

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0919666	(X3) Date Survey Completed 06/17/2026
Name of Provider or Supplier Respiratory Virus Diagnostic Laboratory	Street Address, City, State Baylor College Of Medicine, Houston, 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	The laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey completed on 06/17/2026 and recertification is recommended. Standard level deficiencies were cited.
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on the review of CAP participant summary, the laboratory's CAP PT events from 2025 to 2026, CMS 116 application, and confirmed in an interview, the laboratory failed to follow CAP's instructions to self-evaluate results with exception code 26 for 4 of 4 PT events reviewed. The findings were: 1. Review of CAP Participant Summary titled "Surveys and Anatomic Pathology Education Programs" under Actions Laboratories Should take when a PT Result Is Not Graded revealed Code [26]: Educational challenge: Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges, Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. 2. Review of the laboratory's PT events from 2025 to 2026 revealed the laboratory failed to follow CAP's instructions to self-evaluate results with exception code 26 for 4 of 4 PT events reviewed. IDR-A 2025 Infectious Disease, Respiratory Coronavirus Strains IDR-01 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-02 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-03 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-04 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-01 Your result: NL63 Your Grade:</p>

See Note [26] Intended Response: NL63 IDR-B 2025 Infectious Disease, Respiratory Parainfluenza Subtype IDR-06 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-07 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-08 Your result: Type 4 Your Grade: See Note [26] Intended Response: Detected (positive) Type 4 IDR-09 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-10 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) Coronavirus Strains IDR-06 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-07 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-08 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-09 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-10 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-C 2025 Infectious Disease, Respiratory Parainfluenza Subtype IDR-11 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-12 Your result: Type 2 Your Grade: See Note [26] Intended Response: Detected (positive) Type 2 IDR-13 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-14 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-15 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) Coronavirus Strains IDR-11 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-12 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-13 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-14 Your result: Not Applicable (Neg) Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-15 Your result: 229E Your Grade: See Note [26] Intended Response: Detected (positive) 229E IDR-A 2026 Infectious Disease, Respiratory Parainfluenza Subtype IDR-01 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-02 Your result: Type 2 Your Grade: See Note [26] Intended Response: Detected (positive) Type 2 IDR-03 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-04 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) IDR-05 Your result: Parainfluenza Not Det Your Grade: See Note [26] Intended Response: Not Detected (negative) 3. Review of the CMS 116 application, signed by the laboratory director on 06/15/2026, revealed the laboratory annual volume in Microbiology subspecialty was 150. 4. An interview on 06/16/2026 at 12:30 pm, the technical supervisor (indicated on CMS 209 form) confirmed the above findings. Key: CAP=College of American Pathologists PT=Proficiency Testing CMS=Center for Medicare and Medicaid Services