Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2223084	02/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Walgreens #10893	1080 Sw 1st Ave, Canby, OR	

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) 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: Based on interview with the Pharmacy Operations Manager, the Store General Manager and review of Quality Control (QC) and patient records, the laboratory failed to follow the manufacturers package insert for external QC and for testing personnel training for the ABBOTT ID NOW COVID 19 test system. Findings include: 1. The ABBOTT ID NOW Information for use (IFU) states: External Positive and Negative Controls: Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. ID NOW COVID-19 kits contain a PositiveControl Swab and SterileSwabsthat can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab ' s standard Quality Control procedures. 2. Review of QC records and patient results, the laboratory failed to document and perform QC on the ABBOTT ID Now from May 2021 until October 2021. The Pharmacy Operations Manager confirmed that no QC was performed from May 2021 through October 2021 on additional lot numbers and shipments of ID NOW kits. 3. Review of randomly selected patient results revealed the following: Patient # 1, tested 07/06/2021, using test kit lot# 1030453 on instrument #471AD91C, did not have QC performed, positive and negative, for this lot number. Patient #2, tested 07/17/2021, using test kit lot # 157380 using instrument #OC7DE61C, did not have QC performed, positive and negative, performed for this lot number. Patient #3, tested 07/30/2021, using lot number 1018917, using instrument #471AD91C, did not

	have QC performed, performed, positive and negative, for this lot number. Patient #4, tested 08/06/2021, using lot number M161729, using instrument # OC7DE61C, did not have QC performed, positive and negative, for this lot number. 3. Instrument # 471AD91C was taken out of service 10/01/2021 and was replaced with insturment F389E61C 10/11/2021. This instrument was QC'd on 10/11/2021 but not again thereafter. Patient testing was performed on this instrument 1/25/2022 without QC. 4. The Pharmacy Operations Manager and the General Manager both confirmed during interview 2/4/2022 at approximately 1230 pm that they were unaware that QC had to be performed on each new lot and shipment and with each new testing personnel for the ABBOTT ID NOW test system. 5. The manufacturers IFU for the ID NOW COVID-19 test states " is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument. The ID NOW COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization". 6. During survey 2/4/2022, no written record of training for this instrument could be produced for any testing personnel. 7. The Pharmacy Operations Manager and the General Store Manager both confirmed during survey interview that no formal training had been provided, conducted or documented.