

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2068695	(X3) Date Survey Completed 03/27/2023
Name of Provider or Supplier Flint Hills Heart, Vascular And Vein Clinic	Street Address, City, State 3905 Vanesta Drive, Manhattan, KS	
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
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based upon review of QC from the last 4 months, 10/1/22 to 2/28/23, test volumes from the CMS116 form and interview with testing personnel (TP) #1 revealed the Technical Consultant (TC) failed to document the review to ensure acceptable levels of analytic performance were maintained for the Abbott i-STAT analyzer. Findings: 1. Examination of the i-STAT analyzer QC logs revealed no written or secure electronic signature of the TC review for 4 months from 10/1/22 to 2/28/23. 2. Review of the CMS116 form provided an estimated patient test volume of 256 chemistry results and 89 hematology results from 10/1/22 to 2/28/23 3. Interview with TP#1 on 3/27/23 at 10:45 a.m. confirmed, the TC failed to document the review to ensure acceptable levels of analytic performance were maintained for the Abbott i-STAT analyzer.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of CMS form 209, competencies, and interview, the technical consultant (TC) failed to evaluate and document competency at least semiannually during the first year the individual tests patient specimens for 1 of 1 new testing personnel (TP). Findings: 1. Review of the site's CMS for 209 for personnel revealed 2 new testing personnel since last survey. One TP had worked at the site for more than 6 months. 2. Review of personnel competency records revealed no semiannual competency was performed by the TC during the first year for TP#5. 3. Interview with the TP #1 on 3/27/23 at 11:30 a.m. confirmed, the technical consultant failed to evaluate and document competency at least semiannually during the first year the individual tests patient specimens for 1 of 1 new TP.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the current CMS-209, lack of documentation and interview, the technical consultant (TC) failed to document the annual competency for 1 of 1 testing personnel (TP). Findings: 1. The CMS-209 document listed 1 person as active testing personnel whom had been testing for more than 1 year. 2. No annual competency document performed by the TC for 2022 on TP #5 was made available at the time of survey. 3. Interview with TP #1 3/27/23 at 11:35 a.m. confirmed, the technical consultant failed to document the annual competency for 1 of 1 testing personnel.