

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0673604	(X3) Date Survey Completed 02/21/2023
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, observation of test performance, record review, record request, review of the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interviews, the laboratory failed to retain Complete Blood Count (CBC) reagent cartridge lot numbers, expiration dates and dates in use for the Sight OLO CBC instrument since patient testing began in June 2021 with approximately 1336 patients reported from June 2021 until the date of the survey on 02/21/23. The findings include: 1. Observation of the laboratory on 02/21/23 at 1:15 pm revealed the Sight OLO CBC instrument (serial #Q821) in use for patient testing. 2. Observation of test performance on 02/21/23 at 1:45 pm revealed the instrument uses individually packaged reagent cartridges. The testing person was observed scanning reagent cartridge information before test performance. 3. Record review revealed patient testing on the OLO Sight CBC instrument began on 06/25/21. 4. Record request on 02/21/23 at 2 pm for reagent lot numbers, expiration dates, and dates in use since patient testing began revealed no records were available. 5. Review of the laboratory's annual test volume as indicated on the Form CMS-116 revealed approximately 891 patients were tested per year, resulting in a calculated number of patients since testing began of approximately 1336. 6. Interviews with the laboratory technical consultant, testing personnel and laboratory director on 02/21/23 at 4:30 pm confirmed the CBC reagent cartridge lot numbers, expiration dates and dates in use</p>

were not retained by the laboratory. The laboratory director further confirmed she called the Sight OLO technical support hotline on 02/21/23 and the support specialist stated there was no way to retrieve the scanned data from the instrument.

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 observation of the laboratory, review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel records and interview with the technical consultant, the technical consultant failed to perform interim competencies during the first year of testing for two of four new testing personnel in 2022. The findings include: 1. Observation of the laboratory on 02/21/23 at 1:15 pm revealed the moderately complex Sight OLO Complete Blood Count (CBC) instrument on the counter in use for patient testing. 2. Review of the Form CMS-209 revealed four new testing personnel listed since the last survey was performed who perform moderately complex patient testing for CBCs on the Sight OLO instrument. 3. Review of testing personnel records revealed no interim competencies were performed for testing personnel numbers three and four during the first year of testing in 2022. 4. Interview with the technical consultant on 02/21/23 at 4:30 pm confirmed the survey findings.