Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2257969	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
United Clinical Lab, Llc	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 an interview with the sole General Supervisor (GS), the Laboratory Director failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for two out of six American Proficiency Institute (API) PT events. This deficient practice had the potential to affect 12,750 out of 12,750 patient tests performed in this laboratory between the 02/28/2024 and 06/26/2024 in the subspecialties of Bacteriology and Virology. Findings Include: 1. Review of the laboratory's "Proficiency Testing Program" policy and procedure, approved via signature and date by the Laboratory Director on 06/20/2024, found the following statement: "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 "SOP-500-A2 Proficiency Testing Management" worksheet procedure, approved via signature and date on 06/20/2024 by the Laboratory Director and provided on the date of the inspection, found the following line item: "Attestation sheets signed by all testing personnel involved and Lab Director? Yes No" 3. Review of the laboratory's 2024 API documentation did not find a Proficiency Testing Management worksheet for the first and second PT events. 4. Further review of the laboratory's 2024 first and second API PT event documentation, provided on the date of the inspection, did not find any attestation signature by the Laboratory Director. 5. The Inspector requested the laboratory's 2024 first and second API PT attestation pages signed by the Laboratory Director from the sole GS. The sole GS confirmed that the Laboratory Director did not attest to the routine integration of proficiency testing (PT) samples into the patient workload using

	the laboratory's routine methods for the 2024 first and second API PT events and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2024 at 2:45 PM.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and an interview with the sole General Supervisor (GS), the laboratory failed to successfully participate in one out of six American Proficiency Institute (API) PT events for influenza A (Flu A) in the subspecialty of Virology. This deficient practice had the potential to affect 1,668 out of 1,668 Flu A tests performed between the 10/09/2024 through 12/04/2024. Findings Include: 1. The laboratory failed to attain an overall testing event score of at least 80% in one out of six American Proficiency Institute (API) PT events for influenza A (Flu A) in the subspecialty of Virology, which is unsatisfactory performance. (Refer to D2056) 2. The laboratory failed to undertake appropriate training, employ the technical assistance and document the remedial action necessary to correct problems associated with one out of six American Proficiency Institute (API) PT events for influenza A (Flu A) testing in the subspecialty of Virology with a score of 60%. (Refer to D2062)
D2056	VIROLOGY CFR(s): 493.831(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole General Supervisor (GS), the laboratory failed to attain an overall testing event score of at least 80% in one out of six American Proficiency Institute (API) PT events for influenza A (Flu A) in the subspecialty of Virology which is unsatisfactory performance. This deficient practice had the potential to affect 1,668 out of 1,668 Flu A tests performed between the 10/09 /2024 through 12/04/2024. Findings Include: 1. Review of the laboratory's 2024 third

	API PT event revealed the laboratory obtained a score of 60% for Flu A. 2. The sole GS confirmed the laboratory's API PT scores of 60% for the third PT event in 2024 for Flu A. The interview occurred on 12/04/2024 at 2:45 PM.
D2062	VIROLOGY CFR(s): 493.831(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole General Supervisor (GS), the laboratory failed to undertake appropriate training, employ the technical assistance and document the remedial action necessary to correct problems associated with one out of six American Proficiency Institute (API) PT events for influenza A (Flu A) testing in the subspecialty of Virology with a score of 60%. This deficient practice had the potential to affect 1,668 out of 1,668 Flu A tests performed between 10/09 /2024 through 12/04/2024. Findings Include: 1. Review of the laboratory's "Proficiency Testing Program" policy and procedure, approved via signature and date by the Laboratory Director and provided on the date of the inspection found the following statements: "t. It is recommended that the laboratory investigate acceptable results that show significant bias or trends. u. Unacceptable indicates the response was not the same as many referees. v. For each unacceptable result, a comprehensive investigation must be done and documented. Lab supervisor initiates the investigation, works with testing personnel to ensures corrective action completion and resolution: i. Review the response form and the worksheets to determine if a clerical error was made. Thaw and retest the frozen specimen, if appropriate. ii. Review QC, PM, calibration, and service logs for the instrument. iii. Cause of the failure should be identified, clerical error, degradation of the PT material, QC out range, Tech error, etc. It is not acceptable to make a general comment, such as random error, without doing a thorough review. iv. If identification of the error cannot be determined, additional PT/validation surveys or alternative assessment should be obtained and analyzed to ensure valid patient results. v. Complete the investigation checklist and document all findings. w. Ungraded results: i. Occasionally, results are not graded because of lack of consensus, because results were submitted after the due date or because results were not submitted. ii. Document explanation using Proficiency Investigation Checklist as if results would not have been acceptable; conduct the same investigation as if they had been graded." 