Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0885664	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier Soddy Daisy Family Care	**Street Address, City, State** 2120 Northgate Park Lane, Suite 402, Chattanooga, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: _____ Based on review of the Laboratory's CLIA Personnel Report Form "CMS-209", the 2017 Proficiency Testing (PT) Attestation records for CBC testing and an interview with the primary laboratory person, determined that PT samples were not tested by all personnel listed on the Personnel Report Form-209 for 2017. The findings include: 1. Review of the CLIA Personnel Report Form "CMS-209" revealed seven testing personnel documented. 2. Review of the 2017 Proficiency Testing Attestation records revealed only one of seven testing personnel's signature as testing PT samples. 3. An interview at approximately 4:00 p.m. May 1, 2018 with the primary laboratory person, confirmed she was the only person that tested the CBC PT samples for 2017. _____
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	_____ Based on review of the Quality Assurance (QA) Plan, testing personnel competency records for 2017 and an interview with the primary laboratory person, determined the laboratory failed to follow policy for performing annual competency review for all testing personnel in 2017. The findings include: 1. Review of the QA Plan revealed policy for performing annual competency reviews for all testing personnel. 2. Review of the personnel records revealed testing personnel number one of seven lacked documentation of competency review for performing CBC testing for 2017. 3. An interview at approximately 4:00 p.m. May 1, 2018 with the primary laboratory person, confirmed the 2017 competency review for testing personnel number one of seven was not available for review. _____
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: _____ Based on review of Quality Assurance (QA) Plan, documented QA meetings and interview with the primary laboratory person, determined the laboratory failed to follow policy for quarterly QA meetings for 2017 and 2018. The findings include: 1. Review of the Quality Assurance Plan states that QA meetings are to be held quarterly. 2. Review of documented QA meetings revealed lack of quarterly meeting documentation for 2017 and 2018. 3. Interview at approximately 4:00 p.m. May 1, 2018 with the primary laboratory person confirmed that only 1 QA meeting per year was documented for 2017 and 2018. _____
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: _____ Based on review of the Laboratory's procedure manual, lack of procedures for Complete Blood Count's (CBC's) to include: specimen collection, labeling and processing, alert values, reporting patient results, course of action if test system becomes inoperable and an interview with the primary laboratory person, determined the procedure manual was lacking several key procedures for review on May 1, 2018. The findings include: 1. Review of the Laboratory's Procedure Manual. 2. Lack of procedures for CBC's to include: a. Specimen collection, labeling and processing. b. Alert or panic values c. Reporting patient results d. Course of action to take if CBC test system becomes inoperable. 3. An interview at approximately 4:00 p.m. May 1, 2018 with the primary laboratory person confirmed the procedure manual was lacking several key procedures (as listed above) for review during survey May 1, 2018. _____