

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0926993	<b>(X3) Date Survey Completed</b>  09/26/2025
<b>Name of Provider or Supplier</b>  Bioagilytix Diagnostics	<b>Street Address, City, State</b>  1320 Soldiers Field Road, Brighton, MA	
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 onsite validation survey was completed on September, 26, 2025 at Bioagilytix Diagnostics Laboratory by the Massachusetts State Agency. The laboratory was surveyed to determine compliance with CLIA Regulations under 42 CFR Part 493.
<b>D5821</b>	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>(k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: Based on review record review and interview with the Technical Services Director, the laboratory failed to report original Human Transforming Growth Factor beta 1 (TGF-b1) reported results on corrected results issued 06/30/2025 and 07/11/2025. The findings include: 1. Record review on 09/24/2025 of corrected reports issued in 2025 revealed two (TGF-b1) corrected reports missing the original TGF-b1 reported results (Sample IDs: 1462414 and 1447804). a. #1462414- corrected report date 07/11/2025 b. #1447804- corrected report date 06/30/2025 2. Interview with the Technical Services Director on 09/24/2025 at 2:00 pm confirmed the findings above. 3. Record review on 09/26/2025 of the CLIA Corrected Test Reports procedure (513816 v 5.0) Effective 09/12/2025, Section 7.4 stated the following: "The corrected report will be clearly labeled "CORRECTED REPORT" or "AMMENDED REPORT" and a note should be included stating: a. 7.4.1 The correction that was made b. 7.4.2 The error in the original report c. 7.4.3 Any change(s) to the patient results or interpretation for use</p>

of the results NOTE: It is never appropriate to note only the last correction made, as clinical decisions may have been made based on information included in the previous incorrect version of the report. "