2. Review of the laboratory's 2024 third API PT event revealed the laboratory obtained a score of 60% for Flu A as well as ungraded "Molecular Resist. Genes-UTI" for samples UTI-11, UTI-12, UTI-13, UTI-14 and UTI-15 with no self-evaluations. 3. Further review of the laboratory's 2024 third API PT event for Flu A only found documentation indicating the test system was not overdue for calibration verification, a lot calibration was conducted anyway and then the API samples that originally achieved unacceptable results were retested and found to be acceptable. The documentation review did not find any mention of retraining of the sole testing personnel, the employment of technical assistance or documentation of an extensive evaluation of the problem to correct. 4. The sole GS confirmed the laboratory's API PT scores of 60% for the third PT event in 2024 for

	Flu A, the laboratory lacked a comprehensive investigation per their policy and procedure and the laboratory did not conduct a self-evaluation of the ungraded "Molecular Resist. Genes-UTI" results for UTI-11 through UTI-15. The interview occurred on 12/04/2024 at 2:45 PM.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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 an interview with the sole General Supervisor (GS), the laboratory failed to establish and follow written policies and procedures to assess the competency of the sole Testing Personnel (TP) as well as the sole Technical Supervisor (TS) and sole General Supervisor (GS) based on the responsibilities of each position, at a frequency determined by the laboratory as specified in the personnel requirements in subpart M for the highly complex testing procedures performed in the subspecialties of Bacteriology and Virology. This deficient practice had the potential to affect 38,250 out of 38,250 patient tests performed between 05/10 /2023 through 12/04/2024. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any competency assessment policy and procedure. 2. Review of the laboratory's Form CMS-209, provided on the date of the inspection and approved by the Laboratory Director on 12 /04/2024, revealed one individual qualified and listed by the Laboratory Director to function as the sole high complexity TP and GS and one individual qualified and listed as the sole TS. 3. Review of the laboratory's 2023 and 2024 competency assessment documentation revealed the sole TP began in 03/2024 with their training and initial demonstration of competency conducted on 04/04/2024 by a non-qualified individual who was not listed on the CMS-209. 4. Further review of the laboratory's 2023 and 2024 competency assessment documentation did not find any competency assessments for the sole TS and the sole GS based on the responsibilities of each position. 5. The Inspector requested the laboratory's competency assessment policy and procedure and the 2024 documentation for the sole TP/GS and the 2023 and 2024 documentation for the sole TS from the sole GS. The sole GS confirmed the laboratory did not establish a competency assessment policy and procedure and that their TP initial demonstration of competency was conducted by a non-qualified individual. The sole GS also confirmed there were no 2023 and 2024 TS and 2024 GS competency assessments conducted based on the responsibilities of each position, at a frequency determined by the laboratory and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2024 2: 07 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole General Supervisor (GS), the laboratory failed to monitor and document refrigerator and freezer temperatures, where testing samples, quality controls, calibration materials, kit reagents and solutions are stored, and were consistent with the manufacturer's and the laboratory's instructions for reliable testing procedures performed. This deficient practice had the potential to affect 38,250 out of 38,250 patient tests performed in the subspecialties of Bacteriology and Virology between 05/10/2023 through 12/04/2024. Findings Include: 1. Review of the laboratory's "Atila Real Time PCR Procedure for COV/FLU /RSV Detection" policy and procedure, provided on the date of the inspection, found the following instructions: "All kit reagents should be stored at -20C for long time storage." "Specimens can be stored at room temperature for up to 12 hours or at 4C for up to 48 hours after collection and before sample processing." "Specimens in 1X iAMP Elution Solution (1XES) can be stored at 4C for up to 12 hours after the elution step." C; degrees Celsius 2. Review of the laboratory's "Atila Real Time PCR Procedure for UTI Detection" policy and procedure, provided on the date of the inspection, found the following instructions: "All kit reagents (iAMP-2DSB, UTIPM1, UTIPM2, UTIPM3, UTIPM4, UTIRM, UTIPC and UTINC) should be stored at -20C for long-term storage." 3. Review of the manufacturer's "URINARY TRACT INFECTIONS KIT" instructions, provided on the date of the inspection, found the following instructions: "Storage of Samples "Samples can be stored in an environment with a temperature of 2-8C for up to 72 hours after sampling." 4. Review of the manufacturer's "STI KIT" instructions, provided on the date of the inspection, found the following instructions: "All reagents should be stored at -10~-30C. It is not recommended to store at +4C. Reagents for daily use can be stored at +4C to avoid multiple freezing and thawing." 