Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2299052	07/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sincera Health Pllc	1518 Washington St, Pella, IA	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory director identifier #1 (LD#1) at 9:40 am on 7/13/2026, the laboratory failed to retain the proficiency testing attestation statements for four out of four proficiency testing events from 1/1/2025 - 7/13/2026. The findings include: 1. The laboratory did not have attestation statements for the following events: *2026 event 1 - microbiology and hematology/coagulation *2025 event 3 - microbiology *2025 event 2 - microbiology and hematology/coagulation *2025 event 1- microbiology 2. At the time of the survey, LD #1 confirmed the laboratory failed to retain to above attestation statements.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by interview with Laboratory Director identifier #1 (LD #1) at 9:40 am on 7/13/2026, the laboratory

	failed to perform a self evaluation when the laboratory received an ungraded PT score from one out of four testing events from 01/01/2025- 7/13/2026. The findings include: 1. For 2026 event 1, the laboratory received an ungraded PT score for QIAstat Enterovirus specimen RSP-04. 2. At the time of the survey, LD #1 confirmed the laboratory did not perform a self evaluation for the ungraded PT test score listed above.
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 proficiency testing (PT) records and confirmed by interview with Laboratory Director identifier #1 (LD #1) at 9:40 am on 7/13/2026, the laboratory failed to take and document corrective action for an unacceptable PT score from one out of four PT testing events from 01/01/2025- 7/13/2026. The findings include: 1. For 2026 event 1 the laboratory received an unacceptable PT score for QIAstat SARS-CoV-2 specimen RSP-5. 2. At the time of the survey, LD #1 confirmed the laboratory did not take and document corrective action for the unacceptable PT test score listed above.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Laboratory Annual Volume and Test List and the GeneXpert System Operator's manual, lack of calibration records and confirmed by interview with laboratory director identifier #1 (LD #1) at 10:54 am on 7/13/2026, the laboratory failed to perform an annual calibration on the Cepheid GeneXpert test system for one out of one year from 1/1/2025 - 12/31/2025. The findings include: 1. The Laboratory Annual Volume and Test List indicated the laboratory used the Cepheid GeneXpert test system to perform Influenza A, Influenza B, SARS CoV-2, Respiratory syncytial virus, Chlamydia trachomatis, Neisseria gonorrhoeae, and Streptococcus group A testing. 2. The GeneXpert System Operator's manual states that test system must be calibrated annually. 3. LD #1 confirmed at the time of the survey, the laboratory did not have calibrations from 1/1/2025 - 12/31/2025 for the Cepheid GeneXpert test system.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observations made during the tour of the laboratory, review of the Laboratory Test List and Annual Volume report, and confirmed by interview with laboratory director identifier #1 (LD #1) at approximately 9:10 am on 07/13/2026, the laboratory failed to perform comparison testing twice annually for three out of three time periods from 01/01/2025 - 7/13/2026 for the analytes: Influenza A, Influenza B, SARS-CoV-2, and Respiratory syncytial virus. The findings include: 1. Observations made during a tour of the laboratory on 7/13/2026 at approximately 9:10 am revealed the laboratory had the QiaStat and Cepheid GeneXpert test systems. 2. The Laboratory Test List and Annual Volume form stated the laboratory performed Influenza A, Influenza B, SARS-CoV-2, and Respiratory syncytial virus on both the QiaStat and Cepheid GeneXpert test systems. 3. At the time of the survey, LD #1 confirmed the laboratory performed the above testing on both analyzers and did not perform comparison testing from 01/01/2025 - 7/13/2026.