Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2302248	09/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Health Consultants	1960 Gallows Road, #310, Vienna, VA	

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	An announced CLIA recertification survey was conducted at Virginia Health Consultants dba True Vitality on September 15, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The specific deficiencies cited are as follows:
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of laboratory forms, calibration records for the Qualigen FastPack IP analyzer, lack of documentation and an interview, the laboratory failed to follow their established policy and perform calibration verification at least every six months for the Prostate Specific Antigen (PSA) and Testosterone

	(Testo) analytes during the nineteen months reviewed (Review timeframe February 2025 to September 2026) The findings include: 1. During a laboratory tour on September 15, 2026, at 9:00 AM, the surveyor noted a Qualigen Fast Pack analyzer in use for patient PSA and Testo testing. 2. Review of the Qualigen FastPack IP chemistry analyzer's calibration records from February 2025 until September 2026 (19-month timeframe) revealed PSA and Testo calibrations were completed with two (2) point calibrations. 3. The surveyor requested to review the every six-month calibration verification documentation for PSA and Testo analytes. The laboratory provided calibration verification documentation for review as listed below: PSA-01/07 /2025, 03/23/2026, 06/02/2026, and 09/10/2026; Testo-01/07/2025, 03/23/2026, 06/04 /2026 and 09/10/2026. The surveyor requested to review additional calibration verification documentation for PSA and Testo for calendar year 2025. The laboratory provided no additional calibration verification documents for review. 4. Review of the laboratory's FastPack forms revealed the following statements, "PSA-Verify Reportable Ranges (Calibration Verifications) every 6 months. Verify that the FastPack IP System is accurate to the limits of the reportable range specified by Qualigen, Inc by using the FastPack IP PSA Method Verification Kit." and "Testosterone-Verify Reportable Ranges (Calibration Verifications) every 6 months. Verify that the FastPack IP System is accurate to the limits of the reportable range specified by Qualigen, Inc by using the FastPack IP Testosterone Method Verification Kit." 5. In an exit interview with the Clinical Manager on September 15, 2026 at 12: 30 PM, the above findings were confirmed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, QC records, lack of documentation, and interviews, the laboratory failed to establish a policy to evaluate quality control results to identify shifts and/or trends for the Qualigen FastPack IP analyzer's quality control materials for nineteen (19) of 19 months reviewed (review timeframe February 2025 until September 2026). The findings include: 1. Review of the laboratory's policies revealed a lack of a policy establishing the performance of statistical analysis to identify shifts and/or trends for the Qualigen FastPack IP analyzer's quality control materials. 2. Review of the QC records for the Qualigen FastPack IP analyzer from February 2025 until September 2026 (19 months) revealed a lack of documentation of the evaluation of the Qualigen FastPack QC for the identification of shifts and/or trends. The surveyor requested to review the Qualigen FastPack QC's statistical analysis for each of the 19 months reviewed. The laboratory provided no documentation for review. 3. In an interview with Clinical Manger on September 15, 2026, at 11:00 AM, the Clinical Manager stated, "We do not perform statistical analysis of the QC. The laboratory director reviews the QC with the

	monthly Quality Assurance Assessment review." 4. Review of the laboratory's "Quality Assurance Assessment" monthly worksheets from February 2025 to September 2026 revealed no evidence of control result evaluation for shifts and/or trends. The monthly worksheets were signed as reviewed by the laboratory director and with no deviations or corrective actions noted for the 19 months reviewed. 5. In an exit interview with the Clinical Manager on September 15, 2026, at 12:30 PM, the above findings were confirmed.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, lack of documentation, and interviews, the laboratory director (LD) failed to provide documentation of onsite visits with evidence of performing oversight director duties during the nineteen (19) of 19 months reviewed (timeframe: February 2025 to September 2026). The findings include: 1. A review of the laboratory's records revealed a lack policy or documentation of LD onsite visits at least once every six months from February 2025 to September 2026. The surveyor requested to review documentation of LD onsite visits. The laboratory provided no documentation for review. 2. In an interview with the Clinical Manager on September 15, 2026, at 11:00 AM, the surveyor inquired with the Clinical Manager regarding the laboratory's policy for the documentation of LD oversight onsite visits. The Clinical Manager stated, "We do not have a policy or form for the documentation of the LD visits. We can provide plane tickets and/or hotel receipts. Those documents are not available today." 3. In an exit interview with the Clinical Manager on September 15, 2026, at 12:30 PM, the above findings were confirmed. .