5. Review of the laboratory's 2023 and 2024 refrigerator and freezer temperature logs, provided on the date of the inspection, revealed the number of days each month that the temperatures were out of the acceptable ranges with no documentation of any corrective action as follows: Refrigerator 06/23 1 out of 22 08/23 3 out of 23 12/23 1 out of 21 03/24 8 out of 21 04 /24 5 out of 22 Freezer 1 08/23 3 out of 23 10/23 8 out of 22 11/23 1 out of 22 12/23 2 out of 21 01/24 6 out of 23 02/24 5 out of 21 03/24 7 out of 21 04/24 11 out of 22 05 /24 8 out of 21 07/24 13 out of 23 08/24 2 out of 22 09/24 3 out of 21 10/24 11 out of 23 11/24 5 out of 22 Freezer 2 01/24 8 out of 23 02/24 6 out of 21 03/24 7 out of 21 04 /24 13 out of 22 05/24 13 out of 21 06/24 12 out of 20 07/24 11 out of 23 08/24 4 out of 22 09/24 12 out of 21 10/24 8 out of 23 11/24 5 out of 22 6. The Inspector requested the laboratory's corrective action policy and procedure and their 2023 and 2024 corrective action documentation for the above listed days of documented unacceptable temperatures from the sole GS. The sole GS confirmed the laboratory did not establish a corrective action policy and procedure to monitor and document temperature conditions consistent with the manufacturer's and the laboratory's instructions. The sole GS further confirmed the laboratory did not document any corrective actions for the unacceptable temperatures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12 /04/2024 at 3:18 PM.
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 an interview with the sole General Supervisor (GS), the Laboratory Director failed to ensure that prior to testing patients' specimens, the sole Testing Personnel (TP) received the appropriate training for the type and complexity of the services offered. The Laboratory Director further failed to ensure the sole TP was assessed by a qualified Technical Supervisor (TS) as required in the personnel requirements in Subpart M and demonstrated that they could perform highly complex testing procedures reliably to provide and report accurate results in the subspecialties of Bacteriology and Virology. This deficient practice had the potential to affect 17,000 out of 17,000 patient tests performed in the subspecialties of Bacteriology and Virology by the sole TP from their start date in 03/2024 through 12/04/2024. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any competency assessment policy and procedure. 2. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 12 /04/2024, revealed one individual qualified and listed by the Laboratory Director to function as the sole high complexity TP and GS and one individual qualified and listed as the sole TS. 3. Review of the laboratory's 2023 and 2024 competency assessment documentation revealed the sole TP began in 03/2024 with their training and initial demonstration of competency conducted on 04/04/2024 by a non-qualified individual who was not listed on the CMS-209. 4. The Inspector requested the laboratory's competency assessment policy and procedure and the 2024 demonstration of competencies of the sole TP assessed by a qualified TS from the sole GS. The sole GS confirmed the laboratory did not establish a competency assessment policy and procedure and that their demonstration of competency was conducted by a non-qualified individual and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2024 2:07 PM.
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 an interview with the sole General Supervisor (GS), the Laboratory Director failed to ensure approved policies and procedures related to competency assessment and corrective action was available to all laboratory personnel. This deficient practice had the potential to affect 38,250 out of 38,250 patient tests conducted in the subspecialties of Bacteriology and Virology from 05/10 /2023 through 12/04/2024. Finding Include: 1. Review of the laboratory's policies and procedures provided on the date of the inspection did not find any policies and procedures related to competency assessment and corrective action. 2. The Inspector requested the laboratory's competency assessment and corrective action policies and procedures approved by the Laboratory Director via signature and date from the sole GS. The sole GS confirmed the laboratory did not establish competency assessment

	and corrective action policies and procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2024 at 2:04 PM.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole General Supervisor (GS), the Technical Supervisor (TS) failed to evaluate and document the competency assessment of the sole Testing Personnel (TP) responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens in the subspecialties of Bacteriology and Virology. This deficient practice had the potential to affect 17,000 out of 17,000 patient tests performed between 04/04/2024 through 12/04/2024. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any competency assessment policy and procedure. 2. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 12/04/2024, revealed one individual qualified and listed by the Laboratory Director to function as the sole high complexity TP and GS and one individual qualified and listed by the Laboratory Director to function as the sole TS. 3. Review of the laboratory's 2024 competency assessment documentation revealed the sole TP began in 03/2024 with their training and initial demonstration of competency conducted on 04/04/2024 by a non-qualified individual who was not listed on the CMS-209. 4. Further review of the laboratory's 2024 competency assessment documentation did not find any semiannual competency assessment for the sole TP. 5. The Inspector requested the laboratory's competency assessment policy and procedure and the 2024 semi-annual documentation for the sole TP from the sole GS. The sole GS confirmed the laboratory did not establish a competency assessment policy and procedure, their TP initial demonstration of competence was conducted by a non-qualified individual and their first semi-annual assessment was not conducted. The sole GS was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2024 2: 07 PM.
