

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2106076	(X3) Date Survey Completed 02/20/2018
Name of Provider or Supplier St Vincent's 119 Health And Wellness	Street Address, City, State 7191 Cahaba Valley Road, Birmingham, AL	
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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the API (American Proficiency Institute) Proficiency Testing (PT) order form, order confirmation, and returned survey results, and an interview with the Manager of the Ambulatory Surgical Center, the surveyor determined the laboratory failed to include the CLIA number on the API order form to ensure API could forward the laboratory's results to the appropriate CLIA State Agency for mandatory review. This affected the survey review period from the previous survey on 6/16/2016 until the day of the current survey. The findings include: 1. A review of the laboratory's API PT order form revealed the space for the CLIA number was blank. 2. A review of the API 2017 Order Confirmation revealed the following comment in bold capitalized letters: "CLIA NUMBER NOT ON FILE-PLEASE CALL CUSTOMER SERVICE AT 800-...". 3. A review of API survey results for the 2016-Events #2 and #3, and 2017-Events #1, #2, and #3 surveys revealed the laboratory's CLIA number was not included on any of the sheets. 4. In an interview on 2/20/2018 at 12:55 PM, the surveyor asked if anyone had noticed the CLIA number was not on the original order form or survey results, and that API had informed the laboratory in the order confirmation the CLIA number was needed. The Manager of the Ambulatory Surgical Center (with the Technical Consultant present) stated she knew the order confirmation need to be retained, but had not noticed the comment concerning the laboratory's CLIA number. Thus the above noted findings were confirmed. .</p>

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on a review of the API (American Proficiency Institute) Proficiency Testing records and an interview with the Technical Consultant, the surveyor determined the laboratory failed to retain program report forms and signed attestation statements for five of five surveys reviewed. The findings include: 1. A review of the API Hematology Proficiency Testing records revealed the following missing documentation for the surveys: A) 2016-Events #2 and #3, and 2017-Events #1, #2, and #3 had no signatures of the Laboratory Director or designee, and no signatures of the testing personnel on the attestation statements. B) 2016-Events #2 and #3, and 2017-Events #1, #2, and #3 included no completed program report forms or printouts of the API on-line submission data. 2. In an interview on 2/20/2018 at 11:25 AM, when asked about the missing proficiency testing records, the Technical Consultant stated all the above records were locked in his office at the main hospital. The surveyor stated she would allow the laboratory to forward the documentation to the CLIA office by Friday 2/23/2018 at 9:00 AM. However, no records were received by the appointed time, thus the above noted findings were confirmed. .

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of the 2016 - 2017 API (American Proficiency Institute) Proficiency Testing records and an interview with the Technical Consultant, the laboratory failed to ensure reviews of five of five of the returned survey results evaluations were documented with a signature and date. The findings include: 1. A review of the API Proficiency Testing records revealed no documentation of review of the returned evaluations for the Hematology 2016-Events #2 and #3, and 2017-Events #1, #2, and #3 surveys. 2. In an interview on 2/20/2018 at 11:25 AM, when asked about the returned proficiency testing results, the Technical Consultant reviewed and confirmed he had failed to document his reviews with his signature. .

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on reviews of the environmental and quality control (QC) logs and the patient results in the Abbott I-Stat (used for Protime and INR testing performed before ambulatory surgical procedures), and interviews with the Technical Consultant, the surveyor determined the laboratory failed to ensure two levels of QC were performed each day of patient testing [Refer to D5447], on I-Stat SN378026 analyzer on which patient testing occurred [Refer to D5465]. For fourteen months (12/27/2016 thru 2/9/2018) the Technical Consultant performed QC off-site using another I-Stat approximately once a month (without implementation of an optional Individualized Quality Control plan). Nineteen patient Protime/INR tests were performed on nineteen days using I-Stat SN378026 during this period with no documentation of QC on this instrument. The facility further failed to monitor and document room temperatures and humidity to ensure the I-Stat was utilized within the environmental parameters specified by the manufacturer [Refer to D5413]. .

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on a lack of the room temperature/humidity records, a review of environmental requirements for the Abbott I-Stat in the System Manual, and interviews with the Technical Consultant and the Manager of the Ambulatory Center, the surveyor determined the laboratory failed to monitor and document room temperature and humidity within the laboratory and surgical areas where nineteen patient tests were performed over a fourteen month period from December 2016 thru February 2018. The findings include: 1. During the entrance interview on 2/20/2018 at approximately 10:15 AM, the surveyor did not observe a thermometer or hygrometer in the laboratory and asked the Manager of the Ambulatory Center and the Technical Consultant if the facility monitored room temperature and humidity in the laboratory and surgical areas (where bed-side patient Protime/INR testing usually occurs). The Manager confirmed she did not because she had not been told it was required. 2. A review of the environmental logs revealed testing personnel only documented the temperatures for the refrigerator used to store I-Stat reagent cartridges. 3. A review of the environmental requirements on page 2-2 in the Abbott I-Stat System Manual, revealed the analyzer should be operated within a temperature range of 16-30 degrees Celsius (61-86 degrees Fahrenheit) and a relative humidity of 90 percent or less. 4.

