

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0940954	(X3) Date Survey Completed 04/20/2023
Name of Provider or Supplier Beacon Health Alliance, Pc	Street Address, City, State 1303 Taft Hwy, Signal Mountain, 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
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's Complete Blood Count (CBC) analyzer calibration procedure, review of the Beckman AcT Diff calibration records, observation of the laboratory and interview with the lead testing person, the laboratory failed to follow their written policy for CBC instrument calibration frequency in 2022. The findings include: 1. Review of the laboratory's AcT diff (CBC analyzer) procedure stated, "Calibrate at least once every six months or after replacing major components that involve the primary measurement characteristics (such as an aperture) or when control values are consistently out of expected assay range." 2. Review of the Beckman AcT diff calibration records revealed calibration was not performed from July 2021 until March 2023, resulting in the laboratory not following their calibration procedure. 3. Observation of the laboratory revealed a Beckman AcT CBC analyzer in use for CBC patient testing. 4. Interview with the lead testing person at approximately 2:00 pm on April 20, 2023 confirmed the laboratory failed to follow their written policy for CBC instrument calibration frequency in 2022.</p>