

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2228778	(X3) Date Survey Completed 06/30/2022
Name of Provider or Supplier Vital Physician Services, Pllc DbA Evolution	Street Address, City, State 3720 Gattis School Road, Suite 800, Round Rock, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the laboratory failed to ensure testing personnel signed the attestation statement attesting that PT samples were tested in the same manner as patient specimens for Testosterone (Testo) and Prostate Specific Antigen (PSA) for two of two events reviewed. Findings follow. A. Review of the American Academy of Family Physicians 2022 A & B* events showed the attestation statements had the name of the testing personnel written in the Laboratory Director's handwriting. B. Interview with the Laboratory Director on June 28, 2022 at 1050 hours confirmed he had written in the name of the testing personnel for the attestation statement, and that the testing personnel had signed the results evaluation page [for 2022 A event]. * Results had not been received for the 2022 B event.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of</p>

the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, interview, and pre-survey paperwork, the laboratory failed to follow manufacturer's instructions of allowing cartridges to warm to room temperature prior to testing for Testosterone and Prostate Specific Antigen (PSA) on the FrenD Nano Entek for two of two months reviewed. Findings follow. A. Manufacturer's Instructions: 1. Review of the Testosterone package insert, revised 05/2022, under Specimen Processing at Preparation stated, "Allow the tubes and the sealed pouches containing the cartridges to come to room temperature for 15 - 30 minutes prior to the start of the testing sequence." Under Warnings and Precautions stated, "Allow sealed cartridges to come to room temperature for approximately 15 - 30 minutes prior to use." 2. Review of the PSA plus package insert, revised 02/02/2021, under Specimen Processing at Preparation stated, "Remove from the refrigerator sufficient cartridges of FrenD PSA Plus to test the number of patient samples and required external quality control material. Allow the cartridges to come to room temperature for 15 - 30 minutes prior to the start of the testing sequence." Under Warnings and Precautions stated, "Allow cartridges to come to room temperature for 15 - 30 minutes prior to use." B. Interview with testing personnel #2 as listed on the CMS form 209, on June 28, 2022 at 1115 hours in the laboratory acknowledged she pulls the cartridge out of the refrigerator a minute before performing the test. Interview with the Laboratory Director on June 28, 2022 at 1120 hours acknowledged that [cartridges could be pulled from the refrigerator and run right away] was a selling point by the manufacturer. C. Review of the CMS form 116 showed the laboratory's annual test volume was 1500 and testing began May 1, 2022.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of validation records, interview, and pre-survey paperwork, the laboratory failed to verify the performance specifications for Testosterone (Testo), Prostate Specific Antigen (PSA), and Sex Hormone Binding Globulin (SHBG) on the Qualigen FastPack and Testosterone and Prostate Specific Antigen (PSA) normal ranges on the FrenD Nano Entek for two of two test systems used from Oct 2021 to June 2022. Findings follow. A. Verification of performance specifications: 1. Review of the validation for Testo, PSA, and SHBG on the Qualigen FastPack used from Oct 8, 2021 to April 30, 2022 showed no calculations for precision and accuracy, and no verification of the normal range. Precision, accuracy, and normal range study were

requested on June 28, 2022 at 1000 hours but not provided. 2. Review of the validation for Testo and PSA on the Frennd Nano Entek used from May 1, 2022 to June 28, 2022 showed no verification of the normal range. The normal range study was requested on June 28, 2022 at 1000 hours but not provided. B. Phone interview with the Laboratory Director on June 30, 2022 at 1230 could not locate the validation study for the Qualigen or the normal range study for the Frennd. C. Review of the CMS form 116 showed the laboratory's annual test volume was 1500.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on review of the calibration verification, interview, and pre-survey paperwork, the laboratory failed to perform calibration verification every six months for Testosterone (Testo), Prostate Specific Antigen (PSA), and Sex Hormone Binding Globulin (SHBG) on the Qualigen FastPack for one of two events reviewed. Findings follow. A. Review of calibration verification showed one performed at installation in Sept 2021 on the Qualigen FastPack for Testo, PSA and SHBG. Six-month calibration verifications were requested on June 28, 2022 at 1000 hours. B. Interview with the Laboratory Director on June 28, 2022 at 1000 hours acknowledged calibration verifications were with the validations. C. Review of the CMS form 116 showed the laboratory's annual test volume was 1500.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, interview, and pre-survey paperwork, the Laboratory Director failed to ensure the laboratory followed

manufacturer's instructions of allowing cartridges to warm to room temperature prior to testing for Testosterone and Prostate Specific Antigen (PSA) on the FrenD Nano Entek for two of two months reviewed (refer to D5311).

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on review of validation records, interview, and pre-survey paperwork, the Laboratory Director failed to ensure the laboratory verified the performance specifications for Testosterone (Testo), Prostate Specific Antigen (PSA), and Sex Hormone Binding Globulin (SHBG) on the Qualigen FastPack and Testosterone and Prostate Specific Antigen (PSA) normal ranges on the FrenD Nano Entek for two of two test systems used from Oct 2021 to June 2022 (refer to D5421).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and interview, the Laboratory Director failed to ensure testing personnel signed the attestation statement attesting that PT samples were tested in the same manner as patient specimens for Testosterone (Testo) and Prostate Specific Antigen (PSA) for two of two events reviewed (refer to D2009).

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of training records and interview, the laboratory failed to provide documentation of training for Testosterone and Prostate Specific Antigen (PSA) using the FrenD Nano Entek for two of three testing personnel reviewed. Findings follow. A.

Review of training records showed no documentation of training for testing personnel #2 & #3 listed on the CMS form 209. B. Interview with the Laboratory Director on June 28, 2022 at 0945 hours confirmed there was no documentation of training.