During a review of the above information in the Abbott I-Stat System Manual on 2/20/2018 at 1:30 PM, the Manager again stated no one had previously told her about the requirement to document the operating environment parameters, and she had not implemented this procedure until the day of the survey. At 2:15 PM, the Technical Consultant reviewed patient results in the I-Stat memory and cited 19 patient PT/INR tests on 19 days had been performed since 12/27/2016. Thus the above noted findings were confirmed. .

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the quality control log and the patient results in the Abbott I-Stat (used for Protime and INR testing performed before ambulatory surgical procedures), and interviews with the Technical Consultant, the surveyor determined the laboratory failed to ensure two levels of quality control (QC) were performed on I-Stat SN (Serial Number) 378026 each day of patient testing. Nineteen patient Protime/INR tests on nineteen days were performed on this analyzer with no QC performed over a fourteen-month period (12/27/2016 thru 2/9/2018). The findings include: 1. A review of the 2017-2018 quality control log for the Abbott I-Stat revealed Protime and INR results of QC performed once a month, with the reagent cartridge lot number, QC lot number and expiration date recorded each day of QC testing. No instrument printouts of the QC data were available because the laboratory had never had a printer for I-Stat SN378026. 2. In an interview with the Technical Consultant on 2/20/2018 at 1:20 PM, the surveyor asked if the laboratory had implemented an optional IQCP (Individualized Quality Control Plan) to allow for decreased QC testing in 2016 and thereafter. The Technical Consultant stated he had considered it, but had never developed an IQCP. He stated once a month he had come to this satellite laboratory with the I-Stat cartridges and QC material, and had performed the QC himself for the testing personnel. He further stated all the QC and patient results data were retained in the I-Stat memory. 3. As the interview continued, the surveyor then asked if she could review the QC data in the I-Stat memory to ensure data in the written log was the same (since there were no instrument printouts). The Technical Consultant stated he would like to step out to locate the data in the I-Stat. 4. The interview resumed at 2:10 PM when the Technical Consultant returned and explained to the surveyor the QC results in the above-mentioned QC log were actually from the I-Stat at the main hospital; he stated he performed the QC on each lot number of Protime cartridges using the hospital I-Stat, and then he would bring the cartridges to the satellite lab approximately once a month. The surveyor then asked if QC had ever been performed using I-Stat SN378026. The Consultant stated QC was performed during the validation (signed by the Laboratory Director on 3/16/2016 and received in the CLIA office in July 2016). The Technical Consultant stated QC was also performed in August 2017, however no record of this QC performed on I-Stat SN378026 was available. 5. When asked how many patient Protime/INR's were performed since the I-

Stat SN378026 had been in use, the Technical Consultant reviewed the patient results in the I-Stat and stated 19 patient tests on 19 days had been performed (12/27/2016 thru 2/9/2018.) Thus the above noted findings were confirmed. .

D5465

CONTROL PROCEDURES

CFR(s): 493.1256(d)(8)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the quality control (QC) log and the patient results in the Abbott I-Stat (used for Protime and INR testing performed before ambulatory surgical procedures), and interviews with the Technical Consultant, the surveyor determined the laboratory failed to ensure QC was performed on the reagent cartridges in the analyzer on which patient testing occurred [I-Stat SN (Serial Number) 378026]. Nineteen patient Protime/INR tests on nineteen days were performed on this analyzer with no QC performed over a fourteen-month period (12/27/2016 thru 2/9/2018). The findings include: 1. A review of the 2017-2018 quality control log for the Abbott I-Stat revealed Protime and INR QC results performed once a month, with the reagent cartridge lot number, QC lot number and expiration date recorded each day of QC testing. No instrument printouts of the QC data were available because the laboratory had never had a printer for I-Stat SN378026. 2. In an interview on 2/20/2018 at 1:20 PM, the Technical Consultant stated once a month he had come to this satellite laboratory with the I-Stat cartridges and QC material to perform the QC himself. He further stated all the QC and patient results data were retained in the I-Stat memory. 3. As the interview continued, the surveyor then asked if she could review the QC data in the I-Stat memory to insure data in the written log was the same (since there were no instrument printouts). The Technical Consultant stated he would like to step out to locate the data in the I-Stat. 4. The interview resumed at 2:10 PM when the Technical Consultant returned and explained to the surveyor the QC results in the above-mentioned QC log were actually from the I-Stat at the main hospital; he stated he performed the QC on each lot number of Protime cartridges using the hospital I-Stat, and then he would bring the cartridges to the satellite lab approximately once a month. The surveyor then asked if QC had ever been performed using I-Stat SN378026 since it is the instrument utilized for patient testing at this facility. The Consultant stated QC was performed during the validation before patient testing began (signed by the Laboratory Director on 3/16/2016 and received in the CLIA office in July 2016). The Technical Consultant stated QC was also performed in August 2017, however no record of this QC performed on I-Stat SN378026 was available. 5. When asked how many patient Protime/INR's were performed since the I-Stat SN378026 had been in use, the Technical Consultant reviewed the patient results in the I-Stat and stated 19 patient tests on 19 days were performed between 12/27/2016 thru 2/9/2018, with no documentation of QC performed during this period. Thus the above noted findings were confirmed. .

