

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2269827	(X3) Date Survey Completed 04/13/2023
Name of Provider or Supplier Openloop Healthcare Partners Pc	Street Address, City, State 317 6th Ave Ste 400, 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	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116 form), observations made at the survey and confirmed with the Director of Operations on 4/13/2023 at approximately 10:30 am, the laboratory failed to meet the requirements in subpart B, Certificate of Waiver, which includes making records and reports available to HHS. The findings include: 1. The CMS-116 application listed the facility planned to perform testing using the following waived test systems: *influenza A and B - Seiksui Diagnostic ULTA flu A&B *respiratory syncytial virus - Quick Vue RSV *Streptococcus, group A - Quidel Quickvue Dipstick Strep A *SARS-CoV-2 antigen - Abbott BinaxNow COVID-19 antigen 2. The facility could not provide the manufacturer's instructions for the above test kits. 3. At the time of the survey, the facility did not have any test kits, temperature records or training records available. 4. The Director of Operations stated "the facility stored all test kits in an off site warehouse, the address of the warehouse could not be provided." 5. The facility could not provide information confirming if any testing had occurred in the state of Iowa.</p>
D8100	<p>INSPECTION REQUIREMENTS CFR(s): 493.1771</p> <p>Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection</p>

requirements in 493.1773 and 493.1780, when applicable.

This CONDITION is not met as evidenced by:
Based on review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116 form), observations made at the survey and confirmed with the Director of Operations the laboratory failed to meet the inspection requirements in 493.1773 and 493.1780, refer to D8103.

D8103

BASIC INSPECTION REQUIREMENTS
CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:
Based on review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116 form), observations made at the survey and confirmed with the Director of Operations on 4/13/2023 at approximately 10:30 am, the laboratory failed to make records and reports available during the inspection. The findings include: 1. On 1/11/2023, the surveyor attempted to perform a complaint survey at this facility. The surveyor could not access the physical space due to security and the facility could not be reached by telephone. 2. On 4/13/2023, the surveyor attempted to perform another survey at the same location. 3. At the survey on 4/13/2023, the facility did not make accessible necessary records and reports. Refer to D1001.