

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2324788	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Pathologists Bio-Medical Laboratories, Pllc Frisco	Street Address, City, State 16050 Everwell Ln Ste 250, Frisco, 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	An onsite initial certification survey was conducted on 03/04/2026. The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologists (CAP) instructions, proficiency testing (PT) records, and confirmed in staff interview, the laboratory failed to document a self-evaluation of ungraded PT results by the PT company for one of one event in 2025 (PM2-B 2025). Findings included: 1. Review of laboratory policy titled "QAQC 1 CAP Proficiency Testing," laboratory director approval date 07/10/2025, stated: "PROCEDURE ... F. Evaluation of CAP PT Survey Results 1. The Laboratory Director or designee reviews, signs, and dates the survey results within a timely manner upon receipt. i. The Laboratory Director or Designee must document a review of analyte performance on educational or ungraded challenges. ii. For any results that are not graded, refer to the "Actions Laboratories Should Take when a PT Result is Not Graded" found in the CAP PT participant survey packet and follow these guidelines. Document the steps taken on the results." 2. Review of CAP "ER and PgR Immunohistochemistry Tissue Microarray PM2-B 2025 Participant Summary" stated: "The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception reason code, review, and document the acceptability of performance as outlined below and retain

documentation of review for at least 2 years ... Code 26 Exception Reason Code Description Educational challenge Action Required 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." 3. Review of the laboratory's CAP PT evaluation records for event PM-2 B 2025 ER /PGR Immunohistochemistry TM A (PM-2) revealed the laboratory failed to verify and document the accuracy of ungraded results for the methods and specimens: Method:ER Core 1 - % Staining SP1 FDA KIT Specimen: PM2-05 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: ER Core 3 - Intensity SP1 FDA KIT Specimen: PM2-05 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: ER Core 7 - Intensity sp1 FDA KIT Specimen: PM2-05 Your Result: STRONG Your Grade: See Note [26] Method: ER Core 8 - Intensity SP1 FDA KIT Specimen: PM2-05 Your Result: STRONG Your Grade: See Note [26] Method: ER Core 9 - Intensity SP1 FDA KIT Specimen: PM2-05 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: ER Core 10 - Intensity SP1 FDA KIT Specimen: PM2-05 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: ER Core 1 - Intensity SP1 FDA KIT Specimen: PM2-06 Your Result: STRONG Your Grade: See Note [26] Method: ER Core 3 - Intensity SP1 FDA KIT Specimen: PM2-06 Your Result: STRONG Your Grade: See Note [26] Method: ER Core 7 - Intensity SP1FDA KIT Specimen: PM2-06 Your Result: STRONG Your Grade: See Note [26] Method: ER Core 8 - Intensity SP1 FDA KIT Specimen: PM2-06 Your Result: WEAK Your Grade: See Note [26] Method: ER Core 9 - Intensity SP1 FDA KIT Specimen: PM2-06 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: ER Core 10 - Intensity SP1 FDA KIT Specimen: PM2-06 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: PgR Core 1 - Intensity 1E2 PER MFR KI Specimen: PM2-07 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: PgR Core 2 - Intensity 1E2 PER MFR KI Specimen: PM2-07 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: PgR Core 3 - Intensity 1E2 PER MFR KI Specimen: PM2-07 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: PgR Core 4 - Intensity 1E2 PER MFR KI Specimen: PM2-07 Your Result: STRONG Your Grade: See Note [26] Method: PgR Core 9 - Intensity 1E2 PER MFR KI Specimen: PM2-07 Your Result: STRONG Your Grade: See Note [26] Method: PgR Core 10 - Intensity 1E2 PER MFR KI Specimen: PM2-07 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: PgR Core 1 - Intensity 1E2 PER MFR KI Specimen: PM2-08 Your Result: WEAK Your Grade: See Note [26] Method: PgR Core 2 - Intensity 1E2 PER MFR KI Specimen: PM2-08 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: PgR Core 4 - Intensity 1E2 PER MFR KI Specimen: PM2-08 Your Result: STRONG Your Grade: See Note [26] Method: PgR Core 6 - Intensity 1E2 PER MFR KI Specimen: PM2-08 Your Result: STRONG Your Grade: See Note [26] Method: PgR Core 7 - Intensity 1E2 PER MFR KI Specimen: PM2-08 Your Result: INTERMEDIATE Your Grade: See Note [26] Method: PgR Core 9 - Intensity 1E2 PER MFR KI Specimen: PM2-08 Your Result: STRONG Your Grade: See Note [26] Method: PgR Core 10 - Intensity 1E2 PER MFR KI Specimen: PM2-08 Your Result: STRONG Your Grade: See Note [26] 4. During an interview in the conference room on 03/04/2026 at 10:03 a.m., the Quality Specialist, after a review of the records, confirmed the laboratory failed to document a self-evaluation of ungraded PT results by the PT company for one of one event in 2025 (PM2-B 2025).