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 lack of quality assurance documentation and interviews with the Technical Consultant, the surveyor determined the laboratory failed to implement effective timely quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of laboratory records revealed the facility had failed to implement a quality assurance program to ensure the quality of patient results. There was no documentation of quality assurance reviews performed or initiation of corrective action for problems found during the survey in the following areas: A) Failure to ensure the proficiency testing results were forwarded to the CLIA State Agency for mandatory review by including the CLIA number on the initial API (American Proficiency Institute) proficiency testing order; the laboratory further failed to review the order confirmation which requested this information. (Refer to D2005.) B.) Failure to implement a mechanism to ensure all required proficiency testing records were retained on site for at least two years, and also to ensure there was documentation of the Laboratory Director/Technical Consultant's review of the returned results evaluations (Refer to D2015 and D5211.) C.) Failure to monitor and document room temperatures and humidity to ensure the I-Stat was utilized within the environmental parameters specified by the manufacturer (Refer to D5413). D.) Failure to implement an optional Individualized Quality Control Plan or ensure two levels of QC were performed each day of patient testing (refer to D5447), on the I-Stat SN378026 analyzer on which patient testing occurred (refer to D5465). For fourteen months (12/27/2016 thru 2/9/2018) the Technical Consultant performed QC off-site using another I-Stat approximately once a month (without implementation of an optional Individualized Quality Control plan). Nineteen patient Protime/INR tests were performed on nineteen days using I-Stat SN378026 during this period with no documentation of QC on this instrument; there was no documentation of review by the Laboratory Director or attending physician, or corrective actions for these patients. 2. During the exit summation on 2/20/2018 at approximately 3:00 PM, these concerns were discussed with the Technical Consultant.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on reviews of the quality control (QC) log and the patient results in the Abbott I-Stat (used for Protime and INR testing performed before ambulatory surgical procedures), and interviews with the Technical Consultant, the Laboratory Director failed to ensure two levels of QC were performed each day of patient testing [Refer to D5447], on I-Stat SN378026 analyzer on which patient testing occurred [Refer to

D5465]. For fourteen months (12/27/2016 thru 2/9/2018) the Technical Consultant performed QC off-site using another I-Stat approximately once a month (without implementation of an optional Individualized Quality Control Plan). Nineteen patient Protime/INR tests were performed on nineteen days using I-Stat SN378026 during this period with no documentation of QC on this instrument. .

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on reviews of proficiency testing and quality control (QC) records, a lack of quality assurance reviews, and interviews with the Technical Consultant, the surveyor determined the Technical Consultant failed to adequately fulfill his responsibilities to provide effective technical and scientific oversight of the laboratory. The findings include: 1. Refer to D6036. .

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on reviews of proficiency testing and quality control (QC) records, a lack of quality assurance reviews, and interviews with the Technical Consultant, the surveyor determined the Technical Consultant failed to adequately fulfill his responsibilities to provide effective technical and scientific oversight of the laboratory. The findings include: 1. A review of laboratory processes revealed the Technical Consultant had failed to provide effective technical and scientific oversight in the following areas: A) Failure to ensure the proficiency testing (PT) results were forwarded to the CLIA State Agency for mandatory review by including the CLIA number on the initial API (American Proficiency Institute) PT order, and further failing to review the order confirmation which requested this information. (Refer to D2005.) B.) Failure to implement a mechanism to ensure all required proficiency testing records were retained on site for at least two years, and also to ensure there was documentation of the Laboratory Director or Technical Consultant's review of the returned results evaluations (Refer to D2015 and D5211.) C.) Failure to ensure testing personnel monitored and documented room temperatures and humidity to ensure the I-Stat was utilized within the environmental parameters specified by the manufacturer (Refer to D5413). D.) Failure to implement an optional Individualized Quality Control Plan or ensure two levels of QC were performed each day of patient testing (refer to D5447), on the I-Stat SN378026 analyzer on which patient testing occurred (refer to D5465). For fourteen months (12/27/2016 thru 2/9/2018) the Technical Consultant performed QC off-site using another I-Stat approximately once a month (without implementation of an optional Individualized Quality Control plan). Nineteen patient Protime/INR tests were performed on nineteen days using I-Stat SN378026 during this period with no documentation of QC on this instrument. E.) Failure to implement effective quality

assessment reviews to identify and correct problems identified in the analytical systems. (Refer to D5791.) 2. During the exit summation on 2/20/2018 at approximately 3:00 PM, these concerns were discussed with the Technical Consultant. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor