

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0673604	(X3) Date Survey Completed 05/20/2024
Name of Provider or Supplier Janice S Algea, Md	Street Address, City, State 8222 Us Hwy 51 North, Millington, TN	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer's operator's manual, review of the laboratory's environmental records, and staff interview, the laboratory failed to define humidity ranges that were consistent with the Sight OLO Complete Blood Count (CBC) instrument manufacturer's requirements for instrument operation. The findings include: 1. Observation of the laboratory on 05/20/24 at 12:45 p.m. revealed the Sight OLO CBC instrument (Serial #Q821) used for performing patient testing for CBC with automated white blood cell differential (CBC w/diff). 2. A review of the manufacturer's operators manual revealed a humidity range of 20-80% for the operation of the Sight OLO instrument. 3. A review of the laboratory's environmental records revealed a humidity requirement of 10-80%. 4. The laboratory director and technical consultant confirmed the survey findings during interview on 05/20/24 at 2:15 p.m.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and</p>

when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on laboratory observation, review of the manufacturer's package insert, and staff interview, the laboratory failed to label three of three CBC control vials with a corrected expiration date after opening. The findings include: 1. Observation of the laboratory on 05/20/24 at 12:45 p.m. revealed the Sight OLO CBC instrument (Serial #Q821) used for performing patient testing for CBC w/Diff. The controls (three of three) were labeled with an open date of 04/26/24 but no corrected expiration date. Lot numbers observed were OPT2404L, OPT2404N and OPT2404H. 2. A review of the manufacturer package insert revealed the controls were stable for 14 days after opening. 3. The laboratory director and technical consultant confirmed the survey findings during interview on 05/20/24 at 2:15 p.m.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's environmental records and staff interviews, the laboratory failed to perform corrective action for temperatures outside its stated temperature range for five (5) of 24 days in February 2024 and six (6) of 24 days in March 2024. The findings include: 1. A review of the laboratory's environmental records revealed the following dates when the recorded temperatures were outside the laboratory's acceptable range with no corrective action performed: 02/16/24, 02/23/24, 02/24/24, 02/28/24, 02/29/24, 03/07/24, 03/08/24, 03/16/24, 03/18/24, 03/19/24, 03/30/24. 2. The laboratory director and technical consultant confirmed the survey findings on 05/20/24 at 2:15 p.m.