

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1010821	(X3) Date Survey Completed 10/31/2022
Name of Provider or Supplier Coastal Bend Oncology	Street Address, City, State 712 Booty Street, Corpus Christi, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS Form 116, laboratory policies, American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview of laboratory personnel, the laboratory failed to ensure proficiency testing samples were entered into patient workload by routine testing methods for 1 of 3 testing events from 2021 (event 3) and 2022 (events 1 and 2). The findings included: 1. Review of the laboratory's submitted CMS Form 116 signed by the laboratory director on October 31, 2022 found the laboratory's hours of operation were as follows: Monday: 0900 - 1700 Tuesday: 1300 - 1700 Wednesday: 0900 - 1700 Thursday: 1300 - 1700 2. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on May 1, 2019 stated, "...PT specimens are to be treated the same as patient samples." 3. Review of the laboratory's API proficiency testing records from 2021 (event 3) and 2022 (events 1 and 2) found the deadline for submission for the 3rd event of 2021 was November 23, 2021. 4. Further review of the laboratory's proficiency testing records found the 3rd event of 2021 was tested as follows: Specimen #: HSY 11 Test Date and Time: 11-08-2021 @2208 Specimen #: HSY 12 Test Date and Time: 11-08-2021 @2212 Specimen #: HSY 13 Test Date and Time: 11-08-2021 @2214 Specimen #: HSY 14 Test Date and Time: 11-08-2021 @ 2215 Specimen #: HSY 15 Test Date and Time: 11-08-2021 @2216 The specimens were tested outside of the laboratory's routine methods. 5. The laboratory was asked to provide documentation of testing the proficiency samples with the laboratory's routine workload. No documentation was provided. 6. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form</p>

CMS-209) on October 31, 2022 at 11:52 hours in her office. Key: CMS - Centers for Medicare and Medicaid Services

D5813

TEST REPORT

CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, review of patient testing records, and confirmed in interview with laboratory personnel, the facility failed to document 2 of 10 patient critical values reviewed in October 2022. The finding included: 1. Review of the laboratory's policy titled "Critical Values" approved by the laboratory director on May 1, 2019 found the laboratory identified the following critical values: WBC 2000 - 20,000 cu.mm HGB 7.5 - 17 g/dl HCT 25 -55 % PLTS 50,000 - 500,000 cu. mm 2. Random review of 10 patient critical values in October 2022 found the following 2 patient critical values were not immediately reported to the provider: Patient Identification #: 5029 Test Date: 10-19-2022 Critical Values: HGB = 6.6 g/dl, HCT 20.7%, Platelets = 30,000 Patient Identification #: 6473 Test Date: 10-20-2022 Critical Values: HGB = 7.1 g/dl 3. The laboratory was asked to provide documentation of immediately alerting the provider of critical values. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on October 31, 2022 at 1227 hours in her office confirmed the findings. Key: WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLTS - platelets g/dl - grams per deciliter cu.mm - cubic millimeters CMS - Centers for Medicare and Medicaid Services