

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0920264	<b>(X3) Date Survey Completed</b> 10/04/2022
<b>Name of Provider or Supplier</b> Southside Medical Clinic	<b>Street Address, City, State</b> 546 West Seminary Drive, Fort Worth, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> 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, training documents, and interview, the laboratory failed to provide documentation of training on the Abbott ID NOW COVID-19 test for four out of ten testing personnel. Findings follow. A. Review of the Abbott ID NOW COVID-19 package insert, Rev. 6 09/2020, stated, "The ID NOW COVID-19 test 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." B. Review of training documents showed no documentation of training for testing personnel #1, 2, 4, and 7. C. Interview with the Clinic Coordinator on October 4, 2022, at 1110 hours in the office confirmed she could not locate the training documents when the test was introduced to the laboratory in 2020.</p>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, interview, and pre-survey paperwork, the laboratory failed to ensure the validation on the Sysmex XN-330 was performed and evaluated for the accuracy, precision, and verifying patient normal ranges for the Complete Blood Count prior to patient testing on March 01, 2022. A. Review of the Sysmex documentation showed there was no validation folder, or documentation of performance specifications except for the reportable range study. B. The validation records were requested on October 4, 2022, at 1130 in the office. Interview with the technical consultant on October 4, 2022, at 1130 in the office acknowledged the instrument was replaced in Nov 2021. The technical consultant called tech support for the validation, but tech support did not have a copy of the validation. Interview with the provider on October 4, 2022, at 1255 in the office acknowledged the first patient test was reported March 1, 2022. C. Review of the CMS form 116 showed an estimated 27000 tests were performed annually.

**D6040**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, interview, and pre-survey paperwork, the technical consultant failed to ensure the validation on the Sysmex XN-330 was performed and evaluated for the accuracy, precision, and verifying patient normal ranges for the Complete Blood Count (CBC) prior to patient testing on March 01, 2022 (refer to D5421).

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

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

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on review of the pre-survey paperwork, interview, and competency evaluations the technical consultant failed to include direct observation of patient testing as part of the evaluation of the competency of testing personnel for 10 of 10 testing personnel performing Complete Blood Counts (CBC) for two of two years reviewed. Findings follow. A. Review of the CMS form 209 showed there were 11 testing personnel. B. Interview with the technical consultant on October 4, 2022, at 0930 in the office as to whether direct observations of patient testing were part of his competency evaluations,

his response was he watched them [testing personnel] while he was here throughout the year. When asked how do you keep up with who you've observed his response was "I don't know how to answer that" and confirmed he used nothing to keep track of who he's observed, or when. C. Review of competency evaluations showed there were 11 current employees performing testing. D. Interview with the Clinic Coordinator on October 4, 2022, at 1230 acknowledged testing personnel #10 on the CMS form 209 was a scribe and verified with the employee via phone call during the survey that she had never performed laboratory testing at this site. E. Review of competency evaluation showed testing personnel #10 had at least three competency evaluations performed 01/17/2022, 01/18/2021, and 01/20/2020, but had never performed any laboratory testing at the site, including for competency. F. Review of the CMS form 116 showed an estimated 27000 tests were performed annually.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of competency evaluations and interview, the technical consultant failed to evaluate and document the performance of individuals responsible for performing Complete Blood Counts (CBC) at least semiannually during the first year the individual tests patient specimens for one of three new employees (see D6047). Findings follow. A. Review of competency evaluations showed one of three employees hired from 07/23/2020 - 07/06/2021 had one semiannual competency evaluation. Testing personnel # 1 as listed on the CMS Form 209 was hired 02/01/2021, was trained 02/16/2021, and had a semiannual competency evaluation on 07/30/2021. The next competency evaluation was performed on 07/25/2021, one year later. B. Interview with the technical consultant on October 4, 2022, at 1020 in the office stated he had not heard of performing two semiannual competency evaluations from the date of hire/training.