealed the following statements: "a. For testing personnel, prior to starting patient/client testing and prior to reporting patient/client results for new methods or instruments, each individual must have

	training and be evaluated for proper test performance. The records must cover all testing performed by each individual." ..."j. Qualifications of Individuals Assessing Competency i. Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed. ii. The laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel. The required qualifications for the assessor vary by the complexity of the testing." 3. Review of the laboratory's competency assessment documentation for the sole TP found the following: Orientation Checklist - initialed and signed by the TP and signed by the prior LD on 03/08/2023. Training Checklist - only initialed and dated by the TP on "04/21" and did not find any indication of a qualified individual who conducted the assessment. 4. The Inspector requested the laboratory's documentation of training and demonstration of the TP's competence via signature and date from a qualified Technical Supervisor or General Supervisor for the high complexity PCR COVID, FluA, FluB and RSV testing procedures, prior to testing patients' specimens, from the LO, TP and LA. The LO, TP and LA confirmed the laboratory did not document, as required, via signature and date from a qualified individual who assessed the training and demonstration of competence of the TP, prior to testing patients' specimens and were not able to provide the requested documentation on the date of the inspection. The interviews occurred on 05/09/2023 at 11:45 AM.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Owner (LO), the sole Testing Personnel (TP) and the Laboratory Assistant (LA), the Laboratory Director (LD) failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing procedures performed. This deficient practice had the potential to affect all patient tests performed in this laboratory in the subspecialty of Virology since the change in laboratory directorship on 04/03/2023. Findings Include: 1. Review of the laboratory's policy and procedure manual, provided on the date of inspection, did not find the policies and procedures approved via signature and date by the current LD upon the change in directorship on 04/03/2023. 2. The Inspector requested the laboratory's approved policies and procedures by the current LD upon the change in directorship from the LO, TP and LA. The LO, TP and LA confirmed the current LD did not approve all of the laboratory policies and procedures via signature and date upon the change in directorship on 04/03/2023 and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 05/09/2023 at 1:13 PM.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Owner (LO), the sole Testing Personnel (TP) and the Laboratory Assistant (LA), the Technical Supervisor (TS) failed to evaluate and verify the laboratory's established test performance activities for the high complexity Polymerase Chain Reaction (PCR) COVID, Influenza A (FluA), Influenza B (FluB) and respiratory syncytial virus (RSV) testing procedures performed. This deficient practice had the potential to affect 13,000 patient tests performed in this laboratory in the subspecialty of Virology since the implementation of testing on 02/01/2023 through 05/09/2023. Findings Include: 1. Review of the laboratory's "Atila Real Time PCR Procedure for COV/FLU/RSV Detection" and "Validation of iAMP COV/FLU/RSV Detection" policies and procedures, provided for the inspection, did not find any mention of instructions on review and approval of the laboratory's performance validation documentation prior to beginning patient testing. 2. Review of the laboratory's Atila Real Time PCR performance validation documentation did not find any review and approval of the performance validation activities via signature and date by the TS. The signatures of the TP and prior LD were dated 03/08/2023 (5 weeks after patient testing was implemented). 3. The Inspector requested the review and approval documentation, via signature and date of the TS, prior to the implementation of patient testing on 02/01 /2023 from the LO, TP and LA. The LO and LA stated that the TS did review and gave a verbal approval of the performance validation activities, the TS did not physically sign and date the performance validation documentation and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 05/09/2023 at 1:20 PM.