

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2073072	(X3) Date Survey Completed 05/13/2021
Name of Provider or Supplier In & Out Clinic	Street Address, City, State 3802 S Medford Drive, Lufkin, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 manufacturer's instructions, patient test records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to include all authorized fact sheets when performing Covid testing using the CareStart COVID-19 Antigen kit for 10 of 10 patient test results reviewed. The findings were: 1. Review of the manufacturer's instructions for use under, "Conditions of Authorization for Laboratory," it stated, "A. Authorized laboratories' using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 2. Review of 10 of 10 patient test results found the laboratory failed to follow the manufacturer's instructions to include CareStart authorized fact sheets with the patient results. 3. The findings were confirmed in interview with testing personnel 1 (as listed on Form CMS-209) on May 13, 2021 at 10:00 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services BD - Becton Dickinson FDA - Food and Drug Administration</p>

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the technical consultant's listed responsibilities, review of the laboratory's personnel records, and confirmed in staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing the competency assessments on 13 of 13 testing personnel competencies reviewed for 2019, 2020, and 2021. The findings were: 1. Review of the technical consultant's assigned responsibilities approved by the laboratory director on January 7, 2021, it stated, " ...Personnel have been appropriately trained and demonstrate competency prior to testing patient specimens." 2. A review of the laboratory's personnel records revealed competency assessment were performed on Testing personnel numbers 2, 3, 4, and 6 as follows: Testing personnel 2 (as listed on Form CMS-209) Date: 07-2019, 08-2020, 04-2021 The competency assessments were documented as being performed by testing personnel 1 Testing personnel 3 (as listed on Form CMS-209) Date: 05-2019, 07-2019, 08-2020, 04-2021 The competency assessments were documented as being performed by testing personnel 1 Testing personnel 4 (as listed on Form CMS-209) Date: 03-2020, 11-2020, 04-2021 The competency assessments were documented as being performed by testing personnel 1 Testing personnel 6 (as listed on Form CMS-209) Date: 07-2019, 08-2019, 08-2020 The competency assessments were documented as being performed by testing personnel 1 3. A review of the personnel records for testing personnel number 1 revealed he did not meet the requirements to be a technical consultant. She did not have a bachelor's degree in a biological, chemical, physical, or medical laboratory science field. 4. The laboratory was asked to provide documentation of the technical consultant performing the competency assessments. No documentation was provided. 5. An interview with testing personnel 1 (as listed on Form CMS-209) on May 13, 2021 at 09:45 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services