

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0698417	(X3) Date Survey Completed 09/17/2020
Name of Provider or Supplier Adc, Pllc, Extended Care At Cedar Bend, The	Street Address, City, State 2400 Cedar Bend Drive 1st Floor, Austin, 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
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: Review of package inserts, policy and procedures, observations, quality control records and interview of facility personnel found that the laboratory failed to follow the manufacturer's instructions when using the Siemens 10 SG Urinalysis Reagent strips. The laboratory failed to test external quality control materials as defined by the manufacturer when using the Siemens 10 SG Urinalysis Reagent strips lot 002064 expiration 2021-08-31. Findings included: 1. Review of the package insert for the Siemens 10 SG urinalysis reagent strips found under the heading QUALITY CONTROL - "Test known negative and positive specimens or controls whenever a new bottle is first opened." 2. Observations made during the tour the laboratory found that the laboratory was currently using Siemens 10 SG Urinalysis Reagent Strips lot 002064 expiration 2021-08-31. The bottle had approximately 20 dipsticks remaining and there was no documentation of the date opened on the bottle. 3. Review of Quality control records for urinalysis testing using the Siemens 10 SG urinalysis reagent strips found no documentation of external quality control materials tested with Lot 002064. 4. Interview of testing person one conducted on September 17, 2020 at 10:13 AM found that external quality control materials were not tested when each new bottle of urinalysis reagent strips is first opened.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Review of Hematology quality control records, maintenance logs, patient test records and interview of facility personnel found that the laboratory failed to test at least two levels of quality control materials on 2 of 92 days between March 1, 2019 and May 31, 2019 when using the Sysmex XP-300 hematology analyzer for Complete Blood Counts (CBC). The findings included: 1. Review of quality control summary logs found no documentation of quality control materials tested on Thursday, March 21, 2019 and Friday, May 24, 2019. 2. Review of maintenance logs found testing person 13 documented performance of quality control for Thursday, March 21, 2019 and Friday, May 24, 2019. Review of patient test records found 10 patient specimens were tested without quality control materials being tested as follows: March 21, 2019 -eight patient specimens were tested patient 882074 patient 1313098 patient 1355878 patient 1272648 patient 1247212 patient 1263218 patient 1169601 patient 802256 May 24, 2019-two patient specimens were tested patient 1278664 patient 1060584 3. Interview of the Technical Consultant conducted on September 17, 2020 at 11:37 AM confirmed the above findings.

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 competency assessments and interview, the technical consultant failed to include direct observation of routine test performance for the Complete Blood Count (CBC) for 7 of 11 personnel with semi-annual and annual competency assessments. Findings follow. 1. Review of the Personnel Assessment forms documenting competency assessments for testing personnel (TP) listed on the CMS form 209 found the technical consultant failed to document the use of direct observation in the following competency assessments: TP 1 was lacking the direct observation from the first semi-annual competency assessment for 2-8/2020 TP 7 was lacking direct observation from the second initial competency assessment for 2-8 /2018 and the 2019 competency assessment TP 8 was lacking direct observation from the second initial competency assessment from 1-7/2018 TP 9 was lacking direct observation from the 2018 competency assessment TP 11 was lacking direct observation from the second initial competency assessment for 11/2018-6/2019. TP 12 was lacking direct observation from the 2019 competency assessment, and TP with the pintails JG not on the CMS209, was lacking the direct observation from 2018. 2. Interview with the technical consultant at 0940 in the office/laboratory acknowledged it was difficult to see a direct observation during the time she is on-site and does request TP to notify her when they have a specimen so that she can observe them testing.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Review of the quality control records, maintenance records, patient test records and interview of facility personnel found that the Technical Consultant failed to ensure that testing personnel performed quality control procedures as documented on the quality control worksheets for each day of patient testing when using the Sysmex XP 300 hematology analyzer.