

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1056727	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Natchez After Hours Clinic, Pllc	Street Address, City, State 46 Seargent Prentiss Drive Suite 101, Natchez, MS	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Policies and Procedure Manual and patient complete blood count (CBC) reports for 9-22-18, 9-23-18 and 12-2-18, the laboratory failed to follow its policy for Cell-Dyn Emerald flags for CBC testing on twenty-five patients on these three days. Findings include: The laboratory policy for "Cell-Dyn Emerald flags indicating a WBC differential" states for flags L1, L2, L3, and L5 to verify the white blood cell (WBC) differential. Review of patient CBC reports for 9-22-18, 9-23-18 and 12-2-18 revealed the following twenty-five patient CBC reports were flagged with L1, L2, or L3 with no verification of the WBC differential: 9-22-18--Patients #39105, #47330, #39854, #458060. 9-23-18--Patients #54868, #91931, #92053, #39854, #28556, #55238, #55975, #57616. 12-2-18--Patients #91582, #92474, #90394, #36986, #92390, #92476, #43552, #88712, #31994, #92477, #38003, #43194, #44244.</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 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.</p>

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records for the Abbott Cell-Dyn Emerald hematology analyzer from 9-1-18 through 12-31-18 and patient electronic medical records, the laboratory failed to include at least two levels of control material each day of patient complete blood count (CBC) testing for two days during this time frame, when a total of fifteen patient CBC tests were performed and reported. Findings include: Review of QC records for the Abbott Cell-Dyn Emerald hematology analyzer from 9-1-18 through 12-31-18 and patient electronic medical records revealed no documentation of performance of at least two levels of control on the following days when patient CBC testing was performed and results reported: 9-22-18--CBC testing performed and results reported for Patients #39105, #91582, #47330, #39854, #458060, #90249. 9-23-18--CBC testing performed and results reported for Patients #54868, #91931, #92053, #39854, #28556, #55238, #55975, #92054, #57616.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records for the Abbott Cell-Dyn Emerald hematology analyzer from 9-1-18 through 12-31-18 and patient electronic medical records, the laboratory failed to ensure at least two levels of control material met the manufacturer's criteria for acceptability on 12-2-18, when a total of fourteen patient complete blood counts (CBC) were performed and results reported. Findings include: Review of QC records for the Abbott Cell-Dyn Emerald hematology analyzer from 9-1-18 through 12-31-18 and patient electronic medical records revealed on 12-2-18, the normal hematology control, of two levels, was outside the manufacturer's acceptable range for red blood cell (RBC) count, when the following patient CBC tests were performed and results reported: Patients #91582, #92474, #90394, #36986, #92390, #92476, #43552, #29722, #88712, #31994, #92477, #38003, #43194, #44244.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Policies and Procedure Manual, quality control (QC) records for the Abbott Cell-Dyn Emerald hematology analyzer from 9-1-18 through 12-31-18, and patient electronic medical records, moderate-complexity testing personnel failed to follow the laboratory's quality control policies for three days during this time frame, when a total of twenty-nine patient complete blood count (CBC) results were reported. Findings include: The Quality Control policy in the Laboratory Policies and Procedure Manual states, "Low, normal, and high QC

samples will be run daily before each shift. If any results are outside of two standard deviations, repeat the sample. If the results remain outside two standard deviations, call technical support and contact the lab director. Notify the practitioner that no lab can be run until the QC error is resolved." Review of QC records for the Abbott Cell-Dyn Emerald hematology analyzer from 9-1-18 through 12-31-18 and patient electronic medical records revealed testing personnel failed to follow the laboratory's QC policy for performing controls on 9-22-18 and 9-23-18 and for ensuring controls were within acceptable range for red blood cell count (RBC) on 12-2-18. A total of twenty-nine patient CBC results were reported on these three days. Refer to D5447 (Failure to include two levels of control material each day of patient CBC testing.) Refer to D5481 (Failure to ensure at least two levels of control material meet the manufacturer's criteria for acceptability each day of patient CBC testing.)