

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2299863	<b>(X3) Date Survey Completed</b> 04/22/2026
<b>Name of Provider or Supplier</b> Oracle Heart & Vascular, Inc	<b>Street Address, City, State</b> 1011 Care Way, Suite 200, Fredericksburg, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Oracle Heart & Vascular, Inc on April 22, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Oracle Heart & Vascular, Inc was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions: D5400 - 42 CFR 493.1250 Condition: Analytic Systems D6000 - 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director
<b>D2014</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b></p> <p>(b)(6) 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to follow their established PT policy to retain the PT agency's submission forms for four (4) of four Chemistry PT events from November 2024 through the date of the survey on April 22, 2026. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation from November 2024 through the date of the survey on April 22, 2026, revealed signed attestation statements and instrument printouts for 2025 API Chemistry Core Events 1, 2, 3 and 2026 API Chemistry Core Event 1. Further review of the laboratory's PT records revealed a lack of result submission</p>

forms for the PT events listed above. The surveyor requested to review the documentation listed above. The laboratory provided no documentation for review. 2. Review of the laboratory's policy and procedure manual revealed a policy, "XII. Proficiency Testing", with the statement, "B. Once test results are obtained, the results must be submitted to the proficiency agency within the allotted time. The preferred method is by online submission of results, but results may be mailed or faxed. Copies must be kept of the reports, and the attestation statement must be signed by the person (s) performing the tests." 3. In an exit interview with the Clinical Manager on April 22, 2026, at 11:05 AM, the above 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 laboratory's policies and procedures, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to follow their established policy to retain and review PT evaluations for four of four Chemistry PT events from November 2024 through the date of the survey on April 22, 2026. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation from November 2024 through the date of the survey on April 22, 2026, revealed signed attestation statements and instrument printouts for 2025 API Chemistry Core Events 1, 2, 3 and 2026 API Chemistry Core Event 1. Further review of the laboratory's PT records revealed a lack of PT evaluation forms and documentation of the review of results for the PT events listed above. The surveyor requested to review the documentation listed above. The laboratory provided no documentation for review. 2. Review of the laboratory's policy and procedure manual revealed the "Laboratory Director Requirements" with the statement, "The laboratory director must- ...D. Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that -- ...c. All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action ..." 3. In an exit interview with the Clinical Manager on April 22, 2026, at 11:05 AM, the above findings were confirmed.

**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 a review of the laboratory's policies and procedures, Quality Control (QC) documents, Quality Assessment (QA) documentation and interviews, the laboratory failed to follow their established: 1. IQCP/QC plan for the Abbott iSTAT Chem8+

cartridge and perform two levels of QC with each new lot number or shipment of cartridges for two (2) of five (5) new lot numbers/shipments of Chem8+ cartridges (refer to D5445). 2. QA plan to document monthly supervisory reviews for sixteen (16) of seventeen (17) months from November 2024 until April 2026 (refer to D5793).

