

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2122986	<b>(X3) Date Survey Completed</b>  03/13/2026
<b>Name of Provider or Supplier</b>  Beaumont Heart & Vascular Center	<b>Street Address, City, State</b>  755 North 11th Street, Suite P3970-A, Beaumont, TX	
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 Validation survey of the laboratory was conducted on 03/13/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's submitted "Laboratory Personnel Report (CLIA)" - Form CMS-209, personnel records, policies/procedures and staff interview, the laboratory failed to ensure technical consultant's competency assessment was documented for one of three of the laboratory's technical consultants, Technical Consultant number three. Findings included: 1. Review of laboratory's submitted Form CMS-209 revealed the laboratory employed three Technical Consultants. 2. Review of laboratory's personnel records revealed Technical Consultant number three (as indicated on submitted Form CMS-209) did not have documentation of competency assessment for this position. 3. Review of laboratory's "General Laboratory Policies" (document: Reference #001, last reviewed: 01/06/2026) revealed: "All technical personnel will participate in competency assessment program." However, the laboratory did not have written protocols in place addressing the specific requirements for competency assessment of Technical Consultants. 4. In an interview on 03/13/2026 at 1130 hours in the breakroom, the laboratory's Technical Consultant number three confirmed the findings.</p>

**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.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, quality assurance (QA) records and staff interview, the laboratory failed to follow its own policy and document monthly QA review for three of fifteen months reviewed from October 2024 through December 2025. Findings included: 1. Review of laboratory's policy "Quality Assurance Plan" (document: Reference #010, last reviewed: 01/06/2026) revealed: "Technical consultant will perform a monthly QA review ..." 2. Review of laboratory's QA records from October 2024 through December 2025 revealed the laboratory did not have documentation of monthly QA review for the following three of fifteen months reviewed: January 2025 June 2025 December 2025 3. In an interview on 03/13 /2026 at 1254 hours in the breakroom, the laboratory's Technical Consultant number three (as indicated on submitted Form CMS-209) confirmed the findings.