Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 16D2204287	**(X3) Date Survey Completed** 02/26/2025
Name of Provider or Supplier Hy-Vee Health Exemplar Care, Plc	**Street Address, City, State** 7300 Westown Parkway, West Des Moines, 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**
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: A. Based on review of the Piccolo operator's manual, lack of maintenance and temperature records and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2025, the laboratory failed to document weekly maintenance as required by the manufacturer for four out of four weeks and document the room temperature for 26 out of 26 days from 2/1/2025 - 2/26/2025. The findings include: 1. The Piccolo operator's manual stated for maintenance the laboratory must clean the external case of the analyzer and display at least weekly. 2. The Piccolo operator's manual stated the operating temperature for the analyzer must be between 15 - 32 degrees Celsius or 59 - 90 degrees Fahrenheit. 3. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not document the required maintenance or operating temperature for the Piccolo. B. Based on review of the OSMO infectious mononucleosis instructions for use, lack of temperature records and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2025, the laboratory failed to document the room temperature for 26 out of 26 days from 2/1/2025 - 2/26/2025. The findings include: 1. The OSMO infectious mononucleosis instructions for use state the test must be stored between 15 - 30 degrees Celsius or 59 - 86 degrees Fahrenheit. 2. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not document storage temperature for the OSMO infectious mononucleosis test kit. C. Based on observations during the survey, review of the Uriscan Optima operator's manual and lack of quality control, calibration, maintenance and temperature records and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2025, the laboratory

failed to document quality controls for one out of one lot number of urine dipsticks, perform calibration for one out of one lot number of urine dipsticks, document daily maintenance and the room temperature for 26 out of 26 days from 2/1/2025 - 2/26 /2025. The findings include: 1. During the survey the laboratory had in use lot number 39307, expiration date 2/28/2025 urine dipsticks. 2. The Uriscan Optima operator's manual stated that two levels of quality controls must be performed with each new shipment of urine dipsticks, every 30 days, with each new bottle of reagent strips, with the training of new operators and whenever test results are in doubt. 3. The Uriscan Optima operator's manual stated the laboratory must calibrate each lot number of urine dipsticks. 4. The Uriscan Optima operator's manual stated the laboratory must clean the strip holder daily or more often if sediment is seen using a soft gauze and distilled water. 5. The Uriscan Optima operator's manual stated the analyzer must be operated at room temperature between 20 - 28 degrees Celsius. 6. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not perform or document quality controls and calibration for lot number 39307, expiration date 2/28/2025 urine dipsticks. The Chief Operating Officer also confirmed the laboratory did not document maintenance or room temperature. D. Based on review of the One Step Urine pregnancy instructions for use, lack of temperature records, and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2025, the laboratory failed to document the room temperature for 26 out of 26 days from 2/1/2025 - 2/26/2025. The findings include: 1. The One Step Urine pregnancy instructions for use state the test must be stored between 4 - 30 degrees Celsius. 2. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not document storage temperature for the One Step Urine pregnancy test kit. E. Based on review of the Quidel Respiratory Syncytial Virus (RSV) instructions for use, lack of temperature records, and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2025, the laboratory failed to document the room temperature for 26 out of 26 days from 2/1/2025 - 2/26 /2025. The findings include: 1. The Quidel RSV instructions for use state the test must be stored between 15 - 30 degrees Celsius. 2. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not document storage temperature for the test kit. F. Based on review of the Quidel Quick Vue Sars Antigen instructions for use, lack of temperature records, and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2025, the laboratory failed to document the room temperature for 26 out of 26 days from 2/1/2025 - 2/26/2025. The findings include: 1. The Quidel Quick Vue Sars Antigen instructions for use state the test must be stored between 15 - 30 degrees Celsius and 59 - 86 degrees Fahrenheit 2. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not document storage temperature for the Quidel Quick Vue Sars Antigen test kit. G. Based on review of the Status Influenza A/B instructions for use, lack of temperature records, and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2025, the laboratory failed to document the room temperature for 26 out of 26 days from 2/1/2025 - 2/26/2025. The findings include: 1. The Status Influenza A/B instructions for use state the test must be stored between 2 - 30 degrees Celsius and 35 - 86 degrees Fahrenheit. 2. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not document storage temperature for the Status Influenza A/B test kit. H. Based on review of the Hemocue Hb801 operator's manual, lack of temperature records and confirmed by interview with the Chief Operating Office at approximately 10:30 am on 2/26/2025, the laboratory failed to document the room temperature for 26 out of 26 days from 2/1 /2025 - 2/26/2025. The findings include: 1. The Hemocue Hb801 operator's manual states the analyzer must be operated between 10 - 40 degree Celsius and 50 - 104 degrees Fahrenheit. 2. At the time of the survey, the Chief Operating Officer

	confirmed the laboratory did not document storage temperature for the Hemocue Hb801 analyzer. I. Based on observations made during the survey, review of the Hemocue Hb201 operator's manual, lack of temperature records, and confirmed by interview with the Chief Operating Officer at approximately 10:30 am on 2/26/2024, the laboratory failed to document the date of open for one out one lot number of microcuvette cartridges and document the room temperature for 26 out of 26 days from 2/1/2025 - 2/26/2025. The findings include: 1. During the survey the laboratory had in use lot number 2409069, expiration date 7/17/2025 of microcuvettes. 2. The Hemocue Hb201 operator's manual stated that the microcuvettes are good for 30 days after opening the microcuvette storage container. 3. The Hemocue Hb201 operator's manual stated the microcuvettes must be stored between 15 - 30 degrees Celsius and 59 - 86 degree Fahrenheit. 4. At the time of the survey, the Chief Operating Officer confirmed the laboratory did not document the date of open for lot number 2409069, expiration date 7/17/2025 of microcuvettes. Additionally, the Chief Operating Officer confirmed the laboratory did not document the storage temperature of the microcucuvettes.