D6181	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(6) Each individual performing high complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole General Supervisor (GS), the Testing Personnel (TP) failed to document all corrective actions taken when the refrigerator and freezer temperatures, where testing samples, quality controls, calibration materials, kit reagents and solutions are stored for reliable testing procedures performed, deviated from the manufacturer's and the laboratory's

	instructions. This deficient practice had the potential to affect 38,250 out of 38,250 patient tests performed in the subspecialties of Bacteriology and Virology between 05 /10/2023 through 12/04/2024. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the inspection did not find any corrective action policy and procedure. 2. Review of the laboratory's "Atila Real Time PCR Procedure for COV/FLU/RSV Detection" policy and procedure, provided on the date of the inspection, found the following instructions: "All kit reagents should be stored at -20C for long time storage." "Specimens can be stored at room temperature for up to 12 hours or at 4C for up to 48 hours after collection and before sample processing." "Specimens in 1X iAMP Elution Solution (1XES) can be stored at 4C for up to 12 hours after the elution step." C; degrees Celsius 3. Review of the laboratory's "Atila Real Time PCR Procedure for UTI Detection" policy and procedure, provided on the date of the inspection, found the following instructions: "All kit reagents (iAMP-2DSB, UTIPM1, UTIPM2, UTIPM3, UTIPM4, UTIRM, UTIPC and UTINC) should be stored at -20C for long-term storage." 4. Review of the manufacturer's "URINARY TRACT INFECTIONS KIT" instructions, provided on the date of the inspection, found the following instructions: "Storage of Samples "Samples can be stored in an environment with a temperature of 2-8C for up to 72 hours after sampling." 5. Review of the manufacturer's "STI KIT" instructions, provided on the date of the inspection, found the following instructions: "All reagents should be stored at -10~-30C. It is not recommended to store at +4C. Reagents for daily use can be stored at +4C to avoid multiple freezing and thawing." 6. Review of the laboratory's 2023 and 2024 refrigerator and freezer temperature logs, provided on the date of the inspection, revealed the number of days each month that the temperatures were out of the acceptable ranges with no documentation of any corrective action as follows: Refrigerator 06/23 1 out of 22 08/23 3 out of 23 12/23 1 out of 21 03/24 8 out of 21 04 /24 5 out of 22 Freezer 1 08/23 3 out of 23 10/23 8 out of 22 11/23 1 out of 22 12/23 2 out of 21 01/24 6 out of 23 02/24 5 out of 21 03/24 7 out of 21 04/24 11 out of 22 05 /24 8 out of 21 07/24 13 out of 23 08/24 2 out of 22 09/24 3 out of 21 10/24 11 out of 23 11/24 5 out of 22 Freezer 2 01/24 8 out of 23 02/24 6 out of 21 03/24 7 out of 21 04 /24 13 out of 22 05/24 13 out of 21 06/24 12 out of 20 07/24 11 out of 23 08/24 4 out of 22 09/24 12 out of 21 10/24 8 out of 23 11/24 5 out of 22 7. The Inspector requested the laboratory's corrective action policy and procedure and their 2023 and 2024 corrective action documentation for the above listed days of documented unacceptable temperatures from the sole GS. The sole GS confirmed the laboratory did not establish a corrective action policy and procedure to monitor and document temperature conditions consistent with the manufacturer's and the laboratory's instructions. The sole GS further confirmed the TP did not document any corrective actions for the unacceptable temperatures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/04/2024 at 3:18 PM.