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

(d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on a tour of the laboratory, review of the laboratory's policy and procedure manual, Individualized Quality Control Plan (IQCP), quality control (QC) records, patient test logs, and interview, the laboratory failed to follow their established IQCP /Quality Control policy for the Abbott iSTAT Chem8+ cartridge and perform two levels of QC with each new lot number or shipment of cartridges for two (2) of five (5) new lot numbers/shipments of Chem8+ cartridges with seventeen (17) patients resulted. Review timeframe: November 2024 through the date of the survey on April 22, 2026. The findings include: 1. During a tour of the laboratory on April 22, 2026 at 9:10 AM, the surveyor noted the laboratory utilizes the Abbott iSTAT System with Chem8+ cartridge to test patient specimens for Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Glucose (Gluc), Blood Urea Nitrogen (BUN), Total Carbon Dioxide (TCO2), Creatinine (Cre), Hematocrit (HCT), Hemoglobin (Hgb) and Anion Gap (AG). 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) and QC policy revealed the statement, "QUALITY CONTROL-EXTERNAL-- For Chem8+ cartridges (with Hgb and HCT), validation must be completed by analysis with iSTAT Tri level 1 and Level 3 control performed: With each new lot number or shipment of cartridges. Anytime the performance of the instrument is questionable. Print results and file on QC form." 3. Review of the "iSTAT Shipping Log" and Chem8+ QC records revealed 5 new lots/shipments of the Chem8+ cartridge were received on 11/08/2024, 04/16/2025, 07/15/2025, 12/04/2025 and 03/02/2026. 4. Review of the iSTAT Chem 8+ QC records revealed: Two levels of Tricontrol (1 & 3) were performed/documented on 11/08/2024, 04/16/2025, and 03/03/2026; One Tricontrol Level 1 was performed/documented on 07/17/2025 and one Tricontrol Level 3 was performed/documented on 12/05/2025. The surveyor requested to review documentation of the Tricontrol Level 3 for 07/15/2025 and the Tricontrol Level 1 QC for 12/05/2025. The laboratory provided no documentation for review. 5. Review of the patient test logs from 07/16/2025 to 03/02/2026 revealed seventeen (17) patients were tested for Na, K, Cl, iCa, Gluc, BUN, TCO2, Cre, HCT, Hgb and AG. 6. In an exit interview with the Clinical Manager on April 22, 2026, at 11:05 AM, the above findings were confirmed.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policies and procedures, Quality Control (QC) records, Quality Assessment (QA) records, lack of documentation and interview, the laboratory failed to follow their established QA plan to document monthly supervisory reviews for fifteen (15) of seventeen (17) months from November 2024 until April 2026. The findings include: 1. Review of the laboratory's QA Plan revealed the following statements, "QA REVIEW PROCESS-Our QA Plan consists of a series of scheduled reviews that address all aspects of the testing process... DOCUMENTATION-All QA Activities are fully documented for a minimum of two years. A Laboratory Quality Assurance--General Form is used to document most QA efforts. In addition to the general form, there are four Supervisory Monthly Checklists...The checklists are used to document supervisory oversight...and include:: Patient Test Management--Annual Chart Audit Record, Proficiency Testing Review Form, Maintenance, Calibration, and Quality Control--Review Form, Communications, Complaints, Problems and Personnel--Review Form." 2. A review of the laboratory's QA Review forms revealed "Laboratory Quality Assurance--General Form and Supervisory Checklist" labeled as "December 2025". Further review of the laboratory's QA Review forms revealed a lack of documentation of the General Form and Supervisory Monthly Checklists from November 2024 to November 2025 (12 months) and January 2026 until March 2026 (3 months). A total of 15 months lacked the General Form and Monthly checklist. The surveyor requested to review the "Laboratory Quality Assurance--General Forms and Supervisory Monthly Checklists" for the above listed months. The laboratory provided no additional checklists to review. 3. In an exit interview with the Clinical Manager on April 22, 2026, at 11:05 AM, the above findings were confirmed.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's Proficiency Testing (PT) records, Quality Control records, Quality Assessment (QA) checklists, Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CMS 209), personnel files, policies and procedures, lack of documentation and interview, the laboratory director failed to: 1. follow the laboratory's established policy to document the review of the laboratory's performance in Chemistry PT events for four (4) of 4 PT events (refer to D6018). 2. ensure the current PT, QC, and QA policies were followed to identify and correct quality issues in the specialties of Chemistry and Hematology for the 18 months reviewed. (refer to D6020). 3. ensure retention of education documentation for

two (2) of 5 testing personnel (refer to D6029). 4. follow an established policy for performing annual competency assessment for one (1) of 5 of testing personnel performing moderate complexity patient testing (refer to D6030).

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, Proficiency Testing (PT) documentation and an interview, the laboratory director (LD) failed to follow the laboratory's established policy to document the review of the laboratory's performance in Chemistry PT events for four (4) of 4 events from November 2024 through the date of the survey on April 22, 2026. (Refer to D5211.)

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, Proficiency Testing (PT) records, Quality Control (QC) and Quality Assurance (QA) logs, lack of documentation, and interviews, the laboratory director failed to ensure that the current PT, QC, and QA policies were followed to identify and correct quality issues in the specialties of Chemistry and Hematology for the 18 months reviewed (Refer to D2014, D5211, D5445, and D5793.)

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CMS 209), personnel files, policy, lack of documentation and interview, the laboratory director failed to ensure retention of education documentation for two (2) of 5 testing personnel (TP). (See Personnel Code Sheet.) Findings include: 1. Review of the survey CMS 209 revealed the laboratory director identified 5 TP trained to perform moderate complexity patient testing. 2. Review of the available laboratory employee personnel files revealed TP #2 and TP #3 files contained initial training records. The inspector noted TP #2, and TP #3's files

lacked a record of education. The surveyor requested to review documentation of education qualifications for the above listed TP. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed a Training and Competency policy that specified that personnel High School diplomas, GEDs, or degrees are to be retained in the employee files. 4. In an exit interview with the Clinical Manager on April 22, 2026 at 11:05 AM, the above findings were confirmed.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), personnel records, policies and procedures, lack of documentation and interview, the laboratory director failed to follow an established policy for performing annual competency assessment for one (1) of five (5) testing personnel (TP) performing moderate complexity patient testing. (See Personnel Code sheet.) Findings include: 1. Review of the CMS 209 form revealed the laboratory director identified 5 TP responsible for moderate complexity patient testing. 2. Review of the laboratory's personnel records revealed a lack of the 2025 annual competency assessments for TP #1. The surveyor requested documentation of the annual competency assessments for TP #1. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed a Training and Competency policy for performing TP competencies on an annual basis and retained in the employee files. 4. In an interview with the Clinical Manager on April 22, 2026 at 11:05 AM, the above findings